EX-10.39 3 v451028\_ex10-39.htm EXHIBIT 10.39  
Exhibit 10.39  
Execution Version  
Certain identified information has been excluded from this exhibit because it is both not  
material and would likely cause competitive harm to the registrant if publicly disclosed.  
MANUFACTURING AND SUPPLY AGREEMENT  
between  
INTERCEPT PHARMA EUROPE LTD.  
and  
PHARMAZELL GMBH  
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This MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”), dated the last date of signature (the “Effective Date”), is made by and between Intercept Pharma Europe Ltd., having a location at 0 Xxxxxxx Xxxxxx, Xxxxx 0, Xxxxxx, Xxxxxx Xxxxxxx X0X 0XX (“Intercept”), and, solely for purposes of Section 10.19, Intercept Pharmaceuticals, Inc. (“Intercept Parent”), and PharmaZell GmbH, a corporation organized under the laws of Germany (“PharmaZell”). Intercept and PharmaZell are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”  
RECITALS  
WHEREAS, pursuant to a certain Development Agreement by and between the Parties dated August 18, 2010, the Parties collaborated to develop a synthesis pathway for the manufacture, production, and validation of an active pharmaceutical ingredient for Intercept referred to as [\*\*]; and  
WHEREAS, Intercept and PharmaZell now wish to enter into this Agreement to arrange for the manufacture and supply by PharmaZell to Intercept of the API (as defined below), on the terms and subject to the conditions set forth in this Agreement.  
NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:  
ARTICLE 1  
DEFINITIONS  
As used herein, the following terms shall have the following meanings:  
1.1 “Adjustment Date” has the meaning set forth in Section 4.4(a).  
1.2 “Adverse Event” means (a) any finding from tests in laboratory animals or in vitro that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity, (b) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use, or occurring following application of a Product to humans, whether expected and whether considered related to or caused by such Product, including such an event or experience as occurs in the course of the use of such Product in professional practice, in a clinical trial, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected therapeutic action of such Product, and (c) those events or experiences that are required to be reported to the Regulatory Authorities under corresponding Applicable Law.  
1.3 “Affiliate” of a Person means any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, such first Person. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with”, means to possess the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract or otherwise.  
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1.4 “Agreement” has the meaning set forth in the preamble hereto, including all Work Orders provided by Intercept.  
1.5 “API” means the active pharmaceutical ingredient [\*\*].  
1.6 “API Precursor” means any intermediary, ingredient, composition or element [\*\*] that arises or is created or produced following production of the Intermediary during the Manufacture of the API.  
1.7 “API Specifications” means the specifications for the API to be Manufactured by PharmaZell and supplied to Intercept hereunder as such specifications are set forth in the Quality Agreement, as the same may be amended from time to time.  
1.8 “Applicable Law” means all laws, statutes, rules, codes, regulations, requirements, orders, judgments and ordinances of any Regulatory Authority, including the FFDCA.  
1.9 “Business Day” means a day other than a Saturday or a Sunday on which banks in New York, New York and Munich, Germany are open for the conduct of regular banking business.  
1.10 “Calendar Quarter” means each period of three (3) consecutive calendar months commencing on 1 January, 1 April, 1 July, and 1 October, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on September 30, 2016, and the last Calendar Quarter of the Term shall commence on the first day of the calendar quarter in which the Term ends and end on the last day of the Term.  
1.11 “Calendar Year” means each successive period of twelve (12) consecutive calendar months commencing on 1 January and ending on 31 December, except that the first Calendar Year of the Term shall commence on the Effective Date and end on 31 December 2016, and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.  
1.12 “Certificate of Analysis” or “COA” has the meaning set forth in the Quality Agreement.  
1.13 “Certificate of Compliance” or “COC” has the meaning set forth in the Quality Agreement.  
1.14 “CMC Data” means the chemistry, manufacturing and controls data required by Applicable Law to be included in a New Drug Application (as defined in the FFDCA and the regulations promulgated thereunder) for a Product or in any other Regulatory Approval outside the United States.  
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1.15 “Confidential Information” means any and all information or material that, at any time before or after the Effective Date, has been or is provided or communicated to the Receiving Party by or on behalf of the Disclosing Party (including by a third party) pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto; any data, ideas, concepts or techniques contained therein; and any modifications thereof or derivations therefrom. Confidential Information may be disclosed either orally, visually, electronically, in writing, by delivery of Materials containing Confidential Information or in any other form now known or hereafter invented.  
1.16 “Control” means, with respect to any item of information, Invention, Regulatory Documentation, patent, trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of any license and other grants hereunder), to assign or grant a license, sublicense or other right to or under, or perform other acts in respect of, such information, Invention, Regulatory Documentation, patent, trademark or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any third party.  
1.17 “Deficiency” has the meaning set forth in Section 2.3(c).  
1.18 “Delivery Date” means the date the API leaves the Facility for shipment to Intercept.  
1.19 “Disclosing Party” means the Party disclosing Confidential Information.  
1.20 “Disqualification” has the meaning set forth in Section 6.2(c).  
1.21 “Effective Date” has the meaning set forth in the preamble hereto.  
1.22 “Employee Inventions” has the meaning set forth in Section 5.1(g).  
1.23 “Existing Work Orders” has the meaning set forth in Section 2.2(a).  
1.24 “Exploit” means to make, have made, import, use, sell, offer for sale or otherwise dispose of a compound, product or process, including all discovery, research, development, commercialization, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, exportation, transportation, distribution, promotion and marketing of such compound, product or process.  
1.25 “Facility” means a Manufacturing facility of PharmaZell located at (i) [\*\*], (ii) [\*\*], and/or (iii) such other facility as the Parties may agree to in writing from time to time.  
1.26 “FDA” means the United States Food and Drug Administration and any successor agency thereto.  
1.27 “FFDCA” means the U.S. Federal Food, Drug, and Cosmetic act codified at 21 U.S.C. § 301 et seq., as may be amended from time to time.  
1.28 “Gesetz über Arbeitnehmererfindungen” has the meaning set forth in Section 5.1(g).  
1.29 “GMI” means the German Producer Price Index (“Index der Erzeugerpreise gewerblicher Produkte”) for pharmaceutical preparations, as compiled and published by the Bureau of Labor Statistics of the United States Department of Labor and using the latest version of data published as of the date of adjustment.  
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1.30 “GMP” or “cGMP” means all applicable standards relating to manufacture of pharmaceutical products, including, as applicable current Good Manufacturing Practices as they apply to the manufacture of Supplied Material, and including (i) standards promulgated by any Regulatory Authority having jurisdiction over the Manufacture of the Supplied Material, in the form of Applicable Laws, including the U.S. current Good Manufacturing Practices regulations promulgated by the FDA, as described in 21 U.S.C. 351, 21 C.F.R. Parts 210 and 211, as amended, and any successor provision thereto and ICH Q7 – Good Manufacturing Practice for Active Pharmaceutical Ingredients; (ii) standards promulgated by any Regulatory Authority having jurisdiction over the Manufacture of the Supplied Material, in the form of draft or final guidance documents (including advisory opinions, compliance policy guides and guidelines); and (iii) such other industry standards as may be agreed upon by the Parties in the Specifications (as defined and set forth in the Quality Agreement).  
1.31 “ICC Rules” has the meaning set forth in Section 10.8(a).  
1.32 “Indemnification Claim Notice” has the meaning set forth in Section 9.3(a).  
1.33 “Indemnified Party” has the meaning set forth in Section 9.3(a).  
1.34 “Indemnifying Party” has the meaning set forth in Section 9.3(a).  
1.35 “Initial Term” has the meaning set forth in Section 8.1.  
1.36 “Intercept” has the meaning set forth in the preamble hereto.  
1.37 “Intercept Indemnified Parties” has the meaning set forth in Section 9.1.  
1.38 “Intercept Information” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, technical assistance, designs, assembly procedures, specifications, assays, test methods, analytical methods, and other material or information owned or Controlled by Intercept or its Affiliates (including information received from a third party) as of the Effective Date or at any time during the Term.  
1.39 “Intercept Intellectual Property” has the meaning set forth in Section 5.1(a).  
1.40 “Intercept Materials” means those Materials identified on Schedule 1.40 to be supplied by Intercept to PharmaZell for Manufacture of the API.  
1.41 “Intermediary” means [\*\*].  
1.42 “Invention” means any discovery, improvement, process, formula, data, information, invention, know-how, trade secret, procedure, device, or other intellectual property, whether or not protectable under patent, trademark, copyright or similar laws, including any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging of a compound or product or any discovery or development of a new indication for a compound or product.  
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1.43 “Joint Invention Patents” has the meaning set forth in Section 5.2(c)(i).  
1.44 “Joint Inventions” mean any and all Inventions that are or have been created, conceived, discovered, developed or otherwise made jointly by or on behalf of the Parties, but excluding Specified Inventions.  
1.45 “Latent Defect” means any deficiency (including any Supplied Material that fails to meet the Supplied Material Warranty or other quality requirements set forth in the Quality Agreement) that is not readily determinable upon a reasonable inspection of the Supplied Material (based on physical inspection, identity test and review of the certificate of analysis).  
1.46 “Losses” has the meaning set forth in Section 9.1.  
1.47 “Manufacture” and “Manufacturing” means all steps, processes, activities and operations from purchase of Materials, through production, quality control, release and storage, to distribution of API, and the related controls.  
1.48 “Material(s)” means all ingredients, raw materials, packaging and labeling components, and all other supplies of any kind, required or used in connection with the Manufacturing of Supplied Material.  
1.49 “Minimum Annual Requirement” has the meaning set forth in Section 2.2(b).  
1.50 “Minimum Percentage Requirement” has the meaning set forth in Section 2.2(b).  
1.51 “Other PharmaZell Invention Patents” has the meaning set forth in Section 5.2(b)(i).  
1.52 “Other PharmaZell Inventions” means [\*\*].  
1.53 “Party” and “Parties” has the meaning set forth in the preamble hereto.  
1.54 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.  
1.55 “PharmaZell” has the meaning set forth in the preamble hereto.  
1.56 “PharmaZell Indemnified Parties” has the meaning set forth in Section 9.2.  
1.57 “Policies” has the meaning set forth in Section 9.4(a).  
1.58 “Products” means the finished product containing the API.  
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1.59 “Purchase Price” has the meaning set forth in Section 4.1(a).  
1.60 “Quality Agreement” means the quality assurance agreement dated August 20, 2014 entered into by the Parties.  
1.61 “Quality Standards” means the obligations set forth in the Quality Agreement as well as compliance with applicable environmental/health/safety requirements and cGMP requirements.  
1.62 “Receiving Party” means the Party receiving Confidential Information.  
1.63 “Recipients” has the meaning set forth in Section 7.1.  
1.64 “[\*\*]” means [\*\*].  
1.65 “Regulatory Approval” means, with respect to any particular country or other jurisdiction, as applicable any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the Exploitation of a Product in such country or jurisdiction, including, where applicable, (a) approval of a Product in such country or jurisdiction, including any marketing authorization and supplements and amendments thereto, including an approved New Drug Application as defined in the FFDCA or any corresponding foreign application, registration or certification necessary or reasonably useful to market any Product in a country or regulatory jurisdiction; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.  
1.66 “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Supplied Material or a product in any country or other jurisdiction, including those responsible for granting approvals for the performance of services by PharmaZell to Intercept or for issuing regulations pertaining to the manufacture or use of the Supplied Material or Product in the intended country of use, including the FDA.  
1.67 “Regulatory Documentation” means as applicable (a) submissions to any Regulatory Authority, including investigational new drug applications, New Drug Applications (as defined in the FFDCA and the regulations promulgated thereunder), correspondence with regulatory agencies (registrations and licenses, regulatory drug lists, advertising and promotion documents), periodic safety update reports, adverse event files, complaint files and manufacturing records and, if applicable, any updates or supplements to any of the foregoing and (b) any minutes or contact logs with respect to any telephone conferences or in-person meetings conducted with any Regulatory Authority relating to the subject matter described in clause (a) of this sentence.  
1.68 “Release Testing” means all testing of the quality attributes of the Supplied Material in accordance with the Specifications and the Quality Agreement.  
1.69 “Renewal Period” has the meaning set forth in Section 8.1.  
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1.70 “Required Manufacturing Changes” has the meaning set forth in Section 3.6(b).  
1.71 “Representative” has the meaning set forth in Section 6.2(a).  
1.72 “Services” means the Manufacturing, supply and other services performed under this Agreement.  
1.73 “Specifications” means the API Specifications.  
1.74 “Specified Invention Patents” has the meaning set forth in Section 5.2(a)(i).  
1.75 “Specified Inventions” means [\*\*].  
1.76 “Supplied Material” means the API.  
1.77 “Supplied Material Warranty” has the meaning set forth in Section 6.2(b).  
1.78 “Term” has the meaning set forth in Section 8.1.  
1.79 “Testing Laboratory” means an independent third party laboratory engaged by the Parties to test conformance of the Supplied Material to the Specifications in accordance with the terms set forth in the Quality Agreement.  
1.80 “Third Party Claim” has the meaning set forth in Section 9.1.  
1.81 “Total Commercial Volume Requirements” means, for purposes of calculating Intercept’s total commercial volume requirements for Supplied Material for a given Calendar Year, the total amount of Supplied Material [\*\*].  
1.82 “United States” means the United States of America, its territories and possessions, including the District of Columbia and Puerto Rico.  
1.83 “Work Order” means a written work order that sets forth, with respect to the period covered thereby, (a) the quantities of each Supplied Material to be processed and delivered by PharmaZell to Intercept or its designee, (b) the required Delivery Dates therefor, and (c) the required delivery locations therefor, in the form attached hereto as Schedule 1.83.  
ARTICLE 2  
MANUFACTURING AND SUPPLY  
2.1 Supply Obligations.  
(a) Generally. Subject to the terms and conditions hereof, PharmaZell shall Manufacture and supply to Intercept such quantities of Supplied Material as Intercept may from time to time during the Term order. Such Manufacture and supply shall be in accordance with Applicable Laws, the Specifications, the Regulatory Documentation, Regulatory Approvals and the terms of this Agreement and the Quality Agreement.  
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(b) Exclusivity of PharmaZell. To the maximum extent permitted by Applicable Law, without the written consent of Intercept, PharmaZell shall not, and PharmaZell shall cause its Affiliates not to, distribute, market, promote, offer for sale, sell, supply or Manufacture API or any API Precursor, directly or indirectly, whether alone or in combination with other molecules or compounds, whether as a raw material or as a finished product, and whether at wholesale or retail, to any Person other than Intercept, its Affiliates or designees.  
(c) Purchase Obligations of Intercept. Subject to the Minimum Percentage Requirement and the Minimum Annual Requirement set forth in Section 2.2(b), this Agreement shall not limit Intercept’s right to obtain Supplied Material from any third party. PharmaZell acknowledges that Intercept has the right to enter into arrangements with one or more third parties to act as additional sources of Supplied Material.  
(d) Subcontractors. PharmaZell may not subcontract with any third party to perform any of its obligations hereunder without the prior written consent of Intercept; provided that with respect to the existing subcontractors and activity set forth on Schedule 2.1(d), Intercept hereby agrees that such subcontractors are hereby permitted subcontractors with respect to the activity identified for such subcontractor. PharmaZell shall be solely responsible for the performance of any permitted subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by PharmaZell itself under this Agreement. PharmaZell shall cause any such permitted subcontractor to be bound by, and to comply with, all confidentiality, quality assurance, regulatory and other obligations and requirements of PharmaZell set forth in this Agreement. PharmaZell and its subcontractors may use Intercept Intellectual Property only for the performance of the Services as specified in this Agreement.  
2.2 Work Orders.  
(a) Existing Work Orders. The Parties acknowledge and agree that Intercept and PharmaZell have, prior to the date hereof, agreed to certain Work Orders with respect to Supplied Materials, including penalties therein for PharmaZell’s failure to deliver Supplied Material in accordance with the terms of such Work Orders. The existing Work Orders are attached hereto as Schedule 2.2(a) (the “Existing Work Orders”). The Parties acknowledge and agree that PharmaZell shall continue to Manufacture the quantities of Supplied Materials set forth in the Existing Work Orders in accordance with the timelines set forth in the Existing Work Orders; provided, however, the Parties acknowledge and agree that the Supplied Materials Manufactured and supplied under the Existing Work Orders shall be governed by the terms and conditions of this Agreement, and this Agreement supersedes and replaces any term or condition contained in such Existing Work Orders and any term or condition associated with such Existing Work Orders other than the delivery obligations, the price, the shared risk provisions and associated penalties of PharmaZell, which shall continue to apply as specified in the Existing Work Orders.  
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(b) New Work Orders; Minimum Percentage Requirement. Intercept shall place Work Orders at least [\*\*] months in advance of the requested Delivery Date but no more than [\*\*] months in advance of the requested Delivery Date. With respect to each Work Order, Intercept shall be obligated to purchase, and PharmaZell shall be obligated to deliver, by the required Delivery Date set forth therein such quantities of the Supplied Material as are set forth therein. Intercept agrees to order from PharmaZell at least [\*\*] of Intercept’s Total Commercial Volume Requirements for delivery in each of [\*\*] (“Minimum Percentage Requirement”); provided that, [\*\*] notwithstanding Intercept’s actual Total Commercial Volume Requirements in Calendar Years 2017 and 2018, at a minimum, Intercept shall order at least [\*\*] of Supplied Material to be delivered in each of Calendar Year 2017 and Calendar Year 2018 (“Minimum Annual Requirement”). Notwithstanding the foregoing, (i) to the extent that Intercept has ordered a quantity of Supplied Material from PharmaZell but PharmaZell fails for any reason to deliver such quantity within [\*\*] days of the Delivery Date or such Supplied Material is rejected by Intercept pursuant to Section 2.3(c), all such ordered Supplied Material shall be considered Supplied Material that was “ordered and delivered” under the terms of this Section 2.2(b) in calculating the Minimum Percentage Requirement and Minimum Annual Requirement, and (ii) if Intercept’s Total Commercial Volume Requirements in a given year are in excess of PharmaZell’s capacity to Manufacture such quantity of Supplied Material, then for purposes of calculating Intercept’s total volume, the percentage shall be based upon PharmaZell’s maximum capacity. In addition, if Intercept has ordered a quantity of Supplied Material from PharmaZell but PharmaZell fails to deliver such quantity as a result of PharmaZell’s inability to satisfy the Quality Standards (and PharmaZell is unable to remedy such inability to satisfy the Quality Standards within [\*\*] days) or the Supplied Material is rejected by Intercept pursuant to Section 2.3(c) as a result of PharmaZell’s failure to satisfy the Quality Standards, then (i) Intercept’s obligation to achieve the Minimum Percentage Requirement and Minimum Annual Requirement shall be suspended until such time as PharmaZell is able to remedy such Quality Standard issue and (ii) Intercept’s Minimum Percentage Requirement and Minimum Annual Requirement for such Calendar Year shall be proportionately reduced by the length of the suspension; provided that if PharmaZell is able to remedy the issue with the Quality Standards and deliver Supply Material to Intercept and Intercept accepts the full amount of the delivery despite the proportional reduction, then Intercept’s Minimum Annual Requirement and Minimum Percentage Requirement for the subsequent Calendar Year shall be reduced by such proportionate amount. To the extent PharmaZell is responsible for manufacturing the Intermediary and to the extent Intercept is responsible for supplying the [\*\*] to PharmaZell for the manufacture of the Intermediary, Intercept shall ensure timely delivery of the [\*\*] to PharmaZell. In addition, in the event that [\*\*], then Intercept shall have no Minimum Annual Requirement commencing on the date of any such event and for the duration of the Agreement. The Parties agree that the first new work order under the Agreement shall be as specified in Schedule 2.2(b) attached hereto.  
(c) Work Order Terms. In the event that the terms of any Work Order are not consistent with or are in addition to the terms of this Agreement, the terms of this Agreement shall prevail. The Parties agree that each Work Order shall be for a minimum of [\*\*] and that Intercept shall attempt to order a batch size of [\*\*]. The Parties further agree that if the Manufacturing is to be done at [\*\*], the size of the batch in a Work Order [\*\*] but otherwise is subject to the terms of this Agreement.  
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2.3 Delivery Terms; Inspection.  
(a) Delivery. PharmaZell shall deliver the quantities of API set forth in each Work Order by the required Delivery Date(s) set forth in such Work Order and in accordance with the reasonable written instructions as such instructions are agreed by the Parties. PharmaZell shall deliver API, DAP (Incoterms 2010), with the delivery address specified by Intercept. Risk of loss and title shall pass to Intercept upon delivery of API as specified in the preceding sentence. In the event Intercept wishes to have an expedited delivery, PharmaZell reserves the right to charge Intercept for the additional costs involved therefor.  
(b) Accompanying Documentation. Each delivery of API shall be accompanied by (i) a Certificate of Analysis, (ii) a Certificate of Compliance, (iii) such other documents as may be required pursuant to the Quality Agreement, and (iv) documentation necessary for the sale or export of the API, as applicable.  
(c) Inspection. Within [\*\*] days of receipt of a given shipment of Supplied Material, Intercept (or its agent) shall verify on the basis of a visual inspection the quantity of Supplied Material delivered. In addition, Intercept (or its agent) shall inspect at Intercept’s discretion (based minimally on physical inspection, identity test and review of the Certificate of Analysis and Certificate of Conformance provided by PharmaZell) the Supplied Material following Delivery for variances and defects; and if Intercept claims that a shipment of Supplied Material did not, at the time of receipt by Intercept, meet the Supplied Material Warranty or the quality requirements set forth in the Quality Agreement (a “Deficiency”), Intercept shall notify PharmaZell based on the foregoing inspection within [\*\*] days after receipt of such Supplied Material at Intercept’s (or its designee’s) site, which notice shall provide the quantities affected, the basis for the claim and other information reasonably necessary for PharmaZell to assess the claim. Notwithstanding the foregoing, if Intercept claims that the Deficiency is a Latent Defect, Intercept shall have the obligation to provide such notification to PharmaZell in writing within [\*\*] days after Intercept’s discovery of such Latent Defect (or within [\*\*] days after Intercept is notified in writing by a third party of such Latent Defect, if later). If Intercept and PharmaZell are unable to agree as to whether such Supplied Material contains a Deficiency, the Parties shall cooperate to have the Supplied Materials in dispute analyzed by the Testing Laboratory. The results of the Testing Laboratory shall be final and binding on the Parties on the issue of whether such Supplied Material contains a Deficiency. If the Supplied Materials are determined to not contain a Deficiency, then Intercept shall bear the cost of the Testing Laboratory and pay the Purchase Price with respect to the Supplied Materials in accordance with this Agreement. If the Supplied Materials are determined to contain a Deficiency, then PharmaZell shall bear the cost of the Testing Laboratory, and PharmaZell shall (i) at Intercept's election, either replace the rejected Supplied Materials at no cost to Intercept, or refund to Intercept the Purchase Price paid for such Supplied Materials, and the cost of all Intercept Materials used for such Supplied Materials plus any applicable delivery charge and (ii) reimburse to Intercept all costs associated with any manufacturing and distribution of Products incorporating such Supplied Material, including formulation, packaging, storage and distribution expenses (and including materials used in connection therewith).  
2.4 Materials. PharmaZell shall be responsible for auditing and qualifying its supplier(s) of Materials and obtaining supplies of Materials in accordance with the Specifications, Applicable Laws, Regulatory Documentation, Regulatory Approvals and the Quality Agreement. Quality and Regulatory and all GMP related issues shall be defined in the Quality Agreement. At all times during the Term, PharmaZell shall (at its own cost and expense) maintain sufficient amounts of available inventory of Materials (other than Intercept Materials) consistent with industry standards and shelf life requirements of such Materials as may be necessary for PharmaZell to Manufacture Supplied Materials.  
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2.5 Costs and Expenses. Except as otherwise explicitly set forth herein, PharmaZell shall be solely responsible for all costs and expenses incurred in connection with the Manufacture of Supplied Materials hereunder, including costs and expenses of personnel, quality control testing, Manufacturing facilities and equipment, and Materials. In addition, at PharmZell’s cost and expense, PharmaZell shall be entitled to maintain an inventory of safety stock of Supplied Material and any of its intermediates.  
2.6 Supply Shortage; Inability to Supply.  
(a) In the event that PharmaZell is unable or anticipates it will be unable to supply, in whole or in part, the quantity of Supplied Material as set forth in any Work Order, PharmaZell shall notify Intercept of such inability upon discovery of the same by PharmaZell, including the underlying reasons for such inability, proposed remedial measures and the date such inability is expected to end. In the event that PharmaZell is unable to Manufacture Supplied Material as a result of a shortage of Materials (other than to the extent such shortage is the result of Intercept’s failure to provide [\*\*]), then PharmaZell hereby agrees and acknowledges that [\*\*].  
(b) In the event that Intercept is unable to provide [\*\*] to PharmaZell within the project timelines agreed to by the Parties, the Parties shall discuss in good faith allowing PharmaZell to manufacture [\*\*] itself and for Intercept to purchase such [\*\*] from PharmaZell.  
(c) Nothing contained in this Section 2.6 shall limit any legal, equitable or other rights or remedies that may be available to Intercept on account of any failure of PharmaZell to Manufacture and supply Supplied Materials hereunder.  
2.7 Intercept Materials.  
(a) PharmaZell shall maintain, handle and store the Intercept Materials in accordance with the cGMP, Applicable Laws and all written instructions as agreed by the Parties. The Intercept Materials shall be stored in a secured area and clearly marked and identified as property of Intercept clearly separated from other products or materials by palette or location. PharmaZell shall be responsible to communicate any necessary information regarding such Intercept Materials (including material safety data sheets and other information provided to PharmaZell relating to the handling and safety of the Intercept Materials) to its employees, agents and representatives engaged in performing the Manufacturing services. PharmaZell shall ensure that Intercept Materials are free and clear of any liens or encumbrances. PharmaZell shall notify Intercept if at any time it believes Intercept Materials have been damaged, lost or stolen.  
(b) PharmaZell shall notify Intercept when the inventories of Intercept Materials become insufficient to Manufacture the API, as required under this Agreement. In addition, at the end of each calendar month, PharmaZell shall provide to Intercept a stock reconciliation report of the Intercept Materials, which report shall include: (a) the opening stock of Intercept Materials at the beginning of the month, (b) the receipt of any additional Intercept Materials, (c) the usage of Intercept Materials during the month (including yield loss), and (d) the stock balance of Intercept Materials.  
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(c) PharmaZell shall use the Intercept Materials solely and exclusively to Manufacture the Supplied Materials under this Agreement and for no other purpose. PharmaZell shall withdraw Intercept Materials from storage on [\*\*].  
(d) PharmaZell shall at all times take such measures as are required to protect the Intercept Materials from risk of loss or damage at all stages of the Manufacturing process that are consistent with those measures that PharmaZell utilizes for its own materials but in no event less than are reasonable and customary in the industry. PharmaZell accepts all risk of loss and full responsibility for the condition of Intercept Materials which may be damaged, lost or stolen by PharmaZell or its personnel. PharmaZell shall at all times take such measures as are required to protect the Intercept Materials from risk of loss or damage. Intercept will be responsible for all transportation costs for such Intercept Materials. Notwithstanding the foregoing, PharmaZell shall be financially responsible for any loss of such Intercept Materials to the extent such loss results from (a) breach of this Agreement by PharmaZell, (b) negligence or willful misconduct of PharmaZell, its Affiliates and any permitted subcontractors, in which case PharmaZell shall reimburse Intercept for costs of such Intercept Materials, plus any shipping costs and out-of-pockets costs incurred by or on behalf of Intercept with respect to such Intercept Materials.  
(e) PharmaZell shall use its best efforts to obtain standard yields. The standard yields are set forth in Schedule 2.7(e). The allowable annual yield variation from the standard yield for the Intercept Materials shall not be more than [\*\*]. For illustration purposes only, an example yield loss calculation is set forth on Schedule 2.7(e). Concurrently with each invoice of Supplied Materials, PharmaZell shall provide Intercept with a written accounting of the disposition of each yield variation of Intercept Materials. In the event that the yield variation exceeds the agreed upon allowable yield variation or any losses of Intercept Materials are due to the negligence or willful misconduct of PharmaZell, Intercept shall, at the option of Intercept, either receive a reimbursement from PharmaZell or reduce Intercept’s payment for the relevant invoice for such Supplied Material in an amount equal to [\*\*]. The Parties shall in good faith reevaluate the standard yield and the annual yield variation at the beginning of each Calendar Year to account for increased efficiencies in the Manufacture of Supplied Material or decreases caused by Required Manufacturing Changes or other agreed changes to the process.  
(f) In the event that PharmaZell obtains excess yields of the Intercept Materials, PharmaZell will invoice the excess quantities to Intercept (such excess quantity not to exceed more than [\*\*] of the amount in Intercept’s Work Order), and Intercept will accept such delivery and invoice.  
(g) To the extent Intercept supplies [\*\*] as part of the Intercept Materials, all such [\*\*] provided by Intercept shall be [\*\*].  
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ARTICLE 3  
QUALITY; COMPLIANCE; REGULATORY  
3.1 Quality Control.  
(a) Quality Agreement. Intercept and PharmaZell have entered into the Quality Agreement that sets forth the terms and conditions upon which both Parties will conduct their quality activities in connection with this Agreement. Each Party shall duly and punctually perform all of its obligations under the Quality Agreement. In the event of any inconsistency between the terms of this Agreement and the terms of the Quality Agreement, the terms of the Quality Agreement shall control with respect to quality related matters, and the terms of this Agreement shall control with respect to any other matters.  
(b) Materials; Vendor and Supplier Qualification and Validation. PharmaZell shall be responsible for: (i) obtaining all starting Materials (other than Intercept Materials) required to Manufacture Supplied Materials in accordance with the Specifications, Applicable Laws and cGMPs and Regulatory Documentation; and (ii) supplying all equipment and personnel necessary for the performance of the Manufacture and supply of the API to Intercept. The Quality Agreement sets forth additional details regarding each Party’s obligations regarding Critical Raw Materials (as defined in the Quality Agreement) and in the qualification and validation of vendors and suppliers retained or contracted in connection with the Manufacture and any other services requested by Intercept.  
(c) Analyses. PharmaZell shall be responsible for all quality control analyses of Supplied Materials and all Supplied Material shall be released by PharmaZell, in each case in accordance with the terms of the Quality Agreement.  
(d) Documentation and Standard Operating Procedures. PharmaZell shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control, laboratory testing, complaint handling, deviations, investigations, and corrective and preventative actions and any other data required under cGMPs, Applicable Laws, and other requirements of any relevant Regulatory Authority in connection with the Manufacture of the Supplied Material. PharmaZell shall make such documentation available for inspection during any audit conducted by or on behalf of Intercept in accordance with the Quality Agreement. Throughout the term of this Agreement, and for so long thereafter as is reasonably necessary, PharmaZell shall strictly monitor and maintain records documenting its compliance with cGMPs and any other Applicable Laws, including through the establishment and implementation of such operating procedures as are reasonably necessary to assure such compliance.  
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(e) Inspection. The Quality Agreement sets forth each Party’s rights and obligations with respect to inspection of the Supplied Material as well as inspection of the Facilities. Notwithstanding the foregoing and without limiting anything contained in the Quality Agreement, Intercept shall have the right to audit the Facilities in their entirety and inspect those portions of the Facilities and the records and information relating to the Facilities and the Manufacture of the Supplied Material, to determine and ensure that PharmaZell meets the obligations of the Quality Agreement and is compliant with the Quality Standards. PharmaZell shall permit any Regulatory Authority to audit and inspect the Facilities and the Manufacture of the Supplied Material. In connection with Intercept’s determination of PharmaZell’s ability to satisfy the Quality Standards pursuant to this Section 3.1(e), Intercept may, at Intercept’s discretion and to the extent determined by Intercept, consult with PharmaZell regarding cGMP quality, technical capability, and performance standards. If a Regulatory Authority or Intercept identifies any observations in connection with any audit or inspection under this Section 3.1(e) or the Quality Agreement, the Parties will discuss in good faith suitable approaches for correcting such observations, and PharmaZell shall have a reasonable time following such consultation with Intercept to make appropriate corrections or dispute Intercept’s observations (but not dispute a Regulatory Authority’s observations which shall be deemed conclusive). If PharmaZell disputes Intercept’s observations and Intercept and PharmaZell are unable to agree as to whether PharmaZell meets the Quality Standards, the Parties shall cooperate to have the Facilities and the records and information relating to the Facilities and the Manufacture of the Supplied Material inspected and audited by an independent inspection company of recognized repute selected by Intercept and approved by PharmaZell, which approval shall not be unreasonably withheld. The results of such inspection company shall be final and binding on the Parties on the issue of whether PharmaZell meets the Quality Standards.  
(f) Recalls; Withdrawals. The Quality Agreement sets forth each Party’s rights and obligations with respect to recalls and withdrawals. If and to the extent such recall or withdrawal is caused by Supplied Material that contains a Deficiency or by PharmaZell’s negligence or willful misconduct or breach of this Agreement, PharmaZell shall reimburse Intercept for [\*\*]; provided that, other than with respect to PharmaZell’s gross negligence or willful misconduct, PharmaZell’s liability pursuant to this Section 3.1(f), on a per claim basis, shall not exceed Fifteen Million United States Dollars ($15,000,000).  
(g) Release. PharmaZell shall perform Release Testing to ensure conformance to the Specifications, in accordance with the Quality Agreement.  
(h) Stability Testing. PharmaZell shall perform stability testing on the API to ensure conformance to the Specifications, in accordance with the Quality Agreement.  
3.2 Maintenance of Facility.  
(a) Except as otherwise approved in writing by Intercept, PharmaZell shall Manufacture Supplied Material exclusively at the Facilities.  
(b) PharmaZell shall at all times during the Term ensure that any and all licenses, registrations, and Regulatory Authority approvals required by Applicable Law to be obtained in connection with the Facilities and their operation and equipment used or to be used in connection with the Manufacture of Supplied Material so as to permit PharmaZell to Manufacture Supplied Material and supply it to Intercept as contemplated hereunder have been obtained and are in all respects current and in full force and effect.  
(c) PharmaZell shall only use disposal services or sites that have appropriate environmental permits and are in compliance with Applicable Law.  
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3.3 Regulatory Cooperation of PharmaZell. PharmaZell shall cooperate with any reasonable requests for assistance from Intercept with respect to obtaining, maintaining, and supporting any and all Regulatory Approvals and Regulatory Documentation required in connection with the sourcing of Supplied Material by Intercept hereunder and the sale of Products, including by:  
(a) at Intercept’s cost, making PharmaZell employees, consultants and other staff available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning Supplied Material and Products;  
(b) at PharmaZell’s own cost, disclosing and making available to Intercept, in whatever form Intercept may reasonably request, all Manufacturing and quality control data, CMC Data, records, and other information related to Supplied Material, the Manufacturing process for Supplied Material, and any other services related to Supplied Material as may be reasonably necessary or desirable for Intercept to prepare, file, obtain, and maintain any Regulatory Approval required in connection with the sourcing of Supplied Material by Intercept hereunder and the sale of Products, as defined in the Quality Agreement; and  
(c) to the extent that Intercept requests any additional regulatory services from PharmaZell, PharmaZell shall provide to Intercept a fee estimate for the provision of such additional regulatory services. Thereafter, the Parties shall negotiate and agree in advance on the cost and time to provide any such additional regulatory services. Intercept shall not be responsible for the cost or expense of any amount to the extent that Intercept has not explicitly agreed in writing to pay for such cost or expense.  
3.4 Cooperation with Regulatory Authorities and Regulatory Correspondence.  
(a) PharmaZell shall immediately notify Intercept in the event that PharmaZell receives notice from FDA or any other relevant Regulatory Authority of its intent to conduct any audit or inspection of PharmaZell with respect to the Facility or its operations, and shall cooperate with the Regulatory Authority in connection with such audit or inspection or related request, including access to records and documentation related to Manufacturing. Without limiting the foregoing, PharmaZell agrees to immediately notify Intercept of any correspondence and other documentation received or prepared by either Party in connection with any of the following events: (i) receipt of a Warning Letter, FDA Form 483, or other regulatory correspondence from the FDA or any other Regulatory Authority in connection with the manufacture or design of the API or Product; (ii) any recall of the API or Product; (iii) the mandate, advice or recommendation from any Regulatory Authority with respect to the withdrawal of any API or Product; and (d) any regulatory comments from the FDA or any other Regulatory Authority relating to the Manufacture of the Supplied Material.  
(b) As applicable, PharmaZell shall provide copies of any notices or communications to Intercept of any FDA or other Regulatory Authority inspection, investigation or other inquiry, or other material governmental notice or communication, relating to the Manufacturing, or Supplied Material. PharmaZell shall consult with Intercept prior to submitting responses to any inquiry posed by any Regulatory Authority relating to the Manufacturing, Supplied Material or Product. PharmaZell shall not initiate communication with any Regulatory Authority concerning the Manufacturing, or Supplied Material absent the prior written, express permission of Intercept concerning any such communications.  
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3.5 Compliance with Applicable Law. With respect to the Manufacturing of Supplied Material and PharmaZell’s other duties and obligations under this Agreement, PharmaZell shall strictly comply with (i) the Specifications, (ii) GMP, and all other Applicable Laws, including those relating to the processing, manufacturing, packaging, labeling, testing, inspection, storage, delivery, shipment, or disposal of the Supplied Material; (iii) the Quality Agreement; and (iv) all Applicable Laws concerning environmental matters, public health, wages, hours and conditions of employment, subcontractor selection, discrimination and occupational health/safety. Without limiting the foregoing, PharmaZell covenants that neither PharmaZell nor any of its permitted subcontractors shall utilize child, or any form of forced or involuntary, labor in the Manufacture of Supplied Material under this Agreement or source Materials from any supplier that uses child, or any form of forced or involuntary, labor. Upon Intercept’s request, PharmaZell shall certify in writing its compliance with this Section 3.5 and shall provide to Intercept true and correct copies of all permits, certificates and licenses that may be required for its performance under this Agreement and, upon Intercept’s request, permit Intercept to inspect originals of the same.  
3.6 Change Requests.  
(a) Changes Requested by Intercept. Intercept shall have the right to request an amendment, change or supplement to any of the following upon written notice to PharmaZell, and except as may be prohibited by Applicable Law, PharmaZell shall use its commercially reasonable efforts to promptly implement such change: (a) the Specifications, (b) the Materials, (c) the source of Materials, (d) the specifications for Materials, (e) the equipment used in Manufacture, (f) the test methods used in connection with the Manufacturing of Supplied Material and Materials, (g) the process for Manufacturing Supplied Material, or (h) any test methods to Manufacture or release Supplied Material. PharmaZell shall ensure that any change in any of the foregoing shall, in each case, comply with cGMPs and all Applicable Laws. PharmaZell and Intercept will jointly discuss the cost resulting from such changes.  
(b) Required Manufacturing Changes. Each Party shall give the other Party reasonable written notice prior to any changes to the Specifications, process of Manufacturing, or other change, as applicable, with respect to the Supplied Materials, in each case that are required by cGMPs or Applicable Laws or a Regulatory Authority (collectively, “Required Manufacturing Changes”). PharmaZell shall use commercially reasonable efforts to promptly implement such Required Manufacturing Changes. PharmaZell shall ensure that any change in any of the foregoing shall, in each case, comply with cGMPs and all Applicable Laws. PharmaZell and Intercept will jointly discuss the cost resulting from such changes.  
3.7 General Cooperation. PharmaZell shall cooperate with any reasonable requests for assistance from Intercept and collaborate with Intercept with respect to any responses by Intercept to any Regulatory Authority and requests for information from Regulatory Authorities, pharmacovigilance and recall matters, and in accommodating Intercept’s needs for Supplied Materials, including accepting changes in forecasting and Work Orders.  
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ARTICLE 4  
FINANCIALS  
4.1 Price.  
(a) Subject to Section 4.4, the purchase price (the “Purchase Price”) for Supplied Material shall be determined as follows:  
Amount of Supplied Material  
 Ordered for Delivery in a  
Calendar Year  
Price  
[\*\*]  
 [\*\*]  
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 [\*\*]  
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 [\*\*]  
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 [\*\*]  
(b) For purposes of determining the Purchase Price applicable to a given quantity of Supplied Material that is ordered for delivery for a given Calendar Year, any quantity of Supplied Material that has been ordered by Intercept for delivery in a given Calendar Year shall be deemed ordered for delivery for such Calendar Year even if such quantity is ordered or Manufactured in an earlier Calendar Year. If Intercept places multiple orders for delivery in the same Calendar Year, such that the total amount of Supplied Material ordered for delivery in such Calendar Year in the aggregate is in a higher tier than a previously placed order, the Parties shall reconcile the total amount ordered for delivery in such Calendar Year and recalculate the Purchase Price and PharmaZell shall pay to Intercept the difference or, to the extent the final invoice for such Calendar Year has not yet been paid, Intercept may reduce the amount of such invoice accordingly. For example, and by way of illustration purposes only, if Intercept places an order for [\*\*].  
4.2 Invoice and Payment. PharmaZell shall invoice Intercept for the Manufacture of Supplied Material as follows:  
(a) PharmaZell shall be entitled to invoice Intercept for a certain percentage of the total Purchase Price calculated in accordance with Section 4.1(a) in accordance with the Work Order for such Supplied Material prior to delivery of the Supplied Material upon achievement of certain steps of the Manufacturing process as follows:  
Step of Manufacturing  
Percentage of total  
Milestone  
 Process  
 Purchase Price  
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(b) Prior to PharmaZell issuing an invoice to Intercept pursuant to Section 4.2(a), PharmaZell shall provide to Intercept the batch documentation and the testing and analytical data, if applicable, for such step of the Manufacturing to demonstrate to Intercept that PharmaZell has successfully completed such step of the Manufacturing. Upon Intercept’s acceptance of the batch documentation and the testing and analytical data, if applicable, but no later than [\*\*] days after PharmaZell has provided such batch documentation, PharmaZell shall invoice Intercept for the percentage of the total Purchase Price for such step of the Manufacturing in accordance with Section 4.2(a) and payment shall be due [\*\*] days after receipt of such invoice by Intercept.  
(c) PharmaZell promptly shall invoice Intercept for the remaining amount of the total Purchase Price calculated pursuant to Section 4.1 for the quantities of API actually delivered (subject to Section 2.7(f)) to Intercept; provided that if the total quantity of API actually delivered is less than [\*\*] of the total quantity ordered for delivery, PharmaZell shall reimburse Intercept for the amounts overpaid pursuant to Section 4.2(a) and the amount actually delivered. Payment for the remaining amount of the total Purchase Price for the quantity of Supplied Material actually delivered shall be due [\*\*] days after receipt by Intercept of the invoice and receipt of corresponding Supplied Material with respect thereto (which shall be sent in electronic form contemporaneously with such delivery); provided that if Intercept rejects such Supplied Material, then payment shall be due within [\*\*] days after receipt by Intercept of notice from the Testing Laboratory that the invoiced Supplied Material does not contain a Deficiency or receipt by Intercept of replacement Supplied Material, as the case may be. If the Supplied Material contains a Deficiency and Intercept does not order replacement Supplied Material, PharmaZell shall promptly reimburse all amounts previously paid by Intercept for such Supplied Material pursuant to Section 4.2(b).  
(d) If Intercept disputes any portion of an invoice, it shall pay the undisputed portion and shall provide PharmaZell with written notice of the disputed portion and its reasons therefor, and Intercept shall not be obligated to pay such disputed portion. The Parties shall use good faith efforts to resolve any such disputes promptly. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control. Payment of invoices shall be made by wire transfer to an account designated in writing by PharmaZell.  
4.3 Currency. PharmaZell will invoice Intercept in [\*\*] and Intercept will pay in [\*\*]. The exchange rate of [\*\*] to [\*\*] at the date of the last signature to this Agreement will be used as Reference Exchange Rate. Should at any time during the Agreement for a period longer than [\*\*] months the then current exchange rate of [\*\*] to [\*\*] deviates more than [\*\*] from the Reference Exchange Rate, both Parties will discuss in good faith impact on Prices and cost and adjust Price as agreed by the Parties in writing.  
4.4 Adjustment of Purchase Price.  
(a) The Purchase Prices set forth in Section 4.1 for Supplied Material shall remain fixed until [\*\*] (the “Adjustment Date”). Effective on [\*\*], the Purchase Price for such Supplied Material shall be adjusted by [\*\*].  
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(b) If at any time market conditions (raw material costs e.g.) result in PharmaZell’s cost of components for the API or manufacturing process being materially greater [\*\*] than normal forecasted increases, then PharmaZell shall be entitled to request an adjustment to the pricing of the Supplied Material to compensate for such increased cost. The Parties shall negotiate in good faith such increase.  
(c) If at any time market conditions result in PharmaZell’s cost of components for the Supplied Material or manufacturing process being materially less [\*\*] than normal, then Intercept shall be notified and an adjustment to the pricing will be given to compensate for such decreased cost.  
(d) The Parties agree to make reasonable efforts to improve the productivity, efficiency and quality of the process under which the Supplied Material is Manufactured. Any investment and/or cost savings as a result of such improvement shall be shared equitably between the Parties.  
4.5 Audit; Late Payments.  
(a) Intercept shall have the right to have an independent accounting firm of internationally recognized standing, and reasonably acceptable to PharmaZell, provided with access by PharmaZell during normal business hours, and upon reasonable prior written notice, to examine only those records of PharmaZell (and its Affiliates) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than [\*\*] prior to Intercept’s request, the correctness of any statement submitted by PharmaZell under this Agreement. Such examinations may not (i) be conducted more than once in any [\*\*] period (unless a previous audit during such [\*\*] period revealed an incorrect statement submitted by PharmaZell in respect of such period or PharmaZell restates or revises its books and records for such period) or (ii) be repeated for any Calendar Year. Results of such audit shall (i) be (A) limited to information relating to the supply of Supplied Material hereunder and use of the Intercept Materials, (B) made available to both Parties in writing, and (C) subject to ARTICLE 7 and (ii) not reveal any specific information of PharmaZell to Intercept other than (A) whether statements submitted by PharmaZell under this Agreement are true and correct and (B) the amount of any excess payment reimbursable to Intercept. The cost of any such examination shall be borne by Intercept unless the examination reveals a variance of more than [\*\*] from the amounts reflected on PharmaZell’s statements, in which case PharmaZell shall bear the cost of the audit. Unless disputed pursuant to Section 4.5(c), if such audit concludes that excess payments were made by Intercept during such period, PharmaZell shall reimburse such amounts, with interest from the date originally due as provided in Section 4.5(d), within [\*\*] days after the date on which such auditor’s written report is delivered to the Parties.  
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(b) Solely for the purposes of ensuring Intercept’s compliance with Section 2.2(b), PharmaZell shall have the right to have an independent accounting firm of internationally recognized standing, approved by Intercept, during normal business hours, and upon reasonable prior written notice which notice shall be at least [\*\*] days prior to the audit, to examine only those records of Intercept (and its Affiliates) as may be necessary to determine whether Intercept has met its Minimum Percentage Requirement, with respect to any Calendar Year ending not more than [\*\*] prior to PharmaZell’s request. Such examinations may not be conducted more than once in any [\*\*] period. The results communicated to Pharmazell regarding any such audit shall be limited solely to whether Intercept ordered the Minimum Percentage Requirement for such Calendar Year and any deviations from the Minimum Percentage Requirement. No other information may be included in the audit results and the audit results must be concurrently communicated to Intercept in writing. The cost of any such examination shall be borne by PharmaZell. Unless disputed pursuant to Section 4.5(c), if such audit concludes that Intercept did not order the Minimum Percentage Requirement for such Calendar Year, Intercept shall order an additional amount of Supplied Material in a subsequent calendar year equal to the difference between the amount of Supplied Material Intercept actually ordered from PharmaZell in such Calendar Year and the amount Intercept would have ordered had Intercept actually ordered the Minimum Percentage Requirement for such Calendar Year.  
(c) In the event of a dispute of any examination conducted under Section 4.5, PharmaZell and Intercept shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [\*\*] days, the dispute shall be resolved in accordance with Section 10.7.  
(d) If any undisputed payment due to a Party under this Agreement is not paid when due, then the owing Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) equal to the lesser of [\*\*], and [\*\*]. Interest payable under this Section 4.5(d) shall run from the date upon which payment of the relevant undisputed principal sum became due through the date of payment thereof in full together with such interest.  
ARTICLE 5  
INTELLECTUAL PROPERTY  
5.1 Ownership of Inventions.  
(a) Intercept shall own all right, title and interest in and to (i) the Specifications and the Intercept Information, (ii) any and all Specified Inventions, (iii) the API and the API Precursor, and (iv) any and all work outputs and reports prepared by PharmaZell (together, “Intercept Intellectual Property”). PharmaZell shall, and shall cause its Affiliates to, promptly disclose in writing to Intercept the discovery, development, making, conception or reduction to practice of any Specified Invention and does hereby, and shall cause its Affiliates, employees, agents, subcontractors to, assign to Intercept any and all right, title or interest PharmaZell or its Affiliates may have in or to any Specified Invention. Intercept shall, and does hereby, grant to PharmaZell and its Affiliates a non-exclusive, royalty-free license to use the Specifications, Intercept Information, Specified Inventions, and Specified Invention Patents for the sole purpose of performing PharmaZell’s obligations hereunder. The Specified Inventions and the work outputs and reports shall be considered Intercept Information.  
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(b) PharmaZell shall keep complete, accurate and dated records of the results of the services performed under this Agreement and all Specified Inventions and will promptly and fully disclose to Intercept such results and Specified Inventions. Such records shall also identify the names of PharmaZell’s employees, officers or Affiliates who performed the work. Intercept may discuss, in person or otherwise, the services and the results thereof from time to time with PharmaZell and such employees. PharmaZell agrees that it shall not publish or present any information related to the Intercept Information, the Product, API or the results thereof, any Specified Inventions or any other Intercept Intellectual Property without the prior written consent of Intercept unless PharmaZell is legally obliged to do so. PharmaZell must identify and obtain Intercept’s approval prior to inclusion of any PharmaZell technology into any Supplied Material or other deliverable hereunder.  
(c) PharmaZell shall own all right, title and interest in and to any and all Other PharmaZell Inventions. PharmaZell shall, and shall cause its Affiliates to, promptly disclose in writing to Intercept the discovery, development, making, conception or reduction to practice of any Other PharmaZell Invention. PharmaZell shall, and does hereby, grant to Intercept a non-exclusive, royalty-free, irrevocable and transferable license to Other PharmaZell Inventions and Other PharmaZell Invention Patents and, to any PharmaZell technology to the extent it is incorporated into or otherwise necessary to Manufacture or use API (including any Intermediary incorporated therein), with the right to sublicense through multiple tiers, to Exploit API and Products (and any Intermediary incorporated therein) in all fields of use in all countries worldwide.  
(d) PharmaZell and Intercept shall jointly own all right, title and interest in and to any and all Joint Inventions. Each of PharmaZell and Intercept shall, and shall cause its respective Affiliates to, promptly disclose in writing to the other Party the discovery, development, making, conception or reduction to practice of any Joint Invention. For those countries worldwide where a specific license is required to be granted by a Joint Invention owner to the other Joint Invention owner in order for the other Joint Invention owner to practice such Joint Inventions in such country, (i) PharmaZell shall, and does hereby, grant to Intercept a non-exclusive, royalty-free, irrevocable, transferable license, with the right to sublicense through multiple tiers, to PharmaZell's interest in all Joint Inventions and Joint Invention Patents in all fields of use and (ii) Intercept shall, and does hereby, grant to PharmaZell a non-exclusive, royalty-free, irrevocable license, with the right to sublicense through multiple tiers, to Intercept 's interest in all Joint Inventions and Joint Invention Patents in all fields of use.  
(e) Without limiting the provisions of this Section 5.1, PharmaZell shall use the Specifications and Intercept Information solely for purposes of performing its obligations hereunder.  
(f) Upon the request and at the expense of Intercept, PharmaZell shall execute and deliver any and all instruments and documents and take such other acts as may be necessary or desirable to document the assignment and transfer described in Section 5.1(a) or to enable Intercept to secure its rights in the Specified Invention and Specified Invention Patents relating thereto in any and all jurisdictions, or to apply for, prosecute and enforce Specified Invention Patents, or to obtain any extension, validation, re-issue, continuance or renewal of any such Specified Invention Patents. Without limiting the foregoing, PharmaZell shall disclose to Intercept all pertinent information and data with respect thereto and shall execute all applications, specifications, oaths and all other instruments which Intercept deems necessary in order to apply for and obtain such rights and in order to assign and convey to Intercept the sole and exclusive right, title and interest in and to such Specified Invention Patents relating thereto. If Intercept is unable for any other reason to secure PharmaZell’s signature to apply for or to pursue any application for any United States or foreign patent, trademark, copyright or other registration covering Inventions assigned to Intercept hereunder, then PharmaZell hereby irrevocably designates and appoints Intercept and its duly authorized officers and agents as PharmaZell’s agent and attorney in fact, to act for and in PharmaZell’s behalf and instead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or trademark, copyright or other registrations thereon with the same legal force and effect as if executed by PharmaZell.  
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(g) Inventorship Acts. To the extent applicable, the Parties understand that Inventions that are conceived, developed, generated or reduced to practice under this Agreement may be subject to the German Act on Employee Inventions (the German “Gesetz über Arbeitnehmererfindungen”). The provisions of such Gesetz über Arbeitnehmererfindungen are, inter alia, designed to protect the rights of employees to so called employee inventions (the “Employee Inventions”); the provisions of the Gesetz über Arbeitnehmererfindungen constitute inalienable rights which may not be changed by contractual arrangements to the detriment of the employees. To the extent that Inventions relate to Employee Inventions under the German Gesetz über Arbeitnehmererfindungen made by employees of a Party or its Affiliates, such Party undertakes to claim the rights in and to such Employee Inventions under Section 5ss. of the Gesetz über Arbeitnehmererfindungen. To the extent that such Party acquires rights to Employee Inventions in accordance with the principles stated in this Section 5.1(g), the further provisions of this 5.1 shall apply to such Inventions. The Party subject to the Gesetz über Arbeitnehmererfindungen shall be solely responsible for any payments to its employees and such Party will take all actions necessary to obtain the rights to use any such Inventions for the other Party. In addition, PharmaZell shall comply with all other inventorship laws of a country in which any portion of a Supplied Material is Manufactured.  
5.2 Patent Prosecution.  
(a) Specified Invention Patents.  
(i) Intercept shall have sole discretion and responsibility to prepare, file, prosecute and maintain all patent applications and patents covering Specified Inventions (the “Specified Invention Patents”) and shall be responsible for related interference and opposition proceedings. PharmaZell shall have no right to prepare, file, prosecute or maintain any Specified Invention Patents.  
(ii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue, re-examination, and post-grant procedure proceedings) Specified Invention Patents shall be borne by Intercept.  
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(b) Other PharmaZell Invention Patents.  
(i) PharmaZell shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all patent applications and patents covering Other PharmaZell Inventions (the “Other PharmaZell Invention Patents”) and shall be responsible for related interference and opposition proceedings; provided, however, that if PharmaZell plans to abandon any Other PharmaZell Invention Patent, PharmaZell shall notify Intercept in writing at least [\*\*] days in advance of the due date of any payment or other administrative action that is required to maintain such Other PharmaZell Invention Patent (i.e., an administrative action that involves routine and customary filings, it being understood that interference, opposition, reissue, re-examination, and post-grant procedure proceedings, prosecution or defense of infringement actions, and the like, shall not be considered administrative actions), and Intercept may elect, upon written notice within such [\*\*]-day period to PharmaZell, to make such payment or take such administrative action on behalf of PharmaZell. Except as expressly permitted in this Section 5.2(b)(i), Intercept shall have no right to prepare, file, prosecute or maintain any Other PharmaZell Invention Patents.  
(ii) If PharmaZell does not wish to file, prosecute or maintain any Other PharmaZell Invention Patent or maintain or defend any Other PharmaZell Invention Patent in a particular country, it shall notify Intercept in writing and, if Intercept elects to maintain such Other PharmaZell Invention Patent as contemplated by Section 5.2(b)(i), PharmaZell shall, and shall cause its Affiliates, as applicable, to (A) reasonably cooperate with Intercept in this regard and, (B) upon Intercept’s request, promptly release or assign to Intercept, without compensation, all right, title and interest in and to such Other PharmaZell Invention Patent in such country. In the event of such assignment, Intercept hereby grants to PharmaZell a non-exclusive, royalty-free, irrevocable license, with the right to sublicense through multiple tiers, under the relevant Other PharmaZell Invention Patent in all fields of use in the relevant country.  
(iii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue, re-examination, and post-grant procedure proceedings) Other PharmaZell Invention Patents as contemplated by this Section 5.2(b) shall be borne by the Party controlling such filing, prosecution and maintenance.  
(c) Joint Invention Patents.  
(i) Intercept shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all patent applications and patents covering Joint Inventions (the “Joint Invention Patents”) and shall be responsible for related interference and opposition proceedings; provided, however, that if Intercept plans to abandon any Joint Invention Patent, Intercept shall notify PharmaZell in writing at least [\*\*] days in advance of the due date of any payment or other administrative action that is required to maintain such Joint Invention Patent (i.e., an administrative action that involves routine and customary filings, it being understood that interference, opposition, reissue, re-examination, and post-grant procedure proceedings, prosecution or defense of infringement actions, and the like, shall not be considered administrative actions), and PharmaZell may elect, upon written notice within such [\*\*]-day period to Intercept, to make such payment or take such administrative action on behalf of Intercept. Except as expressly permitted in this Section 5.2(c)(i), PharmaZell shall have no right to prepare, file, prosecute or maintain any Joint Invention Patents.  
(ii) If Intercept does not wish to file, prosecute or maintain any Joint Invention Patent or maintain or defend any such Joint Invention Patent in a particular country, it shall notify PharmaZell in writing and, if PharmaZell elects to maintain such Joint Invention Patent as contemplated by Section 5.2(c)(i), Intercept shall, and shall cause its Affiliates, as applicable, to reasonably cooperate with PharmaZell in this regard.  
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(iii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue, re-examination, and post-grant procedure proceedings) Joint Invention Patents as contemplated by this Section 5.2(c) shall be borne by the Party controlling such filing, prosecution and maintenance.  
(d) Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 5.2.  
(i) Each Party shall keep the other Party currently informed of all steps to be taken in the preparation and prosecution of all applications filed by it according to Sections 5.2(b) and 5.2(c) and shall furnish such other Party with copies of such applications for patents, amendments thereto and other related correspondence to and from patent offices, and, to the extent reasonably practicable, permit such other Party an opportunity to offer its comments thereon before making a submission to a patent office which could materially affect the scope or validity of the patent coverage that may result. Such other Party shall offer its comments, if any, promptly.  
5.3 Enforcement of Patents.  
(a) If any Specified Invention Patent, Other PharmaZell Invention Patent, or Joint Invention Patent is allegedly or actually infringed by any Person, the Party first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail.  
(b) As between the Parties, Intercept shall have the sole and exclusive right, but not the obligation, to prosecute any infringement described in Section 5.3(a). To the extent any such action relates to an Other PharmaZell Invention Patent or a Joint Invention Patent, PharmaZell shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.  
(c) PharmaZell shall cooperate fully, including furnishing of a power of attorney, being joined as a party plaintiff or indispensable party in such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours in connection with any enforcement action that may be brought by Intercept under this Section 5.3.  
(d) Any costs and expenses relating to any enforcement action commenced by Intercept pursuant to this Section 5.3 shall be borne by Intercept and any damages or other amounts collected in any such enforcement action shall be retained by Intercept.  
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5.4 Third Party Litigation.  
(a) If any Person institutes against PharmaZell any action that alleges that the Manufacture of Supplied Material hereunder in accordance with the terms hereof infringes the intellectual property rights held by such Person, then, as between PharmaZell and Intercept, Intercept shall have the first right, but not the obligation, to contest, and assume direction and control of the defense of, such action, including the right to settle such action; provided that, prior to any such settlement, PharmaZell provides its written consent (such consent not to be unreasonably withheld, conditioned or delayed). If Intercept determines not to defend against such action, then PharmaZell shall, at its sole cost and expense, have the right but not the obligation to control the defense of such action except to the extent it relates to a Specified Invention Patent; provided that, if an Other PharmaZell Invention Patent or Joint Invention Patent is at issue in the action and is the only patent protecting a Product, then PharmaZell shall in any event consult with Intercept with respect to any such action and shall obtain Intercept's written consent prior to taking any steps in respect of such action. Intercept shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.  
(b) Any costs and expenses relating to any defense undertaken pursuant to this Section 5.4 shall be borne by the Party controlling the defense. Any damages or other amounts recovered shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to control the defense of the action.  
(c) In the event that a Party entitled to defend an infringement action does so in accordance with this Section 5.4, the other Party shall cooperate fully, including providing access to relevant documents and other evidence and making its employees available at reasonable business hours. If a Party pursues the defense of such an infringement action, it shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken to remedy such infringement.  
5.5 Third Party Licenses. If, in the absence of a license from a Person, the Manufacture of API or API Precursor hereunder in accordance with the terms hereof infringes or misappropriates any patent or any intellectual property right of such Person, such that PharmaZell or any of its Affiliates cannot Manufacture the API or API Precursor without infringing the patent or intellectual property rights of such Person, then Intercept shall have the sole and exclusive right to take the lead in negotiating the terms of any such license. The Parties shall negotiate in good faith an appropriate allocation of any royalties or other payments to be made pursuant to any such license so as to reflect the economic interests of the Parties under this Agreement with respect to the Product.  
5.6 United States Law. The determination of whether Inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States. In the event that United States law does not apply to the creation, conception, discovery, development or making of any Invention hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions, as well as any intellectual property rights with respect thereto, as necessary to fully effect ownership as contemplated by Section 5.1 and the preceding sentence of this Section 5.6.  
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ARTICLE 6  
REPRESENTATIONS AND WARRANTIES; COVENANTS  
6.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as of the Effective Date, and covenants with the other Party, as follows:  
(a) Such Party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or equity;  
(b) All necessary consents, approvals and authorizations of all Regulatory Authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; and  
(c) The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws, limited partnership agreement or other similar documents of such Party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.  
6.2 Additional Representations, Warranties and Covenants of PharmaZell. PharmaZell hereby represents and warrants to Intercept as of the Effective Date, and covenants to Intercept, as follows:  
(a) PharmaZell has executed agreements with all Affiliates, employees, agents subcontractors and any other representative of PharmaZell performing services for PharmaZell in connection with the Manufacture and supply of Supplied Materials to Intercept, or its designee (each, a “Representative”) requiring such Representative to assign all right, title and interest in and to any intellectual property conceived, discovered, developed or otherwise made by such Representative to PharmaZell;  
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(b) In connection with each delivery, and as of the date of delivery, of Supplied Materials to Intercept or its designee: (i) such Supplied Material has been Manufactured in compliance with the Specifications and is in conformity with the Specifications, the Certificate of Analysis and the Certificate of Conformance therefor provided pursuant to Section 2.3(b); (ii) such Supplied Material has been Manufactured, stored, disposed of and handled in conformance with GMP, all other Applicable Laws, the Regulatory Documentation and Regulatory Approvals, this Agreement and the Quality Agreement; (iii) title to such Supplied Material will pass to Intercept free and clear of any security interest, lien or other encumbrance; (iv) the Facilities are in compliance with all Applicable Law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities); (v) the retest date of such Supplied Material meets the retest set forth in the Specifications or otherwise determined in accordance with Applicable Law after the date of delivery thereof for such Supplied Material; and (vi) such Supplied Material has not been adulterated or misbranded within the meaning of the FFDCA or other Applicable Law, or is an article that may not, under the FFDCA or other Applicable Law, be introduced into interstate commerce (collectively, the “Supplied Material Warranty”);  
(c) neither PharmaZell nor any of its Affiliates, nor any Third Party engaged by PharmaZell has ever been, are currently, nor during the performance of any services hereunder, shall become: (i) disqualified or debarred by the FDA or other Regulatory Authorities for any purpose pursuant to Applicable Laws (including United States law, including the statutory debarment provisions at 21 U.S.C. § 335a(a) or (b)) or is under consideration or investigation to be disqualified or debarred, or has been convicted of, or is currently charged with, a felony for conduct relating to the development, approval, regulation or handing of any drug product under any Applicable Law; (ii) charged or convicted for conduct relating to the development or approval of, or otherwise relating to the regulation of, any drug product under any Applicable Laws; (iii) excluded or, to the best of the knowledge of PharmaZell after due inquiry, threatened with exclusion under state or federal laws, including under 42 U.S.C. § 1320a-7 or relevant regulations in 42 C.F.R. Part 1001, or assessed or, to the best of the knowledge of PharmaZell after due inquiry, threatened with assessment of civil money penalties pursuant to 42 U.S.C. Part 1003; (iv) ineligible for contract with the federal government, including due to disbarment, disqualification, or conviction of a felony related to conduct relating to the development, approval, regulation or handing of any drug product under any Applicable Law; or (v) subject to similar actions by any state, local, or foreign governmental authority (collectively “Disqualification”). PharmaZell agrees to notify Intercept immediately, in the event that PharmaZell or any of its officers, directors, employees, agents, or parties under contract to perform and work under this Agreement, (i) becomes subject to Disqualification, or (ii) receives or becomes aware of an action, notice of action, inquiry, or investigation with relating to or that could result in Disqualification during the Term. In the event that PharmaZell receives any notice of actions set forth in this Section 6.2(c), without limiting any other rights or remedies of Intercept, Intercept shall have the right to terminate this Agreement immediately pursuant to the provisions of this Agreement. Any termination by Intercept pursuant to this Section 6.2(c) shall be deemed to be a termination by Intercept for material breach of this Agreement by PharmaZell;  
(d) its retention as a contractor by Intercept and its Manufacture of Supplied Material do not, and shall not, breach any agreement that obligates PharmaZell to keep in confidence any trade secrets or confidential information of any third party or to refrain from competing, directly or indirectly, with the business of any other party;  
(e) the Manufacture and supply of the Supplied Material shall be performed with requisite care, skill and diligence, in accordance with this Agreement, Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified; and  
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(f) the Manufacturing services provided under this Agreement will not infringe the intellectual property rights of any third party, and PharmaZell will promptly notify Intercept in writing should it become aware of any claims asserting such infringement.  
6.3 Disclaimer of Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY.  
ARTICLE 7  
CONFIDENTIALITY  
7.1 Confidential Information. Subject to the provisions of Sections 7.2 and 7.3, at all times during the Term and for [\*\*] following the expiration or termination of this Agreement, the Receiving Party (a) shall keep completely confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party’s employees, Affiliates, or consultants who have a need to know such information to perform such Party’s obligations hereunder (and who shall be advised of the Receiving Party’s obligations hereunder and who are bound by confidentiality obligations with respect to such Confidential Information no less onerous than those set forth in this Agreement) (collectively, “Recipients”) and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. The Receiving Party shall be jointly and severally liable for any breach by any of its Recipients of the restrictions set forth in this Agreement. Notwithstanding the foregoing, trade secrets of the Disclosing Party shall be maintained by the Receiving Party for so long as such information remains the trade secret of the Disclosing Party.  
7.2 Exceptions to Confidentiality. The Receiving Party’s obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:  
(a) that is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of a Receiving Party or its Recipients;  
(b) that is received from a third party without restriction and without breach of any agreement between such third party and the Disclosing Party;  
(c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;  
(d) that is generally made available to third parties by the Disclosing Party without restriction on disclosure; or  
(e) that the Receiving Party can demonstrate by competent, written evidence was independently developed by the Receiving Party without the use of the Disclosing Party’s Confidential Information.  
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7.3 Disclosure. Each Party may disclose Confidential Information to the extent that such disclosure is:  
(a) made in response to a valid order of a court of competent jurisdiction or other Regulatory Authority of a country or any political subdivision thereof of competent jurisdiction; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in such response to such court or governmental order;  
(b) otherwise required by law or regulation, in the reasonable opinion of legal counsel for the Receiving Party; provided, however, the Receiving Party must promptly give the Disclosing Party notice of any such disclosure and provide the Disclosing Party with reasonable assistance in obtaining a protective order with respect to the Confidential Information subject to disclosure;  
(c) Intercept may disclose Confidential Information to the extent that such disclosure is made to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information; or  
(d) To the extent, if any, that a Party concludes in good faith that it is required by applicable laws or regulations to file or register this Agreement or a notification thereof with any Regulatory Authority, including the U.S. Securities and Exchange Commission, such Party may do so, and the other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. In such situation, the filing Party shall request confidential treatment of sensitive provisions of the Agreement, to the extent permitted by Applicable Law and in consultation with the other Party. The Parties shall promptly inform each other as to the activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.  
7.4 Notification. The Receiving Party shall notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party’s discovery of any loss or compromise of the Disclosing Party’s Confidential Information.  
7.5 Remedies. Each Party agrees that the unauthorized use or disclosure of any information by the Receiving Party in violation of this Agreement will cause severe and irreparable damage to the Disclosing Party. In the event of any violation of this ARTICLE 7, the Receiving Party agrees that the Disclosing Party shall be authorized and entitled to seek to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, as well as any other relief permitted by Applicable Law. The Receiving Party agrees to waive any requirement that the Disclosing Party post bond as a condition for obtaining any such relief.  
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7.6 Use of Names. Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 7.6 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.  
7.7 Press Releases. Except as expressly provided in Section 7.3, neither Party shall make a press release or other public announcement regarding this Agreement, the terms hereof or the transactions contemplated hereby without the prior written approval of the other Party. Each Party shall provide the other with the proposed text of any such press release or public announcement for review and approval, which approval shall not be unreasonably withheld, conditioned or delayed, as early as possible, but in no event less than [\*\*] Business Days in advance of the publication, communication or dissemination thereof; provided, however, that the receiving Party shall be deemed to have approved any such press release or public announcement if it fails to notify the proposing Party in writing of any objections to such press release or public announcement within [\*\*] Business Days after receipt by the receiving Party of the text of such public announcement.  
ARTICLE 8  
TERM AND TERMINATION  
8.1 Term. This Agreement shall commence as of the Effective Date and, unless earlier terminated in accordance with the terms hereof, shall expire on December 31, 2020 (the “Initial Term”). Thereafter, this Agreement shall automatically renew for successive two (2)-year periods (each a “Renewal Period”) unless (a) Intercept provides notice to PharmaZell indicating its desire not to renew at least twelve (12) months prior to the end of the Initial Term or then-current Renewal Period, as applicable, or (b) PharmaZell provides notice to Intercept indicating its desire not to renew at least twelve (12) months prior to the end of the Initial Term or then-current Renewal Period, as applicable. The Initial Term together with any Renewal Periods, shall be the “Term”.  
8.2 Termination. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:  
(a) Intercept may terminate this Agreement immediately upon written notice to PharmaZell in the event that (i) Regulatory Authorities require or cause the withdrawal of Product or if the Product is not approved by the FDA and the European Medicines Agency (EMA) or (ii) [\*\*].  
(b) Intercept may terminate this Agreement immediately upon written notice to PharmaZell if (i) PharmaZell does not deliver at least [\*\*] of the amount of Supplied Material specified in a Work Order within [\*\*] of the Delivery Date specified in such Work Order or (ii) PharmaZell does not deliver at least [\*\*] of Supplied Material in [\*\*] provided that Intercept has ordered at least [\*\*] of Supplied Product for delivery in [\*\*].  
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(c) This Agreement may be terminated by either Party:  
(i) immediately upon written notice if the other Party shall (A) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (B) propose a written agreement of composition or extension of its debts, (C) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [\*\*] days after the filing thereof, (D) propose or be a party to any dissolution or liquidation, (E) make an assignment for the benefit of its creditors, or (F) admit in writing its inability generally to pay its debts as they fall due in the general course;  
(ii) immediately upon written notice in the event of any material breach by the other Party in the performance of any of its obligations herein contained that (if curable) has not been cured by the defaulting Party within [\*\*] days after receiving written notice thereof from the non-breaching Party;  
(iii) immediately upon written notice in the event that, as a result of an order of government or any other official authority, the continued operation of this Agreement in its entirety or in substantial part is prohibited or prevented or delayed for an unspecified and indeterminate period; or  
(iv) as provided in Section 10.2.  
(d) Intercept may terminate this Agreement immediately upon written notice to PharmaZell in the event that (i) any audit by a Regulatory Authority identifies critical or major finding (as defined by the FDA and/or EMA) at a Facility and such critical or major finding is not remedied by PharmaZell within the time period as agreed between the Regulatory Authorities and PharmaZell or as mandated by the Regulatory Authorities after the identification thereof, (ii) PharmaZell fails to meet and/or maintain the Quality Standards and does not remedy such failure within a reasonable time as agreed between Intercept and PharmaZell or, if no agreement is reached with respect to such time, such time as established by an independent auditor, or (iii) any audit reveals that a Facility is in violation of Applicable Laws.  
8.3 Effect of Expiration or Termination.  
(a) The expiration or earlier termination of this Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such termination. Those provisions that by their terms or intent are required to survive the expiration or earlier termination of the Agreement in order to give effect to the intent of the Parties shall so survive. Without limiting the foregoing, the provisions of Sections 4.5, 6.3 and 8.3 and ARTICLE 5, ARTICLE 7, ARTICLE 9 and ARTICLE 10 shall survive the expiration or termination of this Agreement and continue thereafter in accordance with and to the extent of their terms. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available at law or in equity.  
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(b) Upon expiration or earlier termination of this Agreement, each Party, at the request of the other, shall return all data, files, records and other materials in its possession or Control containing or comprising the other Party’s Confidential Information except that the legal department of such Party may retain one copy solely for archival purposes.  
(c) Upon any termination of this Agreement by Intercept pursuant to Section 8.2(a) or by PharmaZell pursuant to Section 8.2(c), (i) PharmaZell shall return to Intercept all Intercept Materials, (ii) Intercept shall purchase from PharmaZell the amount of Supplied Material that is subject to Work Orders outstanding at the time of such termination, (iii) Intercept shall reimburse PharmaZell for work in process and Materials that PharmaZell has purchased for the purpose of supplying Supplied Material to Intercept in accordance with the delivered Work Orders, and (iv) Intercept shall pay PharmaZell’s direct cost for any such work in process in accordance with the Work Orders and PharmaZell’s purchase price from its suppliers for any such Materials ordered for such Work Orders that have a minimum of [\*\*] shelf life and have been stored and controlled by PharmaZell per the Quality Agreement; provided, however that PharmaZell shall use reasonable best efforts to return such Materials to suppliers or use such Materials in the manufacture of product for third parties. In the event of termination of this Agreement by Intercept pursuant to Section 8.2(b), 8.2(c) or 8.2(d), at the request of Intercept, PharmaZell shall fulfill all outstanding Work Orders for Supplied Materials prior to the effective date of such termination and to the extent not used to fulfill Work Orders at Intercept’s request, PharmaZell shall return to Intercept all Intercept Materials.  
(d) Except as and to the extent contemplated by Section 8.3(c), upon expiration of this Agreement or any earlier termination of this Agreement, PharmaZell immediately shall cease all Manufacturing of Supplied Materials pursuant to this Agreement.  
(e) Following expiration or termination of this Agreement, PharmaZell shall (i) provide Intercept with such reasonable cooperation and support with respect to regulatory matters as Intercept may require in order to dispose of previously purchased API, (ii) grant to Intercept a perpetual, irrevocable, non-exclusive royalty-free license (with the right to grant sublicenses) under know-how, patents and other intellectual property rights owned, licensed or otherwise controlled by PharmaZell (or any of its Affiliates) as may be necessary or useful for the purpose of making and having made the API and API Precursor and (iii) within thirty (30) days of such expiration or termination, provide to Intercept copies of the physical embodiment of those processes, protocols, procedures, methods, tests and other know-how, relating to the Manufacturing of the API and API Precursor. In addition, PharmaZell shall provide reasonable assistance to Intercept and its Affiliates with respect to assisting Intercept and its Affiliates in obtaining all necessary regulatory approvals and/or modifying existing Regulatory Approvals for the Manufacture of the API.  
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ARTICLE 9  
INDEMNIFICATION  
9.1 PharmaZell Indemnification. PharmaZell shall indemnify Intercept, its Affiliates and sublicensees and its and their respective directors, officers, employees and agents (the “Intercept Indemnified Parties”), and defend and hold each of them harmless, from and against any and all claims, lawsuits, actions, suits and demands brought by a third party (a “Third Party Claim”) and all associated losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys’ fees and disbursements) (collectively, “Losses”) incurred by any of them arising from or occurring as a result of (a) the breach by PharmaZell of any of its representations or warranties set forth in this Agreement, (b) PharmaZell’s breach of any of its covenants or obligations under this Agreement, (c) PharmaZell’s gross negligence or willful misconduct in the performance of this Agreement, (d) the storage, release, or disposal of any hazardous or regulated material or any waste by PharmaZell, (e) violation of Applicable Law by any PharmaZell Indemnitee, or (f) the enforcement by Intercept of its rights under this Section 9.1, except, in each case, for those Losses for which Intercept has an obligation to indemnify the PharmaZell Indemnified Parties pursuant to Section 9.2, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.  
9.2 Intercept Indemnification. Intercept shall indemnify PharmaZell, its Affiliates and its and their respective directors, officers, employees and agents (the “PharmaZell Indemnified Parties”), and defend and hold each of them harmless, from and against any and all Third Party Claims and all associated Losses incurred by any of them arising from or occurring as a result of (a) the breach by Intercept of any of its representations or warranties set forth in this Agreement, (b) Intercept’s breach of its covenants or obligations under this Agreement, (c) violation of Applicable Law by any Intercept Indemnitee, or (d) the enforcement by PharmaZell of its rights under this Section 9.2, except, in each case, for those Losses for which PharmaZell has an obligation to indemnify the Intercept Indemnified Parties pursuant to Section 9.1, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.  
9.3 Indemnification Procedure.  
(a) Notice of Claim. The indemnified party (the “Indemnified Party”) shall give the indemnifying Party (the “Indemnifying Party”) prompt written notice (an “Indemnification Claim Notice”) of any Third Party Claims and the associated Losses or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 9.1 or 9.2, but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.  
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(b) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [\*\*] days after the Indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party’s claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party, which shall be reasonably acceptable to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Third Party Claim. Subject to Section 9.3(c), if the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless a Intercept Indemnified Party or PharmaZell Indemnified Party, as applicable, from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including reasonable attorneys’ fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim with respect to such Intercept Indemnified Party or PharmaZell Indemnified Party, as applicable.  
(c) Right to Participate in Defense. Without limiting Section 9.3(b), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party’s own expense unless (A) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (B) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.3(b) (in which case the Indemnified Party shall control the defense), or (C) the interests of the Indemnified Party and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable law, ethical rules or equitable principles.  
(d) Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim, without any admission of liability or fault, and that will not result in the Indemnified Party’s becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.3(b), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).  
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(e) Cooperation. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.  
(f) Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a calendar quarter basis in arrears by the Indemnifying Party, without prejudice to the Indemnifying Party’s right to contest the Indemnified Party’s right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.  
9.4 Insurance.  
(a) During the Term, each Party shall maintain adequate liability insurance covering its activities and obligations under this Agreement that is standard and reasonable in the biopharmaceutical industry for companies conducting similar activities; provided that for PharmaZell in no event shall such amounts be less than (i) with respect to comprehensive general liability insurance, a combined single limit for bodily injury and property damage of not less than [\*\*]and (ii) with respect to product liability/completed operations coverage, a per claim limit of not less than [\*\*] (collectively, the “Policies”). If any Policy is written on a claims-made basis, the retroactive date, if any, shall not be later than the Effective Date and such coverage shall be continued for a period of [\*\*] following the Term. Each Party shall provide prompt notice to the other Party in the event that the first Party’s Policies are canceled or subjected to a reduction of coverage or any other material adverse modification.  
(b) Each Party shall furnish certificates of insurance for its Policies to the other Party within [\*\*] days after the Effective Date.  
9.5 Limitation on Damages. IN NO EVENT SHALL: (A) EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION OR LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE AND (B) EITHER PARTY’S LIABILITY EXCEED FIFTEEN MILLION UNITED STATES DOLLARS ($15,000,000) ON A PER CLAIM BASIS. THE FOREGOING LIMITATIONS AND EXCLUSIONS ARE NOT INTENDED TO, NOR SHALL THEY, EXCLUDE OR LIMIT DAMAGES OR CLAIMS CAUSED BY A PARTY’S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR BREACH OF THE PROVISIONS OF ARTICLE 5, OR EXCLUDE OR LIMIT A PARTY’S INDEMNIFICATION OBLIGATIONS UNDER SECTION 9.1 OR 9.2.  
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ARTICLE 10  
MISCELLANEOUS  
10.1 Notices. All notices, requests and other communications hereunder must be in writing, specifically reference this Agreement in a prominent manner, and be delivered personally, sent by first class registered or certified mail, postage prepaid, return receipt requested or by internationally recognized overnight delivery service that maintains records of delivery to the Parties at the following addresses:  
If to Intercept to:  
Intercept Pharma Europe Ltd.  
0 Xxxxxxx Xxxxxx, Xxxxx 0, Xxxxxx  
Xxxxxx Xxxxxxx X0X 0XX  
Attention: [\*\*]  
with copies (which shall not constitute notice) to:  
Intercept Pharma Europe Ltd.  
0 Xxxxxxx Xxxxxx, Xxxxx 0, Xxxxxx  
Xxxxxx Xxxxxxx X0X 0XX  
Attention: Head of Legal  
and  
Intercept Pharmaceuticals, Inc.  
000 X 00xx Xx,  
Xxxxx 000 Xxxxx 0  
Xxx Xxxx, XX 00000  
Attention: General Counsel  
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If to PharmaZell to:  
PharmaZell GmbH  
Xxxxxxxxxxx Xxxxxx 00  
00000 Xxxxxxxx  
Xxxxxxx  
Attention: [\*\*]  
All such notices, requests and other communications will (a) if delivered personally to the address as provided in this Section, be deemed given upon delivery, (b) if delivered by internationally recognized overnight delivery courier be deemed given on the second Business Day (at the place of delivery) after deposit with such internationally recognized delivery service, (c) if sent by first class registered or certified mail, postage prepaid, return receipt requested, within the United States, on the third Business Day following the date of mailing, and (d) if sent by international first class registered or certified mail, postage prepaid, return receipt requested, on the seventh Business Day following the date of mailing. Any Party from time to time may change its address or other information for the purpose of notices to that Party by giving notice specifying such change to the other Party hereto.  
10.2 Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 10.2, where delivery or performance has been affected by fires, floods, embargoes, strikes, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, acts of God or acts or similar condition beyond such Party’s reasonable control; provided that the Party affected by such a condition shall, within [\*\*] days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use commercially reasonable efforts to remedy its inability to perform. Notwithstanding the foregoing, in the event the suspension of performance continues for [\*\*] days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the nonaffected Party may terminate this Agreement immediately by written notice to the affected Party.  
10.3 Entire Agreement; Amendment.  
(a) This Agreement, together with the Schedules and Exhibits attached hereto and the Quality Agreement, which shall be incorporated by reference hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements (including any terms and conditions previously agreed upon by the Parties), understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein.  
(b) No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.  
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10.4 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.  
10.5 Successors and Assigns. The terms and provisions hereof shall inure to the benefit of, and be binding upon, Intercept, PharmaZell and their respective successors and permitted assigns.  
10.6 Governing Law. This Agreement shall be governed and interpreted in accordance with the laws of England and Wales, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, however, for all intellectual property matters, this Agreement shall be governed and interpreted in accordance with the laws of New York, New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. To the extent not resolved pursuant to Section 10.7 or Section 10.8, venue for any litigation between the Parties shall be London, England or, with respect to intellectual property matters, New York, New York. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.  
10.7 Dispute Resolution.  
(a) In the event of a dispute between the Parties, either Party may, by giving written notice of dispute to the other Party, request a meeting of authorized representatives of the Parties for the purpose of resolving the dispute. The Parties agree that, within [\*\*] days after any such request, each Party shall designate a representative to participate in dispute resolution discussions that shall be held in [\*\*] at a mutually acceptable time for the purpose of resolving the dispute. Each Party agrees to negotiate in good faith to resolve the dispute in a mutually acceptable manner.  
(b) If for whatever reason the Parties are unable to resolve the dispute within [\*\*] days after the issuance of a notice of dispute, then either Party may, by written notice to the other Party, submit the dispute to binding arbitration in accordance with the provisions of Section 10.8, except for those disputes excluded from Section 10.8 which shall be subject to the provisions of Section 10.6.  
10.8 Arbitration.  
(a) Except to the extent otherwise provided in Section 4.5, Section 7.5, or arising out of a dispute relating to Article 5, any dispute arising out of or relating to this Agreement, including the breach, termination or validity thereof, shall, after first being subject to negotiations between the Parties as provided in Section 10.7(a), be finally resolved by arbitration in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce (“ICC Rules”) as then in effect, provided that, in the event and to the extent such rules conflict with the terms of this Section 10.8, the terms of this Section 10.8 shall govern. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The place of arbitration shall be [\*\*]. The arbitration shall be conducted in the English language. The place of litigation for disputes relating to Article 5 shall be [\*\*].  
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(b) Except as provided in Section 10.8(c), the arbitration shall be held before a single arbitrator, who shall be selected by agreement of the Parties, or, if the Parties cannot agree within [\*\*] days after commencement of arbitration, then by the International Chamber of Commerce. The arbitrator selected pursuant to this Section 10.8(c) shall be a practicing or retired lawyer or retired judge and have experience relating to agreements concerning the marketing of pharmaceutical products in the United States.  
(c) Notwithstanding Section 10.8(b), in the event that the dispute that is subject to arbitration is one in which a Party seeks to recover an amount of at least [\*\*] from the other Party, then either Party shall have the option, exercisable by written notice to the other Party given at any time within [\*\*] days after commencement of arbitration, to require that the arbitration be held before a panel of three (3) arbitrators. In such case, within [\*\*] days after the provision of notice described in the preceding sentence, each Party shall select one person to act as arbitrator. If a Party shall fail within the designated time period to select an arbitrator, then the arbitrator to be selected by the Party shall be selected by the International Chamber of Commerce. The two (2) persons so selected as arbitrators shall select a third arbitrator within [\*\*] days of their appointment. If the two (2) initially selected arbitrators are unable or fail to agree upon the third arbitrator, the third arbitrator shall be selected by the International Chamber of Commerce. Each arbitrator selected pursuant to this Section 10.8(c) shall be a practicing lawyer or retired judge and have experience relating to agreements concerning the marketing of pharmaceutical products in the United States.  
(d) Each Party shall, upon the written request of the other Party, promptly provide the other Party with copies of documents relevant to the issues raised by the dispute on which the producing Party may rely in support of, or in opposition to, any claim or defense. Any dispute regarding discovery, or the relevance or scope thereof, shall be determined by the arbitrator(s), which determination shall be conclusive. To the extent reasonable under the circumstances and as agreed in writing by the Parties, all discoveries shall be completed within [\*\*] days following the appointment of the arbitrator(s).  
(e) It is the intent of the Parties that, barring extraordinary circumstances, and to the extent reasonable, arbitration proceedings will be concluded within [\*\*] months from the date the arbitrator is appointed (or, where a panel of three (3) arbitrators is used, within [\*\*] months from the date upon which the third arbitrator is appointed). The arbitrator(s) may extend this time limit in the interests of justice. Failure to adhere to this time limit shall not constitute a basis for challenging the award.  
(f) Except as may be required by Applicable Law (including applicable securities laws or rules of a securities exchange) or as may be necessary to enforce the arbitration award or the provisions of this Section 10.8, and except for disclosures made by a Party to its accountants, insurers, consultants, or attorneys or to actual or potential lenders, non-public investors, rating agencies, acquirers, or business partners who are under obligations to the disclosing Party to hold the disclosed information in confidence, neither a Party nor its representatives may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of the other Party.  
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(g) The arbitrator(s) shall have discretion to allocate the Parties’ costs and expenses for the arbitration (including attorneys’ fees), the fees of the arbitrator(s), and the administrative fees of arbitration between the Parties in proportion to the extent to which they prevail. Failing such allocation, each Party shall bear its own costs and expenses and an equal share of the fees of the arbitrators and administrative fees of the arbitration.  
10.9 Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.  
10.10 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.  
10.11 Assignment. Except as expressly provided herein, neither Party may, without the prior written consent of the other Party, sell, transfer, assign, delegate, pledge, subcontract or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that (a) Intercept may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate, (b) Intercept may, without such consent, assign its rights and delegate its obligations under this Agreement in respect of Supplied Materials to the purchaser or sublicensee of Intercept’s rights in and to such Supplied Materials or the relevant Product, (c) PharmaZell may, without such consent, assign this Agreement and its rights and obligations hereunder to one or more Affiliates, and (d) either Party may, without such consent, assign this Agreement and its rights and obligations hereunder to the purchaser of all or substantially all of its assets or to any successor entity or acquirer in the event of a merger, consolidation or change in control of such Party. Any attempt to assign, transfer, subcontract or delegate any portion of this Agreement in violation of this Section 10.11 shall be null and void. In the event either Party assigns all of its rights and delegates all of its obligations under this Agreement to another Person in accordance with the terms hereof and the assignee/delegee acquires all rights and assumes all obligations of its assignor/delegor under this Agreement, then the assignor/delegor shall cease to be a party to this Agreement or to have any rights or obligations under this Agreement from and after the effective date of such assignment or delegation. Except as provided in the preceding sentence, no assignment or delegation shall relieve the assignor or delegor of any of its obligations hereunder.  
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10.12 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.  
10.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.  
10.14 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer, employee, or joint venture relationship between the Parties. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority.  
10.15 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms “hereof,” “herein,” “hereby” and derivative or similar words refer to this entire Agreement; (d) the terms “Article,” “Section,” “Schedule,” “Exhibit” or “clause” refer to the specified Article, Section, Schedule, Exhibit or clause of this Agreement; (e) the term “or” has, except where otherwise indicated, the inclusive meaning represented by the phrase “and/or”; (f) the term “including” or “includes” means “including without limitation” or “includes without limitation”; and (g) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.  
10.16 Remedies. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable law or otherwise available except as expressly set forth herein.  
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10.17 Counterparts; Facsimile Execution. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement (and each amendment, modification and waiver in respect of it) by facsimile or other electronic transmission shall be as effective as delivery of a manually executed original counterpart of each such instrument.  
10.18 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.  
10.19 Parent Guarantee. Intercept Parent hereby agrees to be jointly and severally liable for the prompt and complete performance of Intercept’s financial obligations under this Agreement, and hereby guarantees the financial performance by Intercept of the obligations set forth in this Agreement.  
[Signature Page Follows]  
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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement to be effective as of the last date of signature below.  
INTERCEPT PHARMA EUROPE LTD.  
 PHARMAZELL GmbH  
 By:  
/s/ Xxxxx Xxxxxx  
 By:  
/s/ Xxxxxx Xxxxxxx  
 Name:  
Xxxxx Xxxxxx  
 Name:  
Xxxxxx Xxxxxxx  
 Title:  
SVP  
 Title:  
CEO  
 Date:  
August 12, 2016  
 Date:  
August 12, 2016  
 AGREED TO AND ACCEPTED SOLELY FOR PURPOSES OF SECTION 10.19:  
 INTERCEPT PHARMACEUTICALS, INC.  
 By:  
/s/ Xxxxxx Xxxxxxx  
 Name:  
Xxxxxx Xxxxxxx  
 Title:  
CFO  
 Date:  
August 12, 2016  
 [Signature Page to Manufacturing and Supply Agreement]  
SCHEDULE 1.40  
Intercept Materials  
[\*\*]  
Schedule 1.40 to Manufacturing and Supply Agreement  
SCHEDULE 1.83  
Form of Work Order  
FOR ILLUSTRATION PURPOSES ONLY – DO NOT EXECUTE  
WORK ORDER #\_\_\_\_  
This Work Order #\_\_\_\_ (“Work Order”) is entered into and effective with and as of the last signature to it by either Party by and between Intercept Pharma Europe Ltd. (“Intercept”) and PharmaZell GmbH (“PharmaZell”)and is subject to all of the terms and conditions of the Manufacturing and Supply Agreement between Intercept and PharmaZell, effective as of \_\_\_\_, 2016 (the “Agreement”) and in accordance with this Work Order using, if applicable, the materials provided by Intercept hereunder.  
Specifications supplied by Intercept: as in Quality Agreement signed September 12, 2014  
Description of Services or Scope of Work: PharmaZell shall provide the following Supplied Material to Intercept: Work Order Description. [Or insert Description, including any work product, reports, or presentations contemplated under this Agreement; please be as specific as possible] or [If applicable, “as outlined in Appendix 1 attached hereto and incorporated by reference.”]  
Deliverables: Quantity of Supplied Materials.  
Delivery Date: [Insert desired Delivery Date]  
Place of Delivery: [Insert desired Delivery location]  
Timelines and Milestones: PharmaZell will provide schedule and progress updates in accordance with the terms of the Agreement.  
Compensation: Intercept shall pay the total sum not to exceed of Total Estimated Work Amount (the “Total Fee”) in accordance with the commercial pricing set forth in the Agreement and in consideration for the performance of the above Supplied Material supplied. Payment shall be made in accordance with the details outlined in the Agreement.  
OTHER TERMS TO BE ADDED AS AGREED  
Capitalized terms contained in this Work Order and not otherwise defined herein, shall have the meaning ascribed to them in the Agreement.  
This Work Order may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Work Order delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.  
[Remainder of Page Intentionally Blank]  
Schedule 1.83 to Manufacturing and Supply Agreement  
1  
IN WITNESS WHEREOF, each Party has executed this Work Order by a duly authorized individual effective as of the later of the signatures below.  
INTERCEPT PHARMA EUROPE LTD.  
 PHARMAZELL GMBH  
 By:  
Form Only – Do Not Sign  
 By:  
Form Only – Do Not Sign  
Name:  
 Name:  
 Title:  
 Title:  
 Date:  
 Date:  
 Schedule 1.83 to Manufacturing and Supply Agreement  
2  
SCHEDULE 2.1(d)  
Approved Subcontractors and Activities  
Subcontractor  
 Activity  
 [\*\*]  
 [\*\*]  
 [\*\*]  
 [\*\*]  
 [\*\*]  
 [\*\*]  
 [\*\*]  
 [\*\*]  
Schedule 2.1(d) to Manufacturing and Supply Agreement  
SCHEDULE 2.2(a)  
Existing Work Orders  
[\*\*]  
Schedule 2.2(a) to Manufacturing and Supply Agreement  
Schedule 2.2(b)  
First New Work Order  
[\*\*]  
Schedule 2.2(b) to Manufacturing and Supply Agreement  
SCHEDULE 2.7(e)  
Standard Yields  
[\*\*]  
Schedule 2.7(e) to Manufacturing and Supply Agreement