Exhibit 10.5  
CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS  
DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH  
(I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS  
AS PRIVATE AND CONFIDENTIAL.  
MANUFACTURING AGREEMENT  
BY AND BETWEEN  
RENAISSANCE LAKEWOOD, LLC  
AND  
ARS PHARMACEUTICALS, INC.  
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This Manufacturing Agreement (the “Agreement”) is made as of this 9th day of September, 2020 (the “Effective Date”) by and between ARS Pharmaceuticals, Inc., a corporation organized under the laws of the State of California with its principal office located at [\*\*\*], (hereinafter referred to as “COMPANY”) and Renaissance Lakewood, LLC, a limited liability corporation organized under the laws of the State of Delaware with a place of business at 0000 Xxxx Xxx, Xxxxxxxx, Xxx Xxxxxx, 00000 (hereinafter “RENAISSANCE”).  
WITNESSETH:  
WHEREAS, COMPANY is engaged in the development, manufacture, and commercialization of certain pharmaceutical products; and  
WHEREAS, RENAISSANCE owns and has a broad spectrum of technologies for the development, formulation, testing, control, manufacture, filling and distribution of pharmaceutical products; and  
WHEREAS, COMPANY and RENAISSANCE have entered into that certain Research & Development Services Agreement, dated as of [\*\*\*] (“R&D Agreement”), pursuant to which, among other things, RENAISSANCE has developed a formulation of a certain Product (as hereinafter defined); and  
WHEREAS, COMPANY desires to engage RENAISSANCE to manufacture and supply the Product to COMPANY for its commercial uses, and RENAISSANCE desires to do so.  
NOW, THEREFORE, in consideration of the mutual covenants hereinafter expressed, the parties agree as follows:  
I—DEFINITIONS  
“Acknowledgement” has the meaning set forth in Section 2.6(a) hereof.  
“Act” means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder.  
“Additional Development” has the meaning set forth in Section 10.1 hereof.  
“Administrative Expenses” means, in the context of any Product [\*\*\*].  
 1  
“Affiliate” means, with respect to either party, any Person controlling, controlled by or under common control with such party, for so long as such relationship exists. For the purposes of this definition, “control” means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such party, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such party (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Law of the country of incorporation or domicile), as applicable.  
“Agreement” has the meaning set forth in the Preamble hereof.  
“Annual Product Review” means an analysis conducted by RENAISSANCE personnel on a yearly basis, consistent with 21 C.F.R. § 211.180 and any comparable regulation in the Primary Territory, which examines a multitude of subject matter areas, including production review and changes in processes, raw materials, API, Packaging and shipping components, unit volume, production, and other similar such issues.  
“API” means, Epinephrine, which is the active pharmaceutical ingredient that is contained in the Product, as more fully defined in Schedule A.  
“Applicable Law” means all laws, ordinances, rules, rulings, directives and regulations of any Regulatory Authority: (a) applicable to the Manufacture, distribution and/or sale of Product; or (b) governing the parties; as the context requires under this Agreement, including, (i) all applicable federal, state and local laws and regulations; (ii) the Act (iii) cGMP; and (iv) any other requirements by any Regulatory Authority. For the avoidance of doubt “Applicable Law” when used in this Agreement in relation to RENAISSANCE compliance obligations includes the items set forth in clause (i)-(iv) only for the Primary Territory and not the Secondary Territory or any other country, but with regard to COMPANY includes any country in which it sells Product.  
“Background IP” has the meaning set forth in Section 7.1 hereof.  
“Batch” means a defined quantity of Product that is Manufactured in a single Manufacturing run in accordance with the Specifications.  
“Batch Documentation” has the meaning set forth in Section 5.2 hereof.  
“Certificate of Analysis” has the meaning set forth in Section 5.2 hereof.  
“Certificate of Compliance” has the meaning set forth in Section 5.2 hereof.  
“Change Control Request” or “CCR” means the primary record in RENAISSANCE’s record keeping system in which the overall details of a change are captured, monitored and approved by COMPANY.  
“Commercially Reasonable Efforts” means [\*\*\*].  
 2  
“Common Technical Document” means the document assembling all the quality, safety and efficacy information in a common format developed by the EMA, the FDA, and the Japanese Ministry of Health, Labour and Welfare; in each case, any successor agency thereto, maintained by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).  
“COMPANY” has the meaning set forth in the Preamble hereof.  
“COMPANY Inventions” has the meaning set forth in Section 7.2 hereof.  
“COMPANY Material” has the meaning set forth in Section 2.2(a) hereof and includes [\*\*\*].  
“Confidential Information” has the meaning set forth in Section 9.1(a) hereof.  
“Disclosing Party” has the meaning set forth in Section 9.1(a) hereof.  
“Effective Date” has the meaning set forth in the Preamble hereof.  
“EMA” means the European Medicines Agency and any successor agency or authority having substantially the same function in the European Union.  
“Extraordinary Matters” has the meaning set forth in Section 11.5 hereof.  
“E.U.” means the European Union as it is comprised from time to time and the United Kingdom so long it remains subject to Applicable Law of the E.U. and the EMA.  
“E.U. and Other Country Initial Term” has the meaning set forth in Section 4.1 hereof.  
“E.U. and Other Country Renewal Term” has the meaning set forth in Section 4.1 hereof.  
“E.U. and Other Country Term” has the meaning set forth in Section 4.1 hereof.  
“E.U. Launch Date” means the first Launch Date for the first Product for any country in the E.U.  
“Facility” means the facility of RENAISSANCE located at 0000 Xxxx Xxx, Xxxxxxxx, Xxx Xxxxxx, 00000, where Product will be Manufactured and stored by RENAISSANCE.  
 3  
“FDA” means the United States Food and Drug Administration, or any successor agency or authority having substantially similar function in the United States.  
“Forecasted Needs” means COMPANY’s estimate of Product to be ordered from RENAISSANCE for the [\*\*\*] beginning with the [\*\*\*] in which such estimate is provided.  
“Force Majeure” means causes beyond the control of a party, which are not attributable to any legal violation, breach or default by such party, including acts of God, acts, regulations, or laws of any government, epidemics, pandemics, civil commotion, strikes, shortages of raw materials, terrorism, unavailability of necessary equipment, substantial damage to or destruction of production facilities or material by fire, earthquake or storm, and failure of public utilities or common carriers.  
“Good Manufacturing Practices” or “cGMP” means the current good manufacturing practices and standards applicable to the manufacture of Product as provided for (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations 21 C.F.R. § 210 and 211 in relation to the production of finished pharmaceutical Product and any corresponding practices and standards under U.S. and E.U. Applicable Law , subject to any arrangements, additions, clarifications, and the respective roles and responsibilities agreed from time to time between the parties.  
“Initial Term” has the meaning set forth in Section 4.1 hereof.  
“Inventions” has the meaning set forth in Section 7.2(a) hereof.  
“Label”, or “Labeling” means all labels and other written, printed, or graphic matter: (i) upon Product or any container or wrapper utilized with Product or (ii) accompanying Product.  
“Launch Date” means, with respect to any Product in any country in the Territory, the first day of the month following RENAISSANCE’s initial invoicing of Product to COMPANY designated for sale in such country, which Product has been Manufactured by RENAISSANCE and released for commercial use under this Agreement.  
“Manufacture”, “Manufactured” or “Manufacturing” means any steps, processes and activities necessary to produce Product, including, the manufacturing, processing, formulation, fill/finish, handling, labeling, packaging, inspection, quality control testing, release or storage of Product, but excluding any storage or distribution of Product or validation activity prior to release of that Product.  
“Manufacturing Fee” means the fee paid by COMPANY to RENAISSANCE for services required to Manufacture Product under this Agreement. [\*\*\*].  
 4  
“Maximum Purchase Order Quantity” has the meaning set forth in Section 2.6(a) hereof.  
“Minimum Order Quantities or (MOQ)” means [\*\*\*].  
[\*\*\*]  
“Other Countries” means the countries listed in Schedule E.  
“Packaging” means all primary containers, cartons, shipping cases, inserts or any other like material used in packaging, or accompanying Product in accordance with applicable Specifications, including executed Batch records.  
“Partner” means COMPANY’s commercialization partner.  
 5  
“Partner Trade Dress” means Partner’s Packaging to be used in relation to Product in the Territory, which includes Partner’s Trademarks.  
“PDUFA” has the meaning set forth in Section 6.2 hereof.  
“Permitted Recipients” has the meaning set forth in Section 9.1(b) hereof.  
“Person” means any natural person, partnership, limited liability company, corporation, trust, joint venture, joint stock company, association, unincorporated organization, government or agency or political subdivision thereof, or other entity, whether acting in an individual, fiduciary or other capacity.  
“Primary Territory” means the E.U. and the U.S.  
“Prior CDA” has the meaning set forth in Section 9.1(a) hereof.  
“Product” means each product listed in Schedule B to be Manufactured, by RENAISSANCE hereunder.  
“Project Protocol” means a precise and detailed plan that is mutually agreed and executed by RENAISSANCE and COMPANY, which describes the nature and scope of out-of-scope services to be rendered and fees to be charged, which may include Additional Development.  
“Purchase Commitment” has the meaning set forth in Section 2.1(a) hereof.  
“QBR” has the meaning set forth in Section 5.7 hereof.  
“Quality Agreement” has the meaning set forth in Section 5.1 hereof.  
“R&D Agreement” has the meaning set forth in the Preamble hereof.  
“Receiving Party” has the meaning set forth in Section 9.1(a) hereof.  
“Regulatory Approval” means, with respect to a particular Product, all approvals, licenses, registrations or authorizations necessary for the development or commercialization in the Territory of such Product (including applicable approvals of Labeling, price and reimbursement for such Product in the Territory), including approval of any New Drug Approval (NDA) or Abbreviated New Drug Application (ANDA) by the FDA or of any Marketing Authorization Application (MAA) by the EMA or any other applicable Regulatory Authority in the E.U.  
“Regulatory Authority” means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental agency with authority over the development, manufacture or commercialization (including Regulatory Approvals) of any Product; in each case, with regard to RENAISSANCE, only in the Primary Territory, including the FDA and the EMA.  
 6  
“Regulatory Filing” means any and all filings or applications submitted to a Regulatory Authority with respect to any Product (together with supporting documentation), submitted via the Common Technical Document or otherwise.  
“Rejected Product” has the meaning set forth in Section 2.7(a) hereof.  
“RENAISSANCE” has the meaning set forth in the Preamble hereof.  
“RENAISSANCE Fault” has the meaning set forth in Section 2.7(c) hereof.  
“RENAISSANCE Inventions” has the meaning set forth in Section 7.1 hereof.  
“RENAISSANCE Material” has the meaning set forth in Section 2.2(b) hereof.  
“RENAISSANCE Product Warranty” has the meaning set forth in Section 6.1 hereof.  
“Renewal Term” has the meaning set forth in Section 4.1 hereof.  
“Representatives” means, with respect to a party and its Affiliates, their employees, agents, accountants, attorneys, consultants, subcontractors and other representatives.  
“Required Lead Time” has the meaning set forth in Section 2.6(c) hereof.  
“Requirements” means COMPANY’s actual requirements for Product, which will reflect any instances where its requirements are reduced due to (i) [\*\*\*], (ii) [\*\*\*], or (iii) [\*\*\*].  
“Safety Data Sheet” or “SDS” means written or printed material concerning a hazardous chemical, which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration or any successor entity thereto.  
“Secondary Territory” means United Kingdom (upon it no longer being subject to Applicable Law of the E.U. and the EMA) and the Other Countries.  
“Specifications” means, with respect to a Product, all written product, regulatory, manufacturing, quality control and quality assurance procedures, processes, practices, standards, instructions and specifications provided by COMPANY to RENAISSANCE in writing, including [\*\*\*] in accordance with Article VIII), including RENAISSANCE’s Acceptable Quality Limits, applicable to the Manufacture, storage and shipment of Product as set forth in the applicable Regulatory Approval.  
 7  
“Standard Cost(s)” means the [\*\*\*] cost to [\*\*\*] of materials plus [\*\*\*].  
“Standard Operating Procedures” or “SOPs” means detailed, written instructions to achieve uniformity of the performance of a specific process, which may cover more than one task or area covered by cGMP regulations. SOPs are considered to be supplemental to master batch records, specification documents and standard methods of analysis. Specific instructions provided in master batch records, specification documents and standard methods of analysis will supersede instructions in SOPs (unless otherwise stipulated in the applicable SOP document).  
“Stock Keeping Unit” or “SKU” means a unique number assigned to a finished product.  
“Supply Failure” has the meaning set forth in Section 2.1(b) hereof.  
“Technical and Development Services” means the services provided by RENAISSANCE technical and development personnel to customers of RENAISSANCE with respect to the evaluation, sourcing, qualification, development, manufacture and/or testing of new equipment, products or other items which may become projects hereunder separate from the Manufacture of Product.  
“Target E.U. Launch Date” means [\*\*\*], the target Launch Date for the first Product in the E.U.  
“Target U.S. Launch Date” means [\*\*\*], the target Launch Date for the first Product in the U.S.  
“Technical and Development Hourly Rate” means the standard, reasonable hourly rate charged by RENAISSANCE for Technical and Development Services at the time such Technical and Development Services are provided, which hourly rate is $[\*\*\*] per hour as of the Effective Date.  
“Term” has the meaning set forth in Section 4.1 hereof.  
“Territory” means, collectively, the Primary Territory and the Secondary Territory.  
“Third Party” means any Person other than RENAISSANCE and COMPANY and their respective Affiliates.  
“Total Price per Unit of Product” means, with respect to a unit of a Product, the sum of its [\*\*\*].  
 8  
“Trademarks” means, with regard to any country in the Territory, all marks, logos, trademarks and brand names designated by a party to commercialize Product in such country.  
“U.S.” means the United States of America, its territories, commonwealths and possessions, including, but not limited to, the District of Colombia, Commonwealth of Puerto Rico, the U.S. Virgin Islands, the Xxxxxxxx Islands and Guam.  
“U.S. Initial Term” has the meaning set forth in Section 4.1 hereof.  
“U.S. Renewal Term” has the meaning set forth in Section 4.1 hereof.  
“U.S. Term” has the meaning set forth in Section 4.1 hereof.  
“U.S. Termination Event” means the occurrence of any of the following events: (i) COMPANY has not submitted its first Regulatory Filing for any Product in the U.S. on or before June 30, 2022, (ii) the authorization and approval to distribute or sell Product in the U.S. is not granted or before the Target U.S. Launch Date, (iii) the authorization and approval representing more than [\*\*\*] units of Product sold in in the U.S. during the last calendar year is withdrawn by the FDA, or (iv) COMPANY at its sole discretion determines to cease commercializing all Product in the U.S.  
“U.S. Launch Date” means the first Launch Date for the first Product in the U.S.  
II—PRODUCT MANUFACTURE AND SUPPLY  
 2.1  
Manufacture and Purchase  
 (a)  
General Provisions  
Subject to the terms and conditions of this Agreement (including Section 2.1(b)), RENAISSANCE agrees that it will Manufacture for, and provide to, COMPANY, and COMPANY agrees that during the Initial Term it will order from RENAISSANCE pursuant to Section 2.6, not less than (i) [\*\*\*] of the COMPANY’s aggregate annual Requirements in the E.U.; and (ii) [\*\*\*] of the COMPANY’s annual, aggregate Requirements in the U.S. (the “Purchase Commitment”). COMPANY shall pay RENAISSANCE for Product according to Sections 2.8 and 2.9. RENAISSANCE shall Manufacture Product and perform its obligations hereunder in accordance with U.S. and E.U. Applicable Law, the Specifications, the Quality Agreement, and this Agreement, and shall use [\*\*\*] to Manufacture Product in sufficient quantity to meet COMPANY’s Forecasted Needs for the length of this Agreement. [\*\*\*].  
 9  
 (b)  
Volume Commitment and Duration  
The Purchase Commitment is subject to RENAISSANCE maintaining its ability to supply COMPANY’s Requirements, and if RENAISSANCE [\*\*\*] or is unable to supply COMPANY’s Requirements of Product for a period exceeding [\*\*\*] (a “Supply Failure”), then the Purchase Commitment will be suspended, provided that upon the resumption of RENAISSANCE’s ability to supply COMPANY’s Requirements [\*\*\*], the Purchase Commitment will be reinstated.  
[\*\*\*].  
[\*\*\*].  
 2.2  
Supply of Materials  
 (a)  
Materials Supplied by COMPANY  
If COMPANY is to supply any material for Manufacture of Product as set forth under this Section 2.2, such material shall be described in Schedule C (“COMPANY Material”). COMPANY shall notify RENAISSANCE, in writing of any changes or amendments to Schedule C. COMPANY shall provide RENAISSANCE with COMPANY Material [\*\*\*] expense along with Certificates of Analysis and SDSs relating to such COMPANY Material in accordance with Section 2.4 at a minimum of [\*\*\*] prior to RENAISSANCE’s scheduled production of Product requiring such COMPANY Material and in sufficient amounts for RENAISSANCE’s Manufacture of Product, but not to exceed the greater of (i) quantities necessary to support [\*\*\*] of the most recently-supplied Forecasted Needs, and (ii) any [\*\*\*]. In addition, COMPANY Material in excess of [\*\*\*] of the most recently- supplied Forecast Needs shall be either subject to storage fees in accordance with Schedule D or returned to COMPANY, [\*\*\*]. All COMPANY Material shall be shipped to RENAISSANCE [\*\*\*]. In the event COMPANY ships or causes to ship  
 10  
such COMPANY Material [\*\*\*], [\*\*\*] shall invoice [\*\*\*] for the cost of the freight [\*\*\*], which invoice shall be paid [\*\*\*] promptly upon receipt. COMPANY shall be responsible for the quality of all COMPANY Material. COMPANY shall be responsible for the payment of [\*\*\*] and [\*\*\*] incident to [\*\*\*] of COMPANY Material delivered to RENAISSANCE. For each lot of COMPANY Material supplied by COMPANY, RENAISSANCE shall [\*\*\*] as agreed to in the Specifications unless COMPANY has made arrangements in writing for [\*\*\*]. In the event that any COMPANY Material requires RENAISSANCE to [\*\*\*] that is not included in the Specifications, RENAISSANCE will [\*\*\*] and may charge COMPANY for those services at the [\*\*\*]. COMPANY shall deliver all COMPANY Material so that it is received by RENAISSANCE with not less than [\*\*\*] of shelf life remaining at the time of receipt. RENAISSANCE shall have the right to reject any [\*\*\*] COMPANY Material which does not meet the Specifications in accordance with Section 2.3. To the extent required by Applicable Law, COMPANY is responsible for auditing the facilities of the COMPANY Material, and COMPANY agrees to provide RENAISSANCE, upon RENAISSANCE’s request, a current copy of the audit report of these facilities, subject to COMPANY’s confidentiality obligations to the relevant Third Parties. RENAISSANCE warrants that it will maintain, for the benefit of COMPANY, complete and accurate records of the inventory of all such COMPANY Material. RENAISSANCE will provide to COMPANY a [\*\*\*] report of the ending [\*\*\*] inventory balance of each type of COMPANY Material stored at RENAISSANCE. [\*\*\*]. RENAISSANCE will use the first-expiring, first-out method of inventory management for COMPANY Material. RENAISSANCE shall not transfer, distribute or release any COMPANY Material to any Third Party without the COMPANY’s prior written consent, except to its Representatives conducting activities on behalf of RENAISSANCE, provided that such any such Representative is bound by written agreements or are otherwise bound to retain and use the COMPANY Material only in the manner permitted under this Agreement and are subject to non-use, confidentiality and intellectual property obligations not less stringent than those provided for in Article IX and Article VII, respectively. RENAISSANCE will only use COMPANY Material as authorized under this Agreement. Risk of loss and damage to COMPANY Material shall remain with [\*\*\*] (i) in the case of [\*\*\*], at all times, and (ii) in the case of all other [\*\*\*] Material, until [\*\*\*] Material is delivered to RENAISSANCE following which [\*\*\*] will bear all risk of loss or damage to [\*\*\*] Material until such [\*\*\*] Material is returned to [\*\*\*] or delivered to [\*\*\*] as part of a completed Product.  
 11  
 (b)  
Materials Supplied by RENAISSANCE  
RENAISSANCE shall be responsible for the supply of all materials, other than the COMPANY Material, necessary for the Manufacture of Product (“RENAISSANCE Material”). [\*\*\*].  
 (c)  
Packaging and Labeling  
COMPANY shall provide RENAISSANCE with Specifications (including art proofs) for Packaging and Labeling, and RENAISSANCE shall [\*\*\*] in accordance with the Specifications. As between the parties, prior to the applicable Launch Date, [\*\*\*] shall be responsible for obtaining labeler codes, drug listings and the National Drug Code (NDCs), or the equivalents of the same in non-U.S. parts of the Territory, for use in connection with the sale of Product.  
 (d)  
Additional Charges  
COMPANY shall be responsible for any additional charges [\*\*\*], and incurred in the procurement of any materials and/or Packaging and Labeling components (as detailed in the immediately preceding sub-sections (a), (b) and (c)) required for the Manufacture of Product [\*\*\*].  
 2.3  
Materials Testing  
All materials (including COMPANY Material and RENAISSANCE Material) and Packaging components shall, when received by RENAISSANCE, be submitted to analysis and evaluation in accordance with RENAISSANCE’s SOPs to determine whether or not such materials meet the Specifications. The cost of all such analyses and evaluations shall be borne by [\*\*\*], except as otherwise expressly provided in Section 2.2. RENAISSANCE agrees to maintain and, if necessary, make available records of all such analyses and evaluations. If RENAISSANCE  
 12  
determines that any COMPANY Material does not meet the Specifications, RENAISSANCE shall promptly notify COMPANY thereof, and COMPANY shall have the right to conduct such analysis and evaluation (or engage a Third Party to conduct such analysis and evaluation), subject to Section 2.7(d). COMPANY hereby acknowledges and agrees that RENAISSANCE’s sole and exclusive obligations with regard to the quality of COMPANY Material are set forth in this Section 2.3 and the Quality Agreement and that, provided RENAISSANCE has complied with its obligations under this Section 2.3 and the Quality Agreement, RENAISSANCE will not be responsible for any Product defects caused by COMPANY Material.  
 2.4  
Safety Data Sheets  
Prior to RENAISSANCE’s receipt and testing, and as a condition precedent to any testing or formulation work by RENAISSANCE pursuant to this Agreement, COMPANY shall provide SDSs to RENAISSANCE for finished Product, COMPANY Material and all components necessary for the Manufacture of Product, excluding RENAISSANCE Material. RENAISSANCE shall presume any components or Product requiring disposal to be hazardous, unless otherwise provided in the SDS information provided.  
 2.5  
Commencement of Manufacturing for New Products  
Not later than [\*\*\*] prior to the estimated delivery date of a new Product (or an SKU of an existing Product), COMPANY agrees to notify RENAISSANCE of its delivery requirements for such new Product (or SKU of an existing Product). COMPANY shall provide Forecasted Needs covering the [\*\*\*] period subsequent to the first Launch Date for such new Product for each country in the Territory in order to ensure timely delivery of Product for the initial sales and marketing campaign. Firm orders shall be issued for the first [\*\*\*] of the COMPANY’s Forecasted Needs [\*\*\*].  
 2.6  
Purchase Orders  
 (a)  
Purchase of Product  
Product shall be ordered by COMPANY by the issuance of [\*\*\*]. RENAISSANCE will accept all purchase orders submitted by COMPANY in accordance with this Section 2.6, provided that (i) the total number of Batches does exceed [\*\*\*] (B) [\*\*\*], and (ii) [\*\*\*] (the “Maximum  
 13  
Purchase Order Quantity”). Promptly following receipt of a purchase order (and in no event later than [\*\*\*] following such receipt), RENAISSANCE shall [\*\*\*].  
 (b)  
Forecasted Needs  
COMPANY shall provide RENAISSANCE with a written, non-binding [\*\*\*] projection as to its Forecasted Needs, specifying the number of Batches on a Product-by-Product and [\*\*\*] basis. Such Forecasted Needs shall be updated by COMPANY [\*\*\*] on or before the [\*\*\*] of each calendar [\*\*\*] on a rolling [\*\*\*]. It is understood and agreed that with respect to all Forecasted Needs issued to RENAISSANCE by COMPANY pursuant to the terms hereof, the Forecast Needs for the first [\*\*\*] thereof are not subject to modification and shall [\*\*\*]. COMPANY shall issue a purchase order to RENAISSANCE for such quantity of Product concurrent with the delivery of such Forecasted Needs. RENAISSANCE may initiate production of Product up to [\*\*\*] prior to the requested delivery date in order to accommodate fluctuations in production demands, provided that RENAISSANCE will set a target to release each Batch within [\*\*\*] after filling. The remaining [\*\*\*] of the Forecasted Needs shall be utilized by RENAISSANCE for purposes of planning material acquisition on behalf of COMPANY and RENAISSANCE production planning. RENAISSANCE agrees to [\*\*\*]  
 14  
Any such material which is subsequently rendered in excess of that required to support up to [\*\*\*] of COMPANY’s Forecasted Needs may be subject to [\*\*\*] and [\*\*\*], and RENAISSANCE may require [\*\*\*] of such RENAISSANCE Material.  
 (c)  
Required Lead Time  
COMPANY shall issue written purchase orders for Product to RENAISSANCE at least [\*\*\*] prior to the requested delivery dates (the “Required Lead Time”), provided that COMPANY hereby acknowledges and agrees that for RENAISSANCE to accept any purchase order in excess of the Maximum Purchase Order Quantity (which acceptance is subject to Section 2.6(a)), a longer lead time may be necessary.  
 (d)  
Contents of Purchase Orders  
COMPANY’s purchase orders shall designate the desired quantities of Product, delivery destination, and delivery dates. The terms and conditions of this Agreement shall be controlling over any conflicting terms and conditions stated in COMPANY’s purchase order or RENAISSANCE’s invoice, Acknowledgement or other standardized document, unless the parties mutually agree in writing therein.  
 2.7  
Rejected Product  
 (a)  
Rejection of Product by COMPANY  
Prior to shipment, all Product shall be submitted to inspection and evaluation in accordance with RENAISSANCE’s SOP and the terms and conditions of this Agreement to determine whether or not said Product meets the Specifications. COMPANY may [\*\*\*] (“Rejected Product”). COMPANY shall promptly, but in no event later than [\*\*\*] after its receipt of any shipment of Product and related Batch Documentation (as described in Section 5.2), notify RENAISSANCE in writing of COMPANY’s [\*\*\*], and any claim relating to the [\*\*\*] and, failing such notification, shall be deemed to have accepted [\*\*\*]; provided that, COMPANY may revoke [\*\*\*] and [\*\*\*] any Product contained in such [\*\*\*] within [\*\*\*] of receipt thereof for any [\*\*\*] and COMPANY notifies RENAISSANCE thereof within [\*\*\*] after such [\*\*\*] is discovered. Such notice to RENAISSANCE shall specify why the [\*\*\*] failed to [\*\*\*]. COMPANY shall grant to RENAISSANCE the right to [\*\*\*].  
 15  
 (b)  
Refunds or Replacement of Rejected Product  
As to any Rejected Product (including phases of or complete Batches of bulk product) for which [\*\*\*] has responsibility for costs pursuant to Section 2.7(c) below, [\*\*\*] shall, at [\*\*\*] election (i) refund [\*\*\*] for the amount paid by [\*\*\*] for such Rejected Product, or (ii) replace such Rejected Product promptly within the shortest practical time. The amount refunded and/or replacement cost for any Batch of Rejected Product shall be reasonably allocated as set forth in Section 2.7(c). Upon [\*\*\*] election, [\*\*\*] shall make arrangements with [\*\*\*] for the return or disposal of Rejected Product in accordance with Applicable Law.  
 (c)  
Responsibility for Costs  
For each validation Batch produced by RENAISSANCE [\*\*\*], [\*\*\*] shall bear [\*\*\*] of all costs directly related to and invoiced for such validation Batch, [\*\*\*], which shall be conducted and managed by [\*\*\*] in accordance with Applicable Law. With respect to Rejected Product resulting from [\*\*\*], [\*\*\*]; in each case rendering the Rejected Product unmarketable (collectively, “[\*\*\*] Fault”), then [\*\*\*] shall bear [\*\*\*] of the [\*\*\*]. In the event a Rejected Product results other than [\*\*\*] Fault (including [\*\*\*]) rendering the Product unmarketable, [\*\*\*] shall bear the [\*\*\*]. Destruction of Rejected Product shall be in accordance with Applicable Law. The party conducting the destruction shall also provide to the other party all manifests and other applicable evidence of proper destruction as may be required by Applicable Law.  
 16  
 (d)  
Resolution of Conflict  
In the event of: (i) a conflict between the parties with respect to the conclusions to be drawn from any test results or (ii) a difference of opinion between the parties regarding the [\*\*\*] with respect to any Product in such Batch, in each of clause (i) or (ii) that is not resolved by the parties within [\*\*\*] following [\*\*\*], a sample of such Rejected Product shall be submitted by [\*\*\*] to an independent laboratory or recognized industry expert mutually agreed in writing by the parties for testing against the Specifications and any other mutually agreed tests, utilizing the methods set out in the Specifications or as otherwise mutually agreed by the parties. The fees and expenses of such laboratory testing shall be borne [\*\*\*], unless otherwise agreed to by the parties.  
 (e)  
Product Recall  
Each party will immediately inform the other in writing if it believes one or more Batches should be subject to recall from distribution, withdrawal or some other field action. To the extent permitted by Applicable Law and public safety, the parties will confer before initiating any recall or other field action; provided that [\*\*\*].  
In the event (i) any Regulatory  
Authority issues a request, directive or administrative order that Product be recalled, (ii) a court of competent jurisdiction orders a Product recall, or (iii) COMPANY reasonably determines that any Product should be recalled, the parties shall take all appropriate corrective actions which are reasonable under the circumstances. [\*\*\*] shall initially bear the cost thereof and shall carry out the recall in accordance with best industry practices. In the event that such recall results [\*\*\*] from [\*\*\*], [\*\*\*] shall be responsible for the [\*\*\*] of the recall, [\*\*\*], as well as for the [\*\*\*]. The parties shall each maintain traceability records as are sufficient and as may be necessary to permit a recall.  
 2.8  
Product Price  
 (a)  
Manufacturing Fee  
Each initial Manufacturing Fee to be paid by COMPANY to RENAISSANCE is listed in Schedule B. On the first day of [\*\*\*] of each [\*\*\*] following the Effective Date, the applicable Manufacturing Fee for property designated for commercial sale in the U.S. (as shown in Schedule B, Table 1) [\*\*\*] be adjusted by the change in the most recently published monthly Producer Price Index for Pharmaceutical Preparation Manufacturing PCU 325412, issued by the Bureau of Labor Statistics, U.S. Department of Labor (“PPI”), or comparable successor index, in [\*\*\*] of the preceding [\*\*\*] as compared to the [\*\*\*] of the most recently-completed [\*\*\*], provided that (i) the increase during the period commencing on the Effective Date and ending on the first U.S. Launch Date may not exceed [\*\*\*] during any [\*\*\*] period, and (ii) the total increase for the remainder of the Initial Term may not exceed [\*\*\*]. The Manufacturing Fee for Product designated for commercial sale in the E.U. and the Other Countries will not be subject to adjustment during the Initial Term.  
 17  
The Manufacturing Fee for any new Product not initially included in Schedule B shall be negotiated in good faith, and RENAISSANCE and COMPANY shall arrive at a mutual agreement with respect to the Manufacturing Fee prior to the time of first production.  
 (b)  
Materials Fee  
The estimated Materials Fee to be paid by COMPANY to RENAISSANCE is listed in Schedule B and will be reset [\*\*\*] prior to the commencement of Manufacturing Product to be sold on the Launch Date for that Product. Thereafter, the Materials Fee for that Product will be adjusted [\*\*\*] at the beginning of each [\*\*\*] and Schedule B shall be amended accordingly based on [\*\*\*]. In the event, however, that the total underlying costs of Materials Fee for a Product increases or decreases during any [\*\*\*] by more than [\*\*\*]. The Materials Fee for any new Product not initially included in Schedule B shall be established by mutual agreement of the parties prior to the time of first production.  
 (c)  
Taxes  
COMPANY agrees that the [\*\*\*] and [\*\*\*] will be exclusive of, and that [\*\*\*] shall bear, all taxes, whether direct or indirect [\*\*\*], levies, and duties ([\*\*\*]) as may be imposed on the sale of Product under this Agreement [\*\*\*], and [\*\*\*] shall be responsible for the timely payment of such amounts to such governmental body or authority.  
 2.9  
Payment  
Payment for all deliveries of Product and services shall be made in U.S. Dollars (USD), net [\*\*\*] after the date of RENAISSANCE’s invoice therefor. Invoices shall be generated upon [\*\*\*] of Product from RENAISSANCE. Total invoice price shall be equal to [\*\*\*], plus any other additional amounts listed in Schedule B. Payment shall be made by check, wire transfer, electronic fund transfer or through other instrument accepted by RENAISSANCE. Payment by wire or electronic fund transfer should be made to the following:  
 18  
2.10  
Late Payment  
Without prejudice to any other remedies, including the rights to claim for further damages, any undisputed amount not paid by COMPANY within the applicable time set forth in Section 2.9 shall be subject to a late fee of [\*\*\*] of total invoice which shall be added [\*\*\*] for late payments. RENAISSANCE, [\*\*\*], has the right to discontinue COMPANY’s credit on future orders and to put a hold on any production or shipment of Product if COMPANY’s [\*\*\*]. Such hold on production or shipment shall not constitute a breach of this Agreement by RENAISSANCE. In the event credit is discontinued, a [\*\*\*] material deposit paid by COMPANY to RENAISSANCE will be required prior to RENAISSANCE ordering materials, a [\*\*\*] Manufacturing Fee deposit will be required prior to RENAISSANCE manufacturing any Product and the balance of the invoice must be paid in full prior to shipment.  
 2.11  
Recordkeeping  
RENAISSANCE will prepare, and shall cause its Affiliates or any permitted subcontractors to prepare, in English, records of documents, information, data and materials used or generated under this Agreement in a professional manner so as to permit COMPANY to review such records without disclosing to COMPANY any Third Party confidential or proprietary information. Representatives of COMPANY shall, upon reasonable notice to RENAISSANCE, have access to and shall be permitted to review all such records during the Term and during the applicable retention period thereof. Upon COMPANY’s request, RENAISSANCE shall provide to COMPANY a copy of any or all such records.  
 19  
2.12  
Expansion into Secondary Territory  
COMPANY will initially be selling Product only in the Primary Territory, but COMPANY may later elect to sell Product in the Secondary Territory. In the event that COMPANY wishes to commence sale of Product in any country of the Secondary Territory, COMPANY [\*\*\*] provide RENAISSANCE reasonable advance notice that COMPANY wishes to schedule an audit of the Regulatory Authority for that country, and RENAISSANCE will allow and support that audit. Within [\*\*\*] after receiving the results of that audit, including any additional modifications to its Manufacturing and quality controls that will be required to comply with that audit, RENAISSANCE will advise COMPANY of the costs associated with making the required modifications, which shall be paid for by [\*\*\*] if the COMPANY elects to proceed with the expansion. [\*\*\*] agrees to reimburse RENAISSANCE for all of its expenses, at the [\*\*\*], for all time spent by RENAISSANCE regarding any request by COMPANY to sell Product in any country of the Secondary Territory [\*\*\*]. Further, regardless of any expansion into a country of the Secondary Territory, COMPANY hereby acknowledges and agrees that RENAISSANCE makes no representations and warranties regarding its compliance with Applicable Law in any jurisdictions other than the Primary Territory and will charge for any future inspections conducted by any Regulatory Authority other than the FDA and the EMA pursuant to Section 5.5.  
 2.13  
Expansion Outside the Territory.  
COMPANY hereby acknowledges and agrees that COMPANY may not sell Product outside of the Territory. In the event that COMPANY wishes to expand the Territory beyond its scope on the Effective Date, COMPANY shall provide RENAISSANCE reasonable advance notice that COMPANY wishes to schedule an audit of the Regulatory Authority from that jurisdiction, and RENAISSANCE will allow and support that audit. Within [\*\*\*] after receiving the results of that audit, including any additional modifications to its Manufacturing and quality controls that will be required to comply with that audit, RENAISSANCE will advise COMPANY whether RENAISSANCE will implement the modifications provided for in the audit report, which RENAISSANCE may determine in its sole discretion. If RENAISSANCE elects to implement such modifications such that the Territory may be expanded, RENAISSANCE shall notify COMPANY of that determination and the costs associated with making the required modifications, which shall be paid for by [\*\*\*] if COMPANY elects to proceed with the expansion. COMPANY also agrees to reimburse RENAISSANCE for all of its expenses, at the [\*\*\*], for all time spent by RENAISSANCE regarding any request by COMPANY  
 20  
to expand the Territory [\*\*\*]. Further, regardless of any Territory expansion, COMPANY hereby acknowledges and agrees that RENAISSANCE makes no representations and warranties regarding its compliance with Applicable Law in any jurisdictions other the Primary Territory and will charge for any future inspections conducted by any Regulatory Authority other than the FDA and the EMA pursuant to Section 5.5.  
III—DELIVERY AND RISK OF LOSS  
 3.1  
Delivery  
Delivery of Product shall be in accordance with COMPANY instructions; provided that COMPANY instructions comply with Applicable Law. At COMPANY’s request, (a) RENAISSANCE shall hold Product in RENAISSANCE’s warehouse for up to [\*\*\*], and (b) RENAISSANCE may, in its sole discretion, hold such Product for more than [\*\*\*] provided that (i) RENAISSANCE may [\*\*\*] in accordance with Schedule D attached hereto; and (ii) [\*\*\*]. At the time of release, RENAISSANCE shall to the extent applicable provide to COMPANY all reasonably required shipping and import/export documentation.  
 3.2  
Delivery Terms  
The delivery terms of Product shall be [\*\*\*]. Title to, and risk of loss for, Product shall transfer from RENAISSANCE to COMPANY when [\*\*\*]. [\*\*\*] shall bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance.  
 3.3  
Claims  
The weights and tares set forth in RENAISSANCE’s invoice shall govern unless incorrect. Claims relating to quantity, weight and loss or damage to any Product sold under this Agreement shall be waived by COMPANY unless made within (i) [\*\*\*] of receipt of Product by COMPANY or its designee with respect to Product designated for commercial sale in the E.U. and the Other Countries, and (ii) [\*\*\*] of receipt of Product by COMPANY with respect to all other Product.  
 21  
IV - TERM AND TERMINATION  
 4.1  
Term  
The initial term of this Agreement shall commence on the Effective Date hereof and will continue (a) for Product designated for commercial sale in in the U.S. until the earlier of the fifth (5th) anniversary of the (i) Target U.S. Launch Date and (ii) the initial U.S. Launch Date (the “U.S. Initial Term”), and (b) for Product designated for commercial sale in the E.U. and the Other Countries, the earlier of the fifth (5th) anniversary of (i) the Target E.U. Launch Date and (ii) the initial E.U. Launch Date (the “E.U. and Other Country Initial Term” and with the U.S. Initial Term, each an “Initial Term”); in each case, unless sooner terminated pursuant to Section 4.2. Thereafter, each of the U.S. Initial Term and the E.U. and Other Country Initial Term shall automatically renew for periods of twenty-four (24) months (each a “U.S. Renewal Term” and an “E.U. and Other Country Renewal Term ” respectively and each a “Renewal Term” and collectively with each Initial Term, the “U.S. and Term and “E.U. and Other Country Term” and collectively, the “Term”), unless either party shall give notice to the other to the contrary not later than twenty-four (24) months prior to the expiration of the Initial Term or the then-current Renewal Term. For clarity, each of the U.S. Term and the E.U. and Other Country Term may be independently or collectively renewed pursuant to this Section 4.1.  
 4.2  
Early Termination  
This Agreement may be terminated at any time upon the occurrence of any of the following events:  
 (a)  
Either party shall have the right to terminate this Agreement upon written notice, if the other party commits a material breach or material default in the performance or observance of any of its obligations under this Agreement and such material breach or material default is not cured within [\*\*\*] after receipt by such party of written notice from the non-breaching party specifying the material breach or material default. The party allegedly in default may cure the asserted breach or pursue the dispute resolution process specified in Section 12.6 within the notice period.  
 (b)  
If either party applies for or consents to the appointment of a receiver, trustee or liquidator for all or a substantial part of its assets; admits in writing its inability to pay its debts generally as they mature; makes a general assignment for the benefit of creditors; is adjudicated a bankrupt; submits a petition or an answer seeking an arrangement with creditors; takes advantage of any insolvency law except as a creditor; submits an answer admitting the material allegations of a petition in bankruptcy or insolvency proceeding; has an order, judgment or decree entered by any court of competent jurisdiction approving a petition seeking reorganization of such party or appointing a receiver, trustee or liquidator for such party, or for all or a substantial part of any of its assets and such order, judgment or decree shall continue unstayed and in effect for a period of ninety (90) consecutive days; files a voluntary petition of bankruptcy or fails to remove an involuntary petition in bankruptcy filed against it within ninety (90) days of the filing thereof, the other party may terminate this Agreement immediately upon providing written notice to the first party.  
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 (c)  
This Agreement may be terminated by either party on a Product-by-Product basis on immediate notice if the manufacture, distribution or sale of any of Product in the Territory would materially contravene any Applicable Law; provided, however, no termination shall occur if the manufacture, distribution or sale of such the Product can be brought into compliance with such Applicable Law within ninety (90) days following the notice of non-compliance or violation.  
 (d)  
Either party shall have the right to terminate this Agreement in the U.S. upon ten (10) days’ prior written notice to the other party upon the occurrence of a U.S. Termination Event. If, at the time of such U.S. Termination Event, COMPANY has obtained a marketing authorization in the E.U., then the parties will negotiate in good faith for a thirty (30) day period following such U.S. Termination Event to restructure the commercial terms of this Agreement for it to apply only to the E.U. and the Other Counties (or any sub-set thereof); provided further that if the parties cannot agree on such restructured terms (or if COMPANY has not then obtained a marketing authorization in the E.U.) then this Agreement will terminate as to the entire Territory.  
 (e)  
Either party may terminate this Agreement in the case of a Force Majeure Event pursuant to the terms and conditions set forth in Section 12.4.  
 (f)  
Further to this Section 4.2, a violation by either party of a trade control law and/or an anti-corruption law, including the U.S. Foreign Corrupt Practices Act, shall be grounds for immediate termination of this Agreement by the non-offending party upon written notice given to the offending party.  
 4.3  
Effects of Termination  
In the event of any expiration or termination of this Agreement, (a) COMPANY shall reimburse RENAISSANCE for: [\*\*\*] and other amounts set forth in Schedule B and (b) RENAISSANCE shall promptly deliver to COMPANY all COMPANY Material and [\*\*\*].  
 23  
4.4  
Survival  
Any expiration or termination of this Agreement shall not relieve either party of any obligation accruing prior to such termination or expiration. Sections [\*\*\*] and Articles [\*\*\*] (including all of their Sections) shall survive the expiration or termination of this Agreement for any reason.  
V—CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE  
 5.1  
Quality and Safety Data Exchange Agreement  
Not less than [\*\*\*] before the [\*\*\*], the parties shall enter into a mutually agreeable Quality Agreement (the “Quality Agreement”), in accordance with RENAISSANCE’ SOP’s and in conformity with any Regulatory Authority requirements and Applicable Law setting forth the parties’ obligations with regard to quality matters and Product complaints and adverse drug experiences. Until a Quality Agreement is entered into between the parties, this Agreement, in conjunction with all applicable Regulatory Authority requirements and Applicable Law, shall govern the parties’ responsibilities with respect to procedures impacting the identity, strength, quality, purity and all other aspects of the Product.  
 5.2  
Batch Documentation  
In accordance with Applicable Law and the Quality Agreement, RENAISSANCE shall [\*\*\*]. COMPANY hereby acknowledges and agrees that reporting or documentation not expressly required under this Agreement may be subject to additional, reasonable charge by RENAISSANCE.  
 5.3  
Stability Testing and Retention Samples  
RENAISSANCE shall perform stability testing in accordance with RENAISSANCE’s SOPs, or as separately agreed to in accordance with this Agreement, the Quality Agreement, or a CCR, for each Batch. During each year during the Term, RENAISSANCE will provide to COMPANY the Annual Product Review for the Batches Manufactured during the applicable review period within  
 24  
[\*\*\*] following the closing date of the annual reporting period. If COMPANY elects to perform its own stability testing on Product, COMPANY agrees to provide RENAISSANCE with a copy of the results from such testing on an annual basis. RENAISSANCE shall keep such samples and records in respect of Product as is required by Applicable Law for such period of time as may be required by Applicable Law, subject an agreement on fees for this service to be set forth in the applicable Project Protocol not to exceed [\*\*\*]. Upon the termination of this Agreement, at the sole discretion of COMPANY, RENAISSANCE shall, either dispose of such samples and records or ship such samples and records to COMPANY, at COMPANY’s written request [\*\*\*].  
 5.4  
Validation Work or Additional Testing  
It is understood by the parties that the responsibility for any validation work relating the activities hereunder shall be the sole responsibility of COMPANY. If COMPANY desires for RENAISSANCE to conduct any validation work or additional testing in connection with the Product, RENAISSANCE and COMPANY shall enter into a specific written Project Protocol establishing methodology and pricing for such services, not to exceed [\*\*\*]. It is understood between the parties that if RENAISSANCE is required by any Regulatory Authority to perform validation studies or additional testing in order to continue Manufacturing Product in accordance with Applicable Law, and RENAISSANCE and COMPANY cannot reach an agreement on a written Project Protocol, then RENAISSANCE shall be under no obligation to continue to Manufacture the affected Product.  
 5.5  
Regulatory Inspection  
RENAISSANCE will permit any Regulatory Authority to conduct inspections of the Facility as such Regulatory Authority may request, [\*\*\*], and will cooperate with Regulatory Authorities with respect to the inspections and any related matters, in each case that is related to each Product hereunder. RENAISSANCE will give COMPANY prior notice, to the extent practicable, of any such inspections and will permit COMPANY (and/or its Representatives) to assist in the preparation for such inspections. RENAISSANCE will coordinate with COMPANY where practicable to enable COMPANY to be [\*\*\*] the Facility while the inspection is being conducted. In addition, COMPANY may be present at the inspection (i) if the Regulatory Authority conducting the inspection requests in writing that COMPANY be present at the inspection or (ii) to respond to any specific question or issue agreed to in advance by the respective quality teams if such specific question or issue is raised by the Regulatory Authority during the inspection. In  
 25  
addition, RENAISSANCE shall as soon as practicable (and in any event within [\*\*\*] following receipt of notice thereof) advise COMPANY if the Regulatory Authority requests or requires information or changes regarding or impacting any Product or if RENAISSANCE receives any correspondence from the Regulatory Authority regarding or impacting any Product or that would materially affect RENAISSANCE’s ability to meet its obligations under this Agreement and provide COMPANY copies of such correspondence, redacted as necessary to protect Third-Party confidential information. In addition, COMPANY shall promptly inform RENAISSANCE of any correspondence from the applicable Regulatory Authority regarding any Product that would materially affect COMPANY’s or RENAISSANCE’s ability to meet its obligations under this Agreement and provide RENAISSANCE copies of such correspondence, redacted as necessary to protect Third-Party confidential information. Each party shall notify the other promptly of any materially adverse inspections by the Regulatory Authorities which pertain to the Product or to the Facility, or any occurrences or information that arise out of any activities that have or could reasonably be expected to have adverse regulatory compliance or reporting consequences concerning any Product or which might otherwise be reasonably expected to adversely affect the supply by RENAISSANCE of Product to COMPANY. Each party will provide to the other party upon request all information reasonably necessary to enable the requesting party to respond to any request of a Regulatory Authority regarding any Product under this Agreement. RENAISSANCE will discuss with COMPANY any Regulatory Authority correspondence regarding or impacting any Product or that would materially RENAISSANCE’s ability to meet its obligations under this Agreement and will consider in good faith incorporating any COMPANY comments into its responses to such correspondence.  
 5.6  
Regulatory Filings  
COMPANY shall bear sole responsibility for all Regulatory Approvals, Regulatory Filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies necessary to sell and distribute any Product in the Territory. COMPANY further warrants that, except for any approvals, permits or authorizations with respect to the Facility or the operation of the business of RENAISSANCE, its Affiliates and their respective subcontractors, COMPANY has obtained or will obtain prior to the first Launch Date any and all necessary approvals from all applicable Regulatory Authorities necessary to Manufacture and distribute any Product under this Agreement.  
Upon RENAISSANCE’s reasonable request, COMPANY agrees to provide RENAISSANCE with copies of any sections of NDA’s, ANDA’s, 510(k)’s or other Regulatory Filings and Regulatory Authority correspondence applicable to Product Manufactured by RENAISSANCE, and copies of any changes in or updates of same, in each case, to the extent necessary or reasonably useful for RENAISSANCE to perform its obligations hereunder. Upon COMPANY’s request and at COMPANY’s expense, RENAISSANCE will promptly provide COMPANY with information and data in RENAISSANCE’s possession or control that is necessary for obtaining or maintaining Regulatory Approval for each Product in the Territory, including information relating to the Facility. RENAISSANCE will cooperate with COMPANY’s Representatives with respect to its obligations to submit or report information to the Regulatory Authority for any Product pursuant to Applicable Law.  
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5.7  
Access to RENAISSANCE’s Facilities  
During the Term and through the valid shelf life of the last shipment of Product, COMPANY shall have the right, subject to the confidentiality obligations contained in this Agreement and providing RENAISSANCE with reasonable prior notification, to access the Facility during normal business hours, for the [\*\*\*] purpose of auditing RENAISSANCE’s compliance with Applicable Law. Furthermore, such audits shall be limited in frequency to [\*\*\*] (unless for cause) for [\*\*\*] maximum of [\*\*\*] COMPANY Representatives all of whom shall be subject to the confidentiality obligations not less restrictive than those set forth in this Agreement. COMPANY shall be responsible for its own costs in connection with the audit or inspection permitted under this Section 5.7. In addition, RENAISSANCE will permit COMPANY Representatives [\*\*\*] to visit the Facility or participate virtually [\*\*\*] in order to participate in [\*\*\*] quality and business reviews (each a “QBR”) for the purpose of reviewing and evaluating metrics, data and other information related to Product quality during the prior quarter. [\*\*\*].  
VI – REPRESENTATIONS AND WARRANTIES  
 6.1  
RENAISSANCE Product Warranty  
RENAISSANCE represents and warrants that all Product Manufactured and supplied pursuant to this Agreement will (i) have been [\*\*\*], and (ii) be free and clear from any security interest, lien or other encumbrance (the “RENNAISSANCE Product Warranty”).  
 27  
6.2  
No Debarment; RENAISSANCE Permits; User Fees  
RENAISSANCE represents and warrants that neither it, its Affiliates nor any of their Representatives that are performing any activities under this Agreement has been debarred under Article 306 of the Act, 21 U.S.C. §335a(a) or (b) its successor provisions, or any equivalent foreign or local law, rule or regulation, and neither appears on the United States Food and Drug debarment list. RENAISSANCE represents and warrants that neither it, its Affiliates nor any of their Representatives that are performing any activities under this Agreement has committed any crime or conduct that could result in such debarment or exclusion from any governmental healthcare program. RENAISSANCE represents and warrants that, [\*\*\*], no investigations, claims or proceedings with respect to any such crimes or conduct are pending or threatened against it, its Affiliates or any of their Representatives that are performing any activities under this Agreement. In addition, RENAISSANCE covenants that it will not [\*\*\*] any person if, [\*\*\*], such a person (i) is under investigation by the FDA for debarment or is presently debarred by the FDA Article 306 of the Act, 21 U.S.C. §335a(a) or (b) or its successor provisions, or any equivalent foreign or local law, rule or regulation, or (ii) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions. RENAISSANCE agrees and undertakes to promptly notify COMPANY if it, its Affiliates or any of their Representatives that are performing any activities under this Agreement becomes debarred or proceedings have been initiated against either of them with respect to debarment, whether such debarment or initiation of proceedings occurs during or after the Term.  
RENAISSANCE shall obtain and maintain all permits and licenses (including but not limited to all appropriate DEA licenses) with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which RENAISSANCE Manufactures Product. As between the parties, COMPANY shall be responsible for all other Regulatory Approvals, Regulatory Filings, and necessary approvals from all applicable Regulatory Authorities necessary to Manufacture and distribute all Product supplied to it under this Agreement.  
Each party agrees that any user fees or the equivalent thereof under Applicable Law currently in effect or future enactments thereof associated with any intended Regulatory Filing or Regulatory Approval in the Territory shall, as between the parties, be the [\*\*\*]. COMPANY shall comply with the Prescription Drug User Fee Act (Public Law 112-144, Title I) (“PDUFA”) and [\*\*\*] with RENAISSANCE and [\*\*\*] RENAISSANCE in complying with PDUFA.  
 6.3  
Conformity with Applicable Law; COMPANY-Furnished Equipment  
RENAISSANCE represents and warrants that [\*\*\*].  
 28  
6.4  
Compliance of Packaging and Labeling with Applicable Law  
COMPANY warrants that all Labeling copy and artwork approved, designated or supplied by COMPANY shall be in compliance with Applicable Law. Compliance with Applicable Law concerning Packaging and Labeling shall be [\*\*\*]; provided that [\*\*\*] such Packaging and Labeling as provided in Section 2.2(c).  
 6.5  
Mutual Warranties  
Each party hereby represents and warrants to the other party that (a) it is duly organized and validly existing under the laws of the jurisdiction of its organization and has full corporate or limited liability company power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder; (c) this Agreement is legally binding upon it and enforceable in accordance with its terms and conditions; and (d) the execution, delivery and performance of this Agreement by it do not conflict with any agreement, instrument or understanding, oral or written, to which it is a party, or to which it is bound, and it shall not enter into any agreement, instrument or understanding, oral or written, that conflicts with its rights and obligations under this Agreement.  
 6.6  
No Additional Warranties  
RENAISSANCE AND COMPANY MAKE NO REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, PRODUCT LABELING OR PACKAGING, EXCEPT AS EXPRESSLY DETAILED IN THIS AGREEMENT. ALL OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHT, ARE HEREBY DISCLAIMED.  
VII – INTELLECTUAL PROPERTY  
 7.1  
Background Intellectual Property  
Each party shall own and retain all intellectual property rights (a) owned or controlled by such party prior to the Effective Date, or (b) developed or acquired by or on behalf of such party outside of this Agreement (“Background IP”).  
 29  
7.2  
Inventions  
 (a)  
RENAISSANCE shall own all data, work product, results, reports, inventions, improvements, developments, technologies and information, and all intellectual property rights in any of the foregoing, that are developed, conceived, invented, or first reduced to practice by or on behalf of RENAISSANCE or its Affiliates in the performance of activities under this Agreement (“Inventions”), that (i) are [\*\*\*] applicable to manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products and devices, and (ii) are not [\*\*\*] any COMPANY Background IP, COMPANY Confidential Information, COMPANY Materials or any Product (“RENAISSANCE Inventions”). [\*\*\*].  
 (b)  
COMPANY will own all Inventions other than RENAISSANCE Inventions (collectively, “COMPANY Inventions”). RENAISSANCE hereby assigns to COMPANY all of its right, title and interest in and to any COMPANY Inventions. RENAISSANCE agrees to, and shall cause its Affiliates and their Representatives to, execute such documents and take such other actions as COMPANY may reasonably request to evidence and perfect the foregoing assignment and COMPANY’s rights in and to the COMPANY Inventions.  
 7.3  
License Grants  
 (a)  
COMPANY hereby grants to RENAISSANCE a limited, royalty-free, non-exclusive license under COMPANY Background IP and COMPANY Inventions solely to perform its obligations under this Agreement.  
 (b)  
RENAISSANCE hereby grants to COMPANY an irrevocable, perpetual, fully paid-up, non-exclusive license under RENAISSANCE Background IP and RENAISSANCE Inventions to the extent necessary to make, use, sell and otherwise exploit any Product.  
 7.4  
No Implied Licenses  
Except as expressly set forth herein, no right or license is granted under this Agreement by either party to the other party, whether by implication, estoppel or otherwise.  
 7.5  
Trademarks and Trade Names  
 (a)  
Each party hereby acknowledges that it does not have, and shall not acquire any interest in any of the other party’s Trademarks, unless otherwise expressly agreed; except however, that COMPANY hereby grants to RENAISSANCE the right to use the Partner Trade Dress for the sole and exclusive purpose of performing its obligations under this Agreement (and hereby represents and warrants to RENAISSANCE that it has the authority to grant such license).  
 30  
 (b)  
Each party agrees not to use any trade names or trademarks of the other party, except as specifically authorized in writing by the other party in writing, both as to the names or marks which may be used and as to the manner and prominence of use.  
 7.6  
[\*\*\*]  
 [\*\*\*].  
VIII – CHANGES TO PROCESS OR PRODUCT  
 8.1  
Changes by the Parties  
If either party at any time requests a change to any Product to the other party, the parties shall promptly discuss in good faith the scope and cost adjustments, if any, with respect to such change. If the parties agree to such change, including the scope and cost allocations therefor, (a) such change shall be [\*\*\*] reviewed and agreed upon in writing by both RENAISSANCE and COMPANY; (b) the parties shall adjust the [\*\*\*], if necessary, and Schedule B shall be amended accordingly; and (c) [\*\*\*].  
 8.2  
Changes or Fees by Regulatory Authorities  
The parties agree that any changes required by a Regulatory Authority or by Applicable Law shall be incorporated into the Product, subject to the prior written approval of COMPANY, [\*\*\*], via a CCR prior to such incorporation. Any actual or potential additional Product costs, fees or expenses, [\*\*\*] shall be the [\*\*\*]. At the time of such incorporation, such changes shall become part of the Specifications. If RENAISSANCE is required by Regulatory Authority to perform validation studies for purposes of validating new manufacturing process or cleaning procedures or new material and finished Product assay procedures with respect to Product in order to continue to engage in the Manufacture of said Product for COMPANY, such studies shall be conducted in accordance with Section 5.4. Any costs to RENAISSANCE resulting from the operation of this Section 8.2 shall be [\*\*\*] and subject to the terms and conditions set forth in Section 2.9.  
 8.3  
Obsolete Inventory and Raw Material  
Any inventory procured or developed by RENAISSANCE specifically for the Manufacture of Product, [\*\*\*] at the [\*\*\*]. At such time and as instructed by COMPANY, RENAISSANCE will either destroy such obsolete  
 31  
inventory or raw materials or ship such obsolete inventory or raw materials to COMPANY. [\*\*\*] shall bear [\*\*\*] of all shipping and destruction costs related to such obsolete inventory or raw materials. Any such destruction shall be in accordance with Applicable Law, and each party shall also provide the other party with all manifests and other applicable evidence of proper destruction as may be requested by the other party or required by Applicable Law. If RENAISSANCE does not receive disposition instructions from COMPANY within [\*\*\*] from date of notification, obsolete inventory [\*\*\*] shall be subject to [\*\*\*] or destruction at RENAISSANCE’s discretion.  
IX—CONFIDENTIAL INFORMATION  
 9.1  
Confidential Information  
 (a)  
Definition of Confidential Information  
“Confidential Information” means any information provided by or on behalf of a party (the “Disclosing Party”) to the other party (the “Receiving Party”), its Affiliates or their Representatives under the Mutual Confidentiality Agreement between the parties entered into on January 12, 2017(the “Prior CDA”), the R&D Agreement or this Agreement, whether prior to, on, or after the Effective Date. In addition, (a) all RENAISSANCE Background IP and RENAISSANCE Inventions shall be deemed to be the Confidential Information of RENAISSANCE; (b) all COMPANY Background IP and COMPANY Inventions shall be deemed to be the Confidential Information of COMPANY and (c) the terms of this Agreement and all communications between the parties and their Affiliates relating to the subject matters of this Agreement shall be deemed to be Confidential Information of both parties.  
 32  
 (b)  
Obligations of Confidentiality  
During the Term and for [\*\*\*] thereafter, Receiving Party shall (a) not disclose Disclosing Party’s Confidential Information to any Person except as to the Representatives of Receiving Party and its Affiliates, who need to know such Confidential Information in order to perform, or assist Receiving Party in the performance of, its obligations under this Agreement (collectively, “Permitted Recipients”), provided that any such Permitted Recipient is subject to confidentiality obligations not less restrictive than those set forth in this Article IX; (b) not disclose Disclosing Party’s Confidential Information for any purpose other than the purpose of exercising or performing, or assisting in the exercise or performance of, a party’s rights or obligations under this Agreement; and (c) take, and shall cause the Permitted Recipients to whom it discloses Disclosing Party’s Confidential Information to take, at least such precautions as it normally takes with its own confidential and proprietary information to prevent unauthorized disclosure of Disclosing Party’s Confidential Information, but in no event less than reasonable precautions. Receiving Party shall be responsible for any breach of this Article IX by any of its Affiliates or Permitted Recipients, and shall promptly notify Disclosing Party of any breaches of this Article IX.  
 (c)  
Exceptions  
Any other provisions hereof to the contrary notwithstanding, it is expressly understood and agreed by the parties hereto that the obligations of confidence and non-use herein assumed shall not apply to any information which Receiving Party can demonstrate with competent written evidence:  
 (a)  
is at the time of disclosure, or thereafter so becomes, a part of the public domain (other than as a result of, directly or indirectly, any breach of confidentiality or other act or omission by Receiving Party or its Permitted Recipients); or  
 (b)  
was otherwise in Receiving Party’s lawful possession prior to disclosure as shown by its contemporaneous written record (provided that this exception shall not apply to any COMPANY Inventions generated by or on behalf of RENAISSANCE hereunder); or  
 (c)  
is hereafter disclosed to Receiving Party without any obligations of confidentiality by a Third Party that is not in violation of an obligation of confidentiality relative to said information; or  
 (d)  
is independently developed by or on behalf of Receiving Party without any use of or reference to any Confidential Information of Disclosing Party or breach of this Agreement; or  
 (e)  
is by mutual agreement of the parties released from a confidential status.  
 (d)  
Authorized Disclosure  
 33  
Notwithstanding the foregoing, Receiving Party may make disclosures of Disclosing Party’s Confidential Information in the following instances:  
(a) to comply with Applicable Law or as required by an order of a governmental agency, legislative body or court of competent jurisdiction, provided that Receiving Party: (i) provides Disclosing Party with prompt written notice of such requirement, (ii) cooperates with Disclosing Party at Disclosing Party’s expense in connection with Disclosing Party’s reasonable and lawful actions to obtain confidential treatment for such Confidential Information, and (iii) limits such disclosure of Confidential Information to the fullest extent permitted under applicable law. Any Confidential Information that is disclosed pursuant to this paragraph shall remain confidential for all other purposes;  
(b) in Regulatory Filings, including filings, applications and submissions to Regulatory Authorities;  
(c) disclosure to Receiving Party’s Affiliates, to actual or potential (sub)licensees, or collaborators, and to Receiving Party’s and its Affiliates’ Representatives who have a need to know such information in order for Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential (sub)licensee, collaborator, or Representative is bound by similar terms of confidentiality and non-use as set forth in this Article IX, and such Receiving Party shall be liable for any breach thereof by such Affiliates, actual or potential (sub)licensees, collaborators, or Representatives; and  
(d) disclosure to any Third Party in connection with due diligence or similar investigations by such Third Party, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party needs to know such Confidential Information and is bound by reasonable obligations of confidentiality and non-use and such Receiving Party shall be liable for any breach thereof by such Third Party.  
 (e)  
Return of Confidential Information  
Upon the written request of Disclosing Party, Receiving Party will promptly return the Confidential Information of Disclosing Party to Disclosing Party or, if Disclosing Party directs, destroy all Confidential Information of Disclosing Party disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for Receiving Party (i) may retain one (1) copy which may be maintained by Receiving Party for its legal files for compliance and regulatory purposes, and (ii) need not destroy electronic archives and backups made in the ordinary course of business where it would be commercially impracticable to do so including information included in minutes of the board of directors and committees thereof, subject in either case to its obligations of confidentiality herein.  
 34  
9.2  
Publicity  
Except as permitted in this Article IX ,neither party shall issue any press release or other public statement disclosing the existence of or relating to this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed. However, COMPANY shall have sole discretion over the issuance of any press release or public statement regarding the commercial launch of the Product, so long as RENAISSANCE is not named in such release or statement.  
 9.3  
Security Filings  
The parties acknowledge that either or both parties or their Affiliates may be obligated to file under applicable law a copy of this Agreement with governmental authorities, including,, the U.S. Securities and Exchange Commission. Each party and its Affiliates shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available. In the event of any such filing, such party will provide the other party with a copy of this Agreement marked to show provisions for which such party or its Affiliate intends to seek confidential treatment and shall reasonably consider and incorporate the other party’s timely comments thereon to the extent consistent with the legal requirements, with respect to the filing party or Affiliate, governing disclosure of material agreements and material information that must be publicly filed.  
 9.4  
Injunctive Relief  
Each party hereby acknowledges the unique and proprietary nature of the other party’s Confidential Information and agrees that damages at law may be an inadequate remedy for any breach of Receiving Party’s obligations under this Agreement, and that Disclosing Party may suffer great and irreparable injury as a consequence of such breach. Accordingly, Receiving Party agrees that Disclosing Party will be entitled to seek such temporary, preliminary and permanent injunctive relief as may be necessary to remedy or limit such breach, including specific performance of such obligations and an order enjoining Receiving Party from the continuation of, or from any threatened, breach of such obligations. The rights set forth in this Section 9.4 shall be in addition to, and not in lieu of, any other rights which Disclosing Party may have at law or in equity.  
 35  
X - TECHNICAL & DEVELOPMENT SERVICES  
 10.1  
Additional Development  
From time to time, COMPANY may request, in writing, that RENAISSANCE [\*\*\*] (collectively, “Additional Development”) on behalf of COMPANY. If RENAISSANCE  
agrees to perform such Additional Development, RENAISSANCE shall so notify COMPANY within [\*\*\*] of its receipt of COMPANY’s request. To the extent that RENAISSANCE agrees to perform any Additional Development hereunder for COMPANY, RENAISSANCE shall only be obligated to act in good faith and to use reasonable efforts to accomplish the desired results as outlined in a mutually agreed upon Project Protocol issued under this Agreement. Nothing herein shall obligate RENAISSANCE to achieve any specific results with respect to Additional Development and RENAISSANCE makes no warranties or representations with respect thereto or that it will be able to achieve the desired results.  
 10.2  
Project Protocol  
Should RENAISSANCE agree to perform any Additional Development, RENAISSANCE shall submit a written development proposal in the form of a Project Protocol to COMPANY identifying RENAISSANCE’s best estimate of the costs for such Additional Development. This estimate shall include [\*\*\*]. If this estimate is acceptable to COMPANY, and COMPANY so notifies RENAISSANCE by approving the Project Protocol in writing, RENAISSANCE shall begin working on the Additional Development as outlined in the Project Protocol. It is understood between the parties that during any development project unforeseen circumstances may evolve, including termination of any further activity due to unacceptable results, significant reevaluation due to marginal results, etc. RENAISSANCE will promptly notify COMPANY of any such unforeseen circumstances before proceeding at which time either COMPANY or RENAISSANCE may terminate the Additional Development project or mutually agree to amend or completely revise the Project Protocol. In the case where the Additional Development project is terminated or revised, COMPANY will be obligated to pay for [\*\*\*].  
 10.3  
Costs  
Material costs involved will be billed to COMPANY at RENAISSANCE’s [\*\*\*]. The foregoing development costs shall be paid to RENAISSANCE regardless of whether RENAISSANCE is able to accomplish the results which COMPANY requested. All invoices shall be paid by COMPANY in accordance with Section 2.9.  
 36  
XI - INDEMNIFICATION  
 11.1  
Indemnification by RENAISSANCE  
RENAISSANCE shall indemnify, defend and hold harmless, COMPANY, its Affiliates and their respective directors, officers, employees and agents from and against any and all liabilities, damages, claims, demands, losses, costs, or expenses (including reasonable out-of-pocket attorney’s fees) resulting from any Third Party claims made or suits brought against COMPANY, its Affiliates or their respective directors, officers, employees and agents, which arise from RENAISSANCE’s (a) [\*\*\*], (b) violation of [\*\*\*], or (c) [\*\*\*]. Notwithstanding the foregoing, RENAISSANCE’s obligations under this Section 11.1 shall not apply to the extent that any such liabilities are the result of COMPANY’s [\*\*\*], violation of [\*\*\*] or [\*\*\*].  
 11.2  
Insurance by RENAISSANCE  
Until the later of (a) the termination or expiration of this Agreement, or (b) the date when the shelf life of all Product Manufactured has expired, RENAISSANCE shall maintain in full force and effect the following insurance: Product Liability coverage in the minimum amount of [\*\*\*] per occurrence with an annual aggregate amount of [\*\*\*]; Workers Compensation coverage in accordance with all applicable statutory requirements, and Employers Liability coverage of [\*\*\*] per accident/disease/injury; General Liability coverage, including Contractual Liability coverage, with limits of [\*\*\*] per occurrence and [\*\*\*] in the annual aggregate. The limits required may be satisfied through a combination of both primary and excess casualty programs. RENAISSANCE shall provide to COMPANY evidence of the foregoing insurance upon COMPANY’s request, which evidence may be in the form of an original policy or a certificate of insurance issued by the insurance broker.  
 11.3  
Indemnification by COMPANY  
COMPANY shall indemnify, defend, and hold harmless, RENAISSANCE and its Affiliates and their respective directors, officers, employees and agents from and against any and all liabilities, damages, claims, demands, losses, costs or expenses (including reasonable out-of-pocket attorney’s fees) resulting from any Third Party claims made or suits brought against RENAISSANCE, its Affiliates or their respective directors, officers, employees and agents, which arise from COMPANY’s (a) sale, promotion, marketing, distribution or use of any Product delivered by RENAISSANCE to COMPANY under this Agreement, including product liability, strict liability or infringement with the intellectual property rights of any Third Party, (b) gross negligence or willful misconduct, (c) violation of Applicable Law, or (d) breach of this Agreement. Notwithstanding the foregoing, COMPANY’s obligations under this Section 11.3 shall not apply to the extent that any such liabilities are the result of RENAISSANCE’s gross negligence, willful misconduct, violation of Applicable Law or breach of this Agreement.  
 37  
11.4  
Insurance by COMPANY  
Until the later of (a) the termination or expiration of this Agreement, or (b) the date when the shelf life of all Product Manufactured has expired, COMPANY shall maintain in full force and effect: Commercial General Liability insurance covering bodily injury and property damage, premises liability and personal/advertising injury in an amount not less than [\*\*\*] per occurrence with an annual aggregate amount of not less than [\*\*\*]; Product Liability coverage and Contractual Liability coverage in an amount not less than [\*\*\*] per occurrence with an annual aggregate amount of not less than [\*\*\*]. Such evidence of insurance coverage can be in the form of the original policy or a Certificate of Insurance. Upon RENAISSANCE’s request, COMPANY shall provide evidence of the foregoing insurance coverage to:  
[\*\*\*]  
 11.5  
Disclaimer  
EXCEPT WITH RESPECT TO EACH PARTY’S [\*\*\*] (THE “EXTRAORDINARY MATTERS”), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY [\*\*\*] OF ANY KIND, [\*\*\*], INCLUDING ANY [\*\*\*] OR [\*\*\*], IN CONNECTION WITH OR ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT, WHETHER ALLEGED AS A BREACH OF CONTRACT OR TORTIOUS CONDUCT, INCLUDING NEGLIGENCE, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ADDITION, WITH RESPECT TO ALL CLAIMS MADE BY COMPANY AGAINST RENAISSANCE UNDER THIS AGREEMENT, (I) WITH RESPECT TO THE [\*\*\*], THE TOTAL LIABILITY OF [\*\*\*] TO [\*\*\*] SHALL NOT EXCEED [\*\*\*] AND (II) WITH RESPECT TO ALL OTHER MATTERS, SHALL NOT EXCEED [\*\*\*].  
 38  
11.6  
Conditions of Indemnification  
If either party seeks indemnification from the other party under Sections 11.1 or 11.3 hereof, it (a) shall promptly give notice to the other party of any such claim or suit threatened, made or filed against it which forms the basis for such claim of indemnification, provided that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (b) shall permit the indemnifying party to control the defense or settlement of such claim or suit, and (c) shall cooperate fully with the indemnifying party in the defense of all such claims or suits. No settlement or compromise shall be binding on a party hereto without its prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed. The indemnified party shall have the right to join, but not control, at its own expense and with counsel of its choice, the defense of any claim or suit that has been assumed by the indemnifying party.  
XII - GENERAL PROVISIONS  
 12.1  
Notices  
Any notice, request or other document to be given hereunder to any party shall be in writing and delivered personally, sent by certified mail, postage prepaid, by email transmission with confirmation of receipt, or sent by a commercially recognized overnight courier, provided a receipt is required,  
 If to RENAISSANCE: Renaissance Lakewood, LLC   
With a copy to: Renaissance Lakewood, LLC.   
If to COMPANY: ARS Pharmaceuticals Inc.   
 Attn: Xxxxxxx Xxxxxxxxx, MSc MBA,  
CEO and President  
Email:  
 With Copy to:   
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Any notice, if sent properly addressed, postage prepaid, shall be deemed made [\*\*\*] after the date of mailing as indicated on the registered mail receipt, or [\*\*\*] after the date of entrusting to express courier service or on the date of delivery or transmission (if delivered or sent during ordinary business hours, otherwise on the next business day) if hand-delivered or sent by email transmission.  
 12.2  
Entire Agreement; Amendment  
The parties hereto acknowledge that this Agreement, together with the Quality Agreement and including all Schedules to this Agreement, sets forth the entire agreement and understanding of the parties and supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof, including the Prior CDA, and shall supersede any conflicting portions of RENAISSANCE’s quotation, acknowledgment and invoice forms and COMPANY’s purchase order and other written forms. For clarity, the parties agree that the R&D Agreement shall continue in full force and effect in accordance with its terms. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by the party against whom enforcement is sought. To the extent that the obligations of RENAISSANCE contained in this Agreement conflict with the Quality Agreement, the Quality Agreement will prevail with respect to quality control documents and procedures only; otherwise, the obligations contained in this Agreement will govern and control, including with respect to all financial obligations and financial exposures of the parties.  
 12.3  
Waiver  
No waiver by either party of any default shall be effective unless in writing, nor shall any such waiver operate as a waiver of any other default or of the same default on a future occasion.  
 12.4  
Force Majeure  
Each party shall be excused from the performance of its obligations hereunder in the event performance of this Agreement is prevented by Force Majeure and such excuse shall continue as long as the condition constituting such Force Majeure continues; provided that the affected party shall promptly notify the non-affected of the Force Majeure condition and shall exert Commercially Reasonable Efforts to eliminate, cure or overcome any such causes; and further provided that the affected party shall continue to perform to the extent feasible in view of such Force Majeure event. If such Force Majeure event shall continue for a period of six (6) months or more, then the non-affected party shall have the right to terminate this Agreement upon written notice to the affected party.  
 40  
12.5  
Assignment  
This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the parties and may not be assigned or transferred by either party without the prior written consent of the other; provided however, that a party may assign this Agreement or any part hereof to one of its Affiliates, or in connection with a merger, reorganization, consolidation, change in control, or sale of the assets of the business to which this Agreement relates, without the other party’s consent. No such assignment shall release the original party hereto from its duties and obligations under this Agreement and any purported assignment, transfer, or attempt to assign or transfer any interest or right hereunder by any party, except in compliance with this Section 12.5, shall be null, void and of no effect.  
 12.6  
Governing Law, Waiver of Trial by Jury and Consent to Jurisdiction  
 (a)  
THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF DELAWARE, APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO THE CONFLICTS OF LAW PRINCIPLES OF SUCH STATE.  
 (b)  
Any dispute arising between the parties in connection with this Agreement shall first be presented to the respective senior executives of the parties for their consideration and resolution. If the parties’ executives cannot resolve such dispute within [\*\*\*] , then either party may commence an action, suit or proceeding in the Delaware Chancery Court, or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in any other state court in the State of Delaware or in the United States District Court for the District of Delaware.  
 (c)  
Each party hereby waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement or any transaction contemplated hereby. Each party (i) certifies that no representative, agent or attorney of any other party has represented, expressly or otherwise, that such other party would not, in the event of litigation, seek to enforce the foregoing waiver and (ii) acknowledges that it and the other party have been induced to enter into this Agreement by, among other things, the mutual waivers and certifications in this Section 12.6.  
 41  
 (d)  
Each of party irrevocably submits to the exclusive jurisdiction of the Delaware Chancery Court, any other state court in the State of Delaware, and the United States District Court for the District of Delaware, and any appellate court thereof, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby, and each party irrevocably and unconditionally agrees that all claims in respect of any such suit, action or other proceeding may be heard and determined in such courts. Each of party further agrees that service of any process, summons, notice or document by U.S. registered mail to such party’s respective address set forth in Section 12.1 shall be effective service of process for any action, suit or proceeding in Delaware with respect to any matters to which it has submitted to jurisdiction in this Section 12.6. Each party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in any court referred to in Section 12.6(b) and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.  
 12.7  
Severability  
If any term or provision of this Agreement is invalid, illegal or incapable of being enforced by any applicable law or public policy, all other terms or provisions of this Agreement shall nonetheless remain in full force and effect so long as the economic and legal substance of the transactions contemplated by this Agreement are not affected in any manner materially adverse to any party. Upon such determination that any term or other provision of this Agreement is invalid, illegal or incapable of being enforced, the parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated by this Agreement are consummated as originally contemplated to the fullest extent possible.  
 12.8  
Licenses and Permits  
Each party shall, at its sole cost and expense, maintain in full force and affect all necessary licenses, permits, and other authorizations required by Applicable Law in order to carry out its duties and obligations hereunder.  
 12.9  
Delegation to Affiliates  
Each party shall have a right to delegate certain of its obligations under this Agreement to its Affiliates, provided that such party shall remain fully responsible for any such obligations so delegated. Any breach of any of such party’s obligations (including representations and warranties) under this Agreement by such Affiliate shall be deemed a breach by the delegating party, and the other party may proceed directly against the delegating party without any obligation to first proceed against such Affiliate.  
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12.10  
Headings, Interpretation  
The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The word “or” when used in this Agreement is not exclusive and shall be deemed to include the word “and” (e.g., “and/or”. The word “extent” in the phrase “to the extent” shall mean the degree to which a subject or other thing extends, and such phrase shall not mean simply “if”. All terms defined in this Agreement shall have their defined meanings when used in any certificate or other document made or delivered pursuant hereto, unless otherwise defined therein. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth therein), (ii) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (iii) all references herein to Articles, Sections or Schedules shall be construed to refer to Articles, Sections or Schedules of this Agreement and (iv) the headings contained in this Agreement or any Schedule and in the table of contents to this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Any capitalized terms used in any Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement. In the event of an ambiguity or a question of intent or interpretation, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.  
 12.11  
Counterparts  
This Agreement may be executed in one or more counterparts, all of which, when taken together, shall be considered one and the same agreement, and shall become effective when one or more such counterparts have been signed by each of the parties and delivered to the other party. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means shall be effective as delivery of a manually executed counterpart of this Agreement.  
 12.12  
Independent Contractor  
In performing its obligations hereunder, RENAISSANCE shall act as an independent contractor. The parties agree that no joint venture, partnership, employment, or agency relationship exists as a result of the negotiation and execution of this Agreement and that neither party is granted any right or authority hereunder to assume or create any obligation, express or implied, or to make any representation, warranties or guarantees, except as are expressly granted or made in this Agreement  
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12.13  
Export/Import Laws and Regulations  
This Agreement is subject to any restrictions concerning the import or export of Product, API, chemical or Packaging components (or related technical information or data) to or from the United States as well as the laws and regulations of any other country involved in the import or export of such Product, API, chemical or Packaging components (or related technical information or data). COMPANY acknowledges that it shall be solely and exclusively responsible for the preparation of all import and export documentation and compliance with all import and export laws of the United States as well as the laws and regulations of any other country involved in the import or export of such Product, API, chemical or Packaging components (or related technical information or data); except as otherwise agreed by the parties in writing. COMPANY shall not take any action to identify or otherwise name RENAISSANCE as the importer or exporter of record for any of the aforementioned items. COMPANY shall cooperate with RENAISSANCE as reasonably necessary to permit RENAISSANCE to comply with the laws and regulations of the United States and any other country relating to the control of import or export of Product, API, chemical or Packaging components (or related technical information or data).  
[Remainder of page intentionally left blank; signature page follows.]  
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IN WITNESS WHEREOF, the parties hereto have each caused this Agreement to be executed by their duly authorized officers as of the Effective Date.  
 ARS PHARMACEUTICALS, INC. RENAISSANCE LAKEWOOD, LLC  
By:   
/s/ Xxxxxxx Xxxxxxxxx  
 By:   
/s/ Xxxxx Xxxxxxx  
Its: CEO and President Its: President and CEO  
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EFTA Asia Other CIS Middle East Africa  
Iceland Japan Albania Armenia Afghanistan Algeria  
Lichtenstein Andorra Azerbaijan Bahrain Benin  
Norway Bosnia-Herzegovina Belarus Egypt Burkina Faso  
Switzerland Georgia Kazakhstan Iran Burundi  
 Monaco Kyrgyzstan Iraq Cameroon  
 Montenegro Moldova Israel Central African  
 Rep.  
 North Macedonia Russia Xxxxxx Xxxx  
 Ukraine Tajikistan Kuwait Congo  
 San Marino Uzbekistan Lebanon Dem. Rep. Congo  
 Serbia Oman Djibouti  
 Vatican City Pakistan Equatorial Guinea  
 Palestine Ivory Coast  
 Qatar Lybia  
 Saudi Arabia Madagascar  
 Syria Mali  
 Turkey Mauritius  
 United Arab Morocco  
 Emirates   
 Yemen Niger  
 Rwanda  
 Senegal  
 Seychelles  
 Togo  
 Tunisia  
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