UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported)
July 17, 2012

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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

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

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

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

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

Item 1.01. Entry into a Material Definitive Agreement

On July 17, 2012, VIVUS, Inc. (the "Company") entered into the Commercial Manufacturing and Packaging Agreement (the "Agreement") with Catalent Pharma Solutions, LLC ("Catalent") dated as of July 17, 2012 (the "Effective Date") pursuant to which Catalent will manufacture and supply Qsymia™ (phentermine and topiramate extended-release) capsules CIV (the "Product") for the Company.

Under the Agreement, the Company will purchase from Catalent the Product during the term of the Agreement for commercial use in the United States, Canada, the European Union and any other country that the Company and Catalent mutually agree to in writing. The Agreement commenced on the Effective Date and will continue for four years following the date of the first commercial sale of the Product by the Company to any third party (the "Launch Date"), unless earlier terminated in accordance with the Agreement. A contract year under the Agreement means each consecutive 12 month period beginning on the Launch Date or anniversary thereof, as applicable. In the first two contract years under the Agreement, Catalent will be the exclusive supplier of the Product to the Company. In the third and fourth contract years under the Agreement, Catalent will be a semi-exclusive supplier of the Product to the Company, subject to Catalent's right to earn exclusivity based on certain performance criterion and the build out of a secondary manufacturing site in the European Union. Notwithstanding the above, upon the occurrence of certain events described as an adverse supply event in the Agreement, the Company will have the right to source from an alternative supplier the quantity of the Product that is the subject of the adverse supply event, provided that for the first two years of the Company's retention of such alternative supplier there shall be a specified cap on the amount of Product sourced from such alternative supplier. Nothing in the Agreement shall limit the Company's ability (i) to obtain Product for clinical use from one or more third parties or (ii) after a future date, to qualify one or more third parties for the processing or packaging of Product for commercial sale.

The Agreement may be terminated (i) immediately by either party if the other party files a petition in bankruptcy, enters into an agreement with its creditors or other similar action, (ii) immediately by either party if the other party materially breaches any of the provisions of the Agreement and such breach

is not cured within the period outlined in the Agreement, and (iii) immediately by either party in the event that all applicable regulatory approvals have not been obtained to commence processing at the facilities as outlined in the Agreement.

The above description of the Agreement is a summary only and is qualified in its entirety by reference to the full text of the Agreement, which is filed herewith as Exhibit 10.1 and is incorporated herein by reference. Portions of Exhibit 10.1 have been omitted pursuant to a request for confidential treatment.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
10.1†	Commercial Manufacturing and Packaging Agreement by and between VIVUS, Inc. and Catalent Pharma Solutions, LLC dated as of July 17, 2012.

† Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

VIVUS, INC.

By: /s/ Lee B. Perry
Lee B. Perry
Vice President and Chief Accounting Officer

Date: July 23, 2012

EXHIBIT INDEX

Exhibit No.	Description
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***** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

Execution Version

COMMERCIAL MANUFACTURING and PACKAGING AGREEMENT
(Phentermine Hydrochloride and Topiramate capsules)

This Commercial Manufacturing and Packaging Agreement ("**Agreement**") is made as of this 17th day of July, 2012 ("**Effective Date**"), by and between VIVUS, Inc., a Delaware corporation, with a place of business at 1172 Castro St., Mountain View, CA 94040 ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA ("**Catalent**").

RECITALS

A. Client is a pharmaceutical company that develops, markets and sells pharmaceutical products, including the Product (as defined below);

B. Catalent provides certain pharmaceutical development, manufacturing, packaging and analytical services to the pharmaceutical industry;

C. Client and Catalent have entered into a Development and License Agreement dated 5 September 2006 (the "**Development Agreement**"), pursuant to which Catalent developed a formulation of the API (as defined below); and

D. Client desires to engage Catalent to manufacture and supply Product to Client for commercial use, and Catalent desires to manufacture and supply such Product to Client for such use, 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.

1.2 "**Adverse Supply Event**" means the occurrence of any one of the following: (1) with respect to quantities of Product specified in the Firm Commitment, any failure to deliver, during the initial *** period (the "**Initial Period**"), at least *** percent (***%) of Product within *** days of the requested delivery date and *** percent (***%) of Product within *** days of the delivery date set forth in the Purchase Order; (2) with respect to quantities of Product specified in the Firm Commitment, any failure to deliver, during any *** period following the Initial Period, at least *** percent (***%) of Product within *** days of the requested delivery date and *** percent (***%) of Product within *** days of the delivery date set forth in the Purchase Order; or (3) interruption in supply of Product to Client for a period of *** consecutive days, due to Catalent's failure to maintain Facility Approvals (as defined in

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Section 9.3). For clarity, failure to deliver, shall not include any delay in shipment of Product caused by events outside of Supplier's reasonable control, such as (i) availability of Client-supplied Materials or Raw Materials, (ii) US FDA customs clearance of shipment to Client or its designee, (iii) a delay in Product release approval from Client or receipt of non-conforming Client-supplied Materials or Raw materials, or (iv) any extensions agreed upon pursuant to Section 3.3 with respect to long lead time materials.

1.3 "**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 Pharma Solutions, Inc. ("**CPS, Inc.**") and any corporation, firm, partnership or other entity controlled by CPS, Inc. For the purposes of this definition, "**control**" shall mean the ownership of at least fifty percent (50%) of the voting share capital of an entity or any other comparable equity or ownership interest.

1.4 "**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.

1.5 "**API**" means the compounds Phentermine HCl and Topiramate, as further described in the Specifications, that have been released by Client and provided to Catalent, along with a certificate of analysis, as provided in this Agreement.

1.6 "**Applicable Laws**" means all laws, ordinances, rules and regulations, as amended from time to time, of each country within the Territory applicable to the Processing and/or Packaging or any aspect of either of the foregoing, and the activities of Catalent or Client, as the context requires, under this Agreement, including (A) all applicable federal, state and local laws and regulations of each country within the Territory, (B) the U.S. Federal Food, Drug and Cosmetic Act, (C) if applicable, Drug Enforcement Agency regulations, Regulation no. 726/2004 and Directive 2004/27/EEC, each as implemented in any country of the Territory, and (C) cGMP.

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

1.8 "**Bulk Product**" means the fully Processed pharmaceutical capsule product containing the combination of APIs in the specific strengths and concentrations described in the Specifications and that has been Processed in accordance with the Specifications.

1.9 "**Catalent Defective Processing**" has the meaning set forth in Section 5.1.

1.10 "**Catalent Defective Packaging**" has the meaning set forth in Section 5.1.

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

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

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

1.14 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities, including within the meaning of 21 C.F.R. Parts 210 and 211, as amended, and equivalent non-U.S. regulations (including 2003/94/EEC Directive as implemented in any country of the Territory, as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, solely to the extent such non-U.S. regulations are otherwise included in Applicable Laws.

1.15 "**Change of Control**" means, with respect to a party: (a) any merger, reorganization, consolidation, or other business combination of such party with a Third Party that results in the voting securities of such party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation, or other business combination; (b) a Third Party becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of such party; or (c) the sale, transfer, exchange or other disposition to a Third Party of all or substantially all of a party's assets or business relating to this Agreement (whether alone or in connection with a sale, transfer, exchange or other disposition of other assets or businesses of such Party). Notwithstanding the foregoing, Change in Control shall not include any transaction in which a party or its successor(s) issues securities to investors solely for capital raising purposes.

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

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

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

1.19 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing or Packaging, as provided in Attachment B, including API.

1.20 "**Confidential Information**" has the meaning set forth in Section 10.2.

1.21 "**Contract Year**" means each consecutive 12 month period beginning on the Launch Date or anniversary thereof, as applicable.

1.22 "**Defective Product**" has the meaning set forth in Section 5.1.

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

1.24 "**Exception Notice**" has the meaning set forth in Section 5.1.

1.25 "**Facility**" means each of Catalent's facilities located in ***; or such other facility as agreed in writing by the parties.

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

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

1.28 "**Launch Date**" means the date of the first commercial sale of Packaged Product by Client to a Third Party.

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

1.30 "**Packaging**," "**Package**" or "**Packaged**" means the final (secondary) packaging of Bulk Product in accordance with the Packaging Specifications, as well as any testing or quality-related activities required by this Agreement or the Quality Agreement in connection with the foregoing.

1.31 **"Packaging Facility"** means the facility located in ***, or such other facility as agreed in writing by the parties.

1.32 **"Packaged Product"** means Bulk Product that has been Processed and Packaged in accordance with the Specifications and under the terms of this Agreement.

1.33 **Packaging Specifications"** means the specifications for Packaging set forth in Attachment B, along with any mutually agreed upon valid amendments or modifications thereto, in accordance with Article 8.

1.34 "**Process,**" "**Processed**" or "**Processing**" means the compounding, filling, producing and bulk packaging of the API and Raw Materials into Bulk Product (including the production of beads containing API and encapsulation of such beads), in accordance with the Specifications, Applicable Laws and 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.

1.35 "**Processing Date**" means the day on which Product is scheduled to be compounded by Catalent, as identified in an Acknowledgement in accordance with Section 4.2.

1.36 **"Processing Facility"** means Catalent's facility located in ***.

1.37 **"Processing Specifications"** means the specifications for Processing set forth in Attachment B, along with any mutually agreed upon valid amendments or modifications thereto, in accordance with Article 8.

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1.38 "**Product**" means Bulk Product and/or Packaged Product, as applicable.

1.39 "**Product Maintenance Services**" has the meaning set forth in Section 2.3.

1.40 "**Purchase Order**" has the meaning set forth in Section 4.2.

1.41 "**Qualified Capability**" means, with respect to a particular activity at Catalent's *** site, Catalent having the necessary manufacturing capabilities and Facility Approvals needed for Client to apply for Regulatory Approval for such activity.

1.42 "**Quality Agreement**" has the meaning set forth in Section 9.7.

1.43 "**Raw Materials**" means all raw materials, excipients, supplies, components, labeling and packaging, in each case, as necessary to perform Processing and/or Packaging in accordance with the Specifications, as provided in Attachment B, but not including Client-supplied Materials.

1.44 "**Recall**" has the meaning set forth in Section 9.6.

1.45 "**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 (or equivalent non-U.S. filings within the Territory, such as European marketing authorization applications), as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, packaging, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.46 "**Regulatory Authority**" means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities located within the Territory (including the United States Food and Drug Administration and the European Medicines Agency) responsible for or involved in (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use, including the development, manufacture, marketing, sale, distribution, packaging or use thereof or (B) health, safety or environmental matters generally.

1.47 "**Review Period**" has the meaning set forth in Section 5.1.

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

1.49 "**Specifications**" means, collectively the Processing and Packaging procedures, processes, directions, requirements, standards, quality control testing and other data and the scope of services, in each case as set forth in Attachment B, along with any valid mutually agreed upon written amendments or modifications thereto, in accordance with Article 8. The

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Specifications include, without limitation, the Processing Specifications and the Packaging Specifications.

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

1.51 "**Territory**" means ***.

1.52 **"Third Party**" means any person or entity other than Client, Catalent or their respective Affiliates.

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

1.54 "**Validation Services**" has the meaning set forth in Section 2.1.

ARTICLE 2
VALIDATION, PROCESSING, PACKAGING, & RELATED SERVICES

2.1 Validation Services. Catalent shall perform the qualification, validation and stability services described in Section 7.8 and Attachment A (as amended, the "**Validation Services**").

2.2 Exclusive Supply and Purchase of Product. Catalent shall Process and Package Bulk Product at the Facilities in accordance with the Specifications, the Applicable Laws and the terms and conditions of this Agreement. Except as provided below with respect to an Adverse Supply Event, for the Contract Years specified in the table below, Client shall purchase from Catalent the indicated percentage of Client's and Client's Affiliates' requirements of Product and Packaged Product for commercial sale, physician samples, and trade samples in the Territory.

Contract Year	Percentage of Requirements
1st Contract Year	100%
2nd Contract Year	100%
3rd Contract Year	***%
4th Contract Year	***%

Notwithstanding the foregoing:

(I) the percentage for the 3rd Contract Year shall automatically increase to *** percent (***%) if each of the following requirements ("Requirements") is satisfied:

(a) Catalent is Packaging Product (or has the Qualified Capability to Package Product) in accordance with the terms of this Agreement at its Facility in *** no later than ***; and

(b) Catalent is performing the encapsulation step of Processing (or has the Qualified Capability to do so) in accordance with the terms of this Agreement at its Facility in *** no later than ***; and

(c) Subject to Section (IV) below, Catalent is performing all steps of Processing (or has the Qualified Capability to do so) in accordance with the terms of this Agreement at its Facility in *** no later than ***; and

(d) Catalent has satisfied the KPI requirements as set forth in Attachment E for each and every measurement period during the first two (2) Contract Years; and

(e) as of the end of the 2nd Contract Year, the processing and analytical portion of the Unit Price has decreased by *** percent (***%) relative to the processing and analytical portion of the Unit Price (as set forth on Attachment C) as of the Effective Date (e.g., as a result of the sharing of cost savings with Client pursuant to Section 8.2, or any other reductions in the processing and analytical portion of the Unit Price charged to Client). For clarity, any price increases pursuant to Section 7.2 shall not be counted in calculating the percentage price decrease. For example, if the processing and analytical portion of the Unit Price is $50.00 on the first anniversary of the Effective Date and thereafter is increased to $52.50 pursuant to Section 7.2, a ***% decrease would be satisfied by a processing and analytical portion of the Unit Price of $*** (calculated as follows: ***).

(II) the percentage for the 4th Contract Year shall automatically increase to *** percent (***%), if (x) Requirements (I)(a)-(e) are satisfied, (y) Catalent has met the operational performance KPI requirements set forth in Attachment E for each and every measurement period during the second Contract Year and during the *** period beginning on the first day of the third Contract Year, and (z) as of the end of the 3rd Contract Year, the processing and analytical portion of the Unit Price has decreased by *** percent (***%) relative to the processing and analytical portion of the Unit Price as of the Effective Date (e.g., as a result of the sharing of cost savings with Client pursuant to Section 8.2, or any other reductions in the processing and analytical portion of the Unit Price charged to Client). For clarity, any price increases pursuant to Section 7.2 shall not be counted in calculating the price decrease.

(III) Catalent shall meet operational performance KPIs as set forth in Attachment E. In the event that Catalent does not meet such KPIs during the *** period beginning on the first day of the third Contract Year, then (x) *if*, pursuant to Section (I), the percentage for the 3rd Contract Year has been adjusted to ***%, *then* the percentage in Section 2.2 applicable to the fourth Contract Year remain at ***%; and (y) *if*, pursuant to Section (I), the percentage for the 3rd Contract Year has not been adjusted, *then* the percentage in Section 2.2 applicable to the fourth Contract Year shall automatically change to *** percent (***%).

(IV) On or before ***, the parties shall meet to discuss whether Catalent should obtain the Qualified Capability to permit all steps of Processing to be performed at its Facility in ***. If the parties mutually agree that Catalent should do so, then, and only then, will item (I)(c) be included as a Requirement.

A. The parties agree to negotiate in good faith terms to expand Processing and Packaging capacity in response to market signals if Product demand increases. In the event that, despite such good faith negotiations, the parties fail to agree in principle on the material "heads of terms" to expand the Processing and Packaging capacity within *** days after Client first notifies Catalent of such increased demand, then Client shall have the right to source from an alternative supplier the quantity of Packaged Product that Catalent is unable to Process and/ or Package; provided, however, that for the first two (2) years following Client's retention of such alternative supplier, Client shall be permitted to source from such alternative supplier *** percent (***%) (or a lower percentage selected by Client in its sole discretion) of Client's and Client's Affiliates' requirements of Product and Packaged Product for commercial sale, physician samples, and trade samples in the Territory.

B. In the event of an Adverse Supply Event, Client shall have the right to source from an alternative supplier the quantity of Packaged Product that is the subject of the Adverse Supply Event; provided, however, that for the first *** following Client's retention of such alternative supplier, Client shall be permitted to source from such alternative supplier *** percent (***%) (or a lower percentage selected by Client in its sole discretion) of Client's and Client's Affiliates' requirements of Product and Packaged Product for commercial sale, physician samples, and trade samples in the Territory.

E. For the avoidance of doubt, nothing herein shall limit Client's (or its Affiliates') ability, at its (or their) sole discretion (1) to obtain Bulk Product or Processed Product for clinical use from one or more Third Parties or (2) after ***, to qualify one or more Third Parties for the Processing and/or Packaging of Product for commercial sale (including allowing such Third Parties to Process and/or Package Product in order to generate validation Batches), it being understood that during the first four Contract Years, Client shall not obtain Product for commercial sale from such Third Parties unless and until a Adverse Supply Event has occurred or unless and until the applicable percentage in the table above for a particular Contract Year is less than one hundred percent (100%). After ***, Catalent shall use its commercially reasonable efforts to provide reasonable technical assistance to Client, as reasonably requested by Client, in connection with Client's efforts to establish and qualify the Third Party or Third Parties described in subsection (2) above in a timely and orderly manner at Catalent's then-prevailing rates for such services, which efforts shall include, without limitation,

Catalent providing Client with access to Catalent Background IP and Catalent Inventions licensed to Client pursuant to Article 11**.**

2.3 Product Maintenance Services. Catalent shall provide the following product maintenance services (the "**Product Maintenance Services**"):

A. With respect to Processing, the annual audit rights (as further described in Section 9.5) per Contract Year; regulatory audits (as further described in Section 9.4), including pre-approval inspection activities; one (1) annual Bulk Product review (within the meaning of 21 CFR § 211.180) per contract year (except during the first Contract Year, when Catalent shall provide *** such annual reviews); access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation; assistance in seeking Regulatory Approvals in the United States; Bulk Product document and sample storage relating to cGMP requirements; vendor re-qualification; maintenance, updates and storage of master Batch documentation and audit reports; sampling of all incoming API and Raw Materials, monthly inventory reports in Catalent format and as set forth in Section 3.4(B), coordination of shipping activities as directed by Client; and maintenance of miscellaneous dedicated items, such as tooling, equipment filter bags, PLC and other dedicated electronic systems and equipment replacement parts, as applicable.

B. With respect to Packaging, the annual audit rights (as further described in Section 9.5) per contract year; regulatory audits (as further described in Section 9.4), including pre-approval inspection activities; one (1) annual product review (within the meaning of 21 CFR § 211.180) (except during the ***, when Catalent shall provide *** such annual reviews); and equipment and tooling maintenance, as applicable.

C. For avoidance of doubt, (X) the following services are not included in Product Maintenance Services or Unit Price with respect to Processing: technology transfer; analytical work; stability, other than the bulk stability described above; and process rework, as applicable; and (Y) the following services are not included in Product Maintenance Services or Unit Price with respect to Packaging: tooling purchases and repair; technology transfer; analytical work; stability; auditing of Suppliers; and retain storage. The Parties shall agree on prices for the foregoing services prior to Catalent performing them.

2.4 Other Related Services. Catalent shall provide such Product-related services, other than Validation Services, Processing, Packaging, and 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.

2.5 Approval of Subcontracting. Other than its supply arrangements with respect to Raw Materials pursuant to Article 3 below, Catalent may not subcontract, sublicense or otherwise delegate all or any portion of its obligations under this Agreement to a Third Party without Client's prior written approval, which shall not be unreasonably withheld. Notwithstanding the

foregoing, the parties agree that Catalent may, without further approval or consent, subcontract the Packaging portion of services to an acquirer of Catalent's commercial packaging business. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, provided that it provides Client with prior written notice that is sufficiently in advance of any changes in responsibilities so as to permit Client to make any and all necessary regulatory submissions and obtain any and all necessary regulatory approvals. Any activities performed by subcontractors, including Catalent's Affiliates, shall be subject to the terms of this Agreement and Catalent shall ensure that such subcontractors comply with the terms of this Agreement. In any event, Catalent shall be responsible for all subcontracted activities as if the same were performed by Catalent itself pursuant to the terms of this Agreement.

ARTICLE 3
MATERIALS

3.1 General. Catalent shall be responsible for the procurement of all Raw Materials (other than as set forth in Section 3.2 below) necessary to Process and Package Bulk Product, consistent with the quantity of Product forecasted by Client in the Firm Commitment portion of each Rolling Forecast pursuant to Section 4.1 below and consistent with the requirements set forth in Section 3.3.

3.2 API; Client-supplied Materials.

A. Client shall, at Client's sole cost and risk, provide to Catalent for Processing API, applicable reference standards, and any other Client-supplied Materials agreed to by the Parties from time to time, in quantities sufficient to meet Client's requirements for Product. Upon Client's request, Catalent will procure the applicable reference standards on Client's behalf and charge to the Client the cost thereof as a pass through, without additional mark-up. Client shall deliver such items, together with associated certificates of analysis, to the designated Facility no later than *** days before the Processing Date upon which such items will be used by Catalent, provided that (i) such Processing Date shall be communicated by Catalent to Client in writing at least *** days in advance of its occurrence and (ii) Client shall deliver such items not earlier than *** days before the Processing Date. Until the end of the first Contract Year, upon reasonable notice to Catalent, Client may send API to the Processing Facility earlier (but in no event more than *** days earlier), and Catalent will store any such API at the Processing Facility at no charge to Client. Client shall be responsible at its expense for securing any necessary export or import clearances or permits required in respect of supply to Catalent of such items. Catalent shall use such items solely and exclusively for Processing and Packaging of Product in accordance with this Agreement. Prior to delivery of any such items, Client shall provide to Catalent a copy of all applicable material safety data sheets, safe handling instructions and health and environmental information, and shall promptly provide any updates or revisions thereto.

B. Within *** days of receipt of API or any other Client-supplied Materials by Catalent, Catalent shall inspect such items to verify their identity and to visually check for

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damage to the shipping containers and shall perform only such testing as expressly required of Catalent in the Specifications. Catalent shall not be liable for any defects in API or any other Client-supplied Materials, or in Product as a result of defective API or any other Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective API or any other Client-supplied Materials, at Client's direction and Client's sole cost and risk.

C. Client shall retain title to API and any other Client-supplied Materials at all times and shall bear the risk of loss thereof, provided that during the time API or other Client-supplied Materials are in Catalent's control (including, without limitation, during transport from one Facility to another), Catalent shall bear the risk of loss of API or other Client-supplied Materials arising from the negligence or willful misconduct of, or breach of this Agreement or Applicable Laws by, Catalent, its Affiliates or their respective personnel, subject to the limits set forth in Article 14. Catalent will keep and use the API or other Client-supplied Materials only at the designated Facility. Catalent agrees that the API or other Client-supplied Materials will not be removed from such Facility unless Catalent receives prior written notice from Client to move it. Catalent shall provide appropriate segregated storage for API or other Client-supplied Materials at such Facility in accordance with the Specifications and in full compliance with Applicable Laws. Catalent shall not handle the API or other Client-supplied Materials except as necessary to Process and Package Product or otherwise expressly instructed by Client. Catalent shall limit access to the API and other Client-supplied Materials to those of its employees that require such access for the purposes of Processing and Packaging Product under this Agreement. Catalent agrees to use its commercially reasonable efforts to minimize the wastage of API or other Client-supplied Materials involved in the Processing and Packaging of Product hereunder. Promptly following Client's request at any time during the Term, any and all API and/or other Client-supplied Materials (as specified by Client) will be delivered by Catalent to Client at Client's expense, or made available for collection by Client at the Facility at which such items are stored, as directed by Client, and Catalent will fully cooperate with and assist Client in connection with any such request.

3.3 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 to by the parties in writing. The Unit Price set forth on Attachment C, incorporates the cost of all Catalent-supplied Raw Materials. Catalent shall not be liable for any delay in delivery of Product if all of the following are true: (i) such delivery delay is caused by Catalent being unable to obtain, in a timely manner, a particular Raw Material necessary for Processing or Packaging, (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment, and (iii) Catalent's inability to obtain such Raw Material in a timely manner was the result of circumstances outside Catalent's reasonable control. At all times during the first Contract Year, Catalent shall establish and maintain a stock of Raw Materials sufficient to meet *** percent (***%) of the Firm Commitment. In the event that any Raw Material becomes subject to

purchase lead times beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.1. Catalent shall use commercially reasonable efforts to promptly notify Client in the event that an impairment to Catalent's credit or any other financial issue has, or is reasonably likely to have, a material negative impact on Catalent's ability to purchase the Raw Materials in a timely manner.

B. In obtaining Raw Materials hereunder, Catalent shall only use those specific suppliers, manufacturers, and/or vendors ("**Vendors**") that have been approved by Client in advance. The approved Vendors as of the Effective Date are listed in the Specifications, and the parties agree to update the Specifications to reflect any additions or amendments to the list of Client-approved Vendors. Catalent shall use commercial reasonable efforts to procure the supply of all Raw Materials for Client at the lowest prices reasonably available, consistent with and having regard to such matters as security and sources or supply, quality of product, volume requirements, and terms and conditions of supply. Client will be responsible for all costs associated with qualification of any Vendor who has not been previously qualified by Catalent. If Client requests Catalent to change a Vendor and the cost of the Raw Material from any such alternate Vendor is greater than Catalent's costs for the same raw material of equal quality from the existing Vendor, Catalent shall add the difference between Catalent's cost of the Raw Material and the alternate Vendor's cost of the Raw Material to the Unit Pricing. If Client requests Catalent to change a Vendor and the cost of the Raw Material from any such alternate Vendor is lower than Catalent's costs for the same raw material of equal quality from the existing Vendor, Catalent shall subtract the difference between Catalent's cost of the Raw Material and the alternate Vendor's cost of the Raw Material from the Unit Pricing.

C. All Raw Materials hereunder, and Catalent's use thereof in the Processing and Packaging, shall comply with: (a) the specifications applicable thereto as reasonably determined by Client and as set forth in the Specifications, current batch records, and/or other appropriate documentation (provided that such specifications may only be amended upon Client's prior written approval); (b) all Applicable Laws, the Quality Agreement, and all applicable Regulatory Approvals; and (c) the use, re-test, or expiration date, as applicable, of such Raw Materials, if applicable, in accordance with the recommendations of the manufacturers or vendors thereof.

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3.4 Storage and Use of Raw Materials; Inventory Reports.

A. Storage and Use. Catalent shall ensure that all Raw Materials are stored in accordance with Applicable Laws, any other requirements mutually agreed upon by Client and Catalent, and any instructions of Third Party suppliers. Catalent shall use the first-in, first-out (FIFO) method of materials storage for Raw Materials and Client-supplied Materials, subject to the prudent and appropriate usage of the first expiring, first out (FEFO) method. Catalent shall be responsible, at its expense, to obtain and maintain at all times during the term of this Agreement all permits and licenses required for it to carry out its obligations hereunder. Except as set forth in Section 3.6 below, Catalent shall be responsible for, and shall bear all costs associated with, any obsolete or expired Raw Materials.

B. Inventory Reports. Commencing no later than the first full calendar month after Client provides the first Rolling Forecast pursuant to Section 4.1 below, within five (5) business days after the end of each calendar month, Catalent shall provide to Client a monthly written report outlining, by Facility: (a) the amount of its inventory of all API, other Client-supplied Materials, other critical Raw Materials (as such critical Raw Materials are identified by Client from time to time), and Product (including work-in-process) as of the end of the applicable calendar month, separately identifying such amounts of API, each such other Client-supplied Materials, such other critical Raw Material, and Product (including work-in-process, which will be separately identified); and (b) the quantity of API used in the immediately preceding calendar month and the extent to which such quantity of API was more or less than Catalent's predicted requirements of API for such month.

3.5 Artwork and Packaging. Client shall provide or approve, prior to the procurement of applicable components, all artwork, advertising and packaging information necessary for Processing or Packaging. Such artwork, advertising and packaging information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and packaging information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder. For the avoidance of doubt, (i) Client shall have the right to modify, update or otherwise change any such artwork, advertising and packaging information in its sole discretion, provided Client notifies Catalent of the same as set forth in Section 8.1 and provides Catalent with all necessary materials with respect thereto, and any such modification, update or change shall be considered a change in the Specification (and, in particular, the Packaging Specification), including for purposes of 3.6 below. Client must obtain Catalent's prior written consent prior to utilizing Catalent's name on any packaging.

3.6 Reimbursement for Materials. In the event of (A) a Specification change for any reason, (B) obsolescence of any Raw Material (which, for clarity, does include any expiration of Raw Material), (C) termination of this Agreement by Catalent pursuant to Section 16.2(A) or 16.2(B), or (D) termination of this Agreement by Client, other than pursuant to Section 16.2 (B), Client shall bear the cost of any unused Raw Materials (including packaging at direct cost, plus the

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lower of *** percent (***%) or $***, per event) procured by Catalent, so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Rolling Forecast, including amounts purchased by Catalent to comply with its obligations under Section 4.2(c), and the supplier's minimum purchase obligations (if any). Catalent shall employ commercially reasonable efforts to mitigate such costs, including, to the extent approved by Client, (1) using such Raw Materials in connection with other activities performed by Catalent, including with respect to the supply of product to Third Parties or the performance of services on behalf of Third Parties, or (2) returning such Raw Materials to the original vendor thereof.

ARTICLE 4
MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

4.1 Forecast. On or before the *** of each calendar month, beginning with the first full calendar month following the Effective Date, Client shall furnish to Catalent a written *** rolling forecast of the quantities of Bulk Product and/or Packaged Product that Client intends to order from Catalent during such period ("**Rolling Forecast**"). The first *** of each Rolling Forecast shall constitute a binding order for the quantities of Product specified therein ("**Firm Commitment**") and the following *** of the Rolling Forecast shall be non-binding, good faith estimates. Starting with the first full month in which the *** occurs and for the remainder of the Term, Client shall use its commercially reasonable efforts to ***.

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 of Bulk Product on a per strength basis, the number Batches of Packaged Product in each configuration, and the mutually agreed upon delivery date for such Product ("**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 in accordance with lead times mutually agreed by the parties.

B. Within *** days following receipt of a Purchase Order, Catalent shall issue a written acknowledgement ("**Acknowledgement**") that it accepts such Purchase Order, provided that Catalent may reject a Purchase Order solely (i) to the extent such Purchase Order is for quantities of Product in excess of the Firm Commitment or (ii) if such Purchase Order has not otherwise been submitted in accordance with this Agreement.

C. Notwithstanding Section 4.2(B), and subject to Section 4.2(A), Catalent shall use commercially reasonable efforts to supply Client with quantities of Product which are up to the percentage of the quantities specified in the Firm Commitment that are specified in the table below, subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity:

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Contract Year	Percentage of Firm Commitment
1st Contract Year	***%
First 6 months of 2nd Contract Year	***%
Second 6 months of 2nd Contract Year	***%
3rd and 4th Contract Years	***%

For the avoidance of doubt, Catalent's failure to supply Client with quantities in excess of the quantities specified in the Firm Commitment shall not constitute a breach of this Agreement by Catalent.

D. No terms or conditions contained in any Purchase Order or Acknowledgement, or similar standardized form, given or received pursuant to this Agreement shall be construed to amend or modify the terms of this Agreement. In the event of a conflict between the terms of any Purchase Order or Acknowledgement, or similar standardized form, and this Agreement, the terms of this Agreement shall control.

4.3 Sufficient API and Client-supplied Materials. Client acknowledges and agrees that Catalent's ability to Process and Package Product under this Agreement is dependent upon Client's provision to Catalent of sufficient quantities of API and Client-supplied Materials. Accordingly, Catalent shall have no liability with respect to amounts of Products specified in any Purchase Order to the extent Client refuses or fails to timely supply API or any other Client-supplied Materials in accordance with Section 3.1.

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. Change orders must be submitted at least

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*** days in advance of the earliest Processing Date (of which Catalent notifies Client in accordance with Section 3.2(A) above) covered by such change order. Catalent shall use commercially reasonable efforts to implement any change orders submitted by such deadline. For change orders submitted after this deadline, Catalent will respond within *** days whether or not such change is possible. Notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment.

B. In addition to any amounts due to Catalent with respect to Product ordered pursuant to Section 4.2, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment (which, for clarity, is required by Section 4.2(A)), Client shall, within *** days of receipt of invoice ***.

4.5 Unplanned Delay or Elimination of Processing. Catalent shall use commercially reasonable efforts to meet the mutually agreed upon delivery dates specified in the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance notice as possible (and will use its best efforts to provide at least *** days' advance notice where possible) if Catalent determines that any Processing or Packaging will be delayed or eliminated for any reason.

4.6 Observation of Processing and Packaging. In addition to Client's audit right pursuant to Section 9.5, Client may send *** representatives to each Facility to observe Processing or Packaging activities, the Validation Services, or Product Maintenance Services for a maximum of up to *** per Facility, so long as Client provides Catalent at least *** advance written notice of the attendance of such Client representatives. Return visits of reasonable duration to follow up on deficiencies noted in earlier visits shall not count towards this *** limit. In addition, Client may visit the Facilities for process improvement and other activities, in each case as mutually agreed. Such representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures communicated by Catalent to Client, 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 in breach of such policies and procedures while on Catalent's premises. Client's representatives who are not employees of Client may be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Any information obtained by Client through such inspections and shall be treated as Confidential Information of Catalent in accordance with Article 10 below.

ARTICLE 5
TESTING; SAMPLES; RELEASE

5.1 Testing; Releasing; Rejection. 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, Catalent shall also provide Client or its designee with a certificate of analysis and certificate of conformance for such Batch. Issuance of a certificate of analysis and certificate of conformance constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including any additional testing that it elects to perform) to the market, at its cost. Following Client's receipt of a shipment of a Batch of Packaged Product, Client or Client's designee may test samples of such Batch to confirm that the Specifications have been met (or for any other purpose). Unless, within *** days after Client's receipt of a Batch ("**Review Period**"), Client or its designee notifies Catalent in writing (an "**Exception Notice**") that such Batch does not meet the warranty set forth in Section 12.1(A) ("**Defective Product**"), and provides a sample of the alleged Defective Product, the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch, subject to Section 5.3 with respect to Latent Defects. Upon timely receipt of an Exception Notice from Client, 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 Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is *** ("**Catalent Defective Processing**" or **"Catalent Defective Packaging"**), then Section 5.4 shall apply. For avoidance of doubt, where the parties agree that the cause of nonconformity cannot be determined or assigned, or where the independent third party retained pursuant to Section 5.2 cannot determine or assign the cause of nonconformity, it shall be deemed not Catalent Defective Processing or Catalent Defective Packaging, as applicable.

5.2 Discrepant Results. In the event of a disagreement between the parties regarding whether Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing or Catalent Defective Packaging, then Catalent and Client shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, Catalent and Client shall discuss in good faith mutually acceptable testing procedures pursuant to which both Catalent and Client will re-test a sample of the disputed Product to determine whether such Product is Defective Product. Notwithstanding the foregoing, in the event such disagreement cannot be resolved by the parties within *** days of the date of the Exception Notice, the parties shall cause a mutually agreeable 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 API and other 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. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing or Catalent Defective Packaging, and by Client in all other circumstances.

5.3 Latent Defects. Notwithstanding Section 5.1, Client or its designee shall have the right to reject Defective Product due to a Latent Defect for up to *** from the date of delivery. In such case, Client shall notify Catalent within *** of its discovery of a Latent Defect. For purposes of this Section 5.3, "**Latent Defect**" shall mean any defect which such defect is not reasonably discoverable upon initial inspection and testing by Catalent or the Client or Client's designee, as applicable.

5.4 Defective Processing or Packaging. Catalent shall, at Client's option, either (A) re-Process or re-Package (or if re-Processing or re-Packaging is not permissible under cGMPs, then replace), at Catalent's cost any Batch of Defective Product attributable to Catalent Defective Processing or Catalent Defective Packaging (and Client shall be liable to pay for either the rejected Batch(es) or the replacement Batch(es), but not both), or (B) credit any payments made by Client for such Batch. Any re-Processing, re-Packaging, or replacement under subsection (A) above shall be performed on an expedited basis. THE OBLIGATION OF CATALENT TO (i) REPLACE CATALENT DEFECTIVE PROCESSING OR CATALENT DEFECTIVE PACKAGING IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING OF CATALENT DEFECTIVE PACKAGING AND (ii) REIMBURSE CLIENT FOR API OR CLIENT-SUPPLIED MATERIAL LOST IN CATALENT DEFECTIVE PROCESSING OR CATALENT DEFECTIVE PACKAGING, (SUBJECT, FOR THE AVOIDANCE OF DOUBT, TO SECTION 14.1), SHALL BE, TOGETHER WITH CLIENT'S RIGHTS UNDER SECTIONS 13.1 (indemnification) AND 9.6 (recall), CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

5.5 Supply of Material for Defective Product. In the event Catalent replaces Defective Product pursuant to Section 5.4, Client shall supply, at Client's cost, Catalent with sufficient quantities of API and other Client-supplied Materials in order for Catalent to complete Processing and Packaging for such replacement Product and Catalent shall reimburse Client for its API and Client-supplied Materials costs, subject to the limitations in Article 14.

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall deliver Packaged Product Ex Works (Incoterms 2010) the *** promptly following Catalent's release of the Packaged Product. Catalent

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shall segregate and store all Packaged Product until tender of delivery. Title to the Packaged Product shall transfer to Client upon such tender of delivery. Client shall qualify at least one (1) carrier to deliver Packaged Product; *provided*, that if Client does not provide such carrier, Catalent may select one.

6.2 Failure to Take Delivery. If Client fails to take delivery of any Packaged Product on any scheduled delivery date, Catalent shall store such Product and Client shall be invoiced on the first day of each month following such scheduled delivery at the storage rates specified in Attachment C. ***.

6.3 Transport Between Facilities. Notwithstanding anything the contrary herein, Catalent shall be solely responsible for paying the cost for, and subject to the limitations set forth in Article 14, shall bear the risk of loss associated with, the transport between Facilities of any Raw Materials, API, other Client-supplied Materials, Product (including work-in-process), or any other materials, and shall charge the Client the documented cost thereof as a pass-through. Such transportation shall be performed pursuant to mutually agreed upon instructions from Client.

ARTICLE 7
PAYMENTS

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. Such fees shall be paid within *** days following Client's receipt of invoice, which invoice shall be submitted to Client by Catalent upon the completion of the relevant phase of the Validation Services.

(B) Client shall pay Catalent the unit pricing for Product set forth on Attachment C ("**Unit Pricing**"). Such fees shall be paid within *** days following Client's receipt of an invoice for each shipment of Product, which invoice shall be submitted to Client by Catalent upon tender of delivery of Product or storage as provided in Section 6.1 or 6.2, provided that during the first ***, Catalent shall be permitted to submit to Client an invoice for a progress payment once the Processed Product has been ***. All invoices will be issued by, and all payments will be delivered to, the Processing Site.

(C) Client shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment C. Such fees shall be paid within *** days following Client's receipt of an invoice therefor, which invoice shall be submitted to Client by Catalent upon the Effective Date and upon each anniversary of the Effective Date during the Term.

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(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, 4.5, 6.2 and 16.3. Such fees and expenses shall be paid within *** days following Client's receipt of an invoice therefor, which invoice shall be submitted to Client by Catalent as and when appropriate.

7.2 Unit Pricing Increase. Beginning with (and effective for) the ***, and annually thereafter, the processing and analytical components of the Unit Pricing may be adjusted by Catalent on an annual basis, upon *** days' written notice from Catalent to Client, in proportion to the rate of inflation as measured by the PPI for Pharmaceutical Preparations (PCU325412325412); provided that such annual price increase does not exceed *** percent (***%). Notwithstanding the foregoing or any change in the PPI, price increases for Raw Materials shall be passed through to Client via an increase in the Unit Price (such price increase, a "**Raw Materials Price Increase**").

7.3 Product Approval. Notwithstanding anything to the contrary set forth in this Agreement, Client shall use commercially reasonable efforts to expedite and obtain all Regulatory Approvals (other than any necessary Facility Approvals (as defined in Section 9.3)) necessary for Catalent to commence Processing at the Facilities, and in the event such Regulatory Approvals have not been obtained by Client within *** following the Effective Date, then Client and Catalent shall each have the right to terminate this Agreement immediately upon notice to the other.

7.4 Payment Terms. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. In the event any undisputed payment is not received by Catalent on or before the *** day after Client's receipt of the invoice, then Catalent may, in addition to any other remedies available at equity or in law, at its option, elect to do any one or more of the following: (A) charge interest on the outstanding sum from the due date (both before and after any judgment) at *** per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws) and/or (B) notify Client in writing that such undisputed payment is late and, if such undisputed payment is not paid within *** days after Client's receipt of such notice, suspend any further performance hereunder until such undisputed payment is paid in full.

7.5 Advance Payment. If at any time, Catalent reasonably determines that Client's credit is impaired, Catalent shall have the right to require payment in advance before performing any further Processing or Packaging of the Product. If Client shall fail, within a reasonable time, to make such payment in advance, or if Client shall fail to make payment when due, Catalent shall have the right, at its option, to suspend any further performance hereunder until such default is corrected.

7.6 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on services, API or Product prior to or upon provision or sale to Catalent or Client, as the case may be, and on any other Client-supplied Materials, 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, upon presentation of documentation of such payment by Catalent to Client.

7.7 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, as between the parties hereto, Client shall be responsible for one hundred percent (100%) of its own and all third-party expenses associated with obtaining Regulatory Approvals for the Product (other than any Facility Approvals) and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.8 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 as set forth in Attachment C, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent or engaged in willful misconduct in the manufacture of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of-Specification Batch.

ARTICLE 8
CHANGES TO SPECIFICATIONS

8.1 Changes to Specifications or Processing.

A. Catalent shall not make any changes to Raw Materials (or suppliers thereof), formulations, processes, equipment, tests or any other item in any manner that would adversely impact the Processing and/or Packaging activities related to Product to be supplied by Catalent hereunder, or affect any of Client's Regulatory Approvals (including pending Regulatory Approvals) related to the Product, without Client's prior written approval.

B. All 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 or Packaging 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, or otherwise, without Client's prior written approval or 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, good faith 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 direct costs directly attributable to 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 thereto in accordance with this Section 8.1(B).

8.2 Other Changes. Catalent shall use commercially reasonable efforts to identify and develop changes to the manufacturing process and other mechanisms for maintaining quality and lowering costs by seeking productivity improvements, by minimizing waste and improving yields, by purchasing quality materials at lower cost, by improving manufacturing processes, by streamlining organizational processes, by achieving operational efficiencies, by reducing cycle times and lead times and the like. Catalent shall promptly notify Client regarding any such potential changes that it identifies. In addition, Client may propose to Catalent certain changes to the Specifications or the manufacturing process which 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 and analyze any such change and provide a development plan, cost proposal and timeline for the 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 (net of any costs required to implement such change), and 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.

8.3 Deviations. Without limiting Catalent's obligations under Section 5.1 above, in the event any material deviations occur during the course of the Processing or Packaging of any Product under this Agreement, Catalent shall promptly provide Client with a detailed written description of any such deviation and, to the extent known by Catalent, an explanation of the cause of such deviation. In addition to the provision of such notice, Catalent shall undertake those actions to investigate the cause of such deviation and to correct the same as set out in the Quality Agreement. Notifications and actions taken by Catalent are governed by the Quality Agreement requirements.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Batch Records and Data. Within *** days following the completion of Processing and/or Packaging of each Batch, Catalent shall provide Client with a certificate of conformance, certificate of analysis and, to the extent requested by Client, Batch records, QC data sheets and

other test results; *provided*, that if testing reveals an out-of-Specification result, Catalent shall provide corresponding Batch records within *** days following resolution of the out-of Specification result.

9.2 Recordkeeping. Catalent shall maintain materially complete and accurate books, records, test and laboratory data, reports and all other information relating to Processing, Packaging, Validation Services, and Product Maintenance Services, including all information required to be maintained by Applicable Laws, in accordance with Catalent standard operating procedures and any other reasonable procedures upon which the parties mutually agree. Such information shall be maintained in forms, notebooks and records for a period of at least *** from the relevant finished Product expiration date or longer if required under Applicable Laws or under 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 cost. Without limiting the foregoing, at any time, upon request by Client, and at Client's cost, Catalent shall provide Client with reasonable access to, and copies of, such records.

9.3 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 or Packages Product (any such approval, a "**Facility Approval**"). Other than Facility Approvals, Client shall be solely responsible for all Regulatory Approvals for the Product, including any applications and amendments in connection therewith, and Client shall obtain all necessary Regulatory Approvals (other than Facility Approvals). During the Term, Catalent will assist Client with all regulatory matters relating to Processing and Packaging of Product under this Agreement, and/or to Validation Services or Product Maintenance Services, at Client's request and at Client's expense, including providing all information and data in Catalent's possession or control necessary or useful for Client to apply for, obtain and maintain Regulatory Approvals for Product in any country within the Territory, including information relating to any Facility and/or Raw Materials, or required or requested to be provided to the FDA or any other Regulatory Authority, in each case, subject to Catalent's obligations of confidentiality to its other customers. Moreover, Client shall have, or cooperate with Catalent to obtain, full access to and the right to use and reference any records, correspondence, validation documentation, batch records, reports, analyses and any other data and documentation in connection with the Processing, Packaging, Validation Services, or Product Maintenance Services conducted by Catalent hereunder. Each party intends and commits to cooperate to satisfy all Applicable Laws relating to Processing, Packaging, Validation Services, and Product Maintenance Services.

9.4 Governmental 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 or Packaging. Catalent shall promptly advise Client if an authorized agent of any Regulatory

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Authority visits or schedules a visit to any Facility concerning the Product or its Processing or Packaging. Catalent shall permit Client or its representative to assist in the preparation for and be present on site for such inspections; provided that Client shall not participate in such inspection unless requested to do so by Catalent. Catalent shall furnish to Client a copy of the report by such Regulatory Authority, if any, within *** of Catalent's receipt of such report and notify Client of any actions taken by Catalent to remedy conditions cited in any such report. Further, upon receipt of a Regulatory Authority request to inspect any Facility or audit Catalent's books and records with respect to Processing or Packaging, Catalent shall promptly notify Client, and shall provide Client with a copy of any written document received from such Regulatory Authority. In addition, Catalent agrees to promptly notify and provide Client copies of any request, directive or other communication of any Regulatory Authority relating to the Product or its Processing or Packaging. Prior to responding to any reports, requests, directive or other communications issued by any Regulatory Authority relating to the Product or its Processing or Packaging or general Processing or Packaging issues, Catalent shall provide Client a copy of its proposed response for Client's review and comments and Catalent shall take under careful 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 or Packaging prior to submitting such response to the applicable Regulatory Authority.

9.5 Client Inspections and Audits.

A. During the Term and for *** years thereafter, or as otherwise required by Applicable Law, duly-authorized employees, agents and representatives of Client shall be granted access upon at least *** days prior notice and at reasonable times during regular business hours to (i) the portion of any Facility where Catalent performs Processing, Packaging, Validation Services, or Product Maintenance Services, (ii) relevant personnel involved in Processing, Packaging, Validation Services, or Product Maintenance Services and (iii) Processing, Packaging, Validation Services, or Product Maintenance Services records described in Section 9.2, in each case solely for the purpose of (1) inspecting and verifying that Catalent is Processing, Packaging, Validation Services, and Product Maintenance Services in accordance with cGMPs, this Agreement, the Specifications and the Product master Batch records and environmental, health and safety regulations, (2) performing inventories of the API and Client-supplied Materials, and (3) reviewing correspondence, reports, filings and other documents from or to Regulatory Authorities to the extent related to the Processing or Packaging of Product or the Validation Services or Product Maintenance Services. Client's Representatives who are not employees of the Client may be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Any information obtained by Client through such inspections shall be treated as Confidential Information in accordance with Article 10 below. Catalent agrees to reasonably assist Client in the performance of any such inspections.

B. Client's Quality Assurance Manager will arrange audit visits with Catalent Quality Management. Inspections shall be designed to minimize disruption of operations at the applicable Facility. Subject to Section 4.6, Client may not conduct an inspection under this

Section 9.5 more than *** during any 12-month period; *provided*, that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product, its Processing or Packaging, or the Validation Services or Product Maintenance Services.

9.6 Recall. In the event Catalent believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product provided under this Agreement, Catalent shall immediately notify Client in writing. Client shall be solely responsible for implementing any such Recall and Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws. In the event Client determines a Recall may be necessary with respect to any Product provided under this Agreement, Client shall notify Catalent promptly in writing, and Catalent shall provide all necessary cooperation and assistance to Client. The cost of any Recall shall be borne by Client except to the extent such Recall is caused in whole or in part by Catalent's breach of its obligations, warranties, or representations under this Agreement or Applicable Laws or its negligence or willful misconduct, which such portion of the cost shall be borne by Catalent. For purposes hereof, such cost shall be limited to reasonable, actual and documented costs incurred by Client for such Recall (including freight, and shipping) and replacement of the Product subject to Recall in accordance with Section 5.5 The liability of each party under this Section 9.6 shall be subject to the limitations set forth in Article 14.

9.7 Quality Agreement. Within *** after the Effective Date, and in any event prior to the first Processing and Packaging of Product hereunder, the parties shall negotiate in good faith and enter into a Quality Agreement substantially in the form attached hereto as Attachment D (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein. Additionally, the Quality Agreement is not intended and shall not be construed to limit any of the rights and obligations of the parties set forth in this Agreement. Subject to the foregoing, to the extent possible, the Quality Agreement will be interpreted with the terms set forth in the body of this Agreement. 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 commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Mutual Obligation. Catalent and Client agree that they will not disclose the other party's Confidential Information to any third party without the prior written consent of the other party, except as otherwise permitted in this Article 10. Each party may use or disclose Confidential Information of the other party solely to the extent necessary to perform its obligations and/or

exercise its rights hereunder, and in disclosures to Regulatory Authorities, or as required by law, regulation or court or administrative order; *provided*, that prior to making any such legally required disclosure, the party making such disclosure shall give the other party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances in order for such party to allow the other party to seek a protective order or otherwise prevent or restrict disclosure of such Confidential Information. Notwithstanding the foregoing, each party may disclose the other party's Confidential Information to any of its Affiliates and/or its employees, contractors, advisors (including legal or financial advisors), or consultants that (A) need to know such Confidential Information for the purpose of performing its obligations and/or exercising its rights under this Agreement, (B) are advised of the confidential nature of the Confidential Information, and (C) are bound by confidentiality obligations that are no less onerous than the terms of this Article 10.

10.2 Definition. As used in this Agreement, the term "**Confidential Information**" of a party means all information disclosed or otherwise furnished by such party, or any of its representatives or Affiliates, to the other party or its representatives or Affiliates relating to the disclosing or furnishing party's business, products, or operations (or that is otherwise deemed to be Confidential Information pursuant to other provisions of this Agreement), 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. Confidential Information may include, without limitation, proprietary technologies, know-how, trade secrets, discoveries, inventions and other intellectual property (whether or not patented), analyses, compilations, or business or technical information. The existence of this Agreement and its terms shall be deemed to be the Confidential Information of both parties; provided that either party may disclose the specific terms of this Agreement to its advisors (including legal or financial advisors), current and prospective investors, potential acquirers, or, solely in the case of Client, third parties who have acquired from Client, or who Client reasonably believes may have a bona-fide interest in acquiring, some or all of the rights to the Product, whether by acquisition or license, in each case on a need-to-know basis under reasonable and customary confidentiality obligations. For clarity, it is understood that all Specifications, Client-supplied Materials, Rolling Forecasts, Purchase Orders, and Client Inventions shall be deemed the Confidential Information of Client.

10.3 Exclusions. Notwithstanding Section 10.2, 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 the receiving party at the time of disclosure without any obligation of confidentiality as evidenced by the receiving party's written records, (C) becomes available to the receiving party 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 the receiving party without reference to the Confidential Information of the other party as evidenced by the receiving party's written records.

10.4 No Implied License. Except as expressly set forth in Section 10.1, the receiving party will obtain no right of any kind or license under any Confidential Information of the disclosing party, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the party disclosing such information or data, subject to Article 11.

10.5 Return of Confidential Information. Upon expiration or termination of this Agreement, the party receiving Confidential Information will cease its use and, upon request, within 30 days either return or destroy (and certify as to such destruction) all Confidential Information of the other party, including any copies thereof, except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.

10.6 Prior Agreement. This Agreement supersedes the Mutual Confidentiality Agreement between the Parties dated August 18, 2003 (the "**CDA**") and the confidentiality provisions of the Development Agreement with respect to information disclosed thereunder. All information exchanged between the parties under the CDA and the Development Agreement shall be deemed Confidential Information of the disclosing party and shall be subject to the terms of this Article 10.

10.7 Survival. The obligations of this Article will terminate *** years 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 applicable law.

ARTICLE 11
INTELLECTUAL PROPERTY

For purposes hereof, "**Client Background IP**" means all intellectual property and embodiments thereof owned or controlled by Client as of the date hereof or developed and controlled by Client other than in connection with this Agreement; "**Catalent Background IP**" means all intellectual property and embodiments thereof owned or controlled by Catalent as of the date hereof or developed and controlled by Catalent other than in connection with this Agreement; "**Invention**" means any invention or know-how (whether patentable or not), including intellectual property rights therein, developed solely or jointly by Catalent in connection with this Agreement; "**Client Inventions**" means any Invention that (a) is specific to the ***, or (b) is specific to the *** of the ***, the *** of the ***, or otherwise is specific to the ***; and "**Catalent Inventions**" means (a) any Invention that is specific to the Catalent Background IP or Catalent's Confidential Information, or (b) any Invention, other than a Client Invention, related to ***. All Client Background IP and Client

Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to such items solely to the extent necessary to perform its obligations under this Agreement. All Catalent Background IP and Catalent Inventions shall be owned solely by Catalent and no right therein is granted to Client under the this Agreement, except that, to the extent that the Product incorporates, or the Processing or Packaging of the Product utilizes, any Catalent Background IP and/or Catalent Inventions, Client shall have, and is hereby granted, a non-exclusive, transferable, worldwide, royalty-free, irrevocable license (including the right to grant and authorize sublicenses) to use such Catalent Background IP and/or Catalent Inventions solely in connection with ***. Catalent hereby assigns to Client all Client Inventions. Client hereby assigns to Catalent all Catalent Inventions. Each party hereby agrees to execute such documents and otherwise cooperate with the other party, as reasonably requested by such other party, to achieve the allocation of rights to Inventions as set forth herein. For the avoidance of doubt, each party shall be solely responsible for costs associated with the protection of its own 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 meet all Specifications therefor and shall have been Processed and Packaged in accordance with Applicable Laws and in conformance 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 API or other Client-supplied Materials existing at the time of delivery to Catalent;

B. during the term of this Agreement, each Facility, all equipment used for the Processing and/or Packaging of Product (and the Validation Services or Product Maintenance Services) within each Facility, and the Processing, Packaging, Validation Services, and Product Maintenance Services activities contemplated herein will conform to all Applicable Laws;

C. title to all Product supplied under this Agreement will pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance;

D. each employee and subcontractor of Catalent who will receive or have access to Confidential Information of Client or perform activities hereunder will have signed Catalent's confidentiality agreement (which such agreement contains normal and customary provisions for confidentiality and assignment of inventions), prior to the earlier to occur of: (i) any disclosure of Confidential Information of Client to such employee or subcontractor; or (ii) the commencement of any such performance by such employee or subcontractor;

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E. neither Catalent nor any of its employees or subcontractors performing or involved with its performance under this Agreement have been "debarred" by the FDA or a Regulatory Authority in any jurisdiction outside the United States, nor have debarment proceedings against Catalent or any of its employees or subcontractors been commenced. Catalent will promptly notify Client in writing if any such proceedings have commenced or if Catalent or any of its employees or subcontractors are debarred by the FDA or a Regulatory Authority in any jurisdiction outside the United States; and

F. all Validation Services and Product Maintenance Services shall be carried out in a diligent, professional manner in accordance with Catalent's standard operating procedures and the prevailing standards in the pharmaceutical industry that are applicable to such services, including cGMP and cGLP, if applicable.

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

A. the API and all other 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. to Client's knowledge, no specific safe handling instructions, health and environmental information or material safety data sheets are applicable to Product, API or any other Client-supplied Materials, except as provided to Catalent in writing by Client in accordance with this Agreement;

C. all Product delivered to Client by Catalent will be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws and this Agreement;

D. Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement API and other Client-supplied Materials (including artwork) for purposes of Processing and Packaging Product hereunder; and

E. the content of all artwork provided to Catalent shall comply with all Applicable Laws.

12.3 Mutual. Each party hereby represents and warrants to the other party as of the Effective Date that:

A. Existence and Power. 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. Authorization and Enforcement of Obligations. 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. Execution and Delivery. 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. No Consents. All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such party in connection with the Agreement have been obtained; and

E. No Conflict. 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.

12.4 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 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

13.1 Indemnification by Catalent. Catalent shall indemnify, defend and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents ("**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 its representations, warranties or obligations set forth in this Agreement, (B) actual or alleged infringement or violation of a third party's patent or trade secret that directly results from Catalent's use of Catalent Background IP, Catalent Confidential Information, or any manufacturing method or equipment supplied by Catalent in the performance of its activities under this Agreement, or (C) any negligence or willful misconduct by Catalent; 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. In addition, Catalent shall indemnify, defend and hold harmless the Client Indemnitees from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and

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reasonable investigative costs) associated with any obligation of a Client Indemnitee to respond to third party or government subpoenas that arise from any of the causes listed in Sections 13.1(A), (B), or (C)).

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees and agents ("**Catalent Indemnitees**") from and against any and all Losses to the extent arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture (other than due to Catalent Defective Processing), packaging (other than due to Catalent Defective Packaging), sale, promotion, distribution or use of or exposure to Bulk Product, Packaged Product, API or any other Client-supplied Materials, including product liability or strict liability, (C) the conduct of any clinical trials utilizing Product or API by or under the authority of Client or its designee, (D) any actual or alleged infringement or violation of any patent or trade secret, that results from (i) Catalent's use in accordance with this Agreement of Client Background IP or Client Confidential Information or Client-supplied Materials, or (ii) Client's sale of the Product, or (E) any negligence or willful misconduct by Client; 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. In addition, Client shall indemnify, defend and hold harmless the Catalent Indemnitees from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and reasonable investigative costs) associated with Catalent's obligation to respond to third party or government subpoenas relating to Client or the Product (other than to the extent such third party or government subpoenas arise from any of the causes listed in Sections 13.1(A), (B), or (C)).

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the party seeking indemnification (A) promptly notifying the indemnifying party of any claim or liability of which the party seeking indemnification 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) allowing the indemnifying party, if the indemnifying party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), (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, which shall not be unreasonably withheld or delayed. 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 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. The indemnified party shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 CATALENT'S LIABILITY UNDER THIS AGREEMENT FOR LOST, DAMAGED OR DESTROYED API OR OTHER CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH API OR CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT, SHALL NOT EXCEED $*** PER BATCH (ASSUMING A BATCH SIZE CONTAINING *** KILOGRAMS OF TOPIRAMATE PER BATCH) OF PRODUCT THAT GIVES RISE TO THE APPLICABLE CLAIM FOR LOST, DAMAGED OR DESTROYED API OR OTHER CLIENT-SUPPLIED MATERIALS. For clarity, if the Batch size is changed to a value other than *** kilograms of Topiramate per batch, the foregoing limit shall automatically change in proportion to any such changes; provided that in no event shall it exceed $*** per batch.

14.2 CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT IN ANY *** PERIOD SHALL IN NO EVENT EXCEED $***, PROVIDED THAT THE FOREGOING LIMITATION ON LIABILITY SHALL NOT APPLY TO: (A) ANY LIABILITY ARISING FROM CATALENT'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE *** RESULTING FROM CATALENT'S GROSS NEGLIGENCE OR WILLFULL MISCONDUCT; OR (B) CATALENT'S LIABILITY UNDER ARTICLE 13 (Indemnification) WITH RESPECT TO LOSSES FOR DEATH OR BODILY INJURY DUE TO CATALENT'S NEGLIGENCE. NOTHING IN THIS SECTION 14.2 SHALL LIMIT CATALENT'S LIABILITY FOR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT. In addition, the foregoing limitation on liability shall not apply to, or include any amounts with respect to, (i) any of Catalent's internal overhead or personnel costs associated with Processing and Packaging for replacing Defective Product pursuant to Section 5.4, or (ii) any credits granted for Defective Product pursuant to Section 5.4.

14.3 EXCEPT FOR BREACHES OF ARTICLE ***, 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. 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

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 Insurance with a per-occurrence limit of not less than $***; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than $***; (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than $*** per accident; and (D) All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. 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 its annual EBITDA (earnings before interest, taxes, depreciation and amortization) 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 *** years thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party. Each party shall be named as an additional insured within the other party's products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this Agreement. Such 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.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue for four (4) years following the Launch Date, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the "**Term**"). Notwithstanding the foregoing, in the event of a Change of Control of Client prior to the end of the ***, Client (or its acquiror or successor) may elect to change the percentage in Section 2.2 applicable to the fourth Contract Year to *** percent (***%), which election shall require (A) written notice to Catalent of such election within *** after such Change of Control and (B) payment of the Termination Fee to Catalent within 30 days of such notice. The "Termination Fee" shall be $*** and shall be increased to $*** if at the time of Catalent's receipt of such notice, Catalent is performing the *** (or has the Qualified Capability to do so) at its Facility in ***. If the

Termination Fee has increased to $*** pursuant to the prior sentence, and Client has contributed funds towards the capital expenditure necessary for Catalent to obtain such capability, then the Termination Fee shall be reduced in an amount equal to such contribution.

16.2 Termination. This Agreement may be terminated as provided below:

A. immediately without further action 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

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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 60 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction;

B. immediately by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within *** 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 undisputed payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within *** days of receipt of notice of non-payment from Catalent; or

C. immediately by Client or Catalent in the circumstances described in Section 7.3.

16.3 Effect 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:

A. Catalent shall promptly return to Client, at Client's expense and at Client's direction, any remaining inventory of Product, API or other Client-supplied Materials; *provided*, that Catalent shall have no obligation to so return such items until all outstanding and undisputed invoices sent by Catalent to Client have been paid in full;

B. Client shall pay Catalent all undisputed invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, provided such Product meets the Specifications therefor and conforms to the warranties set forth in Section 12.1, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped and which meets the Specifications and conforms to the warranties set forth in Section 12.1, 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 or Packaged 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)); and

C. in the event that this Agreement is terminated by Catalent pursuant to Section 16.2(A) or (B), or by either Party pursuant to Section 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 (except to the extent that such costs, expenses, and commitments relate to activities for which Catalent has been or will be paid under Section 7.1 or 16.3(B)), so long as such costs, expenses or commitments were made by Catalent in a reasonable manner that is consistent with Client's most recent Rolling Forecast and any vendor's minimum purchase obligations.

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D. in the event that (i) this Agreement is terminated for any reason other than by Catalent pursuant to Section 16.2(A) or (B) or by either Party pursuant to Section 16.2(C), and (ii) Client demonstrates that at the time of such termination Catalent had been the sole supplier of the Product and Packaged Product to Client and its Affiliates over the preceding 12 month period, Catalent shall use its commercially reasonable efforts to assist Client, as reasonably requested, to transition the manufacture and supply of the Product to Client, its Affiliate, or its designated Third Party manufacturer in a timely and orderly manner at Catalent's then prevailing rates for such services, which efforts shall include, without limitation, Catalent providing Client with access to the relevant Catalent Background IP and Catalent Inventions licensed to Client pursuant to Article 11.

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), and under Sections 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third Party Expenses), 9.2 (Recordkeeping), 9.3 (Regulatory Compliance), 9.4 (Governmental Inspections and Requests), 9.5 (Client Inspections and Audits), 9.6 (Recall), 12.1 (Catalent Warranties), 12.2 (Client Warranties,12.3 (Limitations on Warranties), 16.1 (Term),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; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; (D) when delivered if sent by express courier service; or (E) except with respect to Sections 2.5, 3.2(C), 3.3, 3.4, 4.6, 7.2, 8.1, 8.3, 9.2, 9.6, 10.1, 13.3, 16.1, 16.2 and 18.12 (under which Sections such notices shall only be deemed given when delivered pursuant to a method described in (A)-(D) above), when emailed, 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:

VIVUS, Inc.
1172 Castro St.
Mountain View, CA 94040
Attn: Peter Tam
John L. Slebir, Esq.
Facsimile: +1 (650) 934-5389

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To Catalent (as applicable):

Catalent Pharma Solutions, LLC
1100 Enterprise Drive
Winchester, KY 40391
Attn: General Manager
Facsimile: (859)745-6636

With a copy to:

Catalent Pharma Solutions
14 Schoolhouse Road
Somerset, NJ 08873
USA
Attn: General Counsel (Legal Department)
Facsimile: (732) 537-6491

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 contracts, agreements or understandings (oral or written) of the parties, with respect to the subject matter hereof, including the CDA. For the avoidance of doubt, the Development Agreement shall remain in full force and effect according to the terms set forth therein and shall not be modified or otherwise affected by this Agreement, except with respect to the confidentiality provisions therein as stated in Section 10.6 above. 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 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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18.3 Further 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.

18.4 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 to be 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 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.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, and their respective successors and permitted assigns. This Agreement will not be assignable by either party to any third party without the prior written consent of the other party, except that Client will have the right to assign this Agreement without Catalent's consent to an entity that acquires all or substantially all of the business or assets of Client to which this Agreement relates. Similarly, Catalent will have the right to assign this Agreement, in whole or in part, without Client' consent to an entity that acquires all or substantially all of the business or assets of Catalent or the Catalent business unit responsible for performance of any services under this Agreement, unless: (a) such assignment would result in the transfer of the Processing, Packaging, Validation Services, or Product Maintenance Services activities with respect to the Product to facilities other than those in which such activities are being conducted immediately prior to such proposed assignment, such that Client would be required to modify, change or file an amendment to its regulatory filings for the Product; or (b) the acquiring party is a competitor of Client in the field of obesity or any obesity-related disorder(s) in the Territory.

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

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, 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.

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18.10 Alternative Dispute Resolution. If any dispute arises between the parties in connection with this Agreement (other than a dispute described in Section 5.2), such dispute shall be presented to the respective presidents or senior executives of Catalent and Client for their consideration and resolution for *** days. If such parties cannot reach a resolution of the dispute with such *** day period, then such dispute shall be resolved by binding alternative dispute resolution in accordance with the then existing commercial arbitration rules of the Judicial Arbitration and Mediation Services, Inc. (or any successor thereto) ("**JAMS**") as modified by this Agreement. Arbitration shall be conducted by a panel of three (3) arbitrators in ***. Each Party will nominate one (1) arbitrator, and these arbitrators shall mutually agree on a third arbitrator. The panel shall engage an independent expert with experience in the subject matter of the dispute to advise the panel. The parties agree that the decision of the panel shall be the sole, exclusive and binding remedy between them regarding the dispute. Pending the selection of the arbitrators or pending the panel's determination of the merits of any dispute, either party may seek appropriate interim or provisional relief from any court of competent jurisdiction as necessary to protect the rights or property of that party.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement as set forth in Section 18.10, the prevailing party will be entitled to recover all costs associated with such proceedings, including its reasonable attorney's fees, 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 (such approval not to be unreasonably withheld) 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. Notwithstanding the foregoing or anything else in this Agreement (including Article 10), Catalent acknowledges that, pursuant to Client's disclosure obligations as a publicly traded company, Client may file this Agreement with the Securities and Exchange Commission (the "**SEC**") (and/or may disclose the material terms of this Agreement in its filings with the SEC), in which case, Client covenants that it will use commercially reasonable efforts to obtain confidential treatment of certain mutually agreed upon terms of this Agreement pursuant to Rule 24b-2 promulgated by the SEC under the Securities Exchange Act of 1934, as amended.

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, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather,

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labor disturbances, epidemic or failure of suppliers, public utilities or common carriers; *provided*, that the party seeking relief under this Section shall immediately notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section 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 ***, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s). Notwithstanding the foregoing, in the event that Catalent is the party experiencing any such force majeure event, Client shall not be obligated to exclusively purchase Product from Catalent as set forth in Section 2.2 or 4.1.

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]

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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, LLC		**VIVUS, INC.**	
By:	/s/ Ian Muir	By:	/s/ Peter Tam
Name:	Ian Muir	Name:	Peter Tam
Its:	President, MRT	Its:	President

Signature Page to Commercial Manufacturing Agreement

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ATTACHMENT A

VALIDATION SERVICES

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ATTACHMENT B

SPECIFICATIONS

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ATTACHMENT C

UNIT PRICING, FEES

***

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ATTACHMENT D

FORM OF QUALITY AGREEMENT FOR PROCESSING

FORM OF QUALITY AGREEMENT FOR PACKAGING

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ATTACHMENT E

KEY PERFORMANCE INDICATORS

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