

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

FORM 8-K

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

Date of report (Date of earliest event reported): August 13, 2021

GALERA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-39114
(Commission
File Number)

46-1454898
(I.R.S. Employer
Identification No.)

2 W Liberty Blvd #100
Malvern, PA 19355
(Address of principal executive offices) (Zip Code)

(610) 725-1500
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	GRTX	The Nasdaq Global Market

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement

On August 13, 2021, Galera Therapeutics, Inc. (the “Company”) entered into a Master Manufacturing Services Agreement with Patheon Manufacturing Services LLC (“Patheon”) (the “Master Agreement”). The Master Agreement governs the general terms under which Patheon, or one of its affiliates, will provide non-exclusive manufacturing services to the Company for the drug products specified by the Company from time to time. Pursuant to the Master Agreement, the Company has agreed to order from Patheon at least a certain percentage of its commercial requirements for a product under a related Product Agreement (each, a “Product Agreement”). Each Product Agreement that the Company may enter into from time to time will be governed by the terms of the Master Agreement, unless expressly modified in such Product Agreement.

On August 13, 2021, the Company and Patheon entered into a Product Agreement for Avasopasem Manganese (the “Product Agreement”) under the Master Agreement to govern the terms and conditions of Patheon’s manufacture and commercial supply to the Company of avasopasem manganese from Patheon’s Greenville, North Carolina manufacturing site.

The Master Agreement, and any related product agreement, has an initial term that expires on December 31, 2027 and includes renewal terms, as applicable. In addition, each party has the ability to terminate the Product Agreement upon the occurrence of certain customary conditions.

The Master Agreement contains representations, warranties and indemnity obligations customary for agreements of this type, and the Product Agreement establishes certain pricing for avasopasem that may be adjusted as set forth in the Master Agreement.

The Company’s obligation to purchase avasopasem manganese under the Product Agreement is subject to certain binding forecast periods at certain established prices, which will be reviewed each year on January 1 by the Company and Patheon.

The foregoing description of the terms of the Master Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Master Agreement, filed herein. The Company has redacted certain confidential portions of the Master Agreement because such confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

Exhibit 99.1 relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
10.0*	Master Manufacturing Services Agreement between Patheon Manufacturing Services LLC and Galera Therapeutics, Inc., dated August 13, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

* Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

SIGNATURES

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

GALERA THERAPEUTICS, INC.

Date: August 18, 2021

By: /s/ J. Mel Sorensen, M.D.
J. Mel Sorensen, M.D.
President and Chief Executive Officer

[***] = CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL and (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Master Manufacturing Services Agreement

Effective Date: August 13, 2021

PARTIES

PATHEON MANUFACTURING SERVICES LLC

a limited liability company existing under the laws of the State of Delaware, USA, with a place of business at 5900 Martin Luther King Jr Hwy, Greenville, NC 27834, USA ("**Patheon**"),

- and -

GALERA THERAPEUTICS, INC.,

a corporation existing under the laws of the State of Delaware, with its principal place of business at 2 West Liberty Boulevard, Suite 110, Malvern, PA 19355 ("**Client**").

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With effect from the date stated at the start of this Agreement (the “**Effective Date**”), the parties have agreed to the following terms:

1. Structure of Agreement and Interpretation

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon in the business of performing manufacturing services may perform Manufacturing Services for Client or any Affiliate of Client. This master form of agreement is intended to allow the parties, or any of their Affiliates agreed to by the other party, to contract for the manufacture of Product through Patheon's global network of manufacturing sites approved by Client by entering into specific Product Agreements without having to re-negotiate the general terms and conditions that apply.

1.2 Product Agreements.

This Agreement is structured so that Product Agreements may be entered into by the parties (or their Affiliates) for the manufacture of Product at any Patheon manufacturing site agreed to by the parties. Each Product Agreement will be governed by and will incorporate the terms and conditions of this Agreement. Unless otherwise agreed by the parties, each Product Agreement will be substantially in the general form, and contain the information referred to, in Appendix 1. Client must provide Patheon (or the applicable Affiliate) with a Purchase Order before any services are provided under the Product Agreement. Neither Client nor Patheon is obligated to execute any Product Agreement. A Product Agreement may not change any term or condition contained in this Agreement and if there is any irreconcilable inconsistency between any of the terms or conditions of this Agreement and those of a Product Agreement, the terms and conditions of this Agreement will control unless and only to the extent the Product Agreement states otherwise referencing the specific section or terms or conditions of this Agreement that are superseded by the Product Agreement.

1.3 Definitions.

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

"Affiliate" means:

- (a) a business entity which owns, directly or indirectly, a controlling interest in a party; or
- (b) a business entity which is controlled by a party, either directly or indirectly; or
- (c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party;

For this definition, "control" means the lawful right to determine (by ownership of shares or otherwise) the election of the majority of directors (or equivalent managers) of a business entity;

"Annual Volume" means, for the purpose of the Price, Patheon's assumed minimum volume of Product to be manufactured in any Year as set out in the "Annual Volume Forecast" section of Schedule A of the applicable Product Agreement;

"Applicable Laws" means: (i) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Product, the Laws of all jurisdictions where Product is manufactured, distributed, and marketed as these are agreed by the parties in the Product Agreement. Without limiting the foregoing, Applicable Laws also includes for both parties, all applicable local, state, federal laws and regulations of the United States state, territory, region, county, town or municipality including all the export control law and regulations of the United States and other export control law, rules and regulations, as applicable, the United States Food Drug and Cosmetic Act and specifically including standards of Good Laboratory Practices and cGMP, as applicable;

"Authority" means any governmental or regulatory authority, legislature, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether international, supranational, federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or the relevant Product (or its use);

"Business Day" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Patheon's resident jurisdiction, Client's resident jurisdiction, or the jurisdiction where the Manufacturing Site is located;

"Capacity Reservation" has the meaning specified in Section 5.1(f);

"Capital Equipment Agreement" means a separate agreement that the parties may enter into that addresses the rights and responsibilities of the parties regarding capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"cGMPs" means current good manufacturing practices applicable in the country where the Manufacturing Site is situated together with applicable rules and guidance documents issued by the applicable Authority pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time including, without limitation, 21 CFR 11, 210, and 211 and other applicable regulations of the United States of America;

"Client Intellectual Property" means Intellectual Property generated, derived or conceived by Client before entering into the applicable Product Agreement, or generated, derived or conceived by or with Patheon as a result of or while performing any Manufacturing Services other than Patheon Intellectual Property;

"Client-Supplied Components" means those Components supplied or to be supplied by or on behalf of Client as identified in Schedule A of a Product Agreement;

"Components" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture or package Product in accordance with the Processing Instructions, other than the DS;

"**Confidential Information**" has the meaning specified in Section 11.1;

"**DEA**" means the Drug Enforcement Administration of the United States Department of Justice;

"**Deficient Product**" has the meaning specified in Section 6.1(a);

"**Disclosing Party**" has the meaning specified in Section 11.1;

"**DS**" or "**Drug Substance**" means the active materials listed in the applicable Product Agreement (references to "Active Materials" or "Active Pharmaceutical Ingredient" in documents forming part of this Agreement or of a Product Agreement will mean "DS");

"**DS Credit Value**" means the value of the DS for certain purposes of this Agreement, as set out in the applicable Product Agreement;

"**EMA**" means the European Medicines Agency;

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

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

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

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, patent disclosures and all related continuation, continuation-in-part, divisional, reissue, re-examination, utility model, renewals, extensions, certificate of invention and design patents, patent applications, registrations and applications for registrations, formulae, registered and unregistered trademarks, trademark applications, registered and unregistered service marks, service mark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, domain names, know how, information and proprietary rights and processes, similar or other intellectual property rights, subject matter of any of the foregoing, tangible embodiments of any of the foregoing, licenses in, to and under any of the foregoing;

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

"**Inventory**" means, at a point in time, all inventories of Components and work-in-process under Patheon's care or control only used or usable for the manufacture or packaging of Product;

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

"**Long Term Forecast**" has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, sterility testing, bioburden and endotoxin testing, packaging, and related or ancillary services, if applicable, and as set out in the relevant Product Agreement, for the manufacture of Product for distribution in the Territory;

"Manufacturing Site" means the facility identified in a Product Agreement where the Manufacturing Services will be performed;

"Minimum Market Requirement" has the meaning specified in Section 2.1;

"Minimum Order Quantity" means, for each manufacturing campaign ordered, the minimum number of units or batches of a Product that Client must purchase, as set out in Schedule A of the applicable Product Agreement;

"Obsolete Stock" has the meaning specified in Section 5.2(b);

"Patheon Competitor" means a business organization or group that derives greater than 50% of its revenues from performing contract pharmaceutical or biopharmaceutical development or commercial manufacturing services;

"Patheon Intellectual Property" means Intellectual Property (a) that is generated or derived by Patheon or its Affiliates before performing any Manufacturing Services, (b) that is generated, derived or conceived by Patheon while performing the Manufacturing Services, or (c) that is otherwise generated, derived or conceived by Patheon in its business, which Intellectual Property, whether under clause (a), (b) or (c), is not specific to, or dependent upon, the Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products or drug delivery systems unrelated to the specific requirements of the Product;

"Patheon Personnel" means Patheon's employees, subcontractors or consultants;

"Price" means the fees to be charged by Patheon for:

- (a) performing the Manufacturing Services;
- (b) the cost of Components (other than Client-Supplied Components); and
- (c) any separate cost items and other fees,

as set out in Schedule A of the applicable Product Agreement;

"Processing Instructions" means the agreed file, for each Product, which contains documents relating to the Product, including, without limitation:

- (a) quality control testing methods for DS and Components;
- (b) manufacturing instructions, directions, and processes;
- (c) any storage requirements for the DS, Components, or Product;
- (d) all environmental, health and safety information for the Product including material safety data sheets; and

(e) the finished Product quality control testing methods, packaging instructions and shipping requirements for the Product;

"Product" means a product listed in Schedule A of a Product Agreement;

"Product Agreement" means each agreement between Patheon and Client (or their applicable Affiliates) substantially in the form set out in Appendix 1 under which Patheon will perform Manufacturing Services;

"Product Claims" has the meaning specified in Section 6.1(a);

"Quality Agreement" means a separate agreement entered into or to be entered into by the parties that sets out the quality assurance standards for the Manufacturing Services. The Quality Agreement will be deemed to be a part of and incorporated into this Agreement by reference;

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

"Recipient" has the meaning specified in Section 11.1;

"Regulatory Approval" has the meaning specified in Section 7.5(a);

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

"Relationship Manager" has the meaning specified in Section 7.5(a);

"Release Date" means in relation to each batch of Product the scheduled date by which the Product will be released to Client by Patheon's quality department (by confirmation or certification) as agreed in the Quality Agreement and made available for shipment, and as confirmed by Patheon in a Firm Order, subject to Client's approval of the release of Product within five days of receipt of Patheon's confirmation or certification of release unless there are deviations or investigations that need additional time to review;

"Representatives" means, a party's or its Affiliate's directors, officers, employees, agents, consultants, approved subcontractors or professional advisors;

"Rolling Forecast" has the meaning specified in Section 5.1(b);

"Security Breach" means a security breach or unauthorized use, access, misappropriation, modification or other compromise of or relating to any information technology, servers, computer systems, networks, hardware, software, data, or equipment owned or maintained by either party or any of its Affiliates or any event known to either party to be occurring or have occurred to any information technology, servers, computer systems, networks, hardware, software, data, or equipment owned or maintained by any third-party on behalf of the party or any of its Affiliates;

"Specifications" has the meaning set forth in the Quality Agreement or, if not defined in the Quality Agreement, means, for the applicable Product, all of the requirements for final release of the Product as set forth in the Quality Agreement, or, for Materials used in the Product, the requirements for use of the Materials in the Product as set forth in the Quality Agreement;

"**Technical Dispute**" has the meaning specified in Appendix 2;

"**Territory**" means the geographic area described in a Product Agreement where Product manufactured by Patheon will be distributed by or on behalf of Client;

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

"**VAT**" has the meaning specified in Section 13.14; and

"**Year**" means in the first year of this Agreement or a Product Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year.

1.4 Interpretation.

The division of this Agreement into Sections, Subsections, Appendices and Schedules, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Schedule refers to the specified Section, Appendix or Schedule to this Agreement. In this Agreement, the term "**this Agreement**" and similar expressions refer to this Agreement as a whole and not to any part, Section, Appendix or Schedule of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa and the word "or" will be interpreted in the inclusive sense commonly associated with the term "and/or". The words "will" or "must" have the same meaning and effect as the mandatory or obligatory sense of the word "shall". References in this Agreement to a statute, statutory provision, regulation, directive or other enactment will be construed as including a reference to any subordinate legislation or instrument made from time to time under that statute, provision, regulation, directive or enactment whether before, on or after the date of this Agreement; and a statute, statutory provision, regulation, directive, enactment or subordinate legislation will be construed as including a reference to that statute, provision, regulation, directive, enactment or subordinate legislation as in force at the date of this Agreement and as from time to time amended, modified, consolidated, superseded, re-enacted or replaced (whether with or without modification) after the date of this Agreement. General words will not be given a restrictive meaning by reason of the fact that they are preceded by or followed by particular examples intended to be embraced by the general words and accordingly, the rule known as *eiusdem generis* will not apply, and the words "includes", "including" and "in particular" (or similar term) are not to be construed as implying any limitation and will be read and construed as if immediately followed by the words "without limitation". Any reference to this Agreement or any other document is to this Agreement or that document as in force for the time being and as amended from time to time in accordance with this Agreement or that document (as the case may be). If a payment under this Agreement is due on a day which is not a Business Day, the due date for that payment will be the next Business Day. Terms other than those defined in this Agreement will be given their plain English meaning and those terms, acronyms and phrases known in the pharmaceutical/healthcare industry will be interpreted in accordance with their generally accepted meanings.

2. Patheon's Manufacturing Services

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services as set out in the relevant Product Agreement for the Price and in accordance with the Quality Agreement. Patheon agrees to provide all Manufacturing Services promptly and timely and in accordance with prevailing industry standards and practices for the performance of similar services. For each Product Agreement, Patheon will designate a "Project Leader" who will be available for frequent communications with Client regarding the Manufacturing Services provided or to be provided under that Product Agreement. Client will designate a "Representative" who will be the point of contact for the Project Leader. Client may replace their Representative at any time upon written notice to Patheon. Patheon may replace their Project Leader at any time upon written notice to Client. Client may, at any time, request that Patheon replace the Project Leader, which request will be considered in good faith. Subject to the foregoing, Patheon will convert DS and Components into Product, and provide supportive Manufacturing Services such as quality assurance (for example quality controls, analytical testing, and stability programs), primary and secondary packaging, and any other related Manufacturing Services as agreed between the parties.

The parties will agree in the Product Agreement on Patheon's percentage of Client's annual market volume of Products offered for sale by Client or its Affiliates to be manufactured (the "**Minimum Market Requirement**"). Client may cause the Product Agreement to be amended to reflect a new Minimum Market Requirement upon [***] prior written notice to Patheon.

Patheon will not be obliged to perform Manufacturing Services for any Product that will be distributed in any Territory which is listed as an embargoed country in the Thermo Fisher Scientific sanctioned country policy as may be updated from time to time (each an "**Embargoed Country**" and together "**Embargoed Countries**"). The Territories listed as Embargoed Countries as of the Effective Date of this Agreement are Cuba, Iran, North Korea, Sudan and Syria. Where a Territory is defined as Rest of World, Global or other geographic areas including more than one country, the definition will be interpreted to exclude any Embargoed Country.

2.2 Subcontracting.

Patheon may subcontract the Manufacturing Services under a Product Agreement to any of its Affiliates, as agreed in the Product Agreement. Patheon will remain liable to Client for any breach of this Agreement or negligence by its Affiliates in the course of performing: (i) subcontracted Manufacturing Services under a Product Agreement; or (ii) obligations under the Quality Agreement. Patheon may also arrange for non-Affiliate subcontractors to perform specific services arising under any Product Agreement with the prior written consent of Client ("**Third Party Subcontractors**"). Patheon may only subcontract to Third Party Subcontractors those obligations consented to by Client and Patheon must identify the specific Manufacturing Services to be performed by the Third Party Subcontractor prior to disclosing any identifiable information regarding Client to the proposed Third Party Subcontractor. Before the Third Party Subcontractor begins performing the identified Manufacturing Services, Patheon must enter into a binding written agreement with the Third Party Subcontractor that protects Client's rights and interests to at least the same degree as this Agreement. Patheon will be liable to Client for the failure by any Third Party Subcontractor to perform any part of the subcontracted services in accordance with the terms and conditions of this Agreement (including the applicable Product Agreement and the Quality Agreement). But Patheon's liability for Third Party Subcontractors will remain subject to all limitations on Patheon's liability as set out in this Agreement. Patheon will have no liability arising from the performance of services by Third Party

Subcontractors: (i) that are required by Client and are suppliers or service providers not validated and utilized by Patheon prior to the date of this Agreement; or (ii) to the extent that the Third Party Subcontractor is following the direct instructions of Client.

3. Client's Obligations

3.1 Payment.

Client will pay Patheon the applicable Price in accordance with Sections 4 and 5. All cost items agreed upon by the parties in writing that are not included in the Price (as specified in the applicable Product Agreement) will be paid by Client.

3.2 Processing Instructions.

Before the start of commercial manufacturing of Product under this Agreement, Client will give Patheon a copy of the Processing Instructions, which must be accompanied by the applicable DS, Component and finished product specifications (if applicable, precisely matching the specifications approved by the applicable Regulatory Authority). If the Processing Instructions or accompanying documents received are amended or no longer reflect those currently approved by the Regulatory Authority, then Client will give Patheon a copy of the revised documents (if applicable, precisely matching the revised specifications approved by the applicable Regulatory Authority). Upon acceptance of the revised Processing Instructions and accompanying documents, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance. At Patheon's request, Client will provide evidence of the executed original documents submitted by or on behalf of Client to the Regulatory Authority.

3.3 DS and Components.

- (a) Client will [***] deliver the DS and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2020). Client's obligation will include obtaining the release of the DS and any Client-Supplied Components from the applicable customs agency and Regulatory Authority. Unless otherwise agreed in writing, Client or Client's designated broker will be the "**Importer**" or "**Importer of Record**" (or equivalent, as understood under Applicable Laws) for DS, Client-Supplied Components, drug products and intermediates imported to the Manufacturing Site, and Client is responsible for compliance with Applicable Laws (and the cost of compliance) relating to that role. For DS or Client-Supplied Components which may be subject to import or export to or from the United States, Client's vendors and carriers must comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.
- (b) Unless otherwise agreed in writing between the parties, Client will use commercially reasonable efforts to deliver the DS and any Client-Supplied Components to the Manufacturing Site at least [***] before the scheduled manufacture date for Product covered by a Firm Order in sufficient quantity to enable Patheon to manufacture the agreed quantities of Product. For any DS or Client-Supplied Components delivered to the Manufacturing Site [***] before the scheduled manufacture date for Product covered by a Firm Order, Patheon will, if reasonably able to do so, store, in accordance with the requirements therefor, any quantity of DS or Client-Supplied Components in excess of the amount necessary for the Firm Order at Patheon's standard storage rates until [***] prior to the scheduled manufacture date

therefor. If Patheon is not reasonably able to store the excess DS or Client-Supplied Components, then Patheon may refuse to store the excess quantity of DS or Client-Supplied Components until the date that is [***] before the scheduled manufacture date for Product covered by a Firm Order. If Client fails to deliver the DS or Client-Supplied Components at least [***] before the scheduled manufacture date for Product covered by a Firm Order and, despite Patheon making commercially reasonable efforts, Patheon is unable to manufacture Product on the scheduled date because of the delay and is unable to otherwise utilize that manufacturing equipment on the scheduled manufacture date, the Firm Order will be considered cancelled by Client and Section 5.1(e) will apply.

- (c) Patheon will control the unloading of DS and Client-Supplied Components arriving at the Manufacturing Site and Client will comply and ensure that its carrier complies with all related directions of Patheon. The DS and Client-Supplied Components will be held by Patheon on behalf of Client as set out in this Agreement. The DS and Client-Supplied Components will at all times remain the property of Client. Any DS and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services.
- (d) Client will ensure that: (i) all delivered DS meets the specifications for that DS; and (ii) all shipments of DS are accompanied by the required documentation as specified in the applicable Quality Agreement).
- (e) Patheon will promptly advise Client if it encounters DS or Component supply problems, including delays or delivery of non-conforming DS or Components from a Client designated additional supplier. The parties will cooperate to reduce or eliminate any supply problems from these additional suppliers. If supply problems persist, the parties will meet to discuss resolutions to the problems including the possibility of suspending the Manufacturing Services. Client will qualify or certify (as appropriate) all Client designated additional suppliers at least once every two years at its expense and will provide Patheon with copies of the relevant annual reports. If Patheon agrees to certify or qualify a Client designated additional supplier on behalf of Client, it will do so for an additional fee payable by Client.
- (f) For each lot of DS and Client-Supplied Components provided to Patheon, Patheon will perform the quality control and inspection tests as agreed to in the Product or Quality Agreement unless Client notifies Patheon, in writing, that the DS or Client-Supplied Components are pre-approved. Patheon will maintain, for the benefit of Client, complete and accurate records of the inventory of all DS and Client-Supplied Components and will provide to Client a monthly report within five Business Days after the completion of each calendar month or at other times as reasonably requested by Client of the on-hand ending monthly inventory quantity balance of DS and of each Client-Supplied Component stored at the Manufacturing Site. This reporting will be in a format mutually agreeable to Client and Patheon.
- (g) Client hereby represents and warrants that it has the right to supply the DS and the Client-Supplied Components to Patheon and that, to Client's knowledge, Patheon's possession or use thereof in performing the Manufacturing Services do not infringe any Third Party Rights. Patheon acknowledges and agrees that, except as set forth in the preceding sentence, DS and Client-Supplied Components are being provided "AS IS" with no warranties of any kind, express or implied. EXCEPT AS EXPLICITLY SET FORTH IN THIS CLAUSE (g), CLIENT EXPRESSLY DISCLAIMS ALL WARRANTIES WITH RESPECT TO THE DS AND CLIENT-SUPPLIED COMPONENTS INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Notwithstanding the foregoing, as between the parties, Client will be responsible for, and Patheon will have no liability for any failure to perform the Manufacturing Services in accordance with the terms and conditions of this Agreement

to the extent caused by any defect in the DS or Client-Supplied Components at the time of delivery of the DS or Client-Supplied Components to Patheon.

The DS and Client-Supplied Components are provided to Patheon for the sole purpose of performing the Manufacturing Services. Patheon will not engage in any other activity involving the Client-Supplied Components, unless specifically approved by Client in writing, prior to undertaking these activities. Patheon will be responsible for storing Client-Supplied Components as per the specifications or conditions provided by Client, with indication that Client-Supplied Components are the property of Client, in a secure area reasonably protected from fire, theft and destruction.

3.4 Packaging and Artwork.

Client will be responsible for the cost of artwork development and approval of all artwork. Client will be responsible for changes to labels, product inserts, and other packaging for the Product, including obtaining all required approvals. Patheon will cooperate in all reasonable respects with the foregoing as and when requested by Client. Client will be responsible for the cost of labelling obsolescence as contemplated in Section 5.2. Patheon's name will not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. At least [***] prior to the Release Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon and in accordance with the applicable specifications, final camera ready artwork for all packaging Components to be used in the manufacture of the Product. Client will be responsible for the costs associated with complying with any and all regulatory requirements for the labeling and tracking of the manufactured Product, including product serialisation, product data transfer and anti-counterfeiting requirements in the Territory.

4. **Price and Price Adjustments**

4.1 First Year Pricing.

The Price for each Product will be listed in Schedule A of a Product Agreement and may be adjusted under this Section 4.

4.2 Annual Price Adjustments.

Patheon may adjust the Price effective January 1st of each Year as follows:

- (a) Inflation. Patheon may adjust the Price for inflation in accordance with Appendix 4.
- (b) Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the Local Currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made.
- (c) Tier Pricing. If the Pricing is divided into [***] tiers, unless otherwise agreed in a Product Agreement, Client will be invoiced during the Year based at closest estimated volume tier. [***] or on termination of the Product Agreement, Patheon will send Client a reconciliation of the actual volume of Product

ordered by Client during the Year at the actual applicable Pricing tiers. If the reconciliation shows an over or under payment, the appropriate party will issue a credit to the other party for the overpayment [***] or will reimburse the overpayment [***]. The parties will work together to resolve any disagreement over the reconciliation.

- (d) Notwithstanding this Section 4.2, Patheon may not adjust a Price in accordance with this Section if the Price has been in effect for [***]. For example, if the parties enter into a Product Agreement on [***], Patheon may not adjust the Price set forth in the Product Agreement on [***] because the Price would not have been in effect for [***]. Patheon would first be permitted to adjust that Price on [***].

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about October 1 of each Year (unless otherwise agreed in writing) a letter stating the adjusted Pricing under a Product Agreement to be effective for Product to be delivered on or after January 1 of the next Year including any Firm Orders accepted by Patheon before that date. Any omitted adjustment in a Year does not waive Patheon's right to apply that adjustment cumulatively with the next permitted adjustment. Patheon will send a written acknowledgement if it does not make an applicable Price adjustment and the reason for not making the adjustment.

4.3 Price Adjustments at any Time.

The Prices may be adjusted by Patheon at any time upon written notice to Client as follows:

- (a) Extraordinary Increases or Decreases in Component Costs. If the cost of a Component increases or decreases [***], then the parties will agree to an adjustment of the Price proportionate to the increase or decrease unless otherwise agreed in the Product Agreement. The Price will be revised further if the market factor has been resolved and the cost of the Component has decreased or increased. For a Price adjustment under this Section 4.3 (a), Patheon will deliver to Client a revised Schedule A to the Product Agreement and budgetary pricing information, adjusted Components costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified, to Client's reasonable satisfaction. Client will have the right to dispute any Price adjustment in good faith, and for the duration of the dispute, the existing Prices will continue to apply. If necessary, the Price will be retroactively adjusted for the applicable period after the dispute is resolved. Patheon will provide the information supporting the increase or decrease in Component costs confirming that the information reasonably demonstrates that the Price increase or decrease is justified and reasonable. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. For an undisputed Price adjustment, the revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule A to the Product Agreement.
- (b) Pricing Basis. Client acknowledges that the Price in any Year is agreed based upon the applicable [***] for that Year. Patheon may adjust the Price if it reasonably concludes, or is notified by Client, that the [***].
- (c) Changes. The scope of the Manufacturing Services is set by the agreed Processing Instructions, the Regulatory Approvals, the Quality Agreement and any assumptions, inclusions, exclusions, and other parameters set out in the applicable Product Agreement. Changes to the scope of the Manufacturing Services and related changes to the Price must be agreed in writing by the parties (using a "**Change**

of Scope" agreement, or similar, setting out the agreed activities and costs of implementation) and are subject to the change control provisions of the Quality Agreement. Where Patheon requests a change to the Manufacturing Services, the change will be implemented following written approval of Client, which Client will not unreasonably withhold, condition, or delay.

5. Purchasing Product

5.1 Orders and Forecasts.

- (a) Long Term Forecast. Within [***] of signing a Product Agreement or upon Regulatory Approval, and thereafter [***], Client will give Patheon a non-binding written forecast of Client's good faith estimate of its volume requirements for the Product [***] ("**Long Term Forecast**"). If Patheon foresees any capacity constraint affecting any portion of the Long Term Forecast, it will notify Client and the parties will discuss in good faith revising the Long Term Forecast within Patheon's expected capacity.
- (b) Rolling Forecast. Before each Product Agreement is executed, Client will give Patheon a written forecast of the volume of Product that Client expects to order [***] (the "**Rolling Forecast**"). Client will provide an updated Rolling Forecast: (i) [***]; and (ii) [***]. Each updated Rolling Forecast supersedes all previous Rolling Forecasts.
- (c) Orders. [***] in which Client needs to order Product, Client will issue a new purchase order for any required Product. Each purchase order must meet the applicable [***] and specify the purchase order number, quantities by Product type, and requested release dates for the Product (which must occur [***]).
- (d) Acceptance of Purchase Orders. To the extent that a purchase order covers Product, [***], Patheon will accept the purchase order by sending an acknowledgement to Client, including the release date requested by Client. Subject to Section 5.1(f), if Patheon fails to acknowledge receipt of a purchase order within ten Business Days, the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the parties (a "**Firm Order**"), except that either party may request to change any Release Date [***]. Patheon will use [***]. The parties will negotiate in good faith any requested alternative Release Date. Neither party may unreasonably reject an alternative Release Date requested under this Section 5.1(d), but, if the parties cannot agree, the original Release Date confirmed by Patheon will apply.
- (e) Cancellation or Postponement. Patheon, in consultation with Client, will determine the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order, or wishes to postpone the applicable Release Date (subject to Section 5.1(d)) for reasons other than a Force Majeure Event (as defined below) or as a result of Client's good faith concern with respect to quality assurance or compliance matters, [***].
- (f) Capacity Reservation. The parties will agree in the Product Agreement on Patheon's capacity reservation and Client's volume commitment (the "**Capacity Reservation**").
- (g) Controlled Substance Quota Requirements (if applicable). Client will give Patheon the information set out below for obtaining any required DEA or equivalent agency quotas ("**Quota**") needed to perform

the Manufacturing Services. Patheon will be responsible for routine management of Quota information in accordance with Applicable Laws. The parties will cooperate to communicate the information and to assist each other in Regulatory Authority information requirements related to the Product as follows: (i) by April 1 of each Year for the applicable Product, Client will provide to Patheon the next Year's annual Quota requirements for the Product; (ii) by August 1 of each Year, Client will provide to Patheon any changes to the next Year's Quota requirements; (iii) Client will pro-actively communicate any changes to the Quota requirements for the then-current Year in sufficient time to allow Patheon to file and finalize Regulatory Authority filings supporting the changes; (iv) upon Patheon receiving the necessary forecast information from Client in order to request additional Quota, Patheon will submit to the applicable Regulatory Authority, on a timely basis, all filings necessary to obtain Quotas for DS and will use commercially reasonable efforts to secure sufficient Quota from the applicable Regulatory Authority so as to achieve Release Dates for Product as set out in applicable purchase orders and forecasts submitted to Patheon by Client or its designee; and (v) Patheon will not be responsible for any Regulatory Authority's refusal or failure to grant sufficient Quota for reasons beyond the reasonable control of Patheon (including where Client fails to provide the required information in accordance with this Section 5.1(g)).

5.2 Obsolete Stock.

- (a) Client understands and acknowledges that Patheon will rely on purchase orders, Firm Orders, and the Rolling Forecast in ordering the Components (other than Client-Supplied Components) required to meet anticipated Firm Orders. Patheon may purchase the Components in sufficient volumes, and reasonably in advance of the expected use of the Component (taking into account lead times), to meet the production requirements for Products covered by anticipated Firm Orders or to meet the production requirements of any longer period agreed to by the parties. But Patheon will not order Components expected to be used [***] ordering without the prior written consent of Client, nor will Patheon order Components having [***] in the Manufacturing Services unless otherwise agreed.
- (b) Client will reimburse Patheon for the cost of Components ordered by Patheon in relation to Firm Orders or under Section (a) that are not used in the Manufacturing Services [***] the forecasted month for which the purchases have been made or [***] during the period (collectively, "**Obsolete Stock**"). This reimbursement will include [***]. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client. Patheon will use good faith efforts to mitigate Client's cost under this Section 5.2 including the return or resale of the Obsolete Stock or the use of common Obsolete Stock for third parties.

5.3 Storage.

Patheon will provide [***] storage following the Release Date of Product, Obsolete Stock, and any equipment (other than existing Patheon equipment) that is stored at the Manufacturing Site at any time prior to its use in the Manufacturing Services. If Patheon is unable to store any material due to capacity constraints, Patheon may use an Affiliate or qualified third party to store (outside the Manufacturing Site) any material under this Agreement. Unless otherwise agreed, after the limited storage periods stated above, and without limiting Patheon's obligations

under this Agreement (including the Product Agreement and the Quality Agreement) with respect to the handling and storage of Client materials, Client will assume all risk of loss or damage to materials and Client will be responsible for having appropriate insurance coverage in place for this risk. If: (i) Client fails to take possession or arrange for the destruction of Obsolete Stock within [***] of receipt of written notice from Patheon identifying the Obsolete Stock; (ii) any equipment (other than existing Patheon equipment) is stored at the Manufacturing Site at any time prior to its use in the Manufacturing Services; or (iii) Product is not collected by Client within [***] of the Release Date as notified by Patheon and approved by Client, Client will pay Patheon [***] per pallet, per month after that for storing the Obsolete Stock, equipment or Product. Storage fees for Obsolete Stock or Product which contain controlled substances or require refrigeration will be charged at [***] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship Product held by it longer than [***] to Client at Client's expense on [***] written notice to Client.

5.4 Invoices and Payment.

For shipments of Product, Patheon will issue invoices to Client on or after the date on which the Product is finally released to Client by Patheon in accordance with the Quality Agreement. Otherwise, Patheon will issue invoices for Manufacturing Services on completion or as agreed in the Product Agreement. Patheon's Relationship Manager will coordinate the issuance of Patheon's invoices. Each invoice must include: (a) a brief description of the Products released and the Manufacturing Services rendered by Patheon and a reference to the applicable purchase order number; (b) the total amount earned by Patheon in accordance with the applicable Product Agreement therefor; (c) Patheon's tax identification number; and (d) if provided for in the applicable Product Agreement, all documentation in support of any allowable expenses for which Patheon requests reimbursement, including (i) photocopies of expense reports and receipts for related travel expenses, (ii) date and travel destination, (iii) name and title of traveller, and (iv) purpose of trip/expense. Patheon's invoices must also detail, as necessary, all credits, payments and amounts advanced by Client, if any. Client will pay all undisputed invoices within 30 days following Client's electronic receipt of the invoice at the address or location noted below. If any portion of an invoice is disputed, then, upon Client's receipt of a credit memo or other instrument reasonably acceptable to Client therefor, Client will pay the undisputed invoiced amounts in accordance with this Agreement. The parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Invoices will be sent on the date issued by email to the following address: [***] or to such other address or location and by such means as determined by Client after notification to Patheon. Failure to send invoices in accordance with the preceding sentence may cause a delay in payment of an invoice. Interest on undisputed past due accounts will accrue at [***], following Patheon's giving of [***] of late payment to Client. Patheon may, on giving 30 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.

5.5 Delivery and Shipping.

Delivery of Product and any other materials will be made FCA (Incoterms 2020), subject to Client completing any required export documentation, from Patheon's Manufacturing Site unless otherwise agreed in a Product Agreement. Subject to Section 8.3, risk of loss or of damage to Product will remain with Patheon until Patheon loads the Product onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon may, in accordance with Client's written instructions (email being sufficient for this purpose) and as agent for Client, at Client's risk, arrange for shipping (to Client or any third party nominated by

Client) to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight activity under this Agreement.

6. Product Claims and Recalls

6.1 Product Claims.

- (a) Rejection. Client may reject any manufactured Product that it reasonably considers to be deficient based on documentation provided by Patheon or Client's own inspection or testing of delivered Product.
- (b) Product Claims.
- (i) Client may claim a remedy (a "**Product Claim**") for any portion of any batch of Product for which Patheon did not perform the Manufacturing Services in accordance with the agreed Processing Instructions, Specifications, cGMPs, or Applicable Laws ("**Deficient Product**"). Client will inspect Product manufactured by Patheon, or batch documentation provided by Patheon, upon receipt and will give Patheon written notice of all Product Claims [***] (or, in the case of any deficiency not reasonably susceptible to discovery upon receipt, [***], but not after the expiration date of the Product). If Client fails to provide a Product Claim within the applicable [***] period, then the Product will be considered to have been accepted by Client on the [***].
- (ii) Patheon will provide a remedy for Product Claims as specified in Section 10.2, but Patheon will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (i) deficiencies in the Processing Instructions, Specifications, the safety, efficacy, or marketability of the Product or its distribution; (ii) a defect in the DS; (iii) actions of Client or third parties occurring after the Product is delivered by Patheon; (iv) packaging design or labelling defects or omissions for which Patheon has no responsibility; (v) any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Processing Instructions, Specifications, cGMPs, and Applicable Laws; or (vi) any other breach by Client of its obligations under this Agreement. If after a full investigation as set out in the Quality Agreement and this Section 6.1, it is determined that Patheon manufactured the applicable Product fully in accordance with the agreed Processing Instructions, Specifications, cGMPs, or Applicable Laws, and the Quality Agreement but a batch or portion of batch of Product is not released, Client will pay Patheon the Price for the Product. If after a full investigation as set out in the Quality Agreement and this Section 6.1(b)(ii), it is not determined that Patheon manufactured the applicable Product fully in accordance with the agreed Processing Instructions, cGMPs, or Applicable Laws, and the Quality Agreement, then Patheon will reimburse Client for the cost of the Client Supplied Components and DS used in or for the Product, subject to the limitation of Patheon's liability for DS loss is set out in Appendix 3.
- (c) Determination of Deficiency. Upon receipt of a Product Claim, Patheon will have [***] to advise Client by notice in writing whether it disagrees with the contents of the Product Claim. If the parties fail to agree within [***] after Patheon's notice to Client as to whether any Product identified in the Product Claim is Deficient Product, the parties will investigate the matter in accordance with the Quality Agreement. If, after joint testing or investigation has been performed, the parties still cannot agree on

the root cause, the provisions of Appendix 2 will apply and, after the required negotiation, the dispute will be handled as a Technical Dispute.

- (d) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or a Price dispute will be dealt with by reasonable agreement and in good faith by the parties. Any claim for a shortage or a Price dispute will be considered waived by Client if it has not been presented within [***] of the date of the relevant invoice.

6.2 Product Recalls and Returns.

- (a) Records and Notice. The parties will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other of any information which might affect the marketability, safety or effectiveness of a Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of that Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The parties will take all appropriate corrective actions that are reasonable under the circumstances. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. Patheon will cooperate in all commercially reasonable respects with Client in effecting the Recall. "**Recall**" will mean any action: (i) by Client to recover title to or possession of quantities of a Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any Product; or (iii) by either party to refrain from selling or shipping quantities of a Product to third parties which would be subject to a Recall if sold or shipped.
- (b) Recalls. If: (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; (ii) a court of competent jurisdiction orders a Recall; or (iii) Client determines that any Product should be Recalled or that a "**Dear Doctor**" letter is required relating the restrictions on the use of any Product, then Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.
- (c) Recalled Product. To the extent that a Recall results from, or arises from Deficient Product, Patheon will be responsible for the reasonable documented costs and expenses of the Recall including, without limitation, reasonable attorney's fees, and will, at Client's sole option, either (i) use commercially reasonable efforts to replace the Deficient Product with replacement Products as per Section 10, or (ii) refund all amounts paid by Client in respect of the Deficient Product. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense. Patheon's only liability for DS loss is set out in Appendix 3.

6.3 Disposition of Deficient Product.

Client will not dispose of any damaged, returned, or Deficient Product for which it intends to assert a Product Claim against Patheon without Patheon's prior written authorization to do so. Patheon may request Client to return samples of the Products to Patheon. Patheon will bear the cost of return and disposition of any Deficient Products. In all other circumstances, Client will bear the cost of return and disposition, including all applicable fees for Manufacturing Services.

7. Co-operation and Regulatory Affairs

7.1 Governance.

- (a) The Joint Steering Committee. The parties will establish a Joint Steering Committee (the “**Joint Steering Committee**”) to coordinate the parties’ activities with respect to the Manufacturing and supply of Product under this Agreement and to providing support to the Relationship Managers (as defined below). The Joint Steering Committee will be composed of [***] representatives (or a greater number as determined by the Joint Steering Committee) appointed by each of Client and Patheon, including the parties’ respective Relationship Manager (as defined below) and representing the functional areas of quality assurance, manufacturing/product supply or such other function areas as the Joint Steering Committee will determine, with at least one representative of each party having decision making authority for that party. Either party may replace any of its representatives on the Joint Steering Committee at any time upon prior written notice to the other party. The Joint Steering Committee will meet at least [***] or as otherwise agreed by the Joint Steering Committee, which meetings will occur by teleconference, videoconference or in person. The Joint Steering Committee will keep minutes of its meetings. The Joint Steering Committee will make decisions by consensus and the members of the Joint Steering Committee will act in good faith. A member of the Joint Steering Committee may invite other individuals to meetings of the Joint Steering Committee as the need arises and these invitees will not be unreasonably be objected to by the other members of the Joint Steering Committee.
- (b) Role of the Joint Steering Committee. The Joint Steering Committee will be responsible for managing all aspects of the relationship between the parties for the Manufacturing and supply of Product in the Territory and will undertake:
- (i) To review the parties respective performance of its obligations under this Agreement;
 - (ii) to develop and review appropriate metrics of performance under this Agreement, including Patheon's performance of delivering Product on-time and in-full, and the parties’ respective performance in comparison to these metrics, quality metrics such as deviations per batch, duration of investigations, and adherence to target corrective action completion dates;
 - (iii) to approve the schedule of DS and other Components to be acquired by or delivered to Patheon for the Manufacturing Services;
 - (iv) to discuss and resolve any dispute which arises, but cannot be solved by the Relationship Managers;
 - (v) to discuss and approve strategies for the manufacturing of Products under this Agreement;
 - (vi) to exchange any information, as appropriate, regarding filing, prosecution, maintenance or other proceeding with respect to any intellectual property related to the Product;
 - (vii) to determine what other matters should be addressed by the Joint Steering Committee.

- (c) Each party will without delay upon execution of this Agreement or a Product Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties (each, a **“Relationship Manager”**). The Relationship Managers will meet on a frequency agreed between the parties to review the current status of the business relationship, including review of key performance indicators such as DS delivery, on-time delivery, right first time, and attainment of other requirements and specifications, the [***], and manage any issues that have arisen. Each Party will use reasonable efforts to provide the other party with [***] of any change in its Relationship Manager. If there is any dispute that arises between the Relationship Managers, the matter will be submitted to the Joint Steering Committee for its consideration and determination.

7.2 Governmental Agencies.

Subject to any restrictions in the Quality Agreement, each party may communicate with any Regulatory Authority responsible for granting Regulatory Approval for the Product and any other relevant Authority regarding the Product if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of the Authority or Applicable Laws. Otherwise, Client will be solely responsible for all contacts and communications with any relevant Authorities regarding the Product and Patheon will have no contact or communication with any Authority regarding any Product without the prior written consent of Client, which consent will not be unreasonably withheld. Patheon will notify Client immediately, and in no event later than within [***], if Patheon receives any contact or communication from any Regulatory Authority relating in any way to the Product or the Manufacturing Services and will provide Client with copies of the communication [***] by Patheon. Patheon will consult with Client regarding the response to any inquiry or observation from any Authority relating in any way to the Product or Manufacturing Services under this Agreement and will allow Client at its discretion to control or participate in any further contacts or communications relating thereto. Patheon will comply with all reasonable requests and comments by Client with respect to all contacts and communications with any Authority relating in any way to the Product or the Manufacturing Services.

7.3 Records.

Patheon will keep records of the manufacture, testing, storage and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, Applicable Laws, cGMP and the Quality Agreement. Copies of the records and samples will be retained as and for the period specified in the Quality Agreement. Upon written instruction of Client, all records will, at Client's option either be (a) delivered to Client or to its designee in the form in the possession of Patheon at that time, (b) retained by Patheon for a period of [***], or a longer period as otherwise required under Applicable Laws, or (c) disposed of, at the direction and written request of Client, unless these records are otherwise required to be stored or maintained by Patheon in accordance with Applicable Law. Patheon will not dispose of these records without first giving Client [***] of its intent to do so. Patheon may, however, retain copies of any records as is reasonably necessary for regulatory or insurance purposes, subject to Patheon's obligation of confidentiality.

7.4 Audits.

Subject to the limits agreed in the Quality Agreement, Patheon will give Client employees and representatives reasonable access at agreed times to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped to permit Client to verify, review and audit that the Manufacturing

Services are being performed in accordance with the Processing Instructions, Specifications, cGMPs, and Applicable Laws. Patheon will not bill Client for fees or expenses incurred by Patheon due to one such audit per Manufacturing Site in [***]. If Client wishes to audit Patheon more than once in [***], it must request this audit in writing. Patheon will promptly respond to, and will not unreasonably refuse, this request. For emergency or for-cause audits, Client may visit Patheon's Manufacturing Site and facilities upon seven days' prior written notice and these audits will not be subject to or apply against the maximum number of audits in any time period. In addition, the Relationship Managers of the parties and their designees will participate in meetings to review performance of the Manufacturing Services and to coordinate the Manufacturing Services as necessary. The Client Relationship Manager or her designee and a subject matter expert designated by the Client Relationship Manager (who will not be a Patheon Competitor or employed by a Patheon Competitor) will have access at reasonable times to observe the Manufacturing Services in progress or review any and all records generated as a result of Patheon's performance of the Manufacturing Services. If Client wishes to audit Patheon beyond the agreed limits, except where the audit is required due to Patheon's material breach (for cause), Client will [***] for each additional auditor. Under no circumstances will: (a) Client have a right of access to Patheon's financial records; or (b) any Patheon Competitor be permitted access to the Manufacturing Site.

7.5 Regulatory Filings.

- (a) Regulatory Authority Documentation. Client will provide copies of all relevant documents relating to Regulatory Authority approval for the commercial manufacture, distribution, and sale of the Product ("**Regulatory Approval**") to Patheon on request and as required under the Quality Agreement. Patheon will review and verify the accuracy of these documents in accordance with the Quality Agreement. Client is not entitled to submit Regulatory Approvals referring to Patheon or its Affiliates or the Services until approved by Patheon.
- (b) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any regulatory information given by Client is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed, but Client will ultimately determine how to address the Deficiencies.
- (c) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under this Section 7.5 or the Quality Agreement within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents. Client's breach of this requirement will be considered a material breach of this Agreement.
- (d) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including, without limitation, the cost of assistance required of Patheon under the Quality Agreement). Unless required by Applicable Law, neither party will be obliged to exchange with the other party any information or data which it compiles in carrying out pharmacovigilance obligations or activities.

- (e) No Patheon Responsibility. Except as otherwise agreed in the Quality Agreement, Patheon will not assume any responsibility for: (a) the submission, accuracy or cost of any application for Regulatory Approval or related documentation (or the success of those applications); (b) any activity that is required of Client by Applicable Laws for Regulatory Approval (including pharmacovigilance and complaints handling, and preparation and submission of any regular quality or other update); or (c) any dealings with the relevant Regulatory Authority on behalf of Client for Regulatory Approval. If a Regulatory Authority, or other Authority, requires Patheon to incur fees, costs or activities solely with respect to the Products that were not anticipated by the parties under the applicable Product Agreement, then Patheon will notify Client in writing and the parties will discuss appropriate mutually acceptable actions, including fee/cost sharing, or termination of all or any part of this Agreement or a Product Agreement. Patheon will not be obliged to undertake these activities or to pay for the fees or costs until the parties reach agreement on scope and fees for Patheon's assistance.

7.6 Release.

The parties agree that the release of the Products by Client for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations relating to the Manufacturing Services. Nothing in this Agreement will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Product will be released for sale or distribution.

7.7 Withdrawal on Completion.

No later than [***] following completion or permanent cessation of the Manufacturing Services at the applicable Manufacturing Site, Client will: (a) ensure that any regulatory filings relating to the Product are withdrawn or amended to remove all references to the Manufacturing Site and, as applicable, Patheon or its Affiliates and their facilities (except in an historic context); and (b) provide to Patheon written confirmation or other evidence of its compliance with this Section 7.7. If this time is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's best efforts, then Patheon may agree to extend the period based on the written reassurances of Client.

8. Term and Termination

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31, 2027 (the "**Initial Term**"), unless terminated earlier by one of the parties. This Agreement will automatically renew after the Initial Term for successive terms of [***] Years each if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention to terminate this Agreement [***] prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect. Each Product Agreement will have an initial term from the Effective Date of the Product Agreement until December 31 of the Year agreed to by the parties in the Product Agreement (each, an "**Initial Product Term**"). Product Agreements will automatically renew after the Initial Product Term for successive terms

of [***] Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement [***] prior to the end of the then current term.

8.2 Termination for Cause.

- (a) Either party may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of this Agreement or the Product Agreement within 60 days (the "**Remediation Period**") following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for [***] (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be considered to have waived the breach described in the Breach Notice. The right to terminate a Product Agreement under this Section 8.2(a) does not extend to any other Product Agreements where there has been no material breach of those other Product Agreements.
- (b) Either party may immediately terminate this Agreement or a Product Agreement upon written notice to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy or insolvency is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.
- (c) Client may terminate a Product Agreement upon [***] prior written notice if any Authority takes any action, or raises any objection, that permanently prevents Client from selling the Product in the Territory.
- (d) Client may terminate a Product Agreement upon [***] prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Product's discontinuance in the market.
- (e) Patheon may terminate this Agreement or any Product Agreement upon [***] if Client assigns under Section 13.4 any of its rights under this Agreement or a Product Agreement to an assignee that, in the reasonable opinion of Patheon, is (i) unlikely to be able to meet the obligations of this Agreement or a Product Agreement based upon publicly available financial or credit records; or (ii) a Patheon Competitor. This time period will automatically be extended by an additional [***] if, at [***] after the notice, Client is working in good-faith to secure, or obtain required approvals for, another supplier.
- (f) Following good faith discussions, Patheon may terminate this Agreement or any Product Agreement if payment in full of overdue, undisputed invoices is not received within [***] after Patheon delivers a [***] written notice to Client of failure to pay the invoices when due and the invoices remain unpaid after this [***] period.
- (g) If Client forecasts [***] during the term of a Product Agreement (excluding the registration period), then the parties may negotiate other terms and conditions on which the Product Agreement will remain in effect.

8.3 Obligations on Termination.

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

- (a) Client will take delivery of and pay for all undelivered Products that are manufactured or packaged in accordance with this Agreement, the Processing Instructions, Specifications, cGMPs and all Applicable Laws under a Firm Order , at the Price in effect at the time the Firm Order was released;
- (b) Client will purchase all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders, all in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory);
- (c) Client, [***], will remove from the Manufacturing Site, [***] of the Product Agreement, all unused DS and Client-Supplied Components, all applicable Inventory (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**"). Patheon may ship Client Property to Client or to an external warehouse at Client's risk and expense. If Client fails to remove Client Property [***] of the Product Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction; and
- (d) any completion, termination or expiration of this Agreement or a Product Agreement will not affect any prior outstanding obligations or payments due nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. Completion, termination or expiration of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Sections 5.1(e), 5.1(f), 5.4, 5.5, 8.3, 10, 11, 12, 13.14, 13.15 and 13.16, all of which survive any completion, termination or expiration, as well as any other provisions that are by implication or otherwise intended to survive any completion, termination or expiration. Where Patheon has agreed to provide stability services beyond the final supply of Product, the relevant provisions of this Agreement will survive for the agreed duration of those stability services.

8.4 Technology Transfer.

At any time upon the request of Client [***] of a Product Agreement for any reason, Patheon will provide assistance as reasonably requested by Client to transfer part or all of Client's manufacturing process, know-how and analytical testing methodology for the Product to Client or Client's third-party designee ("**Technology Transfer**") to assist Client to manufacture the Product. Patheon will ensure that the Technology Transfer is performed on its behalf by personnel skilled in providing the Manufacturing Services. The Technology Transfer will include provisions of the master batch record all other documents, information and knowledge as necessary or appropriate to transfer work performed as part of the Manufacturing Services by Patheon and may include reasonable consultation, meetings and travel to another site. Patheon will also disclose to Client any Patheon Intellectual Property that is reasonably required to manufacture the Product and grant to Client an irrevocable, fully paid, sublicensable license to exploit the Patheon Intellectual Property as reasonably required to manufacture the

Product. Patheon will, upon request of Client, prepare a written proposal to perform the Technology Transfer. The parties will agree in writing on the fees to be paid by Client for the Technology Transfer performed by Patheon.

9. Representations, Warranties and Covenants

9.1 Authority.

Each party covenants, represents, and warrants that (a) it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement, (b) the execution and delivery of this Agreement has been authorized by all requisite limited liability company or corporate action needed on its part, (c) this Agreement is and will remain a valid and binding obligation of the party, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (d) the execution and delivery of this Agreement and the performance of the party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws, and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of the party.

9.2 Client Warranties.

(a) Non-Infringement. Client covenants, represents, and warrants that:

- (i) the Processing Instructions and Specifications for the Product are its or its Affiliate's property and that Client may lawfully disclose the Processing Instructions and specifications to Patheon for use in accordance with this Agreement;
- (ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services (A) is Client's or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Client and agreed in this Agreement, and (C) does not infringe and will not infringe any Third Party Rights;
- (iii) there are no actions or other legal proceedings involving Client or its Affiliates that concerns the infringement of Third Party Rights related to any of the Processing Instructions or specifications, or any of the DS or Client-Supplied Components, or the sale, use, or other disposition of Product made in accordance with the Processing Instructions.

(b) Quality and Compliance. Client covenants, represents, and warrants that:

- (i) the Processing Instructions and specifications for the Product conforms to all applicable cGMPs and Applicable Laws;
- (ii) the Product, if labelled and manufactured in accordance with the Processing Instructions and in compliance with applicable cGMPs and Applicable Laws may be lawfully sold and distributed in every jurisdiction in which Client markets the Product;
- (iii) on receipt by Patheon, the DS will conform to the specifications for the DS that Client has given to Patheon and that the DS will be adequately contained, packaged, and labelled in accordance with Applicable Laws and will conform to the affirmations of fact on the container;

- (iv) Client will comply with all applicable anti-bribery laws and regulations, including, without limitation, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the U.K. Bribery Act of 2010, as amended, and will not cause Patheon to be in breach of any of the anti-bribery laws and regulations in the countries where Patheon operates. Without limiting the generality of the foregoing, in performing its obligations under this Agreement, neither Client nor any of its officers, directors, employees or other representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof, or to any political party or official thereof or to any candidate for political office, or to any other company, person or entity, corruptly for the purpose of (i) influencing any act or decision of that person in his/her official capacity, including a decision to fail to perform his/her official functions with the governmental agency or instrumentality or the public international organization, or the political party, or any other company, person or entity, or to perform its functions improperly; (ii) inducing the person to use his/her influence with the governmental agency or instrumentality or the public international organization or the political party, or any other company, person or entity to affect or influence any act or decision thereof; or (iii) securing any improper advantage; and
- (v) None of Client and its Affiliates have received any written notice of or have any knowledge of, any event or circumstance that would reasonably be expected to result in any Security Breach. Client and its Affiliates are in compliance with and will at all times continue to comply with all Applicable Laws, as well as internal policies and contractual obligations relating to the protection from and against a Security Breach. Client and its Affiliates have implemented commercially reasonable policies and procedures to protect against and from a Security Breach, along with commercially reasonable back-up and disaster recovery plans. Client will be responsible for, and remain liable to, Patheon for the actions and omissions of all its employees if there is any Security Breach. If Client becomes aware of or receives notice of any Security Breach that may affect Patheon, its business or its Confidential Information, Client agrees to notify Patheon immediately. Client agrees to fully cooperate with Patheon's handling of the matter as it pertains to Patheon, its business or its Confidential Information in such manner as Patheon may determine, including, without limitation: (i) assisting with any investigation; (ii) providing Patheon with physical access to the facilities and operations affected; (iii) facilitating interviews with Client's employees and others involved in the matter; and (iv) making available all relevant records, logs, files, data reporting and other materials required to comply with Applicable Laws, industry standards or as otherwise reasonably required by Patheon. Client agrees that Patheon will have the sole right to determine: (x) whether notice of the Security Breach that may affect Patheon, its business or its Confidential Information is to be provided to any individuals, regulators, law enforcement agencies, consumer reporting agencies or others as required by law or regulation, or otherwise in Patheon's discretion; and (y) the contents of the notice, whether any type of remediation may be offered to affected persons, and the nature and extent of any remediation. Client agrees that money damages may not be a sufficient remedy for any breach of the confidentiality obligations hereunder and that, in addition to all other remedies, Patheon will be entitled to seek injunctive or other equitable relief as a remedy for any breach by Client without having to post a bond.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

- (a) it has engaged and will engage Patheon Personnel with the proper skill, training and experience to provide the Manufacturing Services. Patheon will be solely responsible for paying Patheon Personnel and providing any employee or other benefits that they are owed. Before providing Manufacturing Services, all Patheon Personnel must have agreed in writing to (a) confidentiality obligations consistent with the terms of this Agreement, and (b) assign and otherwise effectively vest in Patheon any and all rights that the Patheon Personnel might otherwise have in the results of their work.
- (b) it will perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws. Without limiting the generality of the foregoing:
 - (i) During the term of this Agreement, if Patheon (or any Patheon Personnel) is a member of a committee that sets formularies or develops clinical guidelines affiliated with any healthcare institute, medical committee, or other medical or scientific organization (collectively, the "**Committee**"), Patheon agrees to disclose to the Committee the existence of its relationship with Client without breaching any obligations of confidentiality to Client as provided under this Agreement for up to [***] following the expiration or termination of this Agreement.
 - (ii) Patheon will comply with all applicable anti-bribery laws and regulations, including, without limitation, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the U.K. Bribery Act of 2010, as amended, and will not cause Client to be in breach of any of the anti-bribery laws and regulations in the countries where Client operates. Without limiting the generality of the foregoing, in performing the Services, neither Patheon nor any of its officers, directors, Patheon Personnel or other representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof, or to any political party or official thereof or to any candidate for political office, or to any other company, person or entity, corruptly for the purpose of (i) influencing any act or decision of that person in his/her official capacity, including a decision to fail to perform his/her official functions with the governmental agency or instrumentality or the public international organization, or the political party, or any other company, person or entity, or to perform its functions improperly; (ii) inducing the person to use his/her influence with the governmental agency or instrumentality or the public international organization or the political party, or any other company, person or entity to affect or influence any act or decision thereof; or (iii) securing any improper advantage.
- (c) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;
- (d) Absence of Debarment.

- (i) it has not been and will not be debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §335a(a) or (b), or similar local law. If Patheon becomes debarred, Patheon agrees to notify Client immediately.
- (ii) it has not and will not use in any capacity the services of any individual, corporation, partnership, or association (including without limitation any Patheon Personnel) which has been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §335a(a) or (b), or similar local law. If Patheon becomes aware of or receives notice of the debarment of any individual, corporation, partnership, or association (including without limitation Patheon Personnel) providing services to Patheon, which relate to the Manufacturing Services being provided under this Agreement, Patheon agrees to notify Client immediately.
- (e) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act.
- (f) None of Patheon and its Affiliates have received any written notice of or have any knowledge of, any event or circumstance that would reasonably be expected to result in any Security Breach. Patheon and its Affiliates are in compliance with and will at all times continue to comply with all Applicable Laws, as well as internal policies and contractual obligations relating to the protection from and against a Security Breach. Patheon and its Affiliates have implemented commercially reasonable policies and procedures to protect against and from a Security Breach, along with commercially reasonable back-up and disaster recovery plans. Patheon will be responsible for, and remain liable to, Client for the actions and omissions of all Patheon Personnel if there is any Security Breach. If Patheon becomes aware of or receives notice of any Security Breach that may affect Client, its business, or its Confidential Information, Patheon agrees to notify Client immediately. Patheon agrees to fully cooperate with Client's handling of the matter as it pertains to Client, its business or its Confidential Information in such manner as Client may determine, including, without limitation: (i) assisting with any investigation; (ii) providing Client with physical access to the facilities and operations affected; (iii) facilitating interviews with Patheon's employees and others involved in the matter; and (iv) making available all relevant records, logs, files, data reporting and other materials required to comply with Applicable Laws, industry standards or as otherwise reasonably required by Client. Patheon agrees that Client will have the sole right to determine: (x) whether notice of the Security Breach that may affect Client, its business or its Confidential Information is to be provided to any individuals, regulators, law enforcement agencies, consumer reporting agencies or others as required by law or regulation, or otherwise in Client's discretion; and (y) the contents of the notice, whether any type of remediation may be offered to affected persons, and the nature and extent of any remediation. Patheon agrees that money damages may not be a sufficient remedy for any breach of the confidentiality obligations hereunder and that, in addition to all other remedies, Client will be entitled to seek injunctive or other equitable relief as a remedy for any breach by Patheon without having to post a bond.

9.4 Permits.

- (a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Product, Processing Instructions or specifications, including, without

limitation, all marketing and post-marketing approvals, and any specific approvals referred to in the Quality Agreement.

- (b) Patheon will maintain at all relevant times when performing the Manufacturing Services all required governmental permits, licenses, approval, and authorities.

9.5 No Warranty.

NEITHER PARTY MAKES ANY WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET OUT IN THIS AGREEMENT. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCT.

10. Liability and Remedies

10.1 Consequential and Other Damages.

[***], under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, indemnity, breach of statutory duty, or otherwise for: (i) any (direct or indirect) delay, penalty, loss of profits, of anticipated savings, of business, of goodwill, or of use of the Product or costs of any substitute services; or (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 liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

- (a) Remedies for Deficient Product. If Client makes a Product Claim under Section 6.1 and, after the process described in Section 6, the parties agree the Product is Deficient Product, or the Product is determined to be Deficient Product under Section 6, Patheon will promptly, at Client's election, either:
 - (i) replace the Product at Patheon's cost (after which Patheon may invoice for the replacement) if Patheon is able to manufacture the replacement Product at the Manufacturing Site and contingent upon the receipt from Client of all DS and Client-Supplied Components required for the manufacture of the replacement Product; or
 - (ii) refund 100% of the Price paid for the Deficient Product (by credit or offset against other amounts due to Patheon under the Product Agreement).

The foregoing is not intended to limit Client's right to reimbursement of costs for DP or Client-Supplied Components, the remedies for which are described below in Section 10.2(b). Except for the indemnity set out in Section 10.3 and any claim for expenses related to a Recall under Section 6.2(c), the remedies described in this Section 10.2 will be Client's sole remedy in contract, tort, negligence, equity or otherwise, for Deficient Product.

The remedy under this Section 10.2, if applicable (including in the case of Recall), will apply only to the extent that the affected Deficient Product is unsold, returned, destroyed, or otherwise disposed of by Client in accordance with this Agreement.

- (b) DS. Except as expressly set out in Appendix 3 [***], under no circumstances whatsoever will Patheon be liable to Client in contract, tort, negligence, indemnity, breach of statutory duty, or otherwise for any loss or damage to the DS. Patheon's maximum aggregate liability for loss of or damage to the DS will not exceed on a per Product basis [***] of revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, in the case of the first Year, the expected revenue for that Product if the agreed Yearly Forecast Volumes were ordered).
- (c) Maximum Liability. In any Year, in addition to the specific remedies under Section 10.2(a) for Deficient Product, [***], Patheon's [***] under or in connection with this Agreement or any Product Agreement (however arising, including contract, tort, negligence, indemnity, breach of statutory duty, losses of DS, or otherwise) [***].
- (d) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement will act to exclude or limit either party's liability for personal injury or death caused by the negligence or willful misconduct of either party or fraudulent misrepresentation.

10.3 Patheon Indemnity.

- (a) Patheon will defend and indemnify Client, its officers and employees, from all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) including reasonable attorneys' fees for defending the foregoing (collectively, "**Claims**") to the extent that the Claim arose out of Patheon's (i) performance of the Manufacturing Services that was not in accordance with the Processing Instructions, cGMPs, and Applicable Laws, (ii) negligence or willful misconduct, or (iii) breach of this Agreement, including without limitation, any representation or warranty contained in this Agreement, except to the extent that the Claims are due to the negligence or wrongful acts of Client, its officers, employees, or Affiliates.
- (b) If a Claim occurs, Client will: (i) promptly notify Patheon of the Claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Patheon in the defense of the Claim; and (iv) permit Patheon to control the defense and settlement of the Claim, all at Patheon's cost and expense. But failure of Client to give prompt notice will not limit Client's right to indemnification except in if the failure materially and adversely affects Patheon's ability to defend against the Claim. Patheon may not settle any Claim if the settlement would impose any liability or obligation on, or include the admission of fault or guilt by, Client or any of its Affiliates or their respective officers, directors, consultants, agents, attorneys or representatives.

10.4 Client Indemnity.

- (a) Client will defend and indemnify Patheon, its officers and employees, from all Claims (i) of infringement of any Third Party Rights in or by the Products or that relates to the manufacture of the Product by a proprietary process disclosed by Client or to Patheon's use of Client's Intellectual Property to perform

the Manufacturing Services, or any portion of them, (ii) of personal injury or property damage to the extent that the injury or damage arises other than from Deficient Product or a breach of this Agreement or the relevant Product Agreement by Patheon, including, without limitation, any representation or warranty contained in this Agreement, (iii) that arise from Client's negligence or willful misconduct, or (iii) that arise from Client's breach of this Agreement or any Product Agreement including, without limitation, any representation or warranty contained in this Agreement, except to the extent that the Claims are due to the negligence or wrongful acts of Patheon, its officers, employees, or Affiliates.

- (b) If a Claim occurs, Patheon will: (i) promptly notify Client of the Claim; (ii) use commercially reasonable efforts to mitigate the effects of the Claim; (iii) reasonably cooperate with Client in the defense of the Claim; and (iv) permit Client to control the defense and settlement of the Claim, all at Client's cost and expense. But the failure of Patheon to give prompt notice will not limit Patheon's right to indemnification except if the failure materially and adversely affects Client's ability to defend against the Claim. Client may not settle any Claim if the settlement would impose any liability or obligation on, or include the admission of fault or guilt by, Patheon, its Affiliates or any of their respective officers, directors, consultants, agents, attorneys or representatives.

10.5 Reasonable Allocation of Risk.

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

10.6 Validation Batches.

Where Product is manufactured by Patheon (or any of its Affiliates) under a separate pharmaceutical development or technology transfer agreement including that certain Umbrella Development Services Agreement between Client and Patheon API Services, Inc. effective as of November 15, 2018 (each agreement, the "**Development Agreement**") and then released by Patheon for commercial sale or distribution by Client, the performance of the applicable pharmaceutical development or technology transfer services including the manufacture of the Product will be governed by the terms of the Development Agreement and will not be subject to the terms and conditions of this Agreement. The terms of this Agreement and the applicable Product Agreement will apply to any Product after release by Patheon.

11. Confidentiality

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how

and other intellectual property, its clients and its clients' confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities, research and development (to the that any is performed under this Agreement) and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing Confidential Information will be considered Confidential Information. Samples or materials provided under this Agreement as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. A party's rights and obligations under this Section 11 will apply to any Confidential Information that is disclosed by or received by that party's Representatives. For the purposes of this Section 11, a party receiving Confidential Information under this Agreement (including through its Representatives) is a "**Recipient**", and a party disclosing Confidential Information under this Agreement (including through its Representatives) is the "**Disclosing Party**". The existence, parties to, and terms of this Agreement or of any Product Agreement will be considered Confidential Information.

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality in this Section 11 will not apply to the extent that Confidential Information:

- (a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;
- (b) is in the Recipient's possession on a non-confidential basis at the time of disclosure by or on behalf of the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;
- (c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to so disclose the Confidential Information, if the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party for the Confidential Information;
- (d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or
- (e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information is not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information are covered by exceptions in this Section 11.3, unless the combination itself is covered by any of those exceptions.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure and limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out in this Agreement. If any public disclosure is required by Applicable Law, the parties will consult, to the extent practicable, concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party may summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information [***] of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies, summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records and for regulatory and compliance purposes. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. Client will not unreasonably require the return of Confidential Information that is necessary or useful to perform the Manufacturing Services.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Section 11 and agree that the non-breaching party will be entitled to seek specific performance, injunctive or other equitable relief to prevent breaches of this Section 11 and to specifically enforce Section 11 in addition to any

other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Section 11 but will be in addition to any and all other remedies available at law or in equity.

12. Intellectual Property

12.1 Inventions.

- (a) For the term of this Agreement, Client grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property to the extent necessary for Patheon to perform the Manufacturing Services.
- (b) As between the parties, all Client Intellectual Property will be the exclusive property of Client.
- (c) As between the parties, all Patheon Intellectual Property will be the exclusive property of Patheon. Unless Patheon identifies in advance any specific Patheon Intellectual Property that will be subject to a separate licensing agreement between the parties, Patheon grants to Client a non-exclusive, perpetual, paid-up, royalty-free, transferable license of the Patheon Intellectual Property used by Patheon in the manufacture of the Product for use in relation to manufacturing that Product only.
- (d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.
- (e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be considered to be improvements or other modifications of the Product, processes or technology owned or otherwise controlled by the party. Without limiting the foregoing, Patheon agrees to make full and prompt disclosure to Client of any Inventions that may be Client Intellectual Property, whether or not the Inventions or processes are patentable or protected as trade secrets. Each party agrees not disclose to any third party the nature or details of any Inventions of the other party without the prior written consent of the other party.

12.2 Intellectual Property.

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

12.3 Cooperation.

Patheon hereby irrevocably assigns, transfers and conveys to Client and agrees to assign, transfer and convey to Client, in each case without additional consideration, all right, title, and interest throughout the world in and to the Client Intellectual Property. Any assignment of or with respect to copyrights under this Agreement includes all Moral Rights. Patheon hereby irrevocably waives, to the extent permitted by Applicable Laws, any and all claims Patheon may now or hereafter have in any jurisdiction to any Moral Rights with respect to the Client Intellectual Property. No rights or licenses to use Client's trademarks are granted under this Agreement. To ensure

Client's ownership of Client Intellectual Property, at Client's request, Patheon will reasonably cooperate with and assist Client, whether during or after the termination of this Agreement, in applying for, perfecting, prosecuting, recording, renewing, registering, restoring, maintaining, protecting and enforcing Client's rights and protection available therefor under patent, copyright, trademark or similar statutes or analogous protection in any country throughout the world. Without limiting the generality of the foregoing, to ensure Client's ownership of Client Intellectual Property, Patheon will, promptly upon Client's reasonable request sign, execute, make and do all deeds, documents, acts and things as Client and its duly authorized agents believe to be necessary or appropriate for that purpose, in any country throughout the world.

13. Miscellaneous

13.1 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for three years after that. This insurance will be with financially sound and nationally reputable insurers rated "A" or better by AM Best and Co. or a wholly-owned subsidiary captive insurance company and will have policy limits of [***] for each occurrence for bodily injury or property damage liability; and (ii) [***] in the aggregate per annum for product and completed operations liability. Products and completed operations coverage may be maintained under a separate policy of insurance. A combination of primary and umbrella/excess policies may be used to satisfy the required limits. In addition, both parties will maintain the following additional minimum insurance coverage with financially sound and nationally reputable insurers rated "A" or better by AM Best and Co.: Network Security & Privacy Liability with a policy limit of not less than [***].

Client's commercial general liability and products liability insurance required herein shall include Patheon as an additional insured, and such insurance shall apply on a primary and non-contributory basis to insurance maintained by Patheon. Client will also, at all times during the term of this Agreement, maintain all-risks insurance for risk of loss or damage to Client-Supplied Components and Drug Substance, and Client acknowledges that Patheon will not insure Client-Supplied Components and Drug Substance. Client will ensure all of Client's designated additional suppliers maintain commercial general liability insurance and products liability insurance that satisfy the same conditions required of Client as set forth herein.

If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. Both parties will provide a minimum of 30 days' written notice to the other of a cancellation of the insurance if a gap in coverage would be reasonably expected to occur. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will without delay notify the other party in writing and the parties will negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.2 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement does not create between the parties any other relationship such as, by way of example only, that of employer and employee,

principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.3 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will be considered a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.4 Assignment.

- (a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld.
- (b) Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon but will provide Patheon with prompt written notice thereof. No assignment will relieve either party of the performance of any accrued obligation that the party may then have under this Agreement. Any partial assignment will be subject to Patheon's cost review of the assigned Product and Patheon may terminate the assigned portion of this Agreement or any Product Agreement or any assigned part of them, on [***] prior written notice to the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time. But this time period will automatically be extended by an [***], Client is working in good faith to secure or obtain required approvals for another supplier. Client will reimburse Patheon for any reasonable out of pocket costs incurred by Patheon in connection with the partial assignment including [***]. But Client will have no liability to Patheon for any expenses incurred by Patheon arising from the negotiation of any new or amended Manufacturing Services fees with the assignee.
- (c) Despite the preceding provisions of this Section 13.4, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party or otherwise enter into a binding obligation whereby it agrees to be bound by the obligations of this Agreement owed to that party.

13.5 Force Majeure.

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

13.6 Additional Product and Services.

Additional Product may be added to, or existing Product deleted from, any Product Agreement by amendment to the Product Agreement including its Schedules as applicable. If Client requests services other than those expressly set out in this Agreement or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), or any cost items that are specifically excluded from the Price, Patheon will provide a written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be agreed in writing by the parties.

13.7 Notices.

Unless otherwise agreed in a Product Agreement, and except for invoices which will be sent in accordance with Section 5.4, any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or email addresses set out below:

If to Client:

Galera Therapeutics, Inc.
2 West Liberty Boulevard, Suite 110
Malvern, PA 19355
Attention: Robert Beardsley, COO
Email address: [***]

With a copy (which will not constitute notice) to:

Galera Therapeutics, Inc.
2 West Liberty Boulevard, Suite 110
Malvern, PA 19355
Attention: Legal Department
Email address: [***]

If to Patheon:

Patheon Manufacturing Services LLC,
5900 Martin Luther King Jr Hwy,
Greenville, NC 27834, USA
Attention: Legal Department

or to any other addresses or email addresses given to the other party in accordance with the terms of this Section 13.7. Notices or written communications made or given by personal delivery, or email will be considered to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt (supported by reasonable written evidence), whichever is sooner.

13.8 Severability.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct. If the scope of any restriction contained herein is too broad to permit enforcement to its full extent, then the restriction will be enforced to the maximum extent permitted by law so as to be judged reasonable and enforceable.

13.9 Entire Agreement.

This Agreement, together with its Appendices, the applicable Product Agreement, Capital Equipment Agreement (if any), and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter of the Agreement and supersedes all previous written or oral negotiations, commitments, representations, collateral warranties, agreements, transactions, or understandings concerning the subject matter of this Agreement. This Agreement does not alter, integrate, or modify any Development Agreement. The basis of the parties' agreement is set out expressly and they have not been induced by or relied on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement, the Quality Agreement, the Capital Equipment Agreement (if any) or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of an irreconcilable conflict, the prevailing order of documents will be this Agreement, the Product Agreement, the Capital Equipment Agreement, if any, and the Quality Agreement (except that the Quality Agreement will prevail above the other documents in relation to quality matters). A document that is lower in the prevailing order may not change any term or condition contained in a prevailing document unless and only to the extent the document that is lower in the prevailing order states otherwise referencing the specific document, section or terms or conditions of the prevailing document that are superseded by the document that is lower in the prevailing order.

13.10 Other Terms.

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

13.11 No Third Party Benefit or Right.

Nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit, collateral warranties, or the right to enforce any express or implied term of this Agreement or any Product Agreement (except that Patheon Affiliates acting as subcontractors under this Agreement may enforce Sections 10.1 and 10.2). The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.

13.12 Execution in Counterparts.

This Agreement, the Quality Agreement and any Product Agreement may be executed in two or more counterparts, by original or electronic (including "pdf" or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) signature, each of which will be considered an original and deemed to have the same legal effect as delivery of an original signed copy of the agreement, but all of which together will constitute one and the same instrument.

13.13 Use of Name.

Neither party may use the other party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other party. In addition to its other confidentiality obligations under this Agreement, neither party will make any announcement, take or release any photographs (except for its internal operation purposes for performance under this Agreement) or release any information concerning this Agreement or any part thereof or with respect to its business relationship with the other party, to any member of the public, press, business entity or any official body, except as required by Applicable Laws, unless prior written consent is obtained from the other party. If either party determines it is obligated by law or a governmental authority to make any announcement or release, that party will promptly notify the other and cooperate to ensure that suitable confidentiality obligations are afforded the information.

13.14 Taxes.

(a) VAT.

Any payment due to Patheon under this Agreement in consideration for the provision of Manufacturing Services to Client by Patheon is exclusive of value added taxes ("**VAT**"), turnover taxes, sales taxes or similar taxes, including any related interest and penalties (together, "**Transaction Tax**").

Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Client are issued in a way to meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so.

If Patheon is acting as Client's buying agent, Patheon will always charge to Client the Transaction Tax in the relevant territory in addition to the amount paid by Patheon to supplier.

Reference to the Manufacturing Services in this Section also includes any element (or the entirety) of the Manufacturing Services characterized as a supply of goods by Patheon, its subcontractors or any tax authority for Transaction Tax purposes.

(b) Duties.

[***] will bear the cost of 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 by Patheon, including (without limitation) those imposed as a result of the shipping of materials (including drug substance, materials, components and finished Product) to, from or between Patheon sites. If these Duties are incurred by [***], then [***] will be entitled to invoice [***] for these Duties at the time that they are incurred.

(c) Withholding Tax.

Where any sum due to be paid to Patheon hereunder 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 then due to Patheon, in a timely manner and promptly transmit to Patheon an official certificate or other evidence of the withholding sufficient to enable Patheon to claim payment of these taxes. The parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate or enable the recovery of any tax withholding or similar obligations for royalties, milestone payments, and other payments made by Client to Patheon under this Agreement.

Patheon will provide Client any tax forms that may be reasonably necessary for Client not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.

Each party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, or similar obligations resulting from payments made under this Agreement, this recovery to be for the benefit of the party bearing the withholding tax.

13.15 Governing Law and Jurisdiction.

This Agreement and any Product Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with them or their subject matter or formation are governed by the laws of the State of Delaware, without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. Both parties hereby submit to the exclusive jurisdiction of the courts in the applicable location. The parties further expressly agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

13.16 Dispute Resolution.

All disputes that arise under or in connection with this Agreement that are not resolved in accordance with Section 7.1 will be resolved in accordance with Appendix 2.

13.17 Cooperation.

Each party will execute and deliver all instruments and perform all other acts as the other party may reasonably request to carry out or evidence the transactions contemplated by this Agreement.

13.18 Headings.

This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement and should not be used in the construction of this Agreement.

[Signature page to follow]

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON MANUFACTURING SERVICES LLC	GALERA THERAPEUTICS, INC.
By: <u>/s/ Michelle P. Logan</u>	By: <u>/s/ Robert Beardsley</u>
Name: <u>Michelle P. Logan</u>	Name: <u>Robert Beardsley</u>
Title: <u>VP GM Greenville NC</u>	Title: <u>Chief Operating Officer</u>
Date: <u>8/16/2021</u>	Date: <u>8/13/2021</u>
	By: <u>/s/ Chris Degnan</u> Name: <u>Chris Degnan</u> Title: <u>Chief Financial Officer</u> Date: <u>8/13/2021</u>

APPENDIX 1 – Form of Product Agreement

Product Agreement for [INSERT PRODUCT NAME]

This Product Agreement (this “**Product Agreement**”) is issued under the Master Manufacturing Services Agreement dated August 13, 2021 between Patheon Manufacturing Services LLC and Galera Therapeutics, Inc. (the “**Master Agreement**”), and is entered into on [INSERT DATE] (the “**Effective Date**”) between [PATHEON ENTITY], a corporation existing under the laws of [], having a principal place of business at [PATHEON ENTITY ADDRESS] (“**Patheon**”) and [CLIENT ENTITY] [insert Client name, legal entity, founding jurisdiction and address] (“**Client**”). For the purpose of this Product Agreement, references in the Master Agreement to “Patheon” and “Client” mean the entities defined respectively as Patheon and Client in this Product Agreement.

The terms and conditions of the Master Agreement are incorporated into this Product Agreement except to the extent this Product Agreement expressly modifies specific provisions in the Master Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

1. **Initial Product Term:** will be from the Effective Date until December 31, 20[YY]
2. **Manufacturing Site:** The Manufacturing Services will be performed at the following Manufacturing Site: []
3. **Territory:**
4. **Minimum Market Requirement:**
5. **Notices:** (if different from Section 13.7 of the Master Agreement): [insert contact details]
6. **DS Name:** [insert DS name]
7. **DS Credit Value:** Client's actual cost for DS not to exceed [] per kilogram. DS value to be provided by Client and supported by such reasonable evidence as Patheon requests.
8. **Inflation Index:** [if different from the Master Agreement]
9. **Governing Law:** [if different from the Master Agreement]
10. **Other Modifications to the Master Agreement (if any):**

Schedule A – Commercial Supply Pricing: Description of the Manufacturing Services and related terms of this Product Agreement, which may include: Product Features and Assumptions, Key Assumptions to be Finalized, Annual Volume Forecasts, Pricing Tables, Costs Included in Price, Costs Not Included in Price, Equipment Requirements (if applicable), Manufacturing Parameters, Packaging Parameters, and Testing Conditions.

In case of conflict between Schedule A and the other parts of this Product Agreement, the Product Agreement will prevail.

August 13, 2021
Confidential

Master Manufacturing Services Agreement

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

[PATHEON ENTITY]	[CLIENT ENTITY]
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

Schedule A – Commercial Supply Pricing

[***]

August 13, 2021
Confidential

Master Manufacturing Services Agreement

APPENDIX 2 – Dispute Resolution

Negotiation

If any dispute arises out of this Agreement or any Product Agreement, the parties will first try to resolve it amicably. Any party may send a notice of a dispute to the other, and each party will appoint, within [***] Business Days from receipt of the notice, an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary to resolve the dispute. If the representatives fail to resolve the matter within [***] from their appointment, or if a party fails to appoint a representative as required above: for Technical Disputes, the expert determination procedure may be started by either party; and for all other disputes, each party will refer the dispute immediately to the Chief Operating Officer or equivalent (or another senior manager as he/she may designate) ("**Senior Officers**") who will meet and discuss as necessary to try to resolve the dispute amicably.

Mediation

If the Senior Officers fail to resolve the dispute, the parties will attempt to settle the dispute promptly by confidential mediation under the then current International Institute for Conflict Prevention and Resolution ("**CPR**") Mediation Procedure, before resorting to litigation. If one party fails to participate in settlement negotiations as provided in this Appendix 2, the other party may initiate mediation prior to the expiration of the applicable negotiation periods. The mediator will be chosen with the assistance of CPR (and CPR's choice will be accepted by the parties in the absence of conflict or bias), unless the parties agree on a specific mediator in writing within [***] Business Days of the referral to mediation. The mediation will take place in Delaware and the language of the mediation will be English. Unless otherwise agreed, the parties will select a mediator from the CPR Panels of Distinguished Neutrals.

Preservation of Rights

Except where proceedings are required for the purpose of an interim injunction or other interim equitable relief or to preserve a party's legal position pending the outcome of negotiation or mediation, neither party may commence any court proceedings in relation to a dispute until the required mediation has ended without resolving that dispute or a party fails to participate in that mediation. Any time-based defense, such as laches or the running of statutes of limitations will be tolled from the time that a party sends a notice of dispute through the date that is [***] following the end of the required mediation. Where a party decides not to take part in mediation in contravention of this Appendix 2, it will send written notice of that decision to the other party.

Technical Disputes

If a dispute arises between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement, including conformance of Product to applicable specifications (a "**Technical Dispute**"), the parties will use all reasonable efforts to resolve the dispute by amicable negotiations as provided above. If the parties are unable to resolve a Technical Dispute by negotiation, the Technical Dispute will, at the written request of either party, be referred for determination to an expert in the following manner:

- (a) Appointment of Expert. Within [***] Business Days after the written request, the parties will appoint a single agreed expert with experience and expertise in the subject matter of the dispute. If the parties fail to agree the appointment within that period, then either party may request that a neutral from the

CPR appoints a suitable expert (and both parties will accept that appointment in the absence of evident conflict or bias). As a condition of the expert's appointment, the parties will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise.

- (b) Procedure. The parties will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) within [***] Business Days (or as agreed by the parties with the expert). Each party will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly and in any event within [***] Business Days of a written request from the expert to do so. At all times the parties will co-operate and seek to narrow and limit the issues to be determined.
- (c) Final and Binding. The determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the parties with respect to the referred Technical Dispute.
- (d) Costs. Each party will bear its own costs for any matter referred to an expert under this Appendix 2 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

APPENDIX 3 – DS Yield Calculation

[***]

August 13, 2021
Confidential

Master Manufacturing Services Agreement

APPENDIX 4 – Price Adjustments

[***]

August 13, 2021
Confidential

Master Manufacturing Services Agreement