Exhibit 10.5  
MANUFACTURING AND SUPPLY AGREEMENT  
This MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”) is entered into and is effective as of this 30 day of July, 2019 (the “Effective Date”), by and between Jubilant HollisterStier LLC (“Supplier”), a Delaware corporation having offices at 0000 Xxxxx Xxxxx Xxxxxx, Xxxxxxx, XX 00000 and Xxxx Life Science US Inc. (“Customer”), a Delaware corporation, having offices at 000 Xxx Xxxx, Xxxxx 000, Xxxxx, XX 00000. Supplier and Customer may be referred to herein individually as a “Party” and collectively as the “Parties.”  
BACKGROUND:  
WHEREAS, Supplier has the manufacturing resources and  
WHEREAS, Customer wishes Supplier to manufacture and supply to Customer, the pharmaceutical product SPRIX® (ketorolac tromethamine) Nasal Spray (the “Product”) and Supplier desires to manufacture, package and sell such Product to Customer, on the terms and subject to the conditions set out below in this Agreement  
NOW THEREFORE, in consideration of the foregoing and the mutual promises contained herein, the Parties agree as follows:  
ARTICLE I  
DEFINITIONS  
For the purposes of this Agreement, the following terms shall have the following meanings:  
1.1 “Act” means the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 et seq.) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211 and 610), as amended from time to time.  
1.2 “Affiliate” means, with respect to either Party, those entities controlled by, in control of, or under common control with such Party. A corporation or non-corporate business entity shall be regarded as in control of another corporation or business entity (a) if it owns or directly or indirectly controls a majority of the voting stock or other ownership interest of the other entity, or (b) in the absence of the ownership of a majority of the voting stock or other ownership interest of such entity, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate business entity, as applicable.  
1.3 “Agreement” has the meaning set forth in the preamble of this Agreement.  
1.4 “API” means the active pharmaceutical ingredient listed on Exhibit A.  
1.5 “API Specifications” means, with respect to a given API, the specifications for such API, including chemical name, structure, reference profile, limits, impurities, physical properties,  
 [\*\*\*\*] Portions omitted pursuant to a request for confidential treatment.  
 identity tests, analytical methods, storage requirements, and similar information, attached hereto as Exhibit A.  
1.6 “Applicable Laws” means all laws, statutes, ordinances, regulations, rules, judgments, decrees or orders of any Authority: (i) with respect to each party, in any jurisdiction in which such party actually operates or performs activities hereunder related to the manufacture and sale of the Product; (ii) with respect to Customer, in any jurisdictions in which API or Product are produced, marketed, distributed, used or sold; and (iii) with respect to Supplier, in any jurisdiction expressly designated in the Specifications. The term Applicable Laws includes cGMPs.  
1.7 “Best Efforts” means the efforts that a prudent person desirous of achieving a result would use in similar circumstances to achieve that result as expeditiously as possible, provided, however, that a person required to use ‘Best Efforts’ under this Agreement will not be required to take actions that would result in a material adverse change in the benefits to such person of this Agreement and the contemplated transactions or to dispose of or make any change to its business, expend any material funds or incur any other material burden.  
1.8 “Binding Forecast” shall have the meaning set forth in Section 2.3  
1.9 “Breaching Party” shall have the meaning set forth in Section 8.2(b).  
1.10 “Business Day” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the states of Pennsylvania or Washington, United States.  
1.11 “Calendar Year” means January 1 – December 31.  
1.12 “Claims” shall have the meaning set forth in Section 7.1.  
1.13 “Commercially Reasonable Efforts” means with respect to either Party, those efforts and resources that a such Party would normally devote to a product or compound owned by it or to which it has rights of the type it has hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account the competitiveness of the global and local marketplace, the pricing and launching strategy for the respective product, the proprietary position of the product, the profitability and the relative potential safety and efficacy of the product and other relevant factors, including technical, legal, scientific, regulatory or medical factors then prevailing. “Commercially Reasonable” as used herein shall be interpreted in a corresponding manner.  
1.14 “Components” means, collectively, all raw materials, ingredients and packaging components required to be used in order to produce the Product in accordance with the Specifications, other than API and those items listed as components in Exhibit B.  
1.15 “Confidential Information” means any information of a Party and/or its Affiliates that is disclosed by the disclosing Party or its Affiliates (“Disclosing Party”) to the receiving Party or its Affiliates (“Receiving Party”) during the Term relating to the obligations of either Party contemplated by this Agreement. Notwithstanding the foregoing, any Confidential Information disclosed by visual observation during a tour, site visit, or audit of Customer’s  
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 or any of its Affiliates’ laboratories, manufacturing plants or other facilities or, reversely, any Confidential Information disclosed by visual observation during a tour, site visit, or audit of Supplier’s or any of its Affiliates’ laboratories, manufacturing plants or other facilities shall automatically be deemed Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include any information that:  
(a) is or becomes part of the public domain without breach by the Receiving Party of this Agreement;  
(b) was in the Receiving Party’s possession before disclosure by the Disclosing Party and was not acquired directly or indirectly from the Disclosing Party; or  
(c) is obtained from a Third Party with no obligation of confidentiality to the Disclosing Party, who has a right to disclose it to the Receiving Party; or  
(d) is developed independently by the Receiving Party without use of the Confidential Information of the Disclosing Party, as evidenced by the Receiving Party’s written records.  
1.16 “Conforming Product” means Product delivered by the Supplier hereunder that meets the Product Warranty.  
1.17 “Control” with respect to any intellectual property means the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party and, with respect to Know-How, also means that such intellectual property is not known to the other Party prior to disclosure thereto, nor freely available from the public domain or any Third Parties.  
1.18 “Customer” shall have the meaning set forth in the preamble of this Agreement.  
1.19 “Customer Indemnitee” shall have the meaning set forth in Section 7.1.  
1.20 “Developed Intellectual Property” shall have the meaning set forth in Section 2.12.  
1.21 “Disclosing Party” shall have the meaning set forth in Section 1.14.  
1.22 “Effective Date” shall have the meaning set forth in the heading of this Agreement.  
1.23 “Failure” shall have the meaning set forth in Section 2.7.  
1.24 “Field Correction” means any action taken or changes performed affecting a distributed product to mitigate a risk to health or correct issues with misbranded or non-conforming product.  
1.25 “FDA” means the U.S. Food and Drug Administration and any successor agency thereto.  
1.26 “Force Majeure” shall have the meaning set forth in Section 10.4.  
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 1.27 “Good Manufacturing Practices” or “cGMP” means the current Good Manufacturing Practices standards as promulgated under each of the following as in effect on the date of this Agreement and as amended or revised after the date of this Agreement: (a) the Act and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of the Products; (b) the quality management systems guidance according to ICH Q10; and as amended from time to time.  
1.28 “Governmental Authority” means any nation or government, any state, local or other political subdivision thereof, and any entity, department, commission, bureau, agency, authority, board, court, official or officer, domestic or foreign, exercising executive, judicial, regulatory or administrative governmental functions.  
1.29 “Law” means each provision of any currently existing federal, state, local or foreign, civil and criminal law, statute, ordinance, order, code, rule, regulation, guideline (including cGMP) or directive or common law, promulgated or issued by any Governmental Authority, as well as any judgments, decrees, injunctions or agreements issued or entered into by any Governmental Authority.  
1.30 “Manufacturing Facility” means any facility utilized by Supplier, its agents and Affiliates in connection with the manufacture, processing, filling, testing, packaging, distribution, importation, exportation, transport or storage of any Product.  
1.31 “Maximum Transfer Prices” shall have the meaning set forth in Section 5.1(a)  
1.32 “Minimum Transfer Price” shall have the meaning set forth in Section 5.1(a).  
1.33 “Non-Breaching Party” shall have the meaning set forth in Section 8.2(b).  
1.34 “Party” or “Parties” shall have the meaning set forth in the preamble to this Agreement.  
1.35 “Patent(s)” means any claim in an issued patent including any extension, substitution, registration, confirmation, reissue, supplemental protection certificate, re-examination or renewal of such patent, to the extent said patent is valid and enforceable (and in each case any foreign counterpart thereto).  
1.36 “Permitted Recipients” shall have the meaning set forth in Section 9.1(b).  
1.37 “Product” means Sprix (ketorolac tromethamine) Nasal Spray 15.75 mg per spray  
1.38 “Product Warranty” means the warranties set forth in Sections 6.2(a), (b) and (c).  
1.39 “Purchase Order” shall have the meaning set forth in Section 2.4.  
1.40 “Quality Agreement” means the Quality Agreement executed by the Parties which shall describe the regulatory and compliance roles and responsibilities of both Supplier and Customer with respect to activities conducted hereunder. The Quality Agreement will be attached hereto as Exhibit C and incorporated herein by reference. The Quality Agreement shall include, without limitation, provisions relating to complaint management, storage and  
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 shipment conditions and controls, product release and environmental, temperature and humidity conditions and controls, as applicable.  
1.41 “Recall” means the removal or correction of a marketed product that the FDA or other Regulatory Authority considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g., seizure) and may be conducted on a firm’s own initiative, by FDA or other Regulatory Authority request, or by FDA or other Regulatory Authority order under statutory authority. The words ‘recalled’ ‘recalling’, etc. shall have correlative meanings.  
1.42 “Recall Costs” means all costs and expenses relating to or arising out of any Recall, Withdrawal or Field Correction including any out-of-pocket expenses incurred by either Party relative to notification, shipping, disposal and return of the Recalled or Withdrawn product and the notification and correction of any product subject to a Field Correction.  
1.43 “Receiving Party” shall have the meaning set forth in Section 4.  
1.44 “Regulatory Approvals” means, with respect to a particular country or regulatory jurisdiction, the registrations, authorizations and approvals (including reimbursement approvals), licenses, supplements and amendments, pre- and post-approvals, of any national, supra-national, regional, state or local Regulatory Authority, department, bureau, commission, council or other Regulatory Authority or Governmental Authority in such country (including, but not limited to the FDA), necessary for the development (including the conduct of clinical trials), manufacture, distribution, importation, exportation, transport, storage, marketing, promotion, offer for sale, use, or sale of a product in such country.  
1.45 “Regulatory Authority” means any national, supra-national, regional, state or local regulatory authority, department, bureau, commission, council or other Governmental Authority in such country (including, but not limited to, the FDA or any successor agencies thereto) responsible for overseeing the development (including the conduct of clinical trials), manufacture, distribution, importation, exportation, transport, storage, marketing, promotion, offer for sale, use, or sale of a Product.  
1.46 “Rolling Forecast” shall have the meaning set forth in Section 2.3.  
1.47 “Specifications” means the current approved finished product specifications for the Product attached hereto as Exhibit D, as may be updated from time to time pursuant to the terms of this Agreement.  
1.48 “Supplier” shall have the meaning set forth in the preamble of this Agreement.  
1.49 “Supplier Indemnitee” shall have the meaning set forth in Section 7.2.  
1.50 “Supplier IP” means the Supplier Know How and the Supplier Patent Rights.  
1.51 “Supplier Know How” means all Know-How Controlled by Supplier that relates to the manufacture and/or supply of a Product and all development, clinical, quality, and regulatory information associated with such Product. For the avoidance of doubt, this includes both the  
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 Know-How Controlled by Supplier at the time of execution of this Agreement, and any future Know How Controlled by Supplier that relates to the manufacture and/or supply of Products. Notwithstanding the foregoing, Supplier Know-How excludes Developed Intellectual Property Rights.  
1.52 “Supplier Patent Rights” all claims of any Patent that is owned or Controlled by Supplier which are necessary or useful for Supplier to manufacture and supply to Customer any of the Products that has not (a) expired or been canceled, (b) been declared invalid by an unreversed and unappealable decision of a court or other appropriate body of competent jurisdiction, (c) been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise or (d) been abandoned. For the avoidance of doubt, this includes both the Patents Controlled by Supplier at the time of execution of this Agreement, and any future Patents Controlled by Supplier that is necessary or useful for the manufacture and/or supply of Products. Notwithstanding the foregoing, Supplier Patent Rights excludes Developed Intellectual Property Rights.  
1.53 “Term” shall have the meaning set forth in Section 8.1.  
1.54 “Territory” means worldwide  
1.55 “Third Party” means any person or entity other than the Parties or their Affiliates, whether such entity is a person, company, corporation, limited liability company, partnership or other legal entity, or a division or operating or business unit of such legal entity.  
1.56 “Transfer Price” shall have the meaning set forth in Section 5.1.  
1.57 “Withdrawal” means a removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or other Regulatory Authority, or which involves no violation of a Law. The words ‘withdrawn’ ‘withdrawing’, etc. shall have correlative meanings.  
ARTICLE II  
MANUFACTURE, PRODUCTION FORECASTS AND PURCHASE ORDERS  
2.1 General Agreement. During the Term of this Agreement, except as may otherwise be provided herein (including, without limitation, the provisions contained in Section 2.7 and Section 5.1 below), Supplier agrees to manufacture and supply Product to Customer, and Customer agrees to purchase Product from Supplier, in accordance with the terms and conditions of this Agreement. Customer agrees to buy at least the minimum order quantity specified in Section 5.1(b) pursuant to the Binding Forecasts and Purchase Orders provided to Supplier by Customer.  
2.2 Conversion of API and Components. Supplier shall convert API and Components into Finished Goods in accordance with this Agreement.  
(a) API and Components. Customer shall purchase at its sole cost and expense all API and Components and deliver API and Components to Supplier in accordance with  
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 Exhibit A. Supplier shall visually inspect API and Components upon receipt to verify identity and quantity and shall test each shipment in accordance with the Quality Agreement and the API Specifications or Component Specifications. Supplier shall store such API on behalf of the Customer, in accordance with API Specifications. The parties acknowledge and agree that title to API and Components shall at all times belong to and remain the property of the Customer.  
(b) Raw Materials. Supplier shall purchase all other raw materials as required by and included in the product formulation and Specifications. Supplier shall procure only raw materials that are warranted by the vendor to have been manufactured in accordance with cGMPs. Supplier shall test all raw materials after receipt at the Manufacturing Site as required by the Specifications and the Quality Agreement.  
(c) For each fill date on which a batch of Product is produced, Supplier shall [\*\*\*\*].  
(d) Supplier shall complete all inspection and packaging of each batch of Product [\*\*\*\*].  
2.3 Rolling Forecasts. Not later than [\*\*\*\*], Customer shall provide Supplier with a non-binding, good faith written forecast of Customer’s expected requirements for Product during the [\*\*\*\*] (the “Rolling Forecast”). The Rolling Forecast shall be based on Customer’s desired Product fill schedule. Notwithstanding the first sentence of this Section 2.3, [\*\*\*\*] included in each Rolling Forecast shall constitute a firm Purchase Order and binding commitment (the “Binding Forecast”). Customer shall not be obligated to purchase nor shall it have any liability in respect of the quantities of Product set forth in the remaining [\*\*\*\*] of any such Rolling Forecast.  
2.4 Orders. Customer shall place binding orders for Product by written or electronic Purchase Order (each a “Purchase Order”) (or by any other means agreed to by the parties) with Supplier. Supplier shall acknowledge and accept any Customer Purchase Order in writing [\*\*\*\*] of its receipt thereof. All such Purchase Orders shall be irrevocable and binding on both Parties. Purchase Orders shall be placed at least [\*\*\*\*] prior to the required fill date based on the Binding Forecast and include the desired date of delivery with respect to the Product ordered. Supplier shall deliver all Product ordered by Customer under this Agreement [\*\*\*\*] set forth in the applicable purchase order, unless otherwise agreed upon by both parties.  
2.5 Cancellation or Postponement. Customer reserves the right to cancel or postpone any purchase order, provided that all postponements and cancellations are in accordance with each of the following terms:  
(a) Should Customer cancel or postpone all or part of any purchase order [\*\*\*\*].  
(b) Should Customer cancel or postpone all or part of any purchase order [\*\*\*\*].  
(c) Should Customer cancel or postpone all or part of any purchase order [\*\*\*\*].  
(d) Should Customer cancel or postpone all or part of any purchase order [\*\*\*\*].  
(e) Should Customer cancel or postpone a purchase order [\*\*\*\*].  
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 (f) [\*\*\*\*].  
2.6 Allocations. Should Supplier, at any time during the course of this Agreement, have reason to believe that it will be unable to meet Customer’s requested delivery dates or the ability of Supplier to deliver Product in accordance with Customer’s forecasted requirements, Supplier will promptly notify Customer stating the reasons for the delay, the expected duration of the delay and the efforts Supplier is taking to address the cause for the delay. In the event of any supply shortage due to the inability of Supplier to procure raw materials, production problems or other circumstances adversely impacting the manufacture and/or supply of Product (including Force Majeure), Supplier shall allocate production line fill slots among Customer and Supplier’s other customers in proportion to the aggregate production line fill slots of the last [\*\*\*\*] of each such party.  
2.7 Failure to Supply.  
(a) Generally. If supplier fails to supply at least [\*\*\*\*] of the aggregate Purchase Orders for Product (based on the number of batches ordered) and such failure continues for a period of [\*\*\*\*] (a “Failure”). A Failure, except in instances of Force Majeure, shall be considered a material breach of this agreement. Supplier shall:  
(i) Use Commercially Reasonable Efforts to work collaboratively with Customer to discuss and promptly resolve any such Failure which Commercially Reasonable Efforts shall include, but shall not be limited to: (A) making its own personnel available for consultation during the term of any such Failure; and (B) ensuring that any remedial actions recommended by Customer are considered in good faith and if accepted, promptly implemented  
(ii) Allow Customer to purchase from a reputable third party (or itself manufacture) Product to cover the shortfall amount with respect to such accepted Purchase Order quantities and all future Product requirements until Supplier provides Customer with reasonably detailed information concerning the actions Supplier has taken to remediate the circumstances that caused Supplier’s failure to deliver and demonstrating that such circumstances have been remediated and that product supply issues are resolved.  
(b) Effect of Remedy of a Failure. If Customer’s manufacturing rights under this Section 2.7 become effective because of a Failure and Supplier is thereafter, during the Term of the Agreement, able to demonstrate to Customer’s reasonable satisfaction that Supplier is capable of re-establishing a satisfactory supply of Product, then Customer shall resume purchasing Product from Supplier (subject to the remainder of this Section 2.7(b) within [\*\*\*\*] after Supplier satisfactorily demonstrates its ability to meet Customer’s Product forecasts. Notwithstanding the foregoing, Customer shall be permitted to fulfill any then-existing contractual commitments, which are non-terminable or non-refundable, under any third party contracts entered into by Customer as a result of the Failure (if any).  
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 2.8 Compliance with Laws. Supplier shall manufacture all Products in accordance with the applicable Specifications, the Quality Agreement, cGMP standards, the applicable Regulatory Approvals, the Act and all other applicable United States Laws. In connection therewith, Supplier shall comply with all applicable United States Laws related to the manufacturing, labeling, packaging, storage and handling of the Product, including maintaining qualified quality facilities and procedures and shall maintain all required licenses including, but not limited to, all establishment licenses and cGMP licenses.  
2.9 Audits. Upon reasonable prior notice to Supplier by Customer, Supplier shall allow reasonable access to the applicable Supplier facilities, the Manufacturing Facilities and records to allow Customer and any Regulatory Authority to conduct full quality and/or compliance audits or inspections relating to the manufacturing, labeling, packaging, storage and handling of the Product. Such audits shall, to the extent requested by Customer and to the extent reasonably practical, be scheduled at mutually agreeable times upon reasonable advance written notice to Supplier, and shall be at Customer’s expense. In connection with performing such audits, Customer shall comply with all reasonable rules and regulations promulgated by Supplier and its Third Party Contractors. Except in the case where Customer has reasonable cause, Customer shall be limited to one audit per calendar year that consists of [\*\*\*\*].  
2.10 Notification of Production Issues. Supplier shall inform Customer promptly in writing, and in any case within [\*\*\*\*] Business Days of learning thereof, of any problems that could reasonably be expected to prevent Supplier from providing timely deliveries of Product to Customer. Supplier shall, in good faith, consider any recommendations made by Customer to resolve any problems relating to the manufacture and supply of any Product under this Agreement. Supplier shall and shall ensure that each Third Party Contractor shall coordinate maintenance outages and shut-downs of the Manufacturing Facility to minimize any delivery disruptions.  
2.11 Equipment. Supplier will use the Customer-owned equipment [\*\*\*\*] specified in Exhibit E (the “Customer Equipment”) solely for manufacturing and supplying the Product to Customer, and may not use such equipment for any other purpose or customer. Title to all Customer Equipment will remain solely with Customer. Supplier will keep the Customer Equipment free and clear of any security interests, liens, pledges, claims, charges, restrictions, or other encumbrances. All Customer Equipment will be labelled as property owned by Customer. Supplier will perform maintenance and servicing of such Customer Equipment while located at Supplier’s facilities in accordance with the vendor’s instructions, and liable for any damage, destruction or other loss to or of the Customer Equipment caused by the negligence or misconduct of Supplier, ordinary wear and tear excepted. Such expenses of maintenance and service will be reviewed and agreed upon by both parties and may be charged back to Customer. Upon reasonable advanced notification, Supplier will permit Customer and its personnel and agents, and the manufacturers of the Customer Equipment, to have access to the Customer Equipment in order to monitor the operation of the Customer Equipment. Customer acknowledges that Customer Equipment is validated in an ISO 5, multi-use area and will require significant lead time to coordinate any access to equipment. Any transfer or seizure of equipment, upon prior written notice from Customer to Supplier authorizing such actions, will require review and coordination as well as agreed  
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 upon costs to remove from Supplier site. With the exception of any fixed equipment, as listed in Exhibit D, Customer will have the right to require Supplier to deliver to Customer, or to permit Customer or its agents to remove from Supplier’s premises and take possession of, the Customer Equipment, and Supplier will provide all reasonable cooperation in connection therewith at Customer’s expense. Removal of fixed equipment shall be at Supplier’ timeline (which shall be reasonable) and at Customer expense for reasonable, actual and direct costs incurred by Supplier to remove such equipment. Removal of equipment will require a quotation to be agreed upon reasonably and in good faith and executed by both parties to cover any and all charges for the removal and an agreed upon timeline will be established to complete the work.  
2.12 Title to Intellectual Property. All Patents, Know-How and other intellectual property generated or derived by Supplier while performing its obligations under this Agreement, to the extent it is specific to the development, manufacture, use and/or sale of the Products, is dependent on such Products, or is an improvement to or derivative of Customer’s Patents, Know-How or other intellectual property, will be the exclusive property of Customer (“Developed Intellectual Property”), and Supplier hereby irrevocably assigns to Customer, and Customer hereby accepts, all right, title and interest in and to the Developed Intellectual Property. Supplier shall cause its employees, agents and contractors to do the same. Subject to the preceding sentences, all right, title and interest in and to the Supplier IP shall remain vested in Supplier.  
ARTICLE III  
MANUFACTURING STANDARDS; SPECIFICATIONS; ACCEPTANCE  
3.1 Production and Manufacturing Standards. All amendments to the Specifications (if any) will be managed in accordance with the terms of the Quality Agreement and all amendments or changes to the Specifications (if any) shall be attached to this Agreement as an Exhibit in place of the previously applicable Exhibit for such Specifications. In the event of a conflict between the provisions of this Agreement and any of the Specifications, the provisions of this Agreement shall prevail.  
3.2 Shipping; Delivery. Unless otherwise instructed by Customer, Supplier shall use its Commercially Reasonable Efforts to ship each lot of Product promptly upon completion of manufacturing. All Product manufactured and supplied hereunder shall be delivered Ex-Works (INCOTERMS 2010) by freight carrier of Customer’s choice. Customer is responsible to obtain the best commercial rates for shipping costs. All customs duties shall be at Customer’s expense. All other costs, taxes, insurance premiums, and other expenses associated with transport and delivery shall be at Customer’s expense. Customer shall arrange for shipping in compliance with the applicable Product requirements regarding temperature, duration and other environmental factors as required to properly preserve the Products without materially impacting their shelf life and/or integrity.  
3.3 Testing and Documentation. Supplier shall test all Product to ensure compliance with the applicable Specifications in accordance with the Quality Agreement and pursuant to any changes thereof if such may be forthcoming due to any regulatory source(s). Copies of all  
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 documentation and test results, including batch records, certificate of analysis, standard operating procedures, laboratory assay methods, deviation and investigation reports, appropriately signed, as are necessary to demonstrate Supplier’s cGMP compliance shall be provided to Customer in accordance with the Quality Agreement.  
3.4 Acceptance.  
(a) Each Batch of Product delivered hereunder shall be accompanied by a Certificate of Analysis signed by a duly authorized representative of Supplier. Customer shall have [\*\*\*\*] from the date of receipt of Product to inspect and reject acceptance by written notice to Supplier; provided, however, that any such notice shall set forth Customer's reasons for rejection in reasonable detail and provided, further, that Customer may reject Product only if: (i) Customer claims a material breach of Supplier's representations and warranties in Article VI of this Agreement with respect to such Product; or (ii) Supplier has failed to deliver a Certificate of Analysis for such Product; (iii) the Product fails to conform to the Product Warranty. If Supplier does not receive Customer's written notice of rejection within such [\*\*\*\*] period, Customer shall be deemed to have accepted Product.  
(b) In the event Customer provides Supplier with a timely notice of rejection as set forth in Section 3.4(a), Customer shall return the rejected Product to Supplier at Supplier's expense. Supplier shall have [\*\*\*\*] following receipt of rejected Product in which to test such Product. If Supplier does not dispute a rejection, Supplier shall rework or replace the rejected Product promptly, at Supplier's expense (except for replacement API, which will be provided by Customer at Customer’s expense but subject to Section 3.6) and, except for Sections 4.7, and 7.1, such rework or replacement shall constitute Customer's exclusive remedy and Supplier's sole liability with respect to such rejection. If Supplier disputes a rejection, Supplier shall provide Customer with written notice of such dispute within [\*\*\*\*] after receiving the returned Product, and the Parties shall use commercially reasonable efforts to resolve the dispute amicably and promptly. If the Parties are unable to reach a resolution within [\*\*\*\*] after Customer's notice of rejection, the returned Product shall be submitted to an independent laboratory or consultant mutually acceptable to the Parties, whose decision as to the conformity of such Product with the requirements of this Agreement shall be final and binding. The Party against whom the dispute is decided shall pay any charges for such laboratory or consultant. If the laboratory or consultant determines that the returned Product did not conform to the standards of this Agreement, Supplier shall replace the rejected Product at no charge to Customer (except that Customer shall provide replacement API at Customer’s expense but subject to Section 3.6), and such replacement shall constitute Customer's exclusive remedy and Supplier's sole liability with respect to such rejected Product.  
3.5 Latent Defects. If, after accepting any lot or shipment of Product, Customer subsequently discovers latent material defects which were not reasonably discoverable during the acceptance period set forth in Section 3.4, Customer may revoke its acceptance of such lot or shipment by giving written notice and disclosing the nature of any defects to Supplier promptly after discovering such defects within [\*\*\*\*] of discovery of the defect. The existence and cause of  
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 such latent material defect will be investigated through the root cause analysis according to the procedures in the Quality Agreement. Any disputes as to whether such latent material defect was or was not ‘reasonably discoverable’ shall be referred to the Parties’ senior management for resolution.  
3.6 API.  
(a) [\*\*\*\*]. All such API shall conform to the API Specifications. Title to API shall remain at all times with Customer. Except as expressly provided otherwise in Section 3.6(b), risk of loss of the API shall remain at all times with Customer.  
(b) In the event any loss or damage of API (whether prior to or during processing) results from Supplier's negligent acts or omissions, as Supplier's sole liability and Customer's sole remedy with respect to such loss or damage of API, Supplier, at Customer’s option, shall (i) reimburse Customer for the documented actual direct manufacturing cost or price charged to Customer of the lost or damaged API, or (ii) allow Customer a purchase price credit equal to the documented actual direct manufacturing cost or price charged to Customer of the lost or damaged API. The maximum liability of Supplier under this Section 3.6 during any calendar year of this Agreement for the [\*\*\*\*]. [\*\*\*\*].  
ARTICLE IV  
REGULATORY MATTERS  
4.1 Product Registrations. Except as otherwise agreed upon by the Parties, Customer shall be solely responsible for obtaining and maintaining all permits, licenses, and authorizations necessary market, distribute and otherwise sell the Product. Supplier shall be solely responsible for securing and maintaining approval of Supplier’s facility as a registered FDA facility and all licenses, permits and approvals in respect to the operation of Supplier’s business generally, the Facilities, and the performance of services of the nature of the manufacturing services to be provided under this Agreement.  
4.2 Records. Supplier shall maintain all records relating to the manufacturing and supply of Products as specified in the Quality Agreement. Additionally, Supplier shall maintain all records necessary to comply with all applicable Laws related to the manufacture of Product. All such records shall be maintained for a period of not less than three (3) years from the date of expiration of each lot of Product to which said records pertain, or such longer period as may be required by Law or Supplier’s standard operating procedures.  
4.3 Supplier Production Issues. Supplier shall promptly notify Customer of any production issues relating to the Products or other information of which Supplier becomes aware which may affect the regulatory status of or the ability of Supplier to supply Product to Customer in accordance with Customer’s forecasted requirements. All such communications provided by Supplier shall be treated as Supplier Confidential Information.  
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 4.4 Complaints and Adverse Reactions. Customer shall have primary responsibility for safety monitoring and consumer complaint investigation; provided that Supplier shall reasonably cooperate and provide assistance as reasonably requested by Supplier in any such complaint investigation. In connection therewith, Supplier shall provide to Customer copies of all information it uniquely has in its possession that is necessary to allow Customer to make timely reports as required by any Regulatory Authority regarding the Product. Supplier shall notify Customer in accordance with agreed upon complaint handling procedures of any information concerning any complaint involving the possible failure of the Product to meet any requirement of applicable Laws and any serious or unexpected side effect, injury, toxicity or other reaction or any unexpected incidents associated with the use of the Product.  
4.5 Approval for Changes. Except as otherwise permitted under the Quality Agreement, no changes may be made to any Specifications for the Product without Customer’s and Supplier’s prior written consent, as applicable.  
4.6 Inspections. Notwithstanding anything to the contrary in the Quality Agreement, upon reasonable prior notice to Supplier, Customer or its agents shall have reasonable access to observe and inspect Supplier and its Manufacturing Facilities, records, and procedures including, without limitation, manufacturing, and environmental health and safety operations, and practices, including all analytical and manufacturing documentation related to Products, at reasonable intervals and upon reasonable notice to Supplier.  
4.7 Recalls.  
(a) Generally. In the event that:  
(i) Customer determines that an event, incident, or circumstance has occurred which may result in the need for a Recall, Withdrawal Field Correction or other removal of any Product or any lot or lots thereof from the market in the Territory, or Supplier determines that an event, incident, or circumstance that could reasonably adversely affect the Product in the Territory has occurred which is reasonably likely to result in the need for a Recall, Withdrawal Field Correction or other removal of any Product, or any lot or lots thereof from the market;  
(ii) either Party becomes aware that a Regulatory Authority is threatening or has initiated an action to remove the Product from the market in the Territory or, if such event could reasonably adversely affect the Product in the Territory, any Regulatory Authority is threatening or has initiated an action to remove the Product from the market; or  
(iii) either Party is required by any Regulatory Authority to distribute a “Dear Doctor” letter or its equivalent regarding use of the Product in the Territory or, if such event could reasonably adversely affect Product in the Territory, any Regulatory Authority has required distribution of a “Dear Doctor” letter or its equivalent regarding use of the Product outside the Territory,  
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 then it shall promptly advise the other Party in writing with respect thereto, and shall provide to the other Party copies of all relevant correspondence, notices, and the like in the possession or Control of such Party. In such event, Customer shall have the sole authority to determine if a recall or other removal of the Product is required in the Territory, and shall be responsible for conducting any such Recall, Withdrawal Field Correction or other removal of any Product from the Territory, whether voluntary or involuntary, or taking such other remedial action required by applicable Laws in the Territory and except as provided in Section 4.7(c), shall bear all Recall Costs therefor.  
(b) Supplier Assistance. At Customer’s request, Supplier shall assist Customer, at Customer’s expense, with respect to any such recall or remedial action, and shall provide Customer with all information that Customer may request in connection with its dealings with a Regulatory Authority in connection with such recall or remedial action.  
(c) Costs Resulting from Breach. Notwithstanding anything else contained in this Agreement to the contrary, to the extent that any Recall, Withdrawal Field Correction or other removal of any Product or any lot or lots thereof from the market in the Territory results from a breach by Supplier or its Affiliates or agents of the terms of this Agreement then Supplier shall bear Recall Costs and shall bear all costs for any assistance provided to Customer by Supplier or its Affiliates or agents in connection with such Recall, Withdrawal Field Correction or other removal. Without limiting any other rights of Customer hereunder, including under Section 3.6, Supplier is limited in such recall expenses [\*\*\*\*].  
ARTICLE V  
FINANCIAL TERMS  
5.1 Transfer Prices; Adjustments.  
(a) Transfer Price. The price to be paid by Customer to Supplier for each batch of Product (the “Transfer Price”) shall be [\*\*\*\*].  
(b) Minimum Order Quantity. Subject to Sections 5.1(c) and 5.1(d), Customer agrees to place Purchase Orders for [\*\*\*\*] of Product per full Calendar Year, for each Calendar Year that this Agreement is in effect. In the event the total quantity of Products actually ordered by Purchaser is [\*\*\*\*], Customer shall pay to Supplier a compensation (the "Yearly Compensation") calculated as follows:  
[\*\*\*\*]  
[\*\*\*\*]  
Example: If Purchaser [\*\*\*\*]:  
Yearly Compensation: [\*\*\*\*]  
14  
 Contractor shall calculate if the minimum ordered quantity of Product has been met each Calendar Year as of December 31 of each year, and, if not, shall send an invoice for the Yearly Compensation within sixty (60) days following the end of such period.  
(c) Supply Disruption. If Customer has the right pursuant to Section 2.7 to purchase Product from third parties due to a Failure, each batch of Product ordered from such third parties shall be deemed a batch of Product ordered under this Agreement for purposes of satisfying the minimum order quantity in Section 5.1(b). In addition, if during any Calendar Year, Supplier is unable to supply [\*\*\*\*] batches of Product due to delays or supply shortages described in Section 2.6, Force Majeure, or any other reason, then the minimum order quantity requirement of Section 5.1(b) shall be waived for such Calendar Year.  
(d) Generic Competition. In the event that a third party commences sales of a generic version of the Product in the United States, then Customer’s obligations under Section 5.1(b) shall terminate.  
(e) Adjustments. Beginning [\*\*\*\*], the then current price shall be increased by the annual percentage increase, if any, for the most recent twelve (12) month period for which final (non-preliminary) figures are available in the "Producer Price Index - Pharmaceutical Preparations" (code PCU2834) (the "PPI") published by the U.S. Bureau of Labor Statistics (the "BLS") or, if the same is no longer published, the successor index published by the BLS that is most similar thereto. If the PPI is discontinued and not replaced with a corresponding or similar index, then the Parties shall, in good faith, agree upon a replacement PPI. Price increases shall be effective for all purchase orders placed for manufacture dates after the applicable anniversary.  
Example calculation: If in March 2017, the PPI is 748.1 and the previous year March 2016, the PPI was 706.9, the difference is 41.2. The difference (41.2) would be divided by the then previous year PPI (706.9) resulting in a PPI increase of 5.83%.  
[\*\*\*\*].  
(f) Complaint Investigations [\*\*\*\*].  
Example calculation: [\*\*\*\*]. [\*\*\*\*] .  
5.2 Invoices; Payment Terms. Supplier shall invoice Customer for all Product supplied to Customer at the time of delivery to Customer. Payment to Supplier by Customer shall be made in U.S. dollars, [\*\*\*\*] calendar days following receipt by Customer of an invoice for the Product. Any invoiced amount which is not paid by its due date may be assessed a late payment fee at the rate of [\*\*\*\*] per month.  
5.3 Payment Information. All payments due hereunder to Supplier shall be sent to Supplier by wire transfer of funds via the Federal Reserve Wire Transfer System to:  
[\*\*\*\*]  
15  
 5.4 Taxes and Duties. The Parties shall file required forms and provide each other with any information required by tax authorities to obtain a reduction to or an exemption from any otherwise applicable sales, use VAT or similar tax.  
5.5 Audits. Customer shall have the right to request copies of records of Supplier with respect to the Products supplied hereunder to confirm Supplier’s compliance with the terms of this agreement.  
ARTICLE VI  
REPRESENTATIONS AND WARRANTIES  
6.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that:  
(a) it is a legal entity duly organized, validly existing and in good standing (to the extent such concept exists under the Laws of the jurisdiction of such Party's incorporation) under the Laws of country in which it incorporated and this Agreement has been duly authorized by all necessary corporate action;  
(b) it has all necessary corporate power and authority to enter into this Agreement and to perform all of its obligations hereunder;  
(c) this Agreement has been duly authorized, executed and delivered by it and is the legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; and  
(d) neither the execution, delivery and performance by it of this Agreement nor the consummation of the transactions contemplated hereby violate or conflict with its charter documents, any material contract, agreement or instrument to which it is a party or by which it or its properties are bound, or any judgment, decree, order or award of any court, Governmental Authority, body or arbitrator by which it is bound, or any Law applicable to it.  
6.2 Supplier Warranties. Supplier represents and warrants as follows:  
(a) All Product manufactured and supplied under this Agreement will have been manufactured, labeled and packaged in accordance with, and the Product will conform to, the Specifications and all Applicable Laws.  
(b) No Product manufactured and supplied pursuant to this Agreement will, at the time of delivery, be adulterated within the meaning of the Act or within the meaning of any applicable Law in which the definition of adulteration is substantially the same as that contained in the Act, as such Act and such Laws are constituted and effective at the time of delivery nor will such Product be an article which may not, under the provisions of such Act, except those relating to misbranding, be introduced into interstate commerce.  
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 (c) Each lot of Product manufactured and supplied for Customer will at the time of delivery have the applicable shelf life set forth in the Specifications and will continue, until the applicable expiration date, conform to the Specifications and will be free from defects in materials and workmanship.  
(d) The facilities and processes utilized by Supplier for the manufacture of the Products will, at all times, comply with all applicable FDA regulations including, without limitation, applicable cGMP, and all other Applicable Laws.  
(e) Supplier, and all Product delivered under this Agreement are in material compliance with all applicable environmental, health, safety and transportation regulations.  
(f) Each item of environmental, health and safety information, including but not limited to, all Material Safety Data Sheets, related to the Product, Supplier or its Third Party Contractors supplied by Supplier under this Agreement shall be complete and accurate on the date on which it is supplied to Customer.  
(g) Supplier shall throughout the Term and for a period of [\*\*\*\*] thereafter, maintain a system that is capable of tracking all source materials for the Product and shall, upon request, provide all such data to Customer and the applicable Regulatory Authorities.  
6.3 Customer Warranties. Customer represents and warrants as follows:  
(a) Neither Customer’s Technology Package, nor the use thereof by Supplier, shall infringe, violate or misappropriate the rights of any Third Party.  
(b) Any excipients, API and other materials/components provided by Customer to Supplier shall comply with the API Specifications and shall not be adulterated or misbranded within the meaning of the Act or other applicable law.  
6.4 THE WARRANTIES SET FORTH HEREIN ARE THE SOLE AND EXCLUSIVE WARRANTIES MADE BY EITHER PARTY UNDER THIS AGREEMENT, AND NEITHER PARTY MAKES ANY OTHER WARRANTIES EXPRESS OR IMPLIED OR ARISING BY LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE OR ARISING FROM THE COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE.  
6.5 EXCEPT AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED UNDER ARTICLE VII OF THIS AGREEMENT, EXCEPT AS PROVIDED IN SECTIONS 3.6 AND 4.7, AND EXCEPT FOR SUPPLIER’S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, CUSTOMER'S SOLE AND EXCLUSIVE REMEDY, AND SUPPLIER'S SOLE AND EXCLUSIVE LIABILITY AND OBLIGATION, FOR ANY BREACH OF A REPRESENTATION AND WARRANTY SET FORTH IN SECTIONS 6.4(A)-(C) SHALL BE FOR SUPPLIER, AT ITS OPTION, EITHER TO (A) PROCESS REPLACEMENT PRODUCT AT NO COST TO CUSTOMER EXCEPT THAT, AT ITS EXPENSE (SUBJECT TO SECTION 3.6) CUSTOMER SHALL PROVIDE SUBSTITUTE  
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 API, OR (B) CREDIT OR REFUND THE PRICE TO CUSTOMER OF THE DEFECTIVE PRODUCT.  
6.6 WITHOUT LIMITING SECTION 6.5 OR ANY OTHER PROVISION OF THIS AGREEMENT, EXCEPT AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED UNDER ARTICLE VII OF THIS AGREEMENT, AND/OR IN THE EVENT OF A BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE IX OF THIS AGREEMENT OR A PARTY’S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, UNDER NO CIRCUMSTANCES WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER ANY CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHER LEGAL OR EQUITABLE THEORY, FOR COVER OF ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS) IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, WITH RESPECT TO ANY PRODUCT OR ANY SERVICES PROVIDED IN CONNECTION WITH A PRODUCT.  
ARTICLE VII  
INDEMNIFICATION AND INSURANCE  
7.1 Supplier Indemnification. Supplier shall indemnify, defend and hold harmless Customer, its Affiliates and each of their respective shareholders, directors, officers, employees and agents (each, an “Customer Indemnitee”) from and against all costs, losses, expenses (including reasonable attorneys’ fees) and damages resulting from all lawsuits, claims, demands, actions and other proceedings by or on behalf of any Third Party (collectively “Claims”) to the extent arising out of or resulting from: (a) the breach of any representation, warranty, covenant or material obligation of Supplier under this Agreement; (b) the gross negligence, recklessness or willful misconduct of Supplier or any of its agents or subcontractors in the performance of its obligations under this Agreement; or (c) failure of the Product to conform to the relevant Specifications.  
7.2 Customer Indemnification. Subject to Section 7.1, Customer shall indemnify, defend and hold harmless Supplier, its Affiliates and each of their respective shareholders, directors, officers, employees and agents (each, an “Supplier Indemnitee”) from and against all Claims to the extent arising out of or resulting from: (a) the ownership, use, handling, distribution, marketing or sale of the Product, (b) the breach of any representation, warranty, covenant or material obligation of Customer under this Agreement or (c) the gross negligence, recklessness or willful misconduct of Customer or any of its agents or subcontractors in the performance of its obligations under this Agreement.  
7.3 Insurance. Each of Customer and Supplier shall obtain and maintain, either itself or through one or more of its Affiliates, with reputable carriers, product liability insurance with limits of [\*\*\*\*] by no later than the scheduled manufacturing date for the first Batch of Product(s) delivered as part of the first Product Development Program(s) conducted under this Agreement. Upon request, each Party shall furnish the other Party with a certificate that such insurance is in force. In the event of any proposed cancellation, non-renewal, or material adverse change in a Party's insurance coverage, the other Party shall be given at least [\*\*\*\*]  
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 advance written notice thereof. In addition, Supplier shall maintain, at its expense, at least [\*\*\*\*] of property insurance covering all bulk, finished or in-process inventory of Product and API and Components while on Supplier’s premises or under Supplier’s control, and comprehensive general liability insurance in the amount of at [\*\*\*\*]. Supplier shall maintain in place all insurance required by Section 7.3 for: (i) at least [\*\*\*\*] following expiration or termination of this Agreement or, (ii) for at least [\*\*\*\*] after the termination or expiration of this Agreement if insurance is written on a claims-made basis.  
7.4 Limitation of Liability and Claims. Notwithstanding any other provision of this Agreement, Supplier's aggregate indemnification liability to Customer and its Affiliates for Third Party Claims shall not [\*\*\*\*]. The foregoing shall not apply to (i) Supplier’s fraud, willful misconduct or gross negligence, (ii) any amounts due to Third Parties by Supplier as a result of Supplier’s indemnification obligations under Section 7.1, or (iii) Supplier’s breach of Article IX (Confidentiality).  
7.5 Procedures. If any Claim covered by ARTICLE VII is brought, the indemnifying Party’s obligations are conditional upon the following:  
(a) the indemnified Party shall promptly notify the indemnifying Party in writing of such Claim, provided, however, the 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 or delay;  
(b) the indemnifying Party shall assume, at its cost and expense, the sole defense of such Claim through counsel selected by the indemnifying Party and reasonably acceptable to the indemnified Party, except that the indemnified Party may at its option and expense select and be represented by separate counsel;  
(c) the indemnifying Party shall maintain control of such defense and/or the settlement of such Claim;  
(d) the indemnified Party may, at its option and expense, participate in such defense, and if it so participates, the Parties shall cooperate with one another in such defense;  
(e) the indemnifying Party will have authority to consent to the entry of any settlement or otherwise to dispose of such Claim (provided and only to the extent that an indemnified Party does not have to admit liability and such judgment does not involve equitable relief or the payment of any amounts by the indemnified party and the indemnified Party may not consent to the entry of any judgment, enter into any settlement or otherwise to dispose of such Claim without the prior written consent of the indemnifying Party (not to be unreasonably withheld or delayed); and  
(f) the indemnifying Party shall pay the full amount of any judgment, award or settlement with respect to such Claim and all other reasonable and documented costs, fees and expenses related to the resolution thereof; provided, however, that such other  
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 costs, fees and expenses have been incurred or agreed, as the case may be, by the indemnifying Party in its defense or settlement of the Claim.  
ARTICLE VIII  
TERM AND TERMINATION  
8.1 Term. This Agreement shall become effective immediately upon execution hereof by both Parties and shall expire [\*\*\*\*] years after the Effective Date (the “Term”) unless terminated earlier pursuant to Section 8.2 below. The Agreement shall thereafter automatically renew for periods of [\*\*\*\*], unless either Party shall give notice to the other to the contrary at least [\*\*\*\*] prior to the expiration of the initial term or any renewal of the Agreement.  
8.2 Termination. This Agreement may be terminated immediately:  
(a) upon mutual written agreement of the Parties;  
(b) by either Party (the “Non-Breaching Party”) upon written notice as a result of a material breach by the other Party (the “Breaching Party”) of any material obligation, condition or covenant of this Agreement (including, without limitation, the occurrence of a Failure, if such material breach shall not have been remedied, or steps initiated to remedy the same to the Non-Breaching Party’s reasonable satisfaction, within [\*\*\*\*] calendar days after receipt by the Breaching Party of a notice thereof from the Non-Breaching Party; or  
(c) by either Party upon written notice in the event: (i) the other Party voluntarily enters into bankruptcy proceedings, reorganization, or other insolvency proceedings; (ii) the other Party makes an assignment of all or a material portion of its assets for the benefit of creditors; (iii) a petition is filed against the other Party under a bankruptcy Law, a corporate reorganization Law, or any other Law for relief of debtors or similar Law analogous in purpose or effect, which petition is not stayed or dismissed within [\*\*\*\*] calendar days of filing thereof; or (iv) the other Party enters into liquidation or dissolution proceedings or a receiver is appointed with respect to any assets of the other Party, which appointment is not vacated within [\*\*\*\*] calendar days.  
8.3 Regulatory Considerations. Customer may terminate this Agreement as to any Product and applicable portion of the Territory upon thirty (30) days’ prior written notice to Supplier in the event that (i) any Regulatory Authority takes any action or raises any objection that prevents Customer from importing, exporting, purchasing or selling such Product in all or part of the Territory, or (ii) Customer elects to discontinue selling or otherwise withdraws from the market such Product in all or part of the Territory.  
8.4 Effect of Termination.  
(a) The expiration or termination of this Agreement shall not relieve Supplier from its obligation to deliver Product subject to the Binding Forecast prior to the effective date of such expiration or termination, nor shall expiration or termination relieve Customer from accepting and, upon acceptance, paying for any such Product or, unless Customer has terminated this Agreement  
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 pursuant to Section 8.2(b), from obligation for cancellation or postponement penalties under Section 2.5, unless otherwise agreed in writing by the Parties.  
(b) Survival of Certain Terms. Unless expressly provided to the contrary, the provisions of Sections 2.8, 2.10, 2.11, 3.5, 3.6, 4.2, 4.4, 4.6, 4.7, 5.1(f), 5.5, 6.2, 6.3, 6.4, 6.5, 6.6, 7, 8.4, 9, and 10 shall survive the expiration or termination of this Agreement. Expiration or termination shall not extinguish the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement.  
ARTICLE IX  
CONFIDENTIALITY  
9.1 Confidentiality.  
(a) Generally. It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose Confidential Information to the other. Each Party represents that it has the right to deliver the Confidential Information it discloses to the Receiving Party pursuant to this Agreement. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any Governmental Authority necessary approvals or licenses or to obtain Patents with respect to the Product.  
(b) Use; Disclosure. Each Party shall (a) use the Confidential Information disclosed to it solely for the performance of this Agreement and (b) not disclose such Confidential Information without the Disclosing Party’s prior written consent to any other person or entity other than those of its employees, legal advisors, accountants, contractors or agents and those of its Affiliates who: (i) have a need to know such Confidential Information in connection with the performance of the Agreement and (ii) have been informed of the confidential nature of such information and the Receiving Party’s obligations under this Agreement (collectively, “Permitted Recipients”). All Permitted Recipients shall be bound to maintain such Confidential Information in confidence, and each Party will take reasonable steps to require its Permitted Recipients to preserve such trust and confidence. Each Party shall be responsible for any breach of this Agreement by its Permitted Recipients.  
(c) Protection; Return.  
(i) Each of the Parties shall in all respects treat the Confidential Information and all trade secrets (as defined by applicable Law) disclosed to it hereunder at least as carefully as such Party treats its own Confidential Information and will carry out, with respect to it, those security measures that it follows to protect its own Confidential Information, but in no event shall the Receiving Party use less than reasonable care to prevent unauthorized disclosure with respect to such Confidential Information and trade secrets.  
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 (ii) Upon expiration or earlier termination of this Agreement and upon written request of the Disclosing Party, the Receiving Party will: (i) return to the Disclosing Party all Confidential Information (including copies) provided by the Disclosing Party under this Agreement; (ii) destroy all summaries, extracts and the like prepared by the Receiving Party that incorporate the Disclosing Party’s Confidential Information; and (iii) certify to the destruction of the same; provided, however, that: (y) the Receiving Party may retain one complete copy of the Confidential Information in its legal archives for the purpose of determining its obligations under this Agreement and as necessary to comply with Applicable Laws, and (z) Permitted Recipients may retain one copy of the reports or other materials such persons personally prepared based upon the Confidential Information (but may not retain the Disclosing Party’s Confidential Information itself) for legal, regulatory, ethical or insurance purposes. Further, to the extent that the Receiving Party’s computer back-up or archiving procedures create copies of Confidential Information, the Receiving Party may retain such copies for the period it normally archives backed-up computer records, so long as such copies are kept confidential in accordance with the terms of this Agreement.  
(d) Required Disclosure.  
(i) The obligations of confidentiality set forth in this Article IX shall not prohibit the Receiving Party from disclosing any part of the Confidential Information which, in the written advice of counsel, is required to be revealed in response to a court decision or administrative order, or to comply with Laws of a Governmental Authority or rules of a securities exchange. If the Receiving Party becomes legally compelled to disclose a Disclosing Party’s Confidential Information, the Receiving Party shall provide prompt notice to the Disclosing Party and the Parties shall cooperate so that a protective order or other appropriate remedy may be sought, unless the Disclosing Party agrees to authorize the Receiving Party to disclose such Confidential Information. In the event that such protective order or other remedy is not obtained, or Disclosing Party waives compliance with the provisions of this Agreement, the Receiving Party shall furnish only that portion of the Confidential Information that it is required to disclose, based on the opinion of counsel, and shall take all reasonable efforts to obtain a protective order or other reasonable assurance that confidential treatment will be accorded to such Confidential Information.  
(ii) Notwithstanding the foregoing, if either Party determines that applicable securities Laws require the disclosure of Confidential Information, Receiving Party shall promptly notify Disclosing Party and Receiving Party shall be permitted to make and issue a disclosure consistent with the requirements of such Laws. Receiving Party shall take reasonable steps to: (i) limit the disclosure to that disclosure it has determined is required by Law and (ii) seek confidential treatment for all Confidential Information so disclosed, except to the extent such information is determined, based upon the advice of counsel, to be material and would therefore be required to be disclosed.  
22  
 (e) Export. Each Receiving Party of Confidential Information shall adhere to all applicable import and export controls and shall not export or re-export any technical data or products received from the Disclosing Party or the direct product of such technical data to any prohibited country, party or entity.  
(f) Remedies. In the event of any unauthorized disclosure, loss or use of Confidential Information, in whole or in part by the Receiving Party, the Disclosing Party shall be entitled to seek, upon application to any court of proper jurisdiction, a temporary restraining order or preliminary injunction to restrain and enjoin the Receiving Party or any Affiliate of the Receiving Party from such violation without prejudice as to any other remedies the Disclosing Party may have at Law or in equity. Further, the Receiving Party acknowledges and agrees that it would be virtually impossible for the Disclosing Party to calculate its monetary damages and that the Disclosing Party would be irreparably harmed in the event of such unauthorized disclosure, loss or use of Confidential Information. If the Disclosing Party seeks such temporary restraining order or preliminary injunction, the Disclosing Party shall not be required to post any bond with respect thereto, or, if a bond is required, it may be posted without surety thereon.  
(g) Litigation and Governmental Disclosure. Each Party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a Party is required by Law to make any such disclosure of the other Party’s Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and will use good faith efforts to assist such other Party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.  
(h) Limitation of Disclosure. The Parties agree that, except as otherwise may be required by Applicable Laws, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission including requests for confidential treatment, and except as may be authorized in Section 9.1(g) or Section 9.1(i), no information concerning this Agreement and the transactions contemplated herein shall be made public by either Party without the prior written consent of the other.  
(i) Publicity and SEC Filings. Neither Party shall make any public announcement or statement concerning this Agreement, its terms or its existence without the prior written consent of the other Party. Notwithstanding the foregoing, the Parties agree to issue a joint press release, which is subject to the review and approval of each Party, promptly following the Effective Date. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures required by the Securities and Exchange Commission and any other Governmental Authority or Regulatory Authority, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure.  
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 (j) Duration of Confidentiality. All obligations of confidentiality and non-use imposed upon the Parties under this Agreement shall expire [\*\*\*\*] years after the expiration or earlier termination of this Agreement; provided, however, that Confidential Information which constitutes the trade secrets of a Party (including, e.g., Customer Licensed Know-How) shall be kept confidential indefinitely, subject to the limitations set forth in this Section 9.1.  
ARTICLE X  
MISCELLANEOUS ISSUES  
10.1 Relationship of the Parties. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. All activities by the Parties hereunder shall be performed by them as independent contractors. Neither Party shall incur any debts or make any commitments for the other Party, except to the extent specifically provided herein. No right is granted by this Agreement to either Party to use in any manner the name of the other or any other trade name or trademark of the other in connection with the performance of this Agreement, except as required by Law or as expressly set forth in this Agreement.  
10.2 Assignability. Unless otherwise expressly permitted hereunder, neither Party may assign this Agreement without the prior written consent of the other Party, except that each Party may assign any or all of its rights and/or responsibilities hereunder without the other Party’s consent as part of (a) the sale of all or substantially all of the assets or the entire business to which this Agreement relates (b) a merger, consolidation, reorganization or other combination with or into another person or entity; or (c) the transfer or assignment to an Affiliate, in each case, pursuant to which the surviving entity or assignee assumes the assigning or merging Party’s obligations hereunder without diminishing any rights of the other Party under this Agreement. Any assignment made in violation of this Section 10.2 shall be null and void.  
10.3 Notices. All notices and demands required or permitted to be given or made pursuant to this Agreement shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, properly addressed to the address of the Party to be notified as shown below:  
If to Supplier:  
Jubilant HollisterStier LLC  
0000 Xxxxx Xxxxx Xxxxxx  
Xxxxxxx, XX 00000  
Attention: President  
FAX: [\*\*\*\*]  
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 With a copy to:  
Attention: Director, Business Development at same address  
If to Customer:  
Xxxx Life Science US Inc.  
000 Xxx Xxxx, Xxxxx 000  
Xxxxx, XX 00000  
Attention: [\*\*\*\*], Chief Operating Officer  
FAX: [\*\*\*\*]  
Email (Optional): [\*\*\*\*]  
With a copy to:  
Attention: VP, Technical Operations at same address  
or to such other address as to which either Party may notify the other. Any notice sent by facsimile transmission shall be followed within twenty-four (24) hours by a signed notice sent by first class mail, postage prepaid.  
10.4 Force Majeure. Neither Party shall be held liable or responsible for any loss or damages resulting from any failure or delay in its performance due hereunder (other than payment of money) caused by force majeure. As used herein, force majeure shall be deemed to include any condition beyond the reasonable control of the affected Party including, without limitation, strikes or other labor disputes, war, riot, earthquake, tornado, hurricane, flood or other natural disasters, fire, civil disorder, explosion, accident, sabotage, lack of or inability to obtain adequate fuel, power, materials, labor, containers, transportation, supplies or equipment despite reasonable and diligent efforts to obtain the foregoing, compliance with governmental requests, laws, rules, regulations, orders or actions; inability despite commercially reasonable efforts to renew operating permits or licenses from Regulatory Authorities; breakage or failure of machinery or apparatus; national defense requirements; or supplier strike, lockout or injunction. In the event either Party is delayed or rendered unable to perform due to force majeure, the affected Party shall give notice of the same and its expected duration to the other Party promptly after the occurrence of the cause relied upon, and upon the giving of such notice the obligations of the Party giving the notice will be suspended during the continuance of the force majeure; provided, however, such Party shall take commercially reasonable steps to remedy or mitigate the force majeure with all reasonable dispatch. The requirement that force majeure be remedied with all reasonable dispatch shall not require the settlement of strikes or labor controversies by acceding to the demands of the opposing party. If such non-performance continues for more than [\*\*\*\*] days and such non-performance would be a material breach of this Agreement absent the operation of this Section 10.4, then Customer may terminate this Agreement on [\*\*\*\*] days prior written notice, without penalty of any kind.  
10.5 Severability. If any provision of this Agreement is determined to be illegal or unenforceable by any court of Law or any competent Government Authority, the remaining provisions shall be severable and enforceable in accordance with their terms so long as this Agreement without such terms or provisions does not fail of its essential purpose. The Parties shall  
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 negotiate in good faith to replace any such illegal or unenforceable provisions with suitable substitute provisions which will maintain as far as possible the purposes and the effect of this Agreement.  
10.6 Waiver. Neither Party’s waiver of any breach or failure to enforce any of the terms and conditions of this Agreement at any time shall in any way affect, limit or waive such Party’s right thereafter to enforce and compel strict compliance with every term and condition of this Agreement. Any such waiver shall be made in writing.  
10.7 Headings. All headings, titles and captions in this Agreement are for convenience only and shall not be of any force or substance.  
10.8 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be an original, but all of which shall constitute but one Agreement. For purposes of this Agreement and any other document required to be delivered pursuant to this Agreement, facsimiles of signatures shall be deemed to be original signatures. In addition, if any of the Parties sign facsimile copies of this Agreement, such copies shall be deemed originals.  
10.9 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.  
10.10 Choice of Law. The construction, validity and performance of this Agreement shall be governed in all respects by the laws of the state of Delaware, excluding its provisions regarding conflicts of law.  
10.11 Dispute Resolution. The Parties hereto agree to perform the terms of this Agreement in good faith, and to attempt to resolve any controversy, dispute or claim arising hereunder in good faith. Any dispute regarding the validity, construction, interpretation, or performance of this Agreement (other than provisions, hereof relating to any intellectual property rights, or the confidentiality obligations contained in Article 8 hereof) shall be (1) first attempted to be resolved between the CEO/President of each Party and failing that (2) submitted to binding arbitration in Chicago, Illinois, U.S.A. to be conducted in accordance with the Arbitration Rules of the American Arbitration Association (“AAA”); provided, however, that nothing in this Section 10.11 shall be construed to preclude either Party from seeking provisional remedies, including, but not limited to, temporary restraining orders and preliminary injunctions, from any court of competent jurisdiction, in order to protect its rights pending arbitration, but such preliminary relief shall not be sought as a means of avoiding arbitration. Any arbitration hereunder shall be submitted to an arbitration tribunal made up of three (3) members, one of whom shall be selected by Customer, one of whom shall be selected by Supplier, and one of whom shall be selected by the other two arbitrators and who shall serve as the chair of the panel. All arbitration proceedings shall be conducted in English. The arbitration panel shall provide a reasoned opinion supported by findings of fact and conclusions of law. The order or award of the arbitrators shall be final and may be enforced in any court of competent jurisdiction. The substantially prevailing Party in any legal or arbitration action brought by one Party against the other Party shall be entitled, in addition to any other rights and remedies it may have, to reimbursement for its expenses  
26  
 incurred thereby, including court cost and reasonable attorney’s fees, from the substantially non-prevailing Party.  
10.12 Compliance with Laws. Each Party will comply with all local, state or federal Law in any jurisdiction relevant to the activities undertaken pursuant to this Agreement or applicable to either of the Parties with respect to performing its obligations and exercising its rights hereunder.  
10.13 Non-Exclusive Remedy. Except as otherwise set forth herein, termination of this Agreement by a Party shall not be an exclusive remedy and all other remedies will be available to the terminating Party, in equity and at Law.  
10.14 Entire Agreement. This Agreement and the Appendices attached hereto set forth the entire agreement between the Parties with respect to the transactions contemplated hereunder, and may not be amended or modified except by written instrument duly executed by both Parties. In the event that this Agreement conflicts with any Purchase Order, invoice or other documents, the terms and conditions of this Agreement shall apply. Any and all previous agreements and understandings between the Parties regarding the subject matter of this Agreement, whether written or oral, are superseded by this Agreement.  
[Signature Page Follows]  
 27  
 [Signature Page to Manufacturing and Supply Agreement]  
IN WITNESS WHEREOF, the Parties hereto have caused their authorized representatives to execute this Agreement by signing below:  
Jubilant HollisterStier LLC  
 Xxxx Life Science US Inc.  
 Signature:  
/s/ XXXX XXXXX  
 Signature:  
/s/ XXXX XXXXXXXX  
 Name: Xxxx Xxxxx  
 Name: Xxxx Xxxxxxxx  
 Title: President  
 Title: EVP and Chief Operating Officer  
 EXHIBIT A  
API AND API SPECIFICATIONS  
API - Ketorolac Tromethamine USP  
API Specifications:  
 EXHIBIT B  
LIST OF PRODUCT COMPONENTS  
Description  
Use  
Supplied by  
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 EXHIBIT C  
QUALITY AGREEMENT  
[\*\*\*\*] Information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.  
 EXHIBIT D  
PRODUCT SPECIFICATIONS  
[\*\*\*\*] Information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.  
 EXHIBIT E  
CUSTOMER-OWNED EQUIPMENT  
Description  
Manufacturer  
Model  
Serial #  
Supplier Equipment #  
Status  
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 EXHIBIT F  
API COST  
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