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CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED, AND HAS BEEN MARKED WITH "[***]" TO INDICATE WHERE OMISSIONS HAVE BEEN MADE.

MANUFACTURING PREPARATION AND COMMERCIAL SUPPLY AGREEMENT

(Sodium Oxybate Beads)

This Commercial Supply Agreement is made as of this 29th day of March 2018 (the "**Effective Date**"), by and between Flamel Ireland Limited (DBA Avadel Ireland), a corporation organized under the laws of Ireland, with a place of business at Block 10 – 1 Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("**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 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;

C. Client desires to have Catalent provide the services set forth in this Agreement (as defined below) in connection with Client's Product (as defined below), and Catalent desires to provide such services, all pursuant to the terms and conditions in this Agreement.

THEREFORE, in consideration of the circumstances described above and 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 4.3(B).

1.2 "**Affiliate(s)**" means, with respect to Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, "**control**" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.

1.3 "**Agreement**" means this document, including all its attachments and other appendices (all of which are incorporated by reference) and any amendment to any of the foregoing made in accordance with Section 18.1.

1.4 "**Annual Product Maintenance Fee**" has the meaning set forth in Section 7.1(C).

1.5 "**API**" means the generic compound sodium oxybate, as further described in the Specifications. The parties acknowledge that API is a controlled substance under Applicable Laws, including DEA regulations.

1.6 "**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 or Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, ordinances, rules and regulations, 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, including cGMP.

1.7 "**Batch**" means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.

1.8 "**Blended Beads Bonus**" has the meaning set forth in Attachment I.

1.9 "**Blended Beads Shortfall**" has the meaning set forth in Attachment I.

1.10 "**Capital Recovery Fee**" has the meaning set forth in Attachment G.

1.11 "**Catalent**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.12 "**Catalent Defective Processing**" has the meaning set forth in Section 5.2.

1.13 "**Catalent Indemnitees**" has the meaning set forth in Section 13.2.

1.14 "**Catalent IP**" has the meaning set forth in Article 11.

1.15 "**Catalent Inventions**" has the meaning set forth in Article 11.

1.16 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; and in the European Union, 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.

1.17 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.18 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.19 "**Client Inventions**" has the meaning set forth in Article 11.

1.20 "**Client IP**" has the meaning set forth in Article 11.

1.21 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing, as described in Attachment B, including API and reference standards.

1.22 "**Commencement Date**" means the first date upon which the FDA approves Catalent as a manufacturer of the Product and provides Regulatory Approval for the Product.

1.23 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.24 "**Contract Year**" means each 12-month period beginning on the Commencement Date or anniversary therefore, as applicable.

1.25 "**CR Beads Bonus**" has the meaning set forth in Attachment I.

1.26 "**CR Beads Shortfall**" has the meaning set forth in Attachment I.

1.27 "**DEA**" means the U.S. Drug Enforcement Agency.

1.28 "**Defective Product**" has the meaning set forth in Section 5.2.

1.29 "**Discloser**" has the meaning set forth in Section 10.1.

1.30 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.31 "**Estimated Capital Outlay**" has the meaning set forth in Section 2.4.

1.32 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.33 "**Facility**" means Catalent's facility located in Winchester, Kentucky, USA, or such other facility in the United States as agreed by the parties in writing.

1.34 "**FDA**" means the U.S. Food and Drug Administration, inclusive of the Center for Veterinary Medicine, or any successor thereto.

1.35 "**Firm Commitment**" has the meaning set forth in Section 4.1.

1.36 "**In-Process Defect**" has the meaning set forth in Section 5.6.

1.37 "**Intellectual Property**" means all intellectual property (whether or not patented or patentable), including without limitation, patents, patent applications, know-how, trade secrets, copyrights, trademarks, inventions, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, processes and data.

1.38 "**Invention**" has the meaning set forth in Article 11.

1.39 "**IR Beads Bonus**" has the meaning set forth in Attachment I.

1.40 "**IR Beads Shortfall**" has the meaning set forth in Attachment I.

1.41 "**Losses**" has the meaning set forth in Section 13.1.

1.42 "**Manufacturing Preparation**" has the meaning set forth in Section 2.1.

1.43 "**Manufacturing Preparation Services**" has the meaning set forth in Section 2.1.

1.44 "**Monthly Manufacturing Preparation Services Fee**" has the meaning set forth in Attachment G.

1.45 "**Monthly Suite Fee**" has the meaning set forth in Section 7.1(G).

1.46 “**Partial Batch Cost**” has the meaning set forth in Section 5.5.

1.47 "**Process**" or "**Processing**" means the compounding, filling or tableting, encapsulating, producing and sachet-filling of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

1.48 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement or as otherwise communicated to the Client.

1.49 "**Product**" means the bulk pharmaceutical stick pack containing beads that include the API, as more specifically described in the Specifications.

1.50 "**Product Bonus**" has the meaning set forth in Attachment I.

1.51 "**Product Shortfall**" has the meaning set forth in Attachment I.

1.52 "**Product Maintenance Services**" has the meaning set forth in Section 2.10.

1.53 "**Purchase Order**" has the meaning set forth in Section 4.3(A).

1.54 "**Quality Agreement**" has the meaning set forth in Section 9.6.

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

1.56 "**Recall**" has the meaning set forth in Section 9.5.

1.57 "**Recipient**" has the meaning set forth in Section 10.1.

1.58 "**Regulatory Approval**" means each approval, permit, product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of Product in the Territory.

1.59 "**Regulatory Authority**" means an international, federal, state or local governmental or regulatory body, agency, department, bureau, court or other entity in the Territory that is 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, this includes the FDA; and in Canada, this includes the Health Portfolio.

1.60 "**Representatives**" of an entity mean such entity's duly authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.61 "**Review Period**" has the meaning set forth in Section 5.2.

1.62 "**Rolling Forecast**" has the meaning set forth in Section 4.1.

1.63 "**Shared/Unassigned Defect**" has the meaning set forth in Section 5.2.

1.64 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment B, as modified from time to

time in accordance with Article 8. Such Specifications will comply with all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the Territory and (if different) the jurisdiction in which Catalent Processes Product.

1.65 "**Success Milestone Fee**" has the meaning set forth in Attachment G.

1.66 "**Suite**" has the meaning set forth in Section 2.1.

1.67 "**Suite Equipment**" has the meaning set forth in Section 2.1.

1.68 [***]

1.69 [***]

1.70 [***]

1.71 [***]

1.72 [***]

1.73 [***]

1.74 [***]

1.75 [***]

1.76 "**Term**" has the meaning set forth in Section 16.1.

1.77 "**Territory**" means [***], and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement, but excluding any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

1.78 "**Unit**" has the meaning set forth on Attachment C.

1.79 "**Unit Pricing**" has the meaning set forth in Section 7.1(B)

1.80 "**Validation Services**" has the meaning set forth in Section 2.7.

1.81 "**Vendor**" has the meaning set forth in Section 3.1(B).

ARTICLE 2
MANUFACTURING PREPARATION, VALIDATION, PROCESSING AND RELATED SERVICES

2.1 Manufacturing Preparation Services. Commencing on the Effective Date and subject to the terms and conditions set forth herein, Catalent will build the manufacturing space at the Facility (the "**Suite**"), procure and install the equipment set forth in Attachment E (the "**Suite Equipment**"), and implement the required infrastructure at the Facility and within the Suite

(collectively, the **"Manufacturing Preparation**") necessary to Process the volume of Product set forth herein. Catalent shall perform all services necessary to complete the Manufacturing Preparation (the "**Manufacturing Preparation Services**") in accordance with the terms set forth in this Agreement.

2.2 Ownership of the Manufacturing Preparation. Catalent shall own and have sole title to the Manufacturing Preparation and other assets acquired or otherwise resulting from the Manufacturing Preparation. Processing of Product for Client shall be given first priority with respect to Catalent's utilization of the Suite and Suite Equipment.

2.3 Repair and Maintenance the Manufacturing Preparation. Catalent shall be responsible for the repair and maintenance of the Manufacturing Preparation, if and as needed at Catalent's sole expense.

2.4 Capital Outlay Estimate and Costs. The estimated capital outlay Catalent will spend to perform the Manufacturing Preparation Services ("the **Estimated Capital Outlay**") is set forth in Attachment F. Catalent shall use commercially reasonable efforts to minimize the costs associated with the implementation of the Manufacturing Preparation.

2.5 Monthly Reports. Catalent shall send to Client a monthly report describing the progress of each event of the Manufacturing Preparation and Manufacturing Preparation Services.

2.6 Documents and Suite Inspection. Upon request by Client, Catalent shall provide Client with copies of relevant documentation with respect to the Manufacturing Preparation. Client shall have the right to inspect the Manufacturing Preparation upon providing [***] prior written notice to Catalent and during normal business hours.

2.7 Validation Services. Catalent shall perform the Product qualification, validation and stability services, if any, described in Attachment A (the "**Validation Services**").

2.8 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.9 Exclusivity.

A. [***]

B. Client Exclusivity. During the Term of this Agreement, Client shall purchase [***] of its annual requirements of Product from Catalent. With respect to the previous sentence, Purchase Orders cancelled by Catalent except those cancelled under Section 4.3 below will count toward Client's annual minimum purchase requirements.

2.10 Product Maintenance Services. Catalent shall provide and Client will receive those product maintenance services specified in Attachment D (the "**Product Maintenance Services**").

2.11 Other Related Services. Catalent shall provide Product-related services, other than Validation Services, Processing or Product Maintenance Services, as either specified in Attachment D or agreed 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.

2.12 Affiliates and Facility. Catalent shall have the right to cause any of its U.S. Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent. Catalent shall not change the Facility without the written consent of Client.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, Client-supplied Materials in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than [***] before the Processing Date. Client shall be responsible at its expense for securing any necessary DEA, export, import or other governmental clearance, permit or certification required in respect of such supply. Catalent shall use Client-supplied Materials solely for Processing. Prior to delivery of any Client-supplied Materials, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the API and Product, and thereafter shall provide promptly any update thereto.

B. Catalent shall inspect all Client-supplied Materials received to verify their identity and conformance with certificates of analyses and the Specifications. Catalent shall not be liable for any defect in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent did not perform or was negligent in performing the foregoing obligations in accordance with the Specifications. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss of any such Client-supplied Materials. Client shall obtain and maintain insurance for such items while at the Facility and in transit to and from any Facility in accordance with Article 15.

3.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed by the parties in writing. Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement.

B. If Client requires a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material, then (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of the other Sections of this Agreement. If the cost of the Raw Material from any such Vendor is greater or less than Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add or reduce 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 associated with qualification of any such Vendor that 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, Client shall bear the cost of any

Raw Materials (including packaging) unusable for Processing or Product and unused by Catalent for another customer, 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.

D. Catalent will charge Client for the purchase of Raw Materials at an amount equal to [***]. The parties agree to collaborate to achieve optimal material supply chain costs. In no event will Catalent mark up any Raw Materials more than [***].

3.3 Artwork 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 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 without Client's written consent.

ARTICLE 4
PURCHASE ORDERS & FORECASTS

4.1 Forecast. On or before [***], beginning at least [***] prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [***] rolling forecast of the quantities of Product that Client intends to order from Catalent during such [***] (the "**Rolling Forecast**"). The first [***]of each Rolling Forecast shall constitute a binding order for the quantities of Product specified in such Rolling Forecast (the "**Firm Commitment**") and the following [***]of the Rolling Forecast shall be non-binding, good-faith estimates.

4.2 Purchase Orders.

A. From time to time as provided in this Section 4.2(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 (each, a "**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. Within [***] following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (each, an "**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, and shall include the Processing Date. Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement. If Catalent does not reject a Purchase Order during [***], the Purchase Order shall be deemed accepted as submitted including acceptance of the delivery date set forth in the Purchase Order.

C. Catalent shall use commercially reasonable efforts to supply Client with quantities of Product set forth in a Purchase Order which are up to [***] in excess 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.

4.3 Catalent's Cancellation of Purchase Orders. Notwithstanding anything in Sections 4.2 and 4.4 to the contrary, Catalent reserves the right to cancel all, or any part of, a Purchase Order

upon written notice to Client, and Catalent shall have no further obligation or liability with respect to such Purchase Order, if Client refuses or fails to supply conforming Client-supplied Materials prior to the deadline set forth in Section 3.1. Any cancellation of Purchase Orders in accordance with this Section 4.3 shall not constitute a breach of this Agreement by Catalent, and the parties will work together in good faith to set a new Processing Date and a new delivery date for the Product quantity set forth in the cancelled Purchase Order.

4.4 Client'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 Processing 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 any such written approval, Client shall remain responsible for the Firm Commitment.

B. Notwithstanding any amount due to Catalent under Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent in accordance with Article 7 the Unit Pricing for all Units that would have been Processed if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment.

4.5 Unplanned Delay of Processing. Catalent shall provide Client with as much advance notice as practicable if Catalent determines that any Processing will be delayed for any reason.

4.6 Observation of Processing. In addition to Client's audit right pursuant to Section 9.4, Client may send up to [***] Representatives to the Facility to observe Processing for a maximum of [***] (unless otherwise agreed by Catalent in writing), upon at least [***] prior notice, at reasonable times during regular business hours. Catalent shall provide Client's Representatives with applicable policies and procedures at the Facility prior to the start of an audit. Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Except to the extent that any of the following arises out of or results from any negligence, willful misconduct or breach of this Agreement by Catalent, its Affiliates, and their respective directors, officers, employees and agents, Client shall indemnify and hold harmless Catalent for any action, omission or other activity of its Representatives while on Catalent's premises for purposes of this Agreement. 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; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties during their ordinary course of dealings, 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, Catalent shall provide such Batch records promptly following resolution of the out-of-Specification result. After Catalent completes Processing of a Batch, quality review and Catalent release, Catalent shall also provide Client or its designee with Catalent's certificate of analysis for such Batch. Issuance of a certificate of analysis and certificate of conformance by Catalent constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product to the market (at its cost and

evidenced by Catalent's receipt of a written notification for release for the particular Batch(es) from Client) in accordance with the Quality Agreement.

5.2 Testing; Rejection. No later than [***] after Client's or its designee's receipt of the Batch ("**Review Period**"), Client shall notify Catalent whether the Batch conforms to the Specifications. Upon receipt of notice from Client that a Batch meets the Specifications, or upon

failure of Client to respond by the end of the Review Period, subject to Section 5.7 (Latent Defects), the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch. If Client 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(A) ("**Defective Product**"), and provides a sample of the alleged Defective Product, then Catalent shall in good faith conduct an appropriate investigation to determine whether the Product is Defective Product and to determine the cause of any nonconformity. If, upon its good faith efforts, Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to Catalent's negligence or willful misconduct ("**Catalent Defective Processing**"), then Section 5.4 shall apply. If, upon its good faith efforts, Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is shared between the parties or cannot be determined or assigned ("**Shared/Unassigned Defect**"), then Section 5.5 shall apply.

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/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 cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. The costs associated with such testing and review shall be borne by [***]. The cost associated with such testing and review shall be shared equally by the parties in the event Product is Defective Product and the cause of nonconformity is a Shared/Unassigned Defect. [***].

5.4 Catalent Defective Processing. If a Batch of Defective Product is attributable to Catalent Defective Processing, Catalent shall, at Client's option, either (A) Process, at Catalent's cost another Batch of Product as a replacement for such Batch using Client-supplied Materials and reimburse Client for the cost of such Client-supplied Materials subject to the limitations set forth in Article 14 or (B) subject to the limitations set forth in Article 14, credit any payment made by Client for such rejected Batch and reimburse client for Client-supplied Materials expended making such rejected Batch of Defective Product. For the avoidance of doubt, in the event the original Defective Batch has not been paid for by Client or has been credited back to Client by Catalent, Catalent will be entitled to charge Client for the one replacement Batch that conforms with the Specifications and is released by Catalent in accordance with Section 5.1 above. THE OBLIGATION OF CATALENT TO (i) REPLACE DEFECTIVE PRODUCT ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT/REIMBURSE PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT SUBJECT TO THE LIMITATIONS SET FORTH IN ARTICLE 14 AND (ii) PAY THE COST OF CLIENT-SUPPLIED MATERIALS LOST IN CATALENT DEFECTIVE PROCESSING, SUBJECT TO THE LIMITATIONS SET FORTH IN ARTICLE 14, SHALL BE, TOGETHER WITH CLIENT'S RIGHTS UNDER SECTIONS 3.1(B), 9.5, AND 13.1, CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT DUE TO CATALENT DEFECTIVE PROCESSING AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

5.5 Shared/Unassigned Defects. If the cause of nonconformity for a Batch of Defective Product is assigned Shared/Unassigned Defect, Catalent shall Process, at Catalent's cost, another Batch of Product as a replacement for such Batch using Client-supplied Materials paid for by Client. If the

Batch of Defective Product was not completed, and a replacement for such uncompleted Batch cannot be Processed by Catalent within [***] of the delivery date set forth in the original Purchase Order due to reasons solely within Client's reasonable control (i.e., not a force majeure event), then Client shall pay Catalent for the cost of the partial Batch ("**Partial Batch Cost**") as set forth in Attachment C. For the avoidance of doubt, in the event the original Defective Batch has not been paid for by Client, Catalent will be entitled to charge Client for the

Processing of the one replacement Batch that conforms with the Specifications and is released by Catalent in accordance with Section 5.1 above. THE OBLIGATION OF CATALENT TO REPLACE A BATCH OF DEFECTIVE PRODUCT WHERE THE CAUSE OF NONCONFORMITY FOR SUCH BATCH IS SHARED BETWEEN THE PARTIES OR CANNOT BE DETERMINED OR ASSIGNED, SUBJECT TO THE LIMITATIONS SET FORTH IN ARTICLE 14, SHALL BE, TOGETHER WITH CLIENT'S RIGHTS UNDER SECTIONS 3.1(B), 9.5, AND 13.1, CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT HAVING SHARED/UNASSIGNED DEFECTS AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

5.6 In-Process Defects. If during, yet prior to completion of, the Processing of a Batch, Catalent determines the Batch is or will be defective ("**In-Process Defect**"), then Catalent shall in good faith determine the cause of any nonconformity and share the results of such determination with Client in writing within [***] of making such determination. If, upon its good faith efforts, Catalent determines the In-Process Defect is attributable to Catalent Defective Processing, then Section 5.4 shall apply. If, upon its good faith efforts, Catalent determines the In-Process Defect is attributable to a Shared/Unassigned Defect, then Section 5.5 shall apply.

5.7 [***]

5.8 [***]

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall deliver Product [***] (Incoterms 2010) the Facility by the sooner of (i) [***] following Client's release of Product (i.e., following Catalent's receipt of a written certificate of release for the particular Batch(es) from Client per Section 5.1. above) or (ii) [***] following Catalent's release of such Product. Catalent shall segregate and store all Product until tender of delivery. 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 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 request, such services are performed by Catalent as a convenience to Client only and do not alter the terms and limitations set forth in this Section 6.1. Catalent shall not be responsible for Product in transit, including any cost of insurance or transport fee for Product, or any risk associated with transit or customs delays, storage and handling.

6.2 Storage Fees; Bill and Hold.

A. If Client fails to take delivery of any Product within [***] of such Product being tendered for delivery, Catalent shall store such Product and have the right to invoice Client monthly (prorate for partial months) following such scheduled delivery for storage costs of [***].

B. From time to time, at Client's request, the agreed delivery date of the Purchase Order may be extended under a bill and hold arrangement as more fully set forth below. For each such Batch of stored Product, Client agrees that: (A) Client has made a fixed commitment to purchase

the Product, (B) risk of loss for such Product passes to Client upon placement into storage, (C) such Product shall be on a bill and hold basis for legitimate business purposes, (D) the Client shall identify a fixed delivery date for the Product and (E) Client agree to be invoiced and to pay such invoice in accordance with the Payment terms set forth in this Agreement. Upon

making a request for a bill and hold arrangement, Client shall provide Catalent with a letter confirming items (A) through (E) of this Section for each Batch of stored Product.

6.3 [***]

ARTICLE 7
PAYMENTS

7.1 Fees.

A. Client shall pay to Catalent the fees for Validation Services, if any, 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. Client shall pay Catalent the initial unit pricing for sodium oxybate beads set forth on Attachment C (together with any subsequent updates to pricing, the "**Unit Pricing**"). Catalent shall submit an invoice to Client for such fees upon tender of delivery of corresponding Product incorporating such beads as provided in Section 6.1.

C. Client shall pay Catalent the **Annual Product Maintenance Fee** set forth on Attachment C for the Product Maintenance Services set forth on Attachment D. Catalent shall submit an invoice to Client for such fees upon the Commencement Date and thereafter, upon the first day of each Contract Year.

D. Client shall pay to Catalent during the time period of the Manufacturing Preparation Services and during the registration batch manufacturing the **Monthly Manufacturing Preparation Services Fees** set forth in Attachment G.

E. Client shall pay to Catalent the **Capital Recovery Fee** set forth in Attachment G.

F. Client shall pay to Catalent the **Success Milestone Fees** set forth in Attachment G.

G. Client shall pay to Catalent the **Monthly Suite Fee** set forth in Attachment H. Catalent will invoice Client for all additional activities necessitated by the one-time dismantling of the Suite Equipment during the FDA review period (after registration manufacturing and prior to re-commissioning) and the re-installation and re-qualification prior to the beginning of Process validation in advance of the Product launch.

H. 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 2.11, 5.5, 6.2 and 16.3. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing Adjustment. The Unit Pricing shall be adjusted [***], effective on [***], upon [***] prior written notice from Catalent to Client, to reflect increases or decreases in, among other things, labor, utilities and overhead and shall be the change 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.

7.3 Payment Terms. Payment to Catalent of all undisputed amounts invoiced to Client shall be due [***] after the date of invoice. If Client disputes any amount of an invoice, it shall notify

Catalent within [***] of its receipt of the invoice. The parties agree to negotiate in good faith and within a reasonable time period to resolve any dispute concerning invoiced amounts. Once the parties resolve such a dispute, Client shall pay the new amount to Catalent by the later of the

original invoice due date or [***] after receiving a new invoice from Catalent reflecting such new amount. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. If any payment is not received by Catalent by its due date, then Catalent may, in addition to 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).

7.4 Advance Payment. Notwithstanding any other provision of this Agreement to the contrary, if at any time Client's credit is materially impaired, Catalent may request further assurances before performing any further service under this Agreement, including any Processing, or making any further shipment of Product. If Client shall fail, within a reasonable time, to make such further assurances, Catalent shall have the right, at its option, to suspend any further performance under this Agreement until such assurances are provided.

7.5 Taxes. All taxes, duties and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of (i) Client-supplied Materials, whether prior to or upon provision or sale, or (ii) Product supplied by Catalent to Client, upon provision or sale, in each case whether assessed on Catalent or Client, are the responsibility of Client, and either Client shall reimburse Catalent for all such taxes, duties or other amounts paid by Catalent or such sums will be added to invoices directed at Client. 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 shall be obliged to pay to Catalent 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.

7.6 Client and Third-Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for one hundred percent (100%) of its own and all third-party expenses associated with development, Regulatory Approval and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.7 Development Batches. Each Batch produced 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 Batch, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent or committed willful misconduct in the Processing of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problem causing the out-of-Specification Batch.

ARTICLE 8
CHANGES TO SPECIFICATIONS

All Specifications, and any change to the Specifications agreed 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, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good-faith efforts to agree to the terms of such change in a timely manner. As soon as practicable 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 costs associated with agreed changes to the Specifications. 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.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain materially complete and accurate Batch records, laboratory data and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least [***] from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Regulatory Approvals required of Client by Applicable Law with respect to Product or the services provided pursuant to this Agreement, including those necessary for Catalent to commence Processing. Client shall not identify Catalent in any ANDA/NDA application or other such initial regulatory filing or submission without Catalent's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both parties. In the event identification of the Product manufacturer is required by a Regulatory Authority for Regulatory Approval of the Product, Client shall be allowed to identify Catalent in such application/filing without Catalent's consent provided Client provides Catalent at least [***] prior written notice (unless regulatory requirements demand a shorter period) of such draft filing and considers in good faith any additions or revisions Catalent suggests. Upon written request, and solely for the purpose of identifying Catalent for accuracy purposes, Client shall provide Catalent with a copy of the relevant section(s) of each Regulatory Approval referencing Catalent that is required to distribute, market or sell Product in the Territory. If Client is unable to provide such information, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense. The parties shall cooperate to allow each party to satisfy their respective obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Government/Regulatory Inspections and Requests. Catalent shall promptly advise Client if any Regulatory Authority (or agent acting on its behalf) notifies Catalent that the Regulatory Authority intends to or does visit the Facility where at least one purpose relates to Processing. Upon request, Catalent shall provide Client with a copy of any report provided to Catalent by such Regulatory Authority following such visit, which report may be redacted as appropriate to protect any confidential information of Catalent or Catalent's other customers; and Client shall provide Catalent with any material correspondence with such Regulatory Authority, including FDA refusal to file, rejection or warning letters. 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. Client shall reimburse Catalent for all reasonable and documented costs associated with inspections by Regulatory Authorities in connection with Product, and pay the fees specified in Attachment C for the services specified in Attachment D, to the extent applicable, only if such inspection(s) is(are) not incepted as a result of a failure by Catalent to follow regulatory requirements with respect to Catalent's Processing. Client may have its Representatives present at the Facility during a regulatory inspection but may not observe or

participate in a regulatory inspection unless the Regulatory Authority specifically requests Client's participation. The presence of such Client Representative shall not constitute a Client facility audit under Section 9.4 below, nor will such presence of such Client Representative constitute an observation of Processing visit under Section 4.6 above

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least [***] prior notice, at reasonable times during regular business hours, to (A) the portion of the 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 and the Product master Batch records. Client may not conduct an audit under this Section 9.4 more than [***]; *except* that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or Processing. Audits and inspections shall be designed to minimize disruption of operations at the Facility. The obligations of Client and its Representatives in Section 4.6 shall apply to all audits undertaken by Client and its Representatives pursuant to this Section 9.4.

9.5 Recall. If a Regulatory Authority orders or requires the recall of Product supplied pursuant to this Agreement or if either Catalent or Client believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other party in writing. 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, such copy being provided no less than [***] prior to submission to a Regulatory Authority. Client shall consider in good faith any comments from Catalent relating to such submission. The cost of any Recall shall be borne by [***].

9.6 Quality Agreement. Within six (6) months after the Effective Date, and in any event prior to the first Processing of Product under this Agreement, the parties shall negotiate in good faith and enter into a quality agreement (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth in that agreement. In the event of a conflict between any provision 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 provision of this Agreement and the Quality Agreement with respect to any other matter, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.7 Regulatory Authority Fees. Catalent reserves the right to charge Client for any Regulatory Authority fees that may be established by any Regulatory Authority, which fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Client's Product or Client-supplied Materials in the Territory (including, for example, the Generic Drug User Fee Amendments of 2017, if applicable).

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential information of the disclosing person of whatever type, including all information furnished by or on behalf of Catalent or Client (as the case may be, "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other party (for purposes of this Article 10, "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished

before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical

information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement.

10.2 Exclusions. Notwithstanding anything in Section 10.1 to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by Recipient at the time of disclosure as evidenced by Recipient's written records, (C) becomes available to Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for Recipient without reference to Discloser's Confidential Information as evidenced by Recipient's written records.

10.3 Mutual Obligation. Recipient (A) will keep confidential all Confidential Information, employing such protections as it would use for its own Confidential Information of a similar type but in no case less than reasonable protections under the circumstances, (B) will not use Discloser's Confidential Information except in connection with the performance of its obligations under this Agreement and (C) will not disclose to any third party, without Discloser's prior written consent, Discloser's Confidential Information, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) are bound to Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

10.4 Permitted Disclosure. Recipient may disclose Discloser's Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, Recipient shall give Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Any such disclosure, however, shall not relieve Recipient of its obligations under this Agreement.

10.5 No Implied License. Except as expressly set forth in Section 10.1, Recipient will obtain no right of any kind or license under any of Discloser's Confidential Information, including any patent application or patent, by reason of this Agreement. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 11.

10.6 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within [***] either return or destroy (and certify as to such destruction) all of Discloser's Confidential Information, including any copy of such information, except for a single copy, which may be retained for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.7 Survival. The obligations of this Article will terminate [***] from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under law.

ARTICLE 11

INTELLECTUAL PROPERTY

As used in this Agreement, "**Client IP**" means all Intellectual Property and related embodiments owned by or licensed to Client as of the Effective Date or developed by Client other than in connection with this Agreement; "**Catalent IP**" means all Intellectual Property and related

embodiments owned by or licensed to Catalent as of the Effective Date 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 [***]; and "**Catalent Inventions**" means [***]. [***]. The parties shall cooperate to achieve the allocation of rights to Inventions set forth in this Article 11 (including jointly-developed Inventions), and each party shall be solely responsible for costs associated with the protection of its Intellectual Property.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

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

A. At the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with Applicable Laws and in conformity with the Specifications and shall 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 represents and warrants to Client that neither it nor any of its Representatives have been debarred, disqualified or restricted by any regulatory or other government authority, including the U.S. Food and Drug Administration pursuant to the Generic Drug Enforcement Act of 1992 or any other equivalent or successor statutes, rules or regulations. In the event Catalent learns of any pending proceeding or threatened debarment or disqualification of Catalent or any of its Representatives, Catalent covenants that it shall immediately notify Client in writing.

C. Catalent shall not incorporate any Catalent IP into the Processing or Products contemplated by this Agreement;

D. To its knowledge, there is (i) no patent owned by a third party related to the Catalent IP used to Process Product that would be infringed or misused by performance under this Agreement, and (ii) no trade secret or other proprietary right of a third party related to the Catalent IP used to Process Product that would be infringed or misused by performance under this Agreement.

E. No transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

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

A. All Client-supplied Materials shall have been produced in accordance with Applicable Laws, 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 provided by or on behalf of Client 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 Client in accordance with Applicable Laws, and Client will otherwise comply with 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 for the purposes of this Agreement all Intellectual Property related to Product, Client-supplied Materials (including artwork) or the Processing of either of them, including all applicable copyrights, trademarks, trade secrets, patents, inventions and developments.

F. To its knowledge, there is (i) no valid patent owned by a third party related to the Client IP used to Process Product that would be infringed or misused by performance under this Agreement and (ii) no trade secret or other proprietary right of a third party related to the Client IP used to Process Product that would be infringed or misused by performance under this Agreement.

G. To its knowledge, the services to be performed by Catalent under this Agreement will not violate or infringe upon any valid trademark, tradename, copyright, patent, trade secret, or other right held by any third party.

H. Client has (or will have prior to delivery) all authorizations and permits required to deliver (or have delivered) API to the Facility.

I. No transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

12.3 Limitations. 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 REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Catalent. Except to the extent that any of the following arises out of or results from any negligence, willful misconduct or breach of this Agreement by Client, its Affiliates, and their respective Representatives (collectively, "**Client Indemnitees**"), Catalent shall indemnify, defend and hold harmless Client Indemnitees from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and expenses and reasonable investigative costs) in connection with any suit, demand or action by any third party ("**Losses**") arising out of, relating to or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement or (B) any negligence or willful misconduct by Catalent or its Representatives.

13.2 Indemnification by Client. Except to the extent that any of the following arises out of or results from any negligence, willful misconduct or breach of this Agreement by Catalent, its Affiliates, and their Representatives (collectively, "**Catalent Indemnitees**"), Client shall indemnify, defend and hold harmless Catalent Indemnitees from and against any and all Losses

arising out of, relating to or resulting from (A) any breach of its 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 instructions or directions violate Applicable Laws, (D) the conduct of any clinical trial

utilizing Product or API, (E) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary right by Intellectual Property or other information provided by Client, including Client-supplied Materials, or (F) any negligence or willful misconduct by Client.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying 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*, *however*, that failure to provide such notice within a reasonable period shall not relieve the indemnifying party of its obligations under this Article 13 except to the extent, if any, the indemnifying party is prejudiced by such failure, (B) allowing 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), *provided*, that the indemnifying party shall promptly provide and continuously maintain such defense, (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 EXCEPT FOR [***], CATALENT'S LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED [***].

14.2 [***].

14.3 EXCEPT FOR [***], CATALENT'S TOTAL AGGREGATE LIABILITY OVER THE TERM OF THIS AGREEMENT FOR ANY AND ALL CLAIMS SHALL NOT EXCEED [***].

14.4 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

Each 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 and/or Foreign Liability Insurance with a per occurrence limit of [***] or equivalent and an annual aggregate limit of [***] or equivalent; (B) Products and Completed Operations Liability Insurance with a per occurrence limit of not less than [***] or equivalent covering each party's own operations arising out of or connecting with this Agreement, providing coverage for bodily injury and property damage claims; (C) Workers' Compensation as required by any applicable law or regulation and in accordance with the provisions of the laws of the nation, state, territory or province having jurisdiction over Customer's employees. If any such jurisdiction has a social scheme to provide insurance or benefits to injured workers, Customer must be in full compliance with the laws of such jurisdiction. Employer's Liability insurance will be provided in amounts not less than the

local currency equivalent of [***]) or equivalent per accident and [***] or equivalent per employee for disease, provided that such coverage is available in the nation, state, territory or province having jurisdiction over Customer’s employees. If there is an exposure of injury to Customer’s employees under the U.S. Longshoremen's and Harbor Workers' Compensation Act,

the Jones Act or under the laws, regulations or statutes applicable to maritime employees, coverage will be included for such injuries or claims; and (D) Auto Liability insurance in a minimum amount of [***] or equivalent combined single limit for all vehicles used in connection with the performance of this contract. Customer shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, All Risk Property Insurance, including transit coverage, an amount equal to the full replacement value of its property while in, or in transit to, or from, a Catalent facility. Customer shall obtain a waiver of subrogation clause from its property insurance carrier in favor of Catalent. Customer shall not seek reimbursement from Catalent corporate affiliates, and their respective officers, directors, employees, agents, successors and assigns for any property claim or portion thereof that is not fully recovered from Customer's Property Insurance policy. Each party shall be named as an additional insured within the other party's General Liability and / or Foreign Liability insurance and Products Completed Operations Liability policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this agreement. The policy(ies) under this Agreement will provide, by endorsement or otherwise, that Customer's insurance will be primary insurance and that any other insurance maintained by or otherwise afforded to Catalent, its corporate affiliates, and their respective officers, directors, employees, agents, successors, and assigns will be excess only and non-contributing except where prohibited by law. 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 [***] thereafter. Each insurance policy that is required under this Agreement shall be obtained from an insurance carrier with an A.M. Best or equivalent rating of at least A- VII or an S&P rating of A. 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 [***] or equivalent or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than [***] or equivalent. Waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's 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. Customer certificates of insurance, which will include the Catalent affiliate contracting party of this Agreement as the certificate holder, will be sent to the following contact:

Catalent Pharma Solutions, LLC
Attn: Risk Management
14 Schoolhouse Rd
Somerset, NJ 08822

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of [***], unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for [***] unless and until one party gives the other party at least [***] prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. 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 [***], or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. by either party if the other party materially breaches this Agreement and such breach is not cured within [***] after the giving of written notice requiring the breach to be remedied; *provided*, and subject to Section 7.3 (Payment Terms), that in the case of a failure of Client to make undisputed payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such undisputed payment breach is not cured within [***] of receipt of written notice of non-payment from Catalent; or

C. by either party if the Commencement Date does not occur within [***] of Client filing its New Drug Application with the FDA.

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

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

B. Client shall pay Catalent all undisputed, invoiced amounts outstanding hereunder, plus, within [***] of receipt of an undisputed 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 Sections 16.2(A) or (B) or Catalent pursuant Sections 16.1 or 16.2(C), all Product being Processed pursuant to Purchase Orders;

C. If this Agreement is terminated by Catalent under Sections 16.2(A) or 16.2(B), or is terminated by Client under Sections 16.1 or 16.2(C), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, including for the Manufacturing Preparation Services, so long as such costs, expenses or commitments were made by Catalent (i) in good faith prior to receiving or giving any notice of termination, and (ii) consistent with (a) the Manufacturing Preparation, or (b) Client's most recent Firm Commitment and the vendor's minimum purchase obligations;

D. If this Agreement is terminated by Client under Section 16.2(A) or (B) or is terminated by Catalent under Section 16.2(C), then Catalent shall work in good faith with Client and any third party(ies) selected by Client (to the extent such third party(ies) allow Catalent to work with them) to transition processes associated with compounding, producing and sachet-filling of Client-supplied Materials and Raw Materials into Product to Client and/or such third party(ies) as determined by Client at Catalent's expense (including up to [***]). In no event shall Catalent be obligated to disclose any Confidential Information, including Catalent IP or Catalent Inventions, in such transfer; and

E. All fees set forth in Section 7.1 shall terminate upon termination of the Agreement.

16.4 Survival. 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 6.2 (Storage Fees; Bill and Hold), 7.3 (Payment Terms), 7.5 (Taxes), 7.6 (Client and Third Party Expenses), 9.1 (Recordkeeping),

9.5 (Recall), 12.3 (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 under this Agreement shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by electronic mail (e-mail); (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):

To Client: Flamel Ireland Limited (DBA Avadel Ireland)
Block 10 – 1 Blanchardstown Corporate Park
Ballycoolin, Dublin 15
Ireland
Attn: VP, Irish & European Operations
E-Mail: [***]

With a copy to: Flamel Ireland Limited (DBA Avadel Ireland)
16640 Chesterfield Grove Road, Suite 200
Chesterfield, MO 63005
USA
Attn: VP, Deputy General Counsel
E-Mail: [***]

To Catalent Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, New Jersey 08873
USA
Attn: General Manager
E-Mail: [***]

With a copy to: Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873
USA
Attn: General Counsel (Legal Department)
E-Mail: [***]

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contract, agreement or understanding (oral or written) of the parties, with respect to its subject matter, including, for avoidance of doubt, the LOI. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the parties as it relates to periods

prior to the Effective Date or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; 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 in this Agreement or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular 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"), (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, and (G) subject to Applicable Laws, all references to liabilities or obligations of Catalent shall be subject to Article 14, regardless of whether the particular provision includes a cross-reference to Article 14. This Agreement shall be construed as if it were drafted jointly by the parties.

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

18.4 No 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 a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. 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.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debt or make any commitment 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 venturers, 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.

18.7 Successors 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 prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement, and any assignment in violation of this Section 18.7 shall be void *ab initio*.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any right or remedy upon any individual or entity other than the parties and their respective successors and permitted assigns, except that the Client Indemnitees and the Catalent Indemnitees may invoke the benefits of the indemnification provisions of this Agreement.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute arising between the parties in connection with this Agreement shall first be presented to the respective senior executives of the parties for their consideration and resolution. If such parties' executives cannot resolve such dispute within ninety (90) days, then such dispute may be submitted by either party to arbitration by the

International Institute for Conflict Prevention and Resolution, 30 E. 33rd Street, 6th Floor, New York, NY 10016 ("**CPR**") by one arbitrator selected by the parties. If no agreement on an arbitrator can be reached within thirty (30) days after the CPR offers names of potential arbitrators, then the CPR will choose one arbitrator having reasonable experience in commercial transactions of the type described in this Agreement. The arbitration shall take place in the English language in New York City, New York, in accordance with the CPR administered arbitration rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction of the matter. The arbitration shall commence within sixty (60) days of the date on which an arbitrator is selected. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages. The arbitrator shall award to the prevailing party, if any, its costs and attorneys' fees and expenses reasonably incurred in connection with the arbitration, in accordance with Section 18.11.

18.11 Prevailing 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, including any subsequent or related enforcement proceeding, from the other party.

18.12 Publicity. 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 use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right 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 a reasonable period no less than sixty (60) days after making reasonable efforts to do so, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set off any and all amounts due from Client to Catalent or any of its U.S. Affiliates under this Agreement for the storage or destruction of any inventories of Product, Client-supplied Materials, equipment, samples, or other items belonging to Client against any credits Client may hold with Catalent or any of its U.S. Affiliates under this Agreement.

18.14 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, 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, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, failure to obtain manufacturing/ procurement quota, war or insurrection, civil commotion, any act of terrorism, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided*, that the party seeking relief under this Section 18.14 shall promptly 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 reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for one hundred eighty (180) days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. 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]

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, LLC	**FLAMEL IRELAND UNLIMITED (DBA AVADEL IRELAND)**
By: /s/ Thomas A. Yezza	By: /s/ Dhiren D'Silva
Name: Thomas A. Yezza	Name: Dhiren D'Silva
Title: Vice President & General Manager – Oral Drug Delivery	Title: VP, Irish & European Operations

ATTACHMENT A

VALIDATION SERVICES

[***]

ATTACHMENT B

SPECIFICATIONS

[***]

ATTACHMENT C

UNIT PRICING AND ADDITIONAL FEES

[***]

ATTACHMENT D

PRODUCT MAINTENANCE SERVICES & OTHER RELATED SERVICES

[***]

ATTACHMENT E

[***]

ATTACHMENT F

[***]

ATTACHMENT G

[***]

I. Monthly Manufacturing Preparation Services Fee. [***]

II. Capital Recovery Fee. [***]

III. Success Milestone Fees. [***]

ATTACHMENT H

SUITE FEES

[***]

ATTACHMENT I

Annual Yield Calculation

[***]