EX-10.4 5 phat-ex104\_267.htm EX-10.4

**Exhibit 10.4**

**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. THE OMISSIONS HAVE BEEN INDICATED BY “[\*\*\*].”**

**EXECUTION VERSION**

**COMMERCIAL SUPPLY AGREEMENT  
((Vonoprazan Fumarate) finished packaged tablets)**

This Commercial Supply Agreement (“**Agreement**”) is made as of this 30th day of June 2021 (“**Effective Date**”), by and between Phathom Pharmaceuticals, Inc., an Illinois company, with a place of business at 2150 E. Lake Cook Road, Suite 800 Buffalo Grove, Illinois 60089, USA (“**Client**”), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA (“**Catalent**”).

**RECITALS**

A.Client is a company that develops, markets and sells pharmaceutical products;

B.Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies; and

C.Client desires to engage Catalent to provide certain services to Client in connection with the Processing of Client’s Product, and Catalent desires to provide such services, all pursuant to the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

**ARTICLE 1**

**DEFINITIONS**

The following terms have the following meanings in this Agreement:

1.1“**Acknowledgement**” has the meaning set forth in Section 4.2(B).

1.2“**Affiliate(s)**” means to any individual, corporation, partnership, limited liability company, association, trust, unincorporated entity, or other legal entity (each a “**Person**”), any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person.  For the purposes of this definition, “**control**” (including, with correlative meanings, “controlled by” and “under common control with”) shall mean possession, directly or indirectly, of the power to direct the management and policies of a Person, whether through ownership of at least fifty percent (50%) of the voting interest in such Person, through contract, or otherwise.

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1.3“**Agreement**” has the meaning set forth in the introductory paragraph and includes all its Attachments and other appendices (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.

1.4“**API**” means the compound Vonoprazan Fumarate, as further described in the Specifications.

1.5“**Applicable Laws**” means, with respect to Client, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which API, Bulk Product, or Product is produced, packaged, marketed, distributed, used or sold, together with all policies, practices, protocols, standards or guidelines of any Regulatory Authority having jurisdiction over Client or Product in such jurisdiction which, although not necessarily having the force of law, are regarded by such Regulatory Authority as requiring compliance as if they had the force of law; and with respect to Catalent, (a) all laws, ordinances, rules and regulations applicable to the services conducted under this Agreement or otherwise bearing on the performance of this Agreement, and the relevant Purchase Order, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Processes Product, and (b) cGMP (as defined below) and other regulatory standards or requirements of Regulatory Authorities.

1.6“**Batch**” means a defined quantity, mutually agreed to by the parties in writing, of Product that has been or is being Processed in accordance with Applicable Laws and the Specifications, as further set forth in Attachment C.

1.7“**Bulk** **Product**” means the bulk pharmaceutical product containing the API, as more specifically described in the Specifications.

1.8“**Business Day**” means a day other than Saturday, Sunday or any other day on which commercial banks located in New York, New York, USA are authorized or obligated by Applicable Law to close.

1.9“**Catalent**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.10“**Catalent Defective Processing**” has the meaning set forth in Section 5.2.

1.11“**Catalent Indemnitees**” has the meaning set forth in Section 13.2.

1.12“**Catalent IP**” has the meaning set forth in Section 11.1.

1.13“**cGMP**” means current Good Manufacturing Practices promulgated by the Regulatory Authorities in (a) the jurisdictions included in Applicable Laws, and (b) jurisdictions within the Territory where the respective final Products are sold or otherwise marketed provided that Catalent is informed about such territories in accordance with the Quality Agreement.  In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; and in Europe, this includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country.

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1.14“**Client**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.15“**Client Indemnitees**” has the meaning set forth in Section 13.1.

1.16“**Client Inventions**” has the meaning set forth in Section 11.1.

1.17“**Client IP**” has the meaning set forth in Section 11.1.

1.18“**Client-supplied Materials**” means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment B, including API, Bulk Product, and reference standards.

1.19“**Commencement Date**” means the first date on which Catalent is scheduled to deliver (pursuant to Section 6.1) to Client Product intended for commercial sale, excluding validation Batches.

1.20“**Contract Year**” means each consecutive twelve (12)-month period beginning on the first day of the calendar quarter in which the Commencement Date falls, or anniversary thereof, as applicable.

1.21“**Defective Product**” has the meaning set forth in Section 5.2.

1.22“**Effective Date**” has the meaning set forth in the introductory paragraph.

1.23“**Europe**” means Albania, Andorra, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kosovo, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, Netherlands, North Macedonia (former Yugoslavic Republic of Macedonia), Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland,United Kingdom of Great Britain and Northern Ireland, and Vatican City (Holy See) and any other countries notified by Client in writing from time to time.

1.24“**Exception Notice**” has the meaning set forth in Section 5.2.

1.25“**Facility**” means Catalent’s facility located in **[\*\*\*]** and/or **[\*\*\*]**; or such other facility as agreed by the parties in writing.

1.26“**FDA**” means the U.S. Food and Drug Administration and any successor entity or agency thereto.

1.27“**Firm Commitment**” has the meaning set forth in Section 4.1.

1.28“**Invention**” has the meaning set forth in Section 11.1.

1.29“**Losses**” has the meaning set forth in Section 13.1.

1.30“**Package**” or “**Packaging**” or “**Packaged**” means the primary and/or secondary packaging of Bulk Product in accordance with the Specifications.

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1.31“**Process**” or “**Processing**” means the compounding, filling or pressing, producing and bulk packaging and Packaging of Client-supplied Materials and Raw Materials into Bulk Product or Packaged Product by Catalent, in accordance with Applicable Laws, the Quality Agreement, the Specifications, any instructions provided by Client, and under the terms of this Agreement, as well as any testing or quality-related activities required by this Agreement or the Quality Agreement in connection with the foregoing.

1.32“**Processing Date**” means the day on which the first step of physical Processing of a Batch is scheduled to occur, as identified in an Acknowledgement.

1.33“**Process Inventions**” has the meaning set forth in Section 11.1.

1.34“**Product**” means the Bulk Product that has been Processed.

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| 1.35 | “**Product Maintenance Services**” has the meaning set forth in Section 2.3. |

1.36“**Purchase Order**” has the meaning set forth in Section 4.2(A).

1.37“**Quality Agreement**” has the meaning set forth in Section 9.6.

1.38“**Raw Materials**” means all raw materials, supplies, components and packaging necessary to Process and ship Product in accordance with the Specifications, as provided in Attachment B, but excluding Client-supplied Materials.

1.39“**Recall**” has the meaning set forth in Section 9.5.

1.40“**Regulatory Approval**” means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications, as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API, Bulk Product, or Product in the Territory.

1.41“**Regulatory Authority**” means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the Territory that are responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally.  In the United States, the term Regulatory Authority shall include the FDA, and in Europe, the term Regulatory Authority shall include the EMA.

1.42“**Representatives**” of an entity mean such entity’s duly-authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.43“**Review Period**” has the meaning set forth in Section 5.2.

1.44“**Rolling Forecast**” has the meaning set forth in Section 4.1.

1.45“**Specifications**” means the approved procedures, requirements, manufacturing instructions, standards, quality control testing and other data and the scope of services, the current

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version of which is set forth in Attachment B, which version will be finalized pursuant to the Quality Agreement prior to performance of the Validation Services.  Once finalized, the Specifications may be modified from time to time in accordance with Article 8 and the Quality Agreement.

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| 1.46 | “**Term**” has the meaning set forth in Section 16.1. |

1.47“**Territory**” means United States, Europe and Canada, and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement, except shall not include countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.  Catalent shall not be obliged to Process Products for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restrictions (such as embargoes) imposed on it by any governmental authorities, including without limitation those imposed by the U.S. Office of Foreign Asset Control.

1.48“**Unit Pricing**” has the meaning set forth in Section 7.1(B).

1.49“**Validation Services**” has the meaning set forth in Section 2.1.

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| 1.50 | “**Vendor**” has the meaning set forth in Section 3.2(B). |

**ARTICLE 2**

**VALIDATION, PROCESSING & RELATED SERVICES**

2.1Validation Services.  Catalent shall perform the Product qualification, validation and stability services pursuant to a validation services plan substantially in accordance with the services described in Attachment A (the “**Validation Services**”), which plan shall be finalized promptly following the Effective Date.  The Validation Services shall be performed in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.2Supply and Purchase of Product.  Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.  During each of the **[\*\*\*]**, Client and its Affiliates shall purchase from Catalent no less than **[\*\*\*]** of all of Client’s and its Affiliates’ requirements of Product **[\*\*\*]**; provided that the foregoing shall cease to apply commencing on the first date of any Failure to Supply.  During the **[\*\*\*]**, Client and its Affiliates shall purchase from Catalent no less than **[\*\*\*]**of all of Client’s and its Affiliates’ requirements of Product **[\*\*\*]**; provided that the foregoing percentage will be increased to **[\*\*\*]**if Catalent **[\*\*\*]**; and provided further that the foregoing shall cease to apply commencing on the first date of any Failure to Supply.  For the avoidance of doubt, neither Client nor its Affiliates shall market or sell the Product outside of the Territory.

Each party shall have the right to cause any of its Affiliates to perform any of its obligations, or exercise some or all of its rights, hereunder, and the other party shall accept such performance as if it were performance by such party.  In each such case, the party permitting such delegation or exercise by such Affiliate shall remain responsible for and be guarantor of the performance by such Affiliate.  Each party shall each cause its respective Affiliates to comply with the provisions of this Agreement in connection with such performance or exercise.  In such event, each reference

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to a party in this Agreement shall be deemed to include a reference to each Affiliate engaged in such performance or exercise.

A.Alternative Source of Supply.  The parties will discuss appropriate methods to ensure consistency of supply of the Product for the Territory, including completing the qualification, at Client’s cost, of (i) a secondary facility in the Catalent network and/or (ii) a third-party site outside the Catalent network as an alternate source of supply if there is a Failure to Supply by Catalent and the primary Catalent Facility cannot supply the Product.  For avoidance of doubt, Client shall have the right to qualify a third party as an alternate source of supply of the Product at any time during the Term.

B.Failure of Supply.  A “**Failure to Supply**” shall occur if at any time during the Term Catalent: (i) during any single Contract Year **[\*\*\*]**, delivers Product pursuant to a Purchase Order **[\*\*\*]**, or (ii) at any time during the Term, is unable to deliver Product pursuant to a Purchase Order **[\*\*\*]**.  Once the parties mutually agree that the Catalent Facility is able to supply Product again, Client shall cease issuing purchase orders for Product from any third party alternate supplier, within a commercially reasonable period of time and in no event later than **[\*\*\*]**.  Notwithstanding anything in this Agreement to the contrary, Catalent shall not be required to transfer any Catalent Confidential Information or other confidential or proprietary materials or information of Catalent to any third party.  Notwithstanding the foregoing, Client shall not be entitled to exercise the remedies in this Section 2.2(B) or terminate this Agreement in accordance with the terms of this Agreement, upon Catalent’s inability to supply Product as a result of **[\*\*\*]**.

2.3Product Maintenance Services.  Client will receive the following product maintenance services (the “**Product Maintenance Services**”): one (other than for-cause audits) annual audit (as further described in Section 9.4); regulatory inspections (as further described in Section 9.3); one annual Product review (within the meaning of 21 CFR § 211.180); drug master file updates for the Territory, if applicable; access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation; assistance in preparing Regulatory submissions; Product document and sample storage relating to cGMP requirements; vendor re-qualification; maintenance, updates and storage of master Batch records and audit reports.  For avoidance of doubt, the following services and items are not included in Product Maintenance **[\*\*\*]**.

2.4Other Related Services.  Catalent shall provide such Product-related services, other than Validation Services, Processing or Product Maintenance Services, as agreed to in writing by the parties from time to time.  Such writing shall include the scope and fees for any such services and be appended to this Agreement.  The terms and conditions of this Agreement shall govern and apply to such services.

**ARTICLE 3**

**MATERIALS**

3.1Client-supplied Materials.

A.Client shall supply to Catalent for Processing, at Client’s cost (except as otherwise set forth in this Agreement), all Client-supplied Materials, in quantities sufficient to meet Client’s Purchase Orders for Product under this Agreement.  Client shall deliver such items and associated

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certificates of analysis to the Facility no later than **[\*\*\*]** before the delivery date for the applicable Products agreed in the Acknowledgement (as defined in Section 4.3(B)).  Client shall be responsible at its expense for securing any necessary DEA, export or import, similar clearances, permits or certifications required in respect of such supply.  Catalent shall use such items solely for Processing.  Prior to delivery of any such items, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any regulatory certifications or authorizations relating to such Client-supplied Materials that may be required under Applicable Laws for Processing of Product under this Agreement, and shall promptly provide any updates thereto.

B.Within **[\*\*\*]**after receipt of Client-supplied Materials **[\*\*\*]**, Catalent shall **[\*\*\*]** to confirm that they meet the associated specifications or certificate of analysis or otherwise.  Thereafter during the Term, within **[\*\*\*]** after receipt of Client-supplied Materials, Catalent shall inspect such items to **[\*\*\*]**.  Notwithstanding anything to the contrary in this Section 3.1, Catalent shall **[\*\*\*]**, as required under Applicable Law.  Except as set forth in this Section 3.1(B), above, unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise.  In the event that Catalent detects a nonconformity with Specifications, Catalent shall give Client prompt written notice of such nonconformity.  Catalent shall not be liable for any defects in Product as a result of defective Client-supplied Materials, unless Catalent failed to properly perform any of the foregoing obligations or caused such defects.  Catalent shall follow Client’s reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client’s reasonable cost.

C.Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss thereof except to the extent caused by Catalent, subject to Article 14.  Within **[\*\*\*]** after the end of each month during the Term, Catalent shall provide a monthly report (in a form mutually agreed upon by the parties) identifying, on a component-by-component basis for each item of Client-supplied Materials, **[\*\*\*]** (such aggregate amount in clause (ii) is referred to herein as the “**Pre-Processing Losses**”).  In the event that, during any such calendar month, the Pre-Processing Losses **[\*\*\*]**, as reflected on the monthly report for such month, Catalent shall promptly credit to Client the value of such Pre-Processing Losses, which shall be applied to subsequent Purchase Orders under this Agreement.

D.The parties shall determine target yield of API supplied by Client for Processing of Bulk Product **[\*\*\*]** (each such determined yield, the “**Calculated Bulk Product Target Yield**”).  Catalent shall use reasonable efforts to minimize waste and loss of API and Bulk Product.  Notwithstanding anything to the contrary in this Section 3.1, in no event shall the actual yield for Bulk Product be **[\*\*\*]**.  In addition, Catalent shall Process at least **[\*\*\*]** (the “**Packaged Product Target Yield**”, and together with the Calculated Bulk Product Target Yield, the “**Target Yield**”).  Catalent shall bear any and all costs and expenses in connection with any failure to meet **[\*\*\*]**.  Catalent shall use commercially reasonable efforts to improve yields in the Processing.  From time to time, the parties shall meet to discuss and set targets and goals of yield improvements.  Within **[\*\*\*]** following the end of each Contract Year, Catalent shall provide a written report of Catalent’s actual yield for such Contract Year.  Catalent shall include with such report any reasonable documentation in support of the actual yield.  If the actual yield for all Batches of Product during any applicable Contract Year is **[\*\*\*]**, Catalent’s sole liability and Client’s exclusive remedy for such shortfall in the actual yield shall be **[\*\*\*]**.

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E.Within **[\*\*\*]**, Catalent shall provide a written report (in form and substance as mutually agreed upon by the parties) documenting and identifying, on a component-by-component basis for each item listed on Attachment D, for such Contract Year, the yield loss (the “**Annual Loss Report**”), and calculating the aggregate amount thereof.  To the extent that such aggregate amount in such report is **[\*\*\*]**and Catalent has not previously credited such amount pursuant to Section 3.1(C), Catalent shall promptly credit to Client the aggregate value of all yield losses for the Contract Year, which shall be applied to subsequent Purchase Orders under this Agreement; provided, however, that in the event such credit is not sufficient to offset against subsequent Purchase Orders prior to or after expiration of the Term or earlier termination of this Agreement, Catalent shall pay the balance of such excess within **[\*\*\*]** after delivery of the written report provided by Client pursuant to this Section 3.1(E).

3.2Raw Materials.

A.Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment unless otherwise agreed to by the parties in writing.  Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable, despite using reasonable efforts, to obtain, in a timely manner, a particular Raw Material necessary for Processing of such Product; (ii) due to reasons outside of Catalent’s reasonable control, provided that Catalent placed orders for such Raw Materials promptly following receipt of Client’s Firm Commitment; and (iii) Client-requested label changes result in lead time delay.  In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in a commercially reasonable manner an appropriate amendment to this Agreement, including Section 4.2.

B.In certain instances, Client may require a specific supplier, manufacturer or vendor (“**Vendor**”) to be used for Raw Material.  In such an event, (i) such Vendor will be identified in the Specifications and (ii) if such Vendor has not previously been qualified by Catalent for the supply of the specified Raw Material, the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of this Agreement; provided, however, Catalent shall remain responsible for procuring, inspecting and releasing such Raw Material as described in Section 3.2(A), unless otherwise agreed to by the parties in writing.  If the cost (as pre-approved in writing by Client) of the Raw Material from any such Vendor is greater than Catalent’s costs for the same Raw Material of equal quality from other vendors, Catalent shall add the difference between Catalent’s cost of the Raw Material and the Vendor’s cost of the Raw Material to the Unit Pricing.  Client will be responsible for all costs (as pre-approved in writing by Client) associated with qualification of any such Vendor who has not been previously qualified by Catalent.

C.In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiration of this Agreement, for any reason other than by Client pursuant to Section 16.2(A) or (B), Client shall bear the cost of any unused Raw Materials (including packaging), so long as Catalent purchased such Raw Materials in quantities consistent with Client’s most recent Firm Commitment and the vendor’s minimum purchase obligations and Catalent delivers such Raw Materials to Client or Client’s designee.

3.3Artwork and Labeling.  Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any.  Such artwork, advertising and labeling information is and shall remain the

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exclusive property of Client, and Client shall be solely responsible for the content thereof.  Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.  The parties acknowledge that delays with respect to the approval of artwork and labeling may result in the revision of the delivery date.

**ARTICLE 4**

**PURCHASE ORDERS & FORECASTS**

4.1Forecast.  On or before the **[\*\*\*]**, Client shall furnish to Catalent a written **[\*\*\*]** rolling forecast of the quantities of Product that Client intends to order from Catalent during such period (“**Rolling Forecast**”).  The first **[\*\*\*]**of such Rolling Forecast shall constitute a binding (on each of the parties) order for the quantities of Product specified therein (“**Firm Commitment**”) and the following **[\*\*\*]**of the Rolling Forecast shall be non-binding, good faith estimates.

4.2Purchase Orders.

A.From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch (“**Purchase Order**”).  Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment.  Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least **[\*\*\*]** in advance of the delivery date requested in the Purchase Order.

B.Promptly (but not later than **[\*\*\*]**) following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (“**Acknowledgement**”) that it accepts or rejects such Purchase Order.  Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date (such date not to be later than **[\*\*\*]** after the delivery date set forth in such Purchase Order), provided the Client-supplied Materials have been provided to Catalent **[\*\*\*]** prior to the delivery date and the Purchase Order is not in excess of the Firm Commitment, and shall include the delivery date.  Subject to Section 4.3(C), Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement.  Catalent shall accept any Purchase Orders that are consistent with the Firm Commitment and Section 4.3(C).

C.Notwithstanding Section 4.3(B), Catalent shall supply Client with, and shall use commercially reasonable efforts to supply Client in excess of, quantities of Product which are up to **[\*\*\*]**of the quantities specified in the Firm Commitment, subject to Catalent’s other supply commitments and manufacturing, packaging and equipment capacity.

D.In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.3Catalent’s Cancellation of Purchase Orders.  Notwithstanding Section 4.4, if Client refuses or fails to timely supply conforming Client-supplied Materials in accordance with Section 3.1 to the extent required for Catalent’s Processing of amounts set forth in a Purchase Order, Catalent reserves the right to cancel all, or any part of, such Purchase Order upon written notice to Client,

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and Catalent shall have no further obligations or liability with respect to such Purchase Order.  Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by Catalent.

4.4Client’s Modification or Cancellation of Purchase Orders.

A.Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least **[\*\*\*]**in advance of the earliest delivery date covered by such change order.  Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment.

B.if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Catalent shall notify Client of such deficiency, and Client shall have **[\*\*\*]**after receipt of such notice to submit any missing Purchase Orders (or shortfall portions thereof).  In the event that Client still fails to submit Purchase Orders to satisfy the Firm Commitment within such **[\*\*\*]**period, Client shall remain obligated to pay to Catalent in accordance with Article 7 the Unit Pricing for all Units that would have been Processed if Client has placed Purchase Orders sufficient to satisfy the Firm Commitment except to the extent Client’s failure to submit such Purchase Orders to satisfy the Firm Commitment is the result of Catalent’s inability to perform under such Purchase Orders or is otherwise caused by Catalent, or Catalent is able to use the Raw Materials, labor, and capacity that it would have used to perform under such Purchase Orders for services performed for Persons other than Client.

4.5Unplanned Delay or Elimination of Processing.  Catalent shall fill all Purchase Orders, subject to the terms and conditions of this Agreement.  If Catalent determines that any Processing will be delayed or eliminated for any reason, Catalent shall notify Client with as much advance notice as practicable, but in no event later than **[\*\*\*]**after such determination.

4.6Observation of Processing.  In addition to Client’s audit right pursuant to Section 2.3 or 9.4, Client may send up to **[\*\*\*]**Representatives to a Facility to observe the performance of Processing activities relating to this Agreement for **[\*\*\*]**, per calendar year (unless otherwise agreed by Catalent in writing), upon at least **[\*\*\*]**, at reasonable times during regular business hours.  Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance.  Client shall indemnify and hold harmless Catalent for any action, omission or other activity of such Representatives while on Catalent’s premises as set forth in Section 13.2.  Client’s Representatives who are not employees of Client shall be required to sign Catalent’s standard visitor confidentiality agreement prior to being allowed access to the Facility.

**ARTICLE 5**

**TESTING; SAMPLES; RELEASE**

5.1Batch Release.  Within **[\*\*\*]** after Catalent completes Processing of a Batch, Catalent shall provide Client with copies of Batch records prepared in accordance with the Specifications; provided that, if testing reveals an out-of-Specification result, or process deviation discovered during review, Catalent shall provide such Batch records within **[\*\*\*]** following resolution of the out-of-Specification result or deviation.  After Catalent completes Processing of a Batch, Catalent shall also provide Client or its designee with Catalent’s certificate of analysis and certificate of

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compliance, and any other documents required pursuant to the Quality Agreement, including Batch records and deviation reports, for such Batch.  Issuance by Catalent, and Client’s signed acknowledgment and acceptance, of a certificate of compliance and any other documents required pursuant to the Quality Agreement, including Batch records and deviation reports, constitutes release of the Batch by Catalent to Client (subject to Section 5.2 and 5.4).  Client shall be responsible for final release of Product to the market (including any additional testing, as applicable), at its cost.

5.2Testing; Rejection.  No later than **[\*\*\*]** after receipt of the Batch and the certificate of analysis and certificate of compliance and any other documents required pursuant to the Quality Agreement, including Batch records and deviation reports, for such Batch (“**Review Period**”), Client or its designee shall notify Catalent whether the Batch conforms to Specifications.  Upon receipt of notice from Client that a Batch meets Specifications, or upon failure of Client to respond by the end of the Review Period, the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch, *provided, however,*Client may revoke its acceptance after the expiration of the Review Period but before the date that is **[\*\*\*]**, if Client discovers Defective Product that could not have been reasonably discovered or detected by Client through its reasonable testing or inspection of the Product upon delivery and provides an Exception Notice to Catalent within **[\*\*\*]**of Client’s discovery of such Defective Product.  If Client or its designee timely notifies Catalent in writing (an “**Exception Notice**”) that a Batch does not conform to the Specifications or otherwise does not meet the warranty set forth in Section 12.1 (“**Defective Product**”), and provides a sample of the alleged Defective Product, Catalent shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity.  If the cause of nonconformity is attributable to Catalent’s material breach of this Agreement or negligence or willful misconduct (“**Catalent Defective Processing**”), then Section 5.4 shall apply.  For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not Catalent Defective Processing.  In the event a series of failures to meet Specifications or in-process requirements occurs during a production campaign, Client has the authority to request a halt in production until the root cause and a mutually agreeable resolution is found and necessary mitigation steps taken in accordance with the Quality Agreement to reasonably assure continuation will not replicate the original events or create new ones.

5.3Discrepant Results.  If the parties disagree as to whether Product is Defective Product or whether the cause of the nonconformity is Catalent Defective Processing, and this is not resolved within **[\*\*\*]** of the Exception Notice date, the parties shall escalate discussions to the appropriate level of management.  Such escalation of discussions will occur within **[\*\*\*]**following the Exception Notice.  Resolution of such disputes that cannot be resolved after good-faith discussions between the parties shall be resolved by an independent third-party laboratory or consultant, mutually agreed upon by the parties, within **[\*\*\*]**of the Exception Notice as set forth in the Quality Agreement.

5.4Defective Processing.  In the event of Catalent Defective Processing, Catalent shall, at Client’s option, either (A) **[\*\*\*]**or (B) **[\*\*\*]**.  In the event of any Defective Product attributable to Catalent Defective Processing, Client shall be entitled to make appropriate adjustments to the requirement obligations in Section 2.2 and the Firm Commitment reflected in the immediately following Rolling Forecast submitted by Client to the extent reasonably necessary to account for any modified requirements of Client as a result of not having received such Defective Product.

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**ARTICLE 6**

**DELIVERY**

6.1Delivery.  Catalent shall deliver Product Ex Works (Incoterms 2020) at the Facility promptly following Catalent’s release of Product, provided that Catalent will bear all risk of loss of such Product until it is loaded onto Client’s carrier, subject to Article 14.  Catalent shall segregate and store all Product until it is loaded onto Client’s carrier.  To the extent not already held by Client, title to Product shall transfer to Client upon Catalent’s tender of delivery.  If Catalent provides storage services, title to such items shall pass to Client upon transfer to storage.  Client shall qualify one or more carriers to ship Product and then designate the priority of such qualified carriers to Catalent.  In the event Catalent arranges shipping or performs similar loading and/or logistics services for Client at Client’s written request, such services are performed by Catalent as a convenience to Client only and do not alter the above and Catalent will use Client’s carrier unless Client otherwise agrees in writing.  Catalent shall not be responsible for Product in transit after it is loaded onto Client’s carrier, including any cost of insurance or other transport fees for Product, or any risks associated with transit or customs delays, storage and handling.

6.2Storage Fees.  If Client fails to take delivery of any Product within **[\*\*\*]**of the mutually agreed upon in writing scheduled delivery date, Catalent shall store such Product and have the right to invoice Client on the first day of each month following such scheduled delivery date for reasonable administration and storage costs in accordance with Attachment C.

**ARTICLE 7**

**PAYMENTS**

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| 7.1 | Fees.  In consideration for Catalent performing services hereunder: |

A.Client shall pay to Catalent the fees for Validation Services set forth on Attachment A.  Catalent shall submit an invoice to Client for such fees upon the completion of the relevant phase of the Validation Services.

B.Unit Pricing.  Client shall pay Catalent the unit pricing for Product set forth on Attachment C (“**Unit Pricing**”), as may be adjusted pursuant to Section 7.2 or 8.2, and subject to any credit set forth in this Agreement.  Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Section 6.1.

C.Product Maintenance.  Client shall pay Catalent the fees for Product Maintenance Services set forth on Attachment C.  Catalent shall submit an invoice to Client for such fees upon the Effective Date or Commencement Date, as applicable and as may be required during the Term.

D.Other Fees.  Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.4, 6.2 and 16.3.  Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2Unit Pricing Increase.  Commencing in calendar year 2022, the Unit Pricing (except to the extent consisting of the price of Raw Materials and components) may be adjusted on an annual basis, effective on the first (1st) day of the first full calendar quarter of each Contract Year upon not less than one hundred twenty (120) days’ prior written notice from Catalent to Client, to reflect increases or decreases in labor, utilities and overhead and shall be in an amount equal to the change

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in the Producer Price Index (“PPI”), "Pharmaceutical Preparation Manufacturing” (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics.  Such adjustment shall not exceed **[\*\*\*]**.  In addition, documented (in writing) price increases or decreases for Raw Materials and components **[\*\*\*]** to be mutually agreed upon by the parties in writing, and in accordance with the efforts of the Joint Steering Committee (“**JSC**”) as set forth in Section 8.2.

7.3Payment Terms.  Payment of all undisputed Catalent invoices shall be due **[\*\*\*]**.  Client shall make payment in U.S. dollars.  If any payment for any undisputed amount is not received by Catalent within **[\*\*\*]**its due date, then Catalent may, in addition to any other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at **[\*\*\*]**until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.4Taxes.  All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on Client-supplied Materials, services or Product prior to or upon provision or sale to Catalent or Client, as the case may be, are the responsibility of Client, and Client shall reimburse Catalent for all such taxes, duties or other expenses paid by Catalent or such sums will be added to invoices directed at Client, where applicable.  If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client will pay such deduction or withholding tax to the appropriate Regulatory Authority on behalf of Catalent; or in the event such payment by Client is not practicable, shall reimburse Catalent for the cost of any such deduction or withholding tax by such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.  Notwithstanding the foregoing, prior to deducting or withholding any amounts from any payment hereunder in respect of taxes, Client will use commercially reasonable efforts to give advance notice to Catalent and take such steps as Catalent may reasonably request and otherwise cooperate with Catalent to reduce or eliminate such deduction or withholding, including by reasonably cooperating in order to execute and file any forms or certificates reasonably required to claim an available reduced rate of, or exemption from, withholding taxes.

7.5Client and Third-Party Expenses.  Except for Raw Materials and other third-party expenses for which Catalent is expressly responsible hereunder, Client shall be responsible for one hundred percent (100%) of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies.  For clarity, Catalent is responsible for all regulatory fees that relate to the qualification and use of the Facility in connection with the development, manufacture, testing, use, storage, exportation, importation, transport of pharmaceutical products generally.

7.6Development Batches.  Each Batch Processed under this Agreement, including those necessary to support the validation portion of Client’s submissions for Regulatory Approvals, will be considered to be a “development batch” unless and until Processing has been validated.  Client shall be responsible for the cost of each such pre-validation Batch, even if such Batch fails to meet the Specifications, unless Catalent did not follow mutually agreed upon directions or instructions for Processing such Batch or was grossly negligent or engaged in willful misconduct in the Processing of the out-of-Specification Batch.  Catalent and Client shall cooperate in good faith to resolve any problems causing such out-of-Specification Batch.

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**ARTICLE 8**

**CHANGES TO SPECIFICATIONS**

8.1All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties.  Any change to the Process shall be deemed a Specification change.  No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change (“**Change Date**”), and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing) (“**Change Costs**”).  Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable efforts to agree to the terms of such change in a timely manner; provided, however, that in the case of any change that is requested by Client in response to (i) requirements imposed by a Regulatory Authority or Applicable Laws, or (ii) a safety or toxicity issue, the only terms of such change that Catalent may object to are the Change Date, the Change Costs and any requested change that would reasonably be expected to affect Catalent’s other customers or regulatory status, and Catalent shall use commercially reasonable, good faith efforts to resolve any such objection in an expedited manner.  As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require.  Client shall pay all reasonable costs associated with such agreed upon changes.  If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control.  Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

8.2Catalent and Client shall use commercially reasonable efforts to continually improve the net cost of Processing and to develop cost reduction initiatives as part of an overall cost improvement program, taking into account the total manufacturing environment including technology, industry standards, specifications, Raw Materials, inventory and forecasting.  After the Effective Date, Catalent and Client shall establish the JSC that will meet from time to time to review and share ideas for these improvements.  Through the JSC, the parties shall promptly notify one another regarding any such potential cost reduction efforts that are identified.  In addition, Client may propose to Catalent certain changes to the Specifications or the manufacturing process that it reasonably believes will improve the manufacturing process or lower costs or that Client otherwise wishes to implement in connection with the Product or the Processing thereof.  Upon Client’s request, Catalent shall review any such proposed change by Client and the parties will discuss in good faith potential implementation of such change.  The parties shall mutually agree on which changes, if any, shall be further developed or implemented in accordance with the change control procedures set forth in the Quality Agreement.  Except as the parties may otherwise agree in writing, Catalent and Client shall share in any cost savings resulting from the implementation thereof based on **[\*\*\*]**.  Notwithstanding anything to the contrary, each party may withhold its consent to implementation of any cost saving changes in its sole discretion.  Promptly following such implementation, the Unit Pricing for the Product payable by Client as set forth on Attachment C shall be reduced to reflect Client’s share of such cost savings.

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**ARTICLE 9**

**RECORDS; REGULATORY MATTERS**

9.1Recordkeeping.  Catalent shall maintain materially complete and accurate Batch, laboratory data, reports and other technical records relating to Processing in accordance with Catalent standard operating procedures and Applicable Laws, as wells as records and documentation relating to yield calculations.  Such information shall be maintained for a period of at least two (2) years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement, provided that prior to Catalent’s destruction of any such books, records, data or information, Catalent shall provide Client with written notice thereof and, if requested by Client, shall transfer such documentation to Client, at Client’s reasonable cost.  Without limiting the foregoing, at any time, upon request by Client, and at Client’s reasonable cost, Catalent shall provide Client with copies of, such records.

9.2Regulatory Compliance.  Catalent shall obtain and maintain all permits, certifications, and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product or which are otherwise required for Catalent’s performance under this Agreement.  Client shall obtain and maintain all other Regulatory Approvals, authorizations and certificates, including those necessary for Catalent to commence Processing.  Client shall not identify Catalent in any regulatory filing or submission without Catalent’s prior written consent; provided that Catalent hereby consents to Client identifying Catalent in the following regulatory submissions:  new drug applications with the U.S. FDA, marketing authorization applications with the EMA and in the United Kingdom and Switzerland, new drug submission with Health Canada, and any amendments or supplements to any of the foregoing.  Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both parties.  Upon Catalent’s written request, Client shall provide Catalent with a copy of any identified documents included in Regulatory Approvals that reference activities to be performed by Catalent, but only to the extent necessary for Catalent perform its obligations under this Agreement.  If Client is unable to provide such information, to the extent required for such performance in accordance with the immediately foregoing sentence (other than for Product ordered prior to Regulatory Approval in anticipation of launch), Catalent shall have no obligation to deliver Product to Client.  During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client’s request and reasonable expense, unless otherwise covered by any fees payable under Section 7.1.  The parties intend and commit to cooperate to allow each party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3Governmental Inspections and Requests.  Catalent shall permit any Regulatory Authority to conduct inspections of any Facility as such Regulatory Authority may request, including pre-approval inspections, and shall cooperate with such Regulatory Authority with respect to such inspections and any related matters, in each case that is related to the Product or its Processing.  Catalent shall promptly (but not later than **[\*\*\*]**after notification) advise Client if an authorized agent of any Regulatory Authority notifies Catalent that it intends to or will visit the Facility for the purpose of reviewing the Processing, or of any written or oral inquiries or communications (including Form 483 letters) from any Regulatory Authority concerning or relating to, or that reasonably could be expected to impact, the Product, including Catalent’s quality systems used in connection with such Processing, including during any pre-approval inspection.  Catalent shall permit Client or its Representative to be present at the Facility during any inspection concerning

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or relating to, or that reasonably could be expected to impact, the Product to the extent not prohibited by Applicable Laws or the applicable Regulatory Authority.  Within **[\*\*\*]**of its receipt, Catalent shall provide Client with a copy of any applicable report or correspondence issued by or provided to such Regulatory Authority in connection with such visit or inquiry, redacted as appropriate to protect any confidential information of Catalent and Catalent’s other customers.  Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities.  Catalent shall permit, and shall cause its Affiliates and Representatives to permit, the relevant Regulatory Authority to inspect its facilities in connection with the Product, provided that Client has provided advanced written notification to Catalent that Client has filed with a new Territory.  **[\*\*\*]**.  Catalent shall, prior to any correspondence or submission delivered to such Regulatory Authority (bearing in mind any time period limitations in responding to any such Regulatory Authority), permit Client to review and provide comments thereto, to the extent concerning or relating to, or that reasonably could be expected to impact, the Product or its Processing, and, prior to responding to any reports, requests, directive or other communications issued by any Regulatory Authority concerning or relating to, or that reasonably could be expected to impact, the Product or its Processing, Catalent shall take under consideration and use good faith efforts to implement any comments or recommendations provided by Client with respect thereto direct towards the Product or its Processing prior to submitting such response to the applicable Regulatory Authority.  In addition, Catalent shall promptly notify and, at Client’s written request, provide Client copies of any request, directive or other communication of any Regulatory Authority concerning or relating to, or that reasonably could be expected to impact, the Product or its Processing.

9.4Client Facility Audits.  During the Term, Client’s Representatives shall be granted access, as mutually agreed to in advance by the parties, at reasonable times during regular business hours, to (A) the portion of a Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.2, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications, the Quality Agreement, and the Product master Batch records.  Client may not conduct an audit under this Section 9.4 more than **[\*\*\*]**; *provided*, that Client will have the right to conduct additional inspections in the event there is a material quality or compliance issue concerning Product or its Processing.  Client’s Quality Assurance Manager will arrange Client audits with Catalent Quality Management.  Audits shall be designed to minimize disruption of operations at the Facility.  Any audit conducted by Client pursuant to this Section shall be conducted by no more than **[\*\*\*]**of Client’s Representatives and have a duration of no more than **[\*\*\*]** Business Days.  Client’s Representatives who are not employees of Client shall be required to sign Catalent’s standard visitor confidentiality agreement prior to being allowed access to the Facility.  Such Representatives shall comply with the Facility’s rules and regulations.  Client shall indemnify and hold harmless Catalent for any action or activity of such Representatives while on Catalent’s premises as set forth in Section 13.2.  Catalent agrees that Client shall have the right to conduct the first such audit within **[\*\*\*]**following the commencement of the Processing of Product, subject to any in-person audit limitations that may be in effect at the Facility.  If any such limitations are in effect, the parties will work in good faith towards a mutually acceptable solution taking into account the expected duration of in-person audit limitations and regulatory requirements applicable to Client regarding the Product.

9.5Recall.  If a Regulatory Authority orders or requires the recall, field alert, Product withdrawal or field correction (“**Recall**”) of any Product supplied hereunder or if either Catalent

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or Client believes a Recall may be necessary with respect to any Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly (within **[\*\*\*]**) notify the other party in writing.  Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws.  If Client believes a Recall may be necessary with respect to any Product supplied under this Agreement, Client shall promptly notify Catalent and Catalent shall provide all necessary cooperation and assistance to Client.  With respect to any Recall, Catalent shall provide all necessary cooperation and assistance to Client.  Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall reasonably consider any comments from Catalent.  The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for reasonable expenses incurred by Catalent in connection with any Recall, except to the extent such Recall is caused by Catalent’s gross negligence, willful misconduct, breach of its manufacturing obligations under this Agreement, or violation of Applicable Laws, then such portion of such cost (including the cost of replacing the applicable Products, including Client-supplied Materials) shall be borne by Catalent.  For purposes hereof, such Catalent cost shall be limited to reasonable, actual and documented costs incurred by Client to execute such Recall, including the reasonable cost of shipment of recalled Product and if applicable, replacement of the Product subject to Recall both in accordance with Article 5.

9.6Quality Agreement.  On or before the Effective Date, the parties have entered into a quality agreement with respect to the manufacturing activities subject to this Agreement (the “**Quality Agreement**”).  The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein.  In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern.  In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any other matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

**ARTICLE 10**

**CONFIDENTIALITY AND NON-USE**

10.1For purposes hereof, all information furnished by or on behalf of Catalent or Client, its Affiliates or any of its or their respective Representatives or any other Confidential Information (as such term is defined in the MNDA) shall be governed by the Mutual Non-Disclosure Agreement entered into by the parties and dated December 10, 2019 (the “**MNDA**”), provided that, notwithstanding anything to the contrary in the MNDA, (i) the Permitted Use shall be deemed to include use by Catalent for solely as necessary for the performance of its Processing activities conducted under this Agreement and use by Client in connection with the exploitation of Products, (ii) the term of confidentiality and non-use obligations shall not expire until the fifth (5th) anniversary of the expiration or termination of this Agreement, and (iii) the MNDA may not be assigned or transferred except together with the assignment or transfer of this Agreement and the MNDA must be assigned or transferred to the same assignee or transferee of this Agreement in such assignment or transfer. Notwithstanding anything to the contrary in the foregoing, Catalent and its Affiliates will remain subject to the MNDA after any such assignment or transfer.

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**ARTICLE 11**

**INTELLECTUAL PROPERTY**

11.1For purposes hereof, “**Client IP**” means all intellectual property and embodiments thereof owned by or licensed to Client as of the date hereof or developed by Client other than in connection with this Agreement; “**Catalent IP**” means all intellectual property and embodiments thereof owned by or licensed to Catalent as of the date hereof or developed by Catalent other than in connection with this Agreement; “**Invention**” means any intellectual property developed by either party or jointly by the parties in connection with this Agreement; “**Client Inventions**” means any Invention that relates to the Client IP, Bulk Product, Product, or API; and “**Process Inventions**” means any Invention, other than a Client Invention, that relates to the Catalent IP or developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally.  All Client IP and Client Inventions shall be owned solely by Client, and Catalent hereby assigns to Client all right, title, and interest therein.  No right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, non-transferable, non-sublicenseable, royalty-free license to such items solely to the extent necessary to perform its obligations under this Agreement.  All Catalent IP and Process Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement.  Catalent shall not incorporate any Catalent IP or Process Inventions into the Product or Bulk Product or manufacturing thereof.  To the extent the services require Catalent to incorporate any Catalent IP or Process Inventions into the Product or Bulk Product or the manufacturing process thereof, Catalent shall obtain Client’s written consent prior to doing so, and the parties shall amend the Agreement to grant Client a non-exclusive license under and to all such Catalent IP or Process Inventions, under mutually agreeable, reasonable commercial terms.

11.2Reserved Rights.  Notwithstanding anything to the contrary herein, no license, sublicense or other rights granted under Section 11.1 includes (or shall be construed to grant) any license, sublicense, right, immunity or authorization, either expressly, by implication, by estoppel or otherwise, under any intellectual property rights that are not expressly licensed hereunder.

**ARTICLE 12**

**REPRESENTATIONS AND WARRANTIES**

12.1Catalent.  Catalent represents, warrants and undertakes to Client that:

A.Product shall have been Processed in accordance with Applicable Laws and in conformance with the Specifications and shall, at the time of delivery by Catalent as provided in Section 6.1, not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling);

B.Catalent has all necessary authority to use, and to permit Client to use pursuant to the terms of this Agreement, any Catalent IP utilized with the Product or Processing under this Agreement; to Catalent’s knowledge, there are no patents owned or controlled by others related to the Catalent IP or manufacturing methods (other than manufacturing methods provided to Catalent by Client or otherwise prescribed by Client) utilized with the Product that would be infringed or misused by Catalent’s performance under this Agreement; and, to Catalent’s knowledge, there are no trade secrets or other proprietary rights of others related to the Catalent IP or manufacturing

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methods (other than manufacturing methods provided to Catalent by Client or otherwise prescribed by Client) utilized with the Product that would be infringed or misappropriated by Catalent’s performance under this Agreement;

C.Neither Catalent nor its Affiliates will in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a), excluded from a federal healthcare program, debarred from federal contracting, or convicted or plead nolo contendere to any felony or to any violation of laws relating to fraud, and Catalent will comply in all material respects with Applicable Laws relating to Catalent’s performance under this Agreement.  If during the Term Catalent becomes aware of any non-compliance with this Section 12.1(C), Catalent shall notify Client immediately.  In either such event, Client will have the right to terminate this Agreement upon written notice to Catalent if such non-compliance is not cured within sixty (60) days following the date Catalent first becomes aware of such non-compliance;

D.All services provided by Catalent to Client under this Agreement shall be carried out in a diligent, professional manner in accordance with Catalent’s standard operating procedures.  All necessary consents, approvals and authorizations required to be obtained by Catalent in order to perform its obligations under this Agreement have been obtained; and

E.No transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

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| 12.2 | Client.  Client represents, warrants and undertakes to Catalent that: |

A.all Client-supplied Materials shall have been produced, manufactured, prepared, preserved, packaged and stored in accordance with Applicable Laws (including cGMP where applicable), shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B.the content of all artwork, advertising and labeling provided to Catalent shall comply with all Applicable Laws;

C.all Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with all Applicable Laws relating to Client’s performance under this Agreement;

D.Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product;

E.Client has all necessary authority to use, and to permit Catalent to use pursuant to the terms of this Agreement all intellectual property related to Product or Client-supplied Materials (including artwork), and any Client IP, in each case provided by Client to Catalent for Processing of Products under this Agreement; there are no issued patents owned by others related to such Client IP utilized with the Product that would be infringed or misused by Client’s performance of this Agreement or Catalent’s Processing of Products in accordance with the Specifications and this Agreement; and, to Client’s knowledge, there are no trade secrets or other proprietary rights of

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others related to such Client IP utilized with the Product that would be infringed or misappropriated by Client’s performance of this Agreement or Catalent’s Processing of Product in accordance with the Specifications and this Agreement; and

F.Client has all authorizations and permits required to deliver API (or have delivered) to Catalent’s Facility.

12.3Mutual Representations.  Furthermore, each party hereby represents, warrants and undertakes to the other party that:

A.Such party (1) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, and (2) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted;

B.Such party (1) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (2) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

C.This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms;

D.The execution and delivery of this Agreement and the performance of such party’s obligations hereunder (1) do not, to the best of such party’s knowledge, conflict with or violate any requirement of Applicable Laws; and (2) do not materially conflict with, or constitute a material default or require any consent under, any contractual obligation of such party;

E.No transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States; and

F.In the performance of its obligations under this Agreement, it will not: (1) provide or promise to provide, directly or indirectly, any unlawful contribution, gift, entertainment, or other unlawful payment to any foreign or domestic government employee relating to political activity; (2) take any action, directly or indirectly, that violates Foreign Corrupt Practices Act (“**FCPA**”), or any other applicable anticorruption law of any foreign jurisdiction, including, without limitation, “use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value” to any “foreign official” (as is defined in the FCPA), any foreign political party or official thereof, or any candidate for foreign political office, to influence their acts or decisions in their official capacity, to induce them to do or omit from doing any act in violation of their lawful duty, or to secure any improper advantage in order to assist in obtaining business, or retaining business, or directing business to any person; and (3) make or propose to make any bribe, payoff, influence payment, kickback, unlawful rebate, or other similar unlawful payment of any nature, including to healthcare providers or those employed by any governmental institutions.

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12.4Limitations.  THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES, OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

**ARTICLE 13**

**INDEMNIFICATION**

13.1Indemnification by Catalent.  Catalent shall indemnify, defend, and hold harmless Client, its Affiliates, and their respective directors, officers and employees (“**Client Indemnitees**”) from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys’ fees and reasonable investigative costs) in connection with any suit, demand or action by any third party (“**Losses**”) to the extent arising out of or resulting from (A) any breach of Catalent’s representations, warranties or obligations set forth in this Agreement, (B) any negligence or willful misconduct by Catalent or any of its Affiliates in connection with the performance of its obligations under this Agreement, or (C) **[\*\*\*]**; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee’s negligence, willful misconduct or breach of this Agreement.

13.2Indemnification by Client.  Client shall indemnify, defend, and hold harmless Catalent, its Affiliates, and their respective directors, officers and employees (“**Catalent Indemnitees**”) from and against any and all Losses to the extent arising out of or resulting from (A) any breach of Client’s representations, warranties or obligations set forth in this Agreement, (B) any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client’s exercise of control over the Processing, to the extent that Client’s written instructions or directions violate Applicable Laws, (D) the conduct of any clinical trials utilizing Product or API, (E) any negligence or willful misconduct by Client or its Affiliates in connection with the performance of its obligations under this Agreement, including its representatives during any audit of the Facility, (F) **[\*\*\*]**, or (G) any negligence or willful misconduct by Client, in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee’s negligence, willful misconduct or breach of this Agreement or is subject to Catalent’s indemnification obligations under Sections 13.1.

13.3Indemnification Procedures.  The indemnified party shall (A) promptly notify the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (B) allow the indemnifying party to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party’s expense), and (C) cooperate with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party’s expense).  The indemnifying party shall have discretion to settle any action subject to indemnification under this Agreement; provided that the indemnifying party shall not enter into any settlement that would adversely affect the

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indemnified party’s rights hereunder, or impose any obligations on the indemnified party, without the indemnified party’s written consent, which shall not be unreasonably withheld or delayed.

**ARTICLE 14**

**LIMITATIONS OF LIABILITY**

14.1OTHER THAN WITH RESPECT TO CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS (WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE USED OR INCORPORATED INTO PRODUCT) ARISING FROM CATALENT’S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, CATALENT’S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS (WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE USED OR INCORPORATED INTO PRODUCT) SHALL NOT EXCEED (I) **[\*\*\*]** WHERE SUCH CLAIM ARISES FROM CATALENT’S PROCESSING OF THE CLIENT-SUPPLIED MATERIALS IN THE PERFORMANCE OF SERVICES AND (II) **[\*\*\*]**WHERE THE CLAIM ARISES FROM OUTSIDE OF CATALENT’S PROCESSING OF THE CLIENT-SUPPLIED MATERIALS IN THE PERFORMANCE OF SERVICES; *PROVIDED, HOWEVER*, CATALENT’S TOTAL AGGREGATE LIABILITY UNDER THIS SECTION 14.1 FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS (WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE USED OR INCORPORATED INTO PRODUCT) MADE BY CLIENT **[\*\*\*]** SHALL NOT EXCEED **[\*\*\*]**.

14.2CATALENT’S TOTAL AGGREGATE LIABILITY UNDER THIS AGREEMENT WITH RESPECT TO THE AGGREGATE CLAIMS BY CLIENT **[\*\*\*]** SHALL NOT EXCEED **[\*\*\*]**.

14.3EXCEPT FOR BREACHES OF ARTICLE 10 FOR WHICH CATALENT’S LIABILITY FOR INDIRECT DAMAGES UNDER THIS QUOTATION OR QAR SHALL NOT EXCEED **[\*\*\*]**, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA (COLLECTIVELY, “**INDIRECT DAMAGES**”) ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT, IN CIVIL LIABILITY OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.  FOR PURPOSES OF CLARITY, INDEMNIFIABLE LOSSES UNDER ARTICLE 13 SHALL NOT BE CHARACTERIZED AS CONSEQUENTIAL TO CLIENT OR CATALENT SOLELY ON THE BASIS THAT SUCH LOSSES ARISE FROM DAMAGES SUFFERED BY A THIRD PARTY.

**ARTICLE 15**

**INSURANCE**

15.1Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than **[\*\*\*]**; and (B) Products Liability Insurance with a per-occurrence limit of not less than **[\*\*\*]**. Catalent shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, Completed Operations Liability Insurance with a per-occurrence limit of not less than **[\*\*\*]**, Workers’ Compensation Insurance with statutory limits and Employers

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Liability Insurance with limits of not less than **[\*\*\*]**per accident.  Client shall maintain Stock Throughput Insurance with limits of not less than **[\*\*\*]** per conveyance and **[\*\*\*]**per location.  Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than **[\*\*\*]**.  Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII.  If any of the required policies of insurance are written on a claims-made basis, such policies shall be maintained throughout the Term and for a period of at least three (3) years thereafter.  Upon the other party’s reasonable written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

**ARTICLE 16**

**TERM AND TERMINATION**

16.1Term.  This Agreement shall commence on the Effective Date and shall continue until the end of the fifth (5th) Contract Year, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the “**Term**”).  The Term shall automatically be extended for successive two (2) year periods unless and until one party gives the other party at least twenty-four (24) months’ prior written notice of its desire to terminate as of the end of the then-current Term.

16.2Termination.  This Agreement may be terminated immediately without further action:

A.by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within sixty (60) days, or takes any equivalent or similar action in consequence of debt in any jurisdiction;

B.by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within sixty (60) days after the giving of written notice requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within ten (10) days of receipt of notice of non-payment from Catalent; provided that, if the basis for such termination is disputed by either party, such termination shall not be effective if and until final resolution pursuant to Section 18.10 that this Agreement is terminated as a result of such material breach; or

C.by Client upon six (6) months’ prior written notice to Catalent in the event that Client or its licensees shall withdraw, or be required by the FDA or other Regulatory Authority in Europe to withdraw the Product from the market in any country in the Territory for any reason for a period that is, or is reasonably expected to be, greater than ninety (90) days.

16.3Effect of Termination.  Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination.  In the event of a termination of this Agreement:

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A.Catalent shall promptly return to Client, at Client’s expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding undisputed amounts in invoices have been paid in full;

B.Client shall pay Catalent all invoiced undisputed amounts due and payable hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), all Product in process of being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii));

C.in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), Client shall pay Catalent for all Firm Orders, costs and expenses incurred, and all noncancelable commitments made in connection with Catalent’s performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client’s most recent Firm Commitment and the vendor’s minimum purchase obligations;

D.in the event that this Agreement is terminated by either party for any reason, for up to a period of **[\*\*\*]**following such termination, Catalent shall, to the extent not already undertaken and at the written request of Client as of the applicable date of notice of termination, reasonably assist Client to qualify an alternate supplier on behalf of Client pursuant to the terms set forth in Section 2.2.

16.4Survival.  The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 3.1(C), 3.1(D), 3.1(E), 7.3 (Payment Terms), 7.4 (Taxes), 7.5 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.5 (Recall), 12.4 (Limitations), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

**ARTICLE 17**

**NOTICE**

All notices and other communications hereunder shall be in writing and shall be deemed given:    (A) when delivered personally or by hand; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

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|  |  |
| --- | --- |
| To Client: | Phathom Pharmaceuticals, Inc. |

2150 E. Lake Cook Road, Suite 800

Buffalo Grove, Illinois 60089

Attn:  Vice President, Manufacturing and Supply Chain

|  |  |
| --- | --- |
| With a copy to: | Phathom Pharmaceuticals, Inc. |

100 Campus Drive, Suite 102

Florham Park, New Jersey 07932

Attn: General Counsel (Legal Department)

Email: **[\*\*\*]**

To Catalent:Catalent Pharma Solutions, LLC

1100 Enterprise Drive

Winchester, Kentucky 40391

Attn:  General Manager

Facsimile: **[\*\*\*]**

|  |  |
| --- | --- |
| With a copy to: | Catalent Pharma Solutions, LLC |

14 Schoolhouse Road

Somerset, New Jersey 08873

Attn: General Counsel (Legal Department)

Facsimile: **[\*\*\*]**

Email: **[\*\*\*]**

**ARTICLE 18**

**MISCELLANEOUS**

18.1Entire Agreement; Amendments.  This Agreement, together with the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties, with respect to the subject matter hereof, including, for avoidance of doubt, that certain quotation letter (PHA-QTE 9155764 Version number: 06), executed on June 12th, 2020.  For the avoidance of doubt, this Agreement does not supersede the MNDA.  No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2Captions; Certain Conventions.  The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement.  Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word  “or” shall be deemed to include the word “and” (e.g., “and/or”), and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement.  This Agreement shall be construed as if it were drafted jointly by the parties.

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18.3Further Assurances.  The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4No Waiver.  Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5Severability.  If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6Independent Contractors.  The relationship of the parties is that of independent contractors, and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement.  Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.  Neither party shall have any responsibility for the hiring, termination or compensation of the other party’s employees or contractors or for any employee benefits of any such employee or contractor.

18.7Successors and Assigns.  This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns.  Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party’s consent (but subject to written notice), assign this Agreement in its entirety to an Affiliate or to a successor, surviving or acquiring entity, of substantially all of the business or assets of the assigning party or the assigning party’s business unit responsible for performance under this Agreement.  Any purported assignment or transfer inconsistent with this Section 18.7 will be null and void.

18.8No Third-Party Beneficiaries.  This Agreement shall not confer any rights or remedies upon any Person other than the parties named herein and their respective successors and permitted assigns.

18.9Governing Law.  This Agreement, and all claims or causes of action (whether in contract, tort, or statute) that may be based upon, arise out of, or relate to this Agreement, or the negotiation, execution, or performance of this Agreement (including any claim or cause of action based upon, arising out of, or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by and enforced in accordance with, the internal laws of the State of New York, USA, without giving effect to any laws, rules, or provisions of the State of New York that would cause the application of the laws rules or provisions of any jurisdiction other than the State of New York.  The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10Alternative Dispute Resolution.  Any dispute that arises between the parties in connection with this Agreement shall first be presented to the senior executives of the parties for consideration and resolution.  If such executives cannot reach a resolution of the dispute within a reasonable time, then such dispute shall be resolved by binding alternative dispute resolution in accordance

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with the then existing commercial arbitration rules of the American Arbitration Association.  Arbitration shall be conducted in the jurisdiction of the defendant party, in the English language.

18.11Prevailing Party.  In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney’s fees and costs in such proceeding from the other party.

18.12Publicity.  Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party’s express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall provide  the other party with a draft of such form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure, and shall consider in good faith any comments provided by the non-disclosing party.

18.13Right to Dispose and Settle.  If Catalent requests in writing from Client direction with respect to disposal of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within ninety (90) days after making such request, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14Force Majeure.  Except as to payments required under this Agreement, neither party shall be liable in damages for any delay or default in such party’s performance hereunder if such default or delay is caused by events beyond such party’s reasonable control, which may include acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, epidemic or failure of public utilities;  provided, that the party seeking relief under this Section 18.14 shall immediately notify the other party of such cause(s) beyond such party’s reasonable control.  The party that may invoke this Section 18.14 shall use commercially reasonable efforts to resume performance of its ongoing obligations to the other party as soon as practicable.  If the cause(s) shall continue unabated for ninety (90) days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s); and if the parties are not able to agree upon such modifications within thirty (30) days after such ninety (90) day period, either party may terminate this Agreement upon written notice delivered by such party to the other party.

18.15Counterparts.  This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument.  Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

*[Signature page follows]*

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**IN WITNESS WHEREOF**, the parties have caused their respective duly authorized representatives to execute this Agreement effective as of the Effective Date.

**CATALENT PHARMA SOLUTIONS, LLCPHATHOM PHARMACEUTICALS, INC.**

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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*Signature Page to Commercial Supply Agreement*

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**ATTACHMENT A**

**VALIDATION SERVICES**

**[\*\*\*]**

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**ATTACHMENT B**

**SPECIFICATIONS**

**I.  Client-supplied Materials (and associated specifications)**

**[\*\*\*]**

**II.Raw Materials (and associated specifications)**

**[\*\*\*]**

**III.Current Product Specifications (including Batch size)**

**[\*\*\*]**

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**ATTACHMENT C**

**UNIT PRICING AND FEES**

**[\*\*\*]**

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**ATTACHMENT D**

**CLIENT-SUPPLIED MATERIALS**

**[\*\*\*]**