UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K/A
(Amendment No. 1)

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

Date of Report (Date of earliest event reported): February 8, 2019

Recro Pharma, Inc.
(Exact name of registrant as specified in its charter)

Pennsylvania	**001-36329**	**26-1523233**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (484) 395-2470

Not Applicable
(Former name or former address, if changed since last report)

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

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

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

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Explanatory Note

This Amendment No. 1 to Current Report on Form 8-K/A amends and restates the Form 8-K originally filed with the Securities and Exchange Commission on February 14, 2019, to include the Agreement (as defined below) as Exhibit 10.1 and to amend Item 1.01 to reflect that the Agreement is filed herewith.

Item 1.01 Entry Into a Material Definitive Agreement.

On February 8, 2019, Recro Pharma, Inc., through its wholly-owned subsidiary, Recro Gainesville LLC (collectively, the "Company") entered into a new Manufacturing and Supply Agreement (the "Agreement") with Novartis Pharma AG ("Novartis"), effective as of January 1, 2019, pursuant to which the Company will continue to be the exclusive global supplier to Novartis of Ritalin LA and Focalin XR capsules (together, the "Products") through 2023.

The Company and Novartis were previously parties to two separate manufacturing and supply agreements, one for the exclusive supply of Ritalin LA capsules and one for the exclusive supply of Focalin XR capsules (the "Prior Agreements"), which were set to expire in late 2019 and mid-2020, respectively. The Agreement terminates and replaces the Prior Agreements. Under the terms of the Agreement, subject to exceptions for the Company's failure to timely supply Novartis' requirements and bankruptcy, the Company will produce and supply the Products exclusively for, and to, Novartis, and Novartis will exclusively purchase its requirements for the Products from the Company, until December 31, 2023. Pursuant to the terms of the Agreement, the Company has granted Novartis a worldwide, exclusive, royalty-free sublicensable license to the intellectual property owned and controlled by the Company relating to the Products.

The Agreement expires December 31, 2023 (the "Initial Term") and will renew automatically thereafter for successive one-year periods unless terminated by either party at least twenty-four (24) months prior to the end of the Initial Term or any subsequent one-year term after the Initial Term. Novartis may terminate the Agreement immediately if (i) any governmental regulatory authority prevents Novartis from supplying the active pharmaceutical ingredients in the Products and/or exporting, purchasing or selling the Products in its bulk or packaged form; (ii) any Product or pharmaceutical product contained therein cannot be reasonably commercialized for medical, scientific or legal reasons; or (iii) the Company fails to comply certain with health, safety and environmental protection requirements. After the Initial Term, Novartis may terminate the Agreement upon 12 months' written notice in the event of any sale or divestment of the Company of its business or assets relating to the Products. Either party may terminate the Agreement for material, uncured breaches or in the event of the other party's bankruptcy.

The Agreement also contains customary representations, warranties, mutual indemnities, limitations of liability and confidentiality provisions.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which is filed as Exhibit 10.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1*	Manufacturing and Supply Agreement, dated as of February 8, 2019, by and between Recro Pharma, Inc. and Novartis Pharma AG.

* Confidential treatment pursuant to Rule 24-b under the Securities Exchange Act of 1934, as amended, has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

Recro Pharma, Inc.

By: /s/ Gerri A. Henwood
Name: Gerri A. Henwood
Title: Chief Executive Officer

Date: March 6, 2019

[***] CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THIS OMITTED INFORMATION.

Exhibit 10.1

MANUFACTURING AND SUPPLY AGREEMENT

(the "**Agreement**")

effective as of 1st January, 2019

(the "**Effective Date**"),

by and between

NOVARTIS PHARMA AG
Lichtstrasse 35
CH-4056 Basel, Switzerland

("**NOVARTIS**")

and

RECRO GAINESVILLE LLC
1300 Gould Drive
Gainesville, GA 30504

("**SUPPLIER**")

EXECUTION VERSION

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WHEREAS:

(A) NOVARTIS is engaged in the manufacture, marketing and sales of pharmaceutical products.

(B) SUPPLIER is a company engaged in the processing and supply of pharmaceutical products holding the necessary manufacturing licenses and permits in this respect.

(C) NOVARTIS and SUPPLIER are parties to that certain License and Supply Agreement dated as of [***] (as amended through the date hereof, the "**License and Supply Agreement**"), and Novartis Pharmaceuticals Corporation and SUPPLIER are parties to that certain Development, License and Supply Agreement dated as of [***] (as amended through the date hereof, the "**Development, License and Supply Agreement**"), pursuant to which agreements SUPPLIER performs certain services related to the processing and supply of certain pharmaceutical products to and for NOVARTIS and Novartis Pharmaceuticals Corporation, respectively.

(D) NOVARTIS, Novartis Pharmaceuticals Corporation and SUPPLIER desire to terminate the Development, License and Supply Agreement and the License and Supply Agreement (together, the "**Original Agreements**") in all respects as of the Effective Date.

(E) NOVARTIS and SUPPLIER desire to amend and restate the terms pursuant to which SUPPLIER shall perform certain services related to the processing and supply of the Products (as defined herein) pursuant to the Specifications and the terms and conditions of this Agreement and SUPPLIER confirms being able to properly perform such activities.

IT IS AGREED AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATIONS

1.1 Defined Terms

The following terms shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

"**Affiliate**" means any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with NOVARTIS or SUPPLIER, as the case may be. For such purposes, "Control" shall mean the direct or indirect ownership of at least fifty percent (50%) of the voting interest in such corporation or other entity or the power in fact to control the management directions of such entity.

"**Alkermes**" means Alkermes Pharma Ireland Ltd.

"**Alkermes Patent Rights**" means all patents and patent applications listed in ANNEX 9 to which SUPPLIER holds an exclusive sub-licensable license under that certain Asset Transfer and License Agreement between Alkermes and SUPPLIER dated 10 April 2015.

"**Annual KPI Compliance Review**" means a meeting between the parties to discuss and review SUPPLIER's level of performance of the KPIs.

"**API**" means the active pharmaceutical ingredient(s) DexMethylphenidate HCL and Methylphenidate HCL, as referenced in the Quality Agreement and the Specifications.

"**Apparent Defect**" means any Defect which is visible or easily detectible through routine incoming quality control measures.

"**Applicable Standards**" means all applicable cGxP as well as all laws, regulations, guidelines, standards, permits and authorizations, including without limitation those listed in the Quality Agreement and those governing health, safety and environmental protection, applicable in the country where the Facility is located and in each country of the Territory.

"**Approved Subcontractor(s)**" means any Affiliate of SUPPLIER or any other third party (including suppliers of API and (Critical) Components) to which SUPPLIER has subcontracted in whole or in part its obligations hereunder in accordance with the terms set out herein and the Quality Agreement. Approved Subcontractors shall be referenced in the Quality Agreement.

"**Batch**" means a defined quantity of Components and API, processed in one process or series of processes, so that it could be expected to be homogeneous.

"**Bridging Stock**" has the meaning in **Clause 21.3**.

"**Business Continuity Management**" has the meaning in **Clause 13.3**.

"**Business Continuity Plan**" has the meaning in **Clause 13.3**.

"**cGxP**" means the current good manufacturing, distribution and storage practices specified by the US Code of Federal Regulations, the EU, PIC, ICH and WHO guidelines and the corresponding national laws and regulations applicable in the country where the Facility is located and in each country of the Territory. In case of conflict, SUPPLIER shall be required to comply with the stricter standard.

"**Claims**" means all third party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

"**Components**" means, collectively, all raw materials, excipients and any other materials (including, to the extent procured by SUPPLIER, the API) required to Manufacture the Product in accordance with the Specifications.

"**Confidential Information**" has the meaning in **Clause 18.1**.

"**Confirmed Delivery Date**" has the meaning in **Clause 5.2**.

"**Confirmed Order**" has the meaning in **Clause 5.2**.

"**Confirmed Order Quantities**" has the meaning in **Clause 5.2**.

"**Contract Year**" means any twelve (12) month period beginning on January 1st, of each calendar year, provided, however, that the first Contract Year of this Agreement shall commence on the Effective Date and shall expire on December 31st of the same calendar year.

"**Controlled Substance(s)**" shall have the meaning ascribed to such term in the Controlled Substances Act (21 U.S.C. § 801-904), as may be amended from time to time, and/or its equivalent in the other countries of the Territory.

"**Critical Components**" means those Components listed as materials in the Quality Agreement.

"**Defective Product**" means Product that: (i) was not Manufactured, prepared, handled and/or shipped in compliance with applicable cGxPs, Applicable Standards, the Quality Agreement, master batch records and/or any other procedures or documents agreed upon by the parties in writing; (ii) does not conform to the Specifications or any other Product related warranties or representations set out in this Agreement; (iii) has less than the Residual Shelf Life; (iv) is adulterated within the meaning of the U.S. Food, Drug, and Cosmetic Act or similar provisions under Applicable Standards; and/or (v) is considered to contain a defect as determined under governing law and Applicable Standards in the Territory. "**Defect**" shall be interpreted accordingly. For the avoidance of doubt, any Product that NOVARTIS is entitled to reject pursuant to the Quality Agreement shall be regarded as Defective Product for the purpose of this Agreement.

"**Deliver**" or "**Delivery**" means the delivery of the Product by SUPPLIER pursuant to **Clause 5.3**.

"**Development, License and Supply Agreement**" has the meaning given in the preamble of this Agreement.

"**Equipment**" means any equipment and machinery required in the Manufacture of the Product at the Facility.

"**Facility(-ies)**" means SUPPLIER's or its Approved Subcontractor's Manufacturing facility(-ies), located at: 1300 Gould Drive, Gainesville, GA 30504, USA and such other facilities as may be approved in writing by NOVARTIS from time to time in accordance with this Agreement and the Quality Agreement.

"**Forecast**" has the meaning in **Clause 5.1**.

"**HSE**" is the abbreviation for "health, safety and environmental protection".

"**HSE Requirements**" has the meaning in **Clause 13.1**.

"**Indemnitee**" and "**Indemnitor**" have the meanings in **Clause 16.3**.

"**Initial Term**" has the meaning in **Clause 19.2**.

"**Intellectual Property**" means patents, trade secrets, Know-How, confidential or proprietary information, technical data, trademarks, service marks, design rights, copyright or any other intellectual property right which may subsist anywhere in the world, whether capable of grant, registration or not.

"**Joint Supply Team**" has the meaning in **ANNEX 4**.

"**Know-How**" means all technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions, products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, relevant to the development, manufacture, use or commercialization of and/or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof.

"**KPI**" means the key performance indicators set out in **ANNEX 3, Part A** and against which the performance by SUPPLIER under this Agreement will be measured and monitored by NOVARTIS.

"**Laboratory**" has the meaning in **Clause 23.3(a)**.

"**Latent Defect**" means any Defect other than Apparent Defects.

"**License and Supply Agreement**" has the meaning given in the preamble of this Agreement.

"**Manufacture"** or "**Manufacturing**" means, as applicable, any and all operations, including without limitation receipt of materials, processing, testing, sterilization, quality control, releasing, storing, sample retention, serialization and packaging for shipment, carried out by or on behalf of SUPPLIER in the preparation and supply of the Products under this Agreement and the Quality Agreement.

"**Manufacturing License(s)**" means all licenses, permits, approvals, authorizations and consents necessary for, or required in connection with, the lawful Manufacture of the relevant Products at the Facility for use, exportation, importation, distribution, marketing, promotion, sale and placement of the Products in the Territory.

"**Minimum Capacity**" has the meaning in **Clause 3.1**.

"**Novartis Material**" means Novartis New Material and Novartis Original Material.

"**Novartis New Material**" means all information, documents and materials that are or will be generated by SUPPLIER, any Approved Subcontractor or NOVARTIS under this Agreement, including without limitation, manufacturing and quality control instructions or requirements under any quality control agreements between the parties (including the Quality Agreement), and specifications necessary to manufacture, label, package, store, handle, stability test, quality control test and release the Product, all in accordance with this Agreement, including without limitation the Product and partially-Manufactured Product.

"**Novartis Original Material**" means all information, documents and materials that are, will be or have been provided by NOVARTIS to SUPPLIER under this Agreement, including without limitation, Confidential Information and, where applicable, the API.

"**Order(s)**" has the meaning in **Clause 5.2(a)**.

"**Order Lead Time**" has the meaning in **Clause 5.2(a)**.

"**Original Agreements**" has the meaning given in the preamble of this Agreement.

"**Patent Rights**" means all patents and patent applications, including all divisionals, continuations, substitutions, re-examinations, reissues, additions, renewals, extensions, registrations, supplemental protection certificates, utility models, design patents and the like of any of the foregoing.

"**Price**" means the price per unit of Product, as further defined in **Clause 6.1** and **ANNEX 1**.

"**Product Marks**" has the meaning in **Clause 15.6**.

"**Products**" means the products listed in **ANNEX 1** (as further specified in the Quality Agreement) conforming to the Specifications, the Manufacturing and supply of which is the subject matter of this Agreement.

"**Quality Agreement**" means that applicable version of the quality agreement between the parties in relation to the Product and its Manufacturing, including, without limitation by way of a master agreement between SUPPLIER and/or its Affiliate(s) and a NOVARTIS Affiliate, a copy of which is attached hereto as **ANNEX 7**.

"**Quality Assurance**" or "**QA**" means the sum total of the quality assurance arrangements made with the purpose of ensuring that the Product meets the Specifications and is of the quality required for its intended use and shall specifically include all terms and activities as set forth in the applicable version of the Quality Agreement.

"**Recro Patent Rights**" means all patents and patent applications listed in **ANNEX 10.**

"**Registration**" means any and all governmental or Regulatory Authority approvals necessary or required for the Manufacture, import, marketing, distribution and sale of the Product or the finished product comprised of the Product (as applicable) as labeled, packaged and presented for sale to the pharmaceutical trade, and the term "Registration" shall also apply to any renewals of such approvals and to any other steps required to maintain such approvals.

"**Regulatory Authority**" means any international, national or other governmental, regulatory or administrative authority or other body competent to grant, maintain and extend approvals, registrations or other consents for the Manufacturing, importation, marketing, distribution or sale of pharmaceutical products and APIs, including without limitation the Products.

"**Renewal Term**" has the meaning in **Clause 19.2**.

"**Representatives**" has the meaning in **Clause 18.1**.

"**Requested Delivery Date(s)**" has the meaning in **Clause 5.2(a)**.

"**Requested Order Quantities**" has the meaning in **Clause 5.2(a)**.

"**Residual Shelf Life**" has the meaning in **Clause 5.5**.

"**Risk Management**" has the meaning in **Clause 13.3**.

"**SEC**" has the meaning in **Clause 18.2**.

"**Specifications**" means the specifications for the Products, the API or Critical Components (as the case may be) as further defined and referenced in the Quality Agreement and which may be amended only upon the mutual written agreement of the parties.

"**Supply Failure**" has the meaning in **Clause 5.8.**

"**Term**" has the meaning in **Clause 19.2**.

"**Territory**" means all countries of the world except Canada.

"**Third Party Infringement**" has the meaning in **Clause 15.5(a)**.

"**Toll Material(s)**" means any API as listed in **ANNEX 8** and supplied by NOVARTIS to SUPPLIER free of charge for the purpose of SUPPLIER Manufacturing and supplying the Product to NOVARTIS under this Agreement.

"**Toll Materials Reimbursement Value**" is set forth in **ANNEX 8.**

"**TSP**" means the Trading Service Procedure as attached hereto as **ANNEX 5**.

"**Validation**" or "**Validate**" means (either collectively or separately, as applicable) (i) the successful completion of all qualification activities in relation to the Facility and the Equipment; (ii) the successful validation of the analytical testing methods for the Product; and (iii) the successful Manufacture, at commercial scale, of [***] validation Batches for the Product meeting predetermined validation acceptance criteria, normal Product release criteria and stability requirements as set forth in the Specifications and in a written validation plan to be mutually agreed by the parties.

1.2 **Currency**. Unless otherwise indicated, all monetary amounts are expressed in this Agreement in US Dollars ("**USD**").

1.3 **Interpretation**. In this agreement unless otherwise specified:

(a) the division of this Agreement into clauses, sub-clauses and Annexes and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement;

(b) any reference in this Agreement to a clause or an annex refers to the specified Clause or Annex to this Agreement;

(c) the terms "this Agreement", "hereof", "herein", "hereunder" and similar expressions refer to this Agreement;

(d) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;

(e) all references to the singaular shall include the plural and vice versa;

(f) the term "including" shall mean "including without limitation"; and

(g) any reference in this Agreement to a "day" or "week" shall be references to a calendar day or week. Where express reference is made to "business day(s)" any such reference shall mean a day (with the exception of Saturday and Sunday) on which banks are open in Switzerland and New York, New York (USA).

2. SCOPE OF THE AGREEMENT

2.1 **Manufacturing and Supply**. During the Term, SUPPLIER shall sell, Manufacture and Deliver the Products to NOVARTIS and its Affiliates in accordance with the terms of this Agreement. The parties acknowledge that NOVARTIS prioritizes consistent high quality and timely supply of the Products to meet patient demand and that supply disruptions may result in irreparable harm to NOVARTIS. To that end, SUPPLIER agrees to act in good faith in performing its obligations under this Agreement and shall not willfully delay Manufacturing nor withhold Delivery of the Products.

2.2 **Exclusivity**. [***] SUPPLIER shall produce and supply the Products exclusively for, and to, NOVARTIS. [***] SUPPLIER shall supply to NOVARTIS its entire requirements of the Products and NOVARTIS will purchase its entire requirements of the Products exclusively from SUPPLIER, all subject to the following:

a) [***] NOVARTIS shall purchase all of NOVARTIS' volume requirements for the Products from SUPPLIER and SUPPLIER shall Manufacture, Deliver and supply all of NOVARTIS' volume requirements for the Products. This exclusivity shall be solely for the Products as listed in

ANNEX 1 and shall not extend to [***]; and

b) Notwithstanding anything to the contrary in this Agreement, the exclusivity obligation pursuant to this **Clause 2.2** shall cease to apply and NOVARTIS shall be free to purchase any of its requirements for the Product(s) from a different third party source or from a site of NOVARTIS (or a site of any NOVARTIS Affiliate) in the event that:

(i) SUPPLIER is not able to (or it can reasonably be anticipated that SUPPLIER will not be able to) and/or fails to supply for [***]; and/or

(ii) SUPPLIER is (or it can reasonably be anticipated that SUPPLIER will) be the subject of any insolvency, bankruptcy or liquidation proceedings or the appointment of a receiver, custodian or trustee or any similar proceeding or appointment under applicable law.

For the avoidance of doubt, the exclusivity pursuant to this **Clause 2.2** shall be limited to commercial manufacturing activities and shall not prevent NOVARTIS from performing any activities in relation to the preparation of a transfer of the Products to another manufacturing site or to the qualification or registration of such other manufacturing site, including without limitation any supply qualification, regulatory registration and manufacturing, testing and validation activities. The parties' obligations under this **Clause 2.2** [***].

2.3 **Supplier Warranty**. SUPPLIER represents and warrants that it shall Manufacture, store, test release, Deliver and supply the Product in compliance with: (i) the Specifications; (ii) cGxP; (iii) the Quality Agreement; (iv) the Manufacturing License(s); (vi) all Applicable Standards, including those governing health, safety and environmental protection and those governing Controlled Substances, and that at Delivery the Product will be free from (vii) any security interest, claims, demands, liens and other encumbrances of any kind or character; and (viii) any Defects. The parties agree that subject to the notification timelines set forth in **Clause 10**, the warranty set forth in this **Clause 2.3** shall remain in full force and effect for the entire Residual Shelf Life of the Products.

2.4 **Subcontractors**. SUPPLIER shall not subcontract or delegate any portion of its obligations hereunder except to an Approved Subcontractor. SUPPLIER shall ensure that any Approved Subcontractor performs its obligations pursuant to the terms of this Agreement, including the Quality Agreement and the HSE Requirements. Notwithstanding the foregoing, SUPPLIER shall remain solely and fully liable for the performance of any Approved Subcontractor or supplier and shall remain exclusively responsible for all costs associated with any such subcontract or supply relationship.

2.5 **Facility**. SUPPLIER will Manufacture the Products exclusively at the Facility. Transfer of the Manufacturing of the Products to another facility requires the prior written approval of NOVARTIS. SUPPLIER shall, at its own expense, provide and maintain all labor, plant, Equipment and services necessary to enable SUPPLIER to fulfil all its obligations under this Agreement, including the Manufacturing of the Products.

2.6 **Novartis Material.** All Novartis Material, whether or not patentable, shall be the sole and exclusive property of NOVARTIS. SUPPLIER shall supply all Novartis New Material to NOVARTIS or its designee in accordance with the terms of this Agreement. SUPPLIER shall not sell or otherwise dispose of any Novartis Materials except as expressly authorized by NOVARTIS, provided that to the extent NOVARTIS requests that SUPPLIER dispose of or destroy any Novartis Material, (i) such disposal or destruction shall be required to occur within [***] of NOVARTIS' authorization of same in accordance with the terms of the Quality Agreement; and (ii) [***]. SUPPLIER hereby grants to NOVARTIS, its designated representatives and employees the right to enter any premises where the Novartis Material is stored in order to inspect or repossess it as NOVARTIS shall in its sole discretion deem fit.

2.7 **Authorizations and Permits**. SUPPLIER represents and warrants that on the Effective Date and throughout the Term, SUPPLER holds, or will cause its Approved Subcontractors to hold, all Manufacturing Licenses and any other approvals, permits, or exemptions from any Regulatory Authority which are required to perform its obligations under this Agreement, and has paid all fees due in relation to them and is not in material breach of any conditions under them. Upon request, SUPPLIER shall provide, or shall cause its Approved Subcontractors to provide to NOVARTIS copies of any Manufacturing Licenses or any other approvals, permits, or exemptions. Without prejudice to any of NOVARTIS' other rights hereunder, SUPPLIER shall inform NOVARTIS promptly in writing if any such Manufacturing Licenses or other approvals or permits are not obtained in a timely manner or are withdrawn or otherwise under investigation.

2.8 **Registration and Regulatory Requirements**. NOVARTIS and its Affiliates shall be responsible for the Registration of the Product with all relevant Regulatory Authorities of all countries of the Territory where they market the Products. SUPPLIER shall provide such assistance as NOVARTIS or its Affiliates may reasonably request in connection therewith, [***]. In addition, SUPPLIER shall provide (and shall cause its Approved Subcontractors and suppliers to provide) NOVARTIS with any information or documentation in its possession, control or ownership and to render any other assistance reasonably necessary to enable NOVARTIS to make an application to any Regulatory Authority, at NOVARTIS' expense.

2.9 **Termination of Original Agreements**. Effective as of the Effective Date, SUPPLIER, NOVARTIS and Novartis Pharmaceuticals Corporation hereby agree that the Development, License and Supply Agreement and the License and Supply Agreement are terminated in all respects as of the Effective Date and that:

(a) [***]

(b) [***];

(c) this Agreement shall apply to and govern the supply of, and associated payments for, those products as listed in **ANNEX 11** which were ordered prior to the termination of the Original Agreements but were not delivered to NOVARTIS or Novartis Pharmaceuticals Corporation, as applicable, in calendar year 2018; and

(d) notwithstanding the amendment and restatement of the Original Agreements as set forth in this Agreement, the rights of inspection and audit and the confidentiality obligations, and any other provisions that by their nature were intended to survive the termination thereof, set forth in such Original Agreements shall continue in force for the period referred to in the relevant provisions of such Original Agreements.

For the avoidance of doubt, subject to this **Clause 2.9**, the termination of the Original Agreements shall not affect the rights of either party against the other accrued or accruing under such Original Agreements before termination.

3. CAPACITY

3.1 **Minimum Capacity**. During the Term, SUPPLIER shall maintain a monthly minimum capacity for the Manufacturing of [***] percent ([***]%) of the applicable Forecast (**"Minimum Capacity"**). SUPPLIER shall use commercially reasonable efforts to increase its capacity up to the required units of Product within a reasonable time if NOVARTIS requires a higher minimum capacity at any time during the Term, provided Supplier's failure to achieve an increased level of capacity that is in excess of [***] percent ([***])% of the then-applicable Forecast shall not constitute a material breach of this Agreement under **Clause 20.1**.

4. COMPONENTS AND TOLL MATERIALS

4.1 **Procurement of Components**. Where SUPPLIER procures Components, SUPPLIER shall ensure that such Components are manufactured as required under this Agreement (including the Quality Agreement and the HSE Requirements). SUPPLIER shall and shall cause its Approved Subcontractors, at its cost, to purchase, qualify, test, inspect and approve all such Components required in the Manufacturing, storage, shipping or receiving of the Product. In relation to its Approved Subcontractors and/or suppliers of such Components, SUPPLIER shall:

(a) [***] and keep NOVARTIS informed of the material terms and status of such supply, subject to any and all confidentiality agreements as may be in place with any and all such Approved Subcontractors and/or suppliers;

(b) proactively manage its Approved Subcontractors and/or suppliers of Components, including by regularly auditing and evaluating such Approved Subcontractors and/or suppliers and by having effective performance management and supplier relationship management regimes;

(c) ensure that Critical Components are only supplied from suppliers approved in writing by NOVARTIS, as may be further detailed in the Quality Agreement; and

(d) keep NOVARTIS informed without undue delay of any possible interruptions with respect to the Components supply as soon as SUPPLIER becomes aware of such interruption possibility.

4.2 **Stock of Components**. During the Term, SUPPLIER will apply first-expiry, first out methods of usage to any stock of Components. SUPPLIER shall ensure that its stock of Components is always sufficient to permit the uninterrupted Manufacturing of the Product in full compliance with Confirmed Orders, Confirmed Delivery Dates and Order Lead Time. For those Products listed in **ANNEX 2**, SUPPLIER shall additionally maintain a rolling safety stock of Components as set forth in **ANNEX 2**. Further, SUPPLIER shall ensure that the quantities of Components ordered and stored by it relate appropriately to Confirmed Orders and shall wind down its safety stock inventory prior to the expiration or termination of this Agreement so that the items in stock do not become obsolete or unsaleable. Subject to the foregoing, [***].

4.3 **Alternative Sources.** NOVARTIS may at any time identify to SUPPLIER suppliers from which SUPPLIER may obtain any of the Components at a lower cost and/or higher quality, in accordance with this Agreement. In such event, SUPPLIER and NOVARTIS shall collaborate in order to obtain the necessary regulatory approvals and SUPPLIER shall utilize the suppliers identified by NOVARTIS following receipt of such approvals [***]. Once such suppliers are fully qualified and/or Validated, SUPPLIER shall be solely and fully liable for the performance of such alternative suppliers, including for the quality of the Components delivered by any of such suppliers and compliance with this Agreement, the Quality Agreement and the HSE Requirements.

4.4 **Supply of Toll Materials**. Solely for purposes of SUPPLIER's Manufacturing of the Products hereunder, NOVARTIS undertakes from time to time to supply (or have supplied by a designated third party) to SUPPLIER, [***], the Toll Materials required in the Manufacture of the Product, in such quantities as may be ordered by SUPPLIER in accordance with **Clause 4.6**. [***].

4.5 **Toll Materials Forecast**. SUPPLIER shall provide NOVARTIS with a written non-binding rolling [***] forecast of the volume of the Toll Materials, in accordance with NOVARTIS' Forecast. SUPPLIER shall submit written orders for the Toll Materials with a lead time of at least [***]. NOVARTIS shall notify SUPPLIER on or before [***] after receipt of an order if it is unable to meet all or a portion of an order by the requested delivery date.

4.6 **Ownership of Toll Materials**. Toll Materials delivered to SUPPLIER shall be held by SUPPLIER or the Approved Subcontractors on behalf of NOVARTIS in accordance with the terms of this Agreement. The Toll Materials shall at all times remain the property of NOVARTIS. SUPPLIER must not use any such Toll Materials delivered for any purpose other than to Manufacture, package and test the Products in accordance with this Agreement. SUPPLIER hereby irrevocably grants, and shall cause its Approved Subcontractors to grant, to NOVARTIS the right for NOVARTIS, its designated representatives and employees to access any premises where the Toll Materials are stored in order to inspect or repossess the Toll Materials.

4.7 **Handling of Toll Materials**. As from its delivery, SUPPLIER shall: (i) store and handle, at its own cost, the Toll Materials in accordance with applicable cGxP, the Quality Agreement, NOVARTIS' handling and storage instructions and, more generally, in a safe and orderly manner and take all necessary care to prevent its damage, loss or theft; (ii) clearly identify all such Toll Materials in storage and in its books as goods belonging to NOVARTIS; (iii) never mix, alter or analyze the Toll Materials except for the purpose of any testing; and (iv) always use FEFO methods of usage.

4.8 **Target Yield Loss Rate**. SUPPLIER will use its best efforts to obtain maximum yield of the Product from the Toll Materials in connection with its Manufacturing services provided under this Agreement. [***]

4.9 **Loss of Toll Materials**. Except where due to the supply by NOVARTIS of Defective Toll Materials, SUPPLIER shall reimburse NOVARTIS the Toll Materials Reimbursement Value together with any additional direct fees, including but not limited to, transportation fees and insurance fees for Toll Materials which as a result of the gross negligence, omission of or breach of contract by SUPPLIER (i) cannot be used in the Manufacturing of the Product; or (ii) have been used in the Manufacturing without resulting in Product or in Product that is free of Defects (including without limitation any Toll Materials used in failed or rejected Batches or in Defective Product). SUPPLIER shall immediately inform NOVARTIS of any loss or damage to Toll Materials and promptly provide in writing all explanations and evidence.

4.10 **Monthly Toll Materials Inventory**. SUPPLIER shall maintain up-to-date records of all Toll Materials and, within the first week of each month or at such other frequency as the parties may agree, shall provide to NOVARTIS a complete and accurate list of all such items held by it on the last day of the immediately preceding calendar month. Such inventory list shall in particular specify the inventory balance of each such item at the relevant date and shall contain a detailed explanation for any inventory discrepancy exceeding [***] percent ([***]%). SUPPLIER shall also provide NOVARTIS with written reports on a quarterly basis reconciling the quantities of Toll Materials provided to and held by SUPPLIER, the consumption of Toll Materials and the estimated yield losses in the Manufacturing.

4.11 **Annual Toll Materials Inventory**. In addition to the monthly inventory report, and at no additional cost to NOVARTIS, SUPPLIER shall provide to NOVARTIS an annual report setting forth the result of an annual inventory count of all Toll Materials held by

SUPPLIER as at October 31 of each Contract Year (or such other date as agreed in writing between the parties), such inventory count to be carried out under the joint supervision of the respective auditors for SUPPLIER and NOVARTIS in accordance with the stock count procedure set forth in **ANNEX 8.** SUPPLIER shall deliver such annual report on or before one (1) month after completion of this annual inventory count (or within such other time as the parties may agree in writing). SUPPLIER shall be responsible for any discrepancies (such as, for example, missing quantities) not accounted for during such annual inventory count or in connection with the monthly inventory report pursuant to **Clause 4.10**, without regard to the reason for such discrepancy. Each party shall pay for its own auditor's fees under this **Clause 4.11**.

4.12 **Defective Toll Materials**. The following shall apply if NOVARTIS supplies any Toll Materials to SUPPLIER and it is established that such Toll Materials are not in conformity with the Specifications:

(a) SUPPLIER shall inform NOVARTIS in case it discovers any non-conformity of any of the Toll Materials with applicable Specifications, such notification to be made promptly upon discovery of such non-conformity.

(b) SUPPLIER shall return the non-conforming Toll Materials to NOVARTIS or destroy them, as per NOVARTIS' written request and instructions and at NOVARTIS' sole cost and expense. In no event shall SUPPLIER destroy said Toll Materials without NOVARTIS' prior written consent.

(c) Subject to **Clause 4.12(d)**, NOVARTIS shall as soon as reasonably possible replace such defective Toll Materials with Toll Materials meeting the Specifications in accordance with the provisions of this Agreement at NOVARTIS' cost, including all reasonable, documented costs associated with any testing, return or destruction of the non-conforming Toll Materials.

(d) Such Toll Materials shall be replaced at SUPPLIER's cost (at the Toll Materials Reimbursement Value together with any additional direct fees, including, but not limited to, transportation fees, insurance fees, duty) if it is established that the non-conformity with the Specifications occurred after delivery of the defective Toll Materials to SUPPLIER and is due to any actions, omissions, breach of this Agreement (including the Quality Agreement) or gross negligence of SUPPLIER. In addition, in such case, SUPPLIER shall bear sole responsibility for all reasonable costs associated with any testing, return or destruction of the non-conforming Toll Materials.

4.13 **Dispute Resolution**. **Clause 23.3** shall apply if an unresolved dispute exists as to the determination of a non-conformity with the Specifications of Toll Materials and/or the root cause of such non-conformity.

5. FORECASTING, ORDERS AND DELIVERY

5.1 **Product Forecast**. Once per month, NOVARTIS shall provide SUPPLIER with a written monthly non-binding rolling [***] forecast ("**Forecast**") of the required Product quantities.

5.2 **Orders.**

(a) **Order Placement and Order Lead Time**. NOVARTIS may from time to time place written purchase orders for the Product ("**Order(s)**"). Any Orders must be submitted with a lead time of at least [***] ("**Order Lead Time**") and shall set forth the requested quantities of Product ("**Requested**

Order Quantities") and the requested delivery date(s) in accordance with such Order Lead Time ("**Requested Delivery Date(s)**"). SUPPLIER shall use commercially reasonable efforts to accommodate any request by NOVARTIS to submit an Order with an order lead time shorter than the Lead Time, but in no event shall such request by NOVARTIS be for less than [***] lead time.

(b) **Order Confirmation Process**. Within [***] business days of receipt of any Order, SUPPLIER shall acknowledge receipt of such Order. Within twenty (20) business days of receipt of any Order, SUPPLIER shall then confirm to NOVARTIS in writing whether SUPPLIER is able to Deliver the Requested Order Quantities by the Requested Delivery Date or agree with NOVARTIS on alternative quantities and/or an alternative delivery date. Notwithstanding anything to the contrary, SUPPLIER shall be obligated to confirm and Deliver any Order which complies with the Order Lead Time and for which the Requested Order Quantities do not exceed [***]. Once SUPPLIER has confirmed the Product quantities and the delivery date in accordance with this **Clause 5.2**, the relevant Order shall be considered binding on the parties ("**Confirmed Order**"), as will the confirmed Product quantities ("**Confirmed Order Quantities**") and the confirmed delivery date(s) ("**Confirmed Delivery Date(s)**"), provided, for clarity, that if SUPPLIER fails to confirm the Product quantities and the delivery date(s) within the [***] business day period set forth above, then the Requested Order Quantities and/or the Requested Delivery Date(s) shall be automatically deemed to be Confirmed Order Quantities and/or Confirmed Delivery Date(s) respectively and shall be binding on both parties.

(c) **Excess Order Quantities**. Subject to and within the Minimum Capacity, SUPPLIER shall (and shall cause its Approved Subcontractors to) use commercially reasonable efforts to satisfy NOVARTIS' requirements of Products in excess of the Forecast, at no additional cost to NOVARTIS. If an Order exceeds the Minimum Capacity, SUPPLIER shall use commercially reasonable efforts to increase Manufacturing capacity at the Facility up to the required capacity [***]. Notwithstanding the foregoing, (i) if SUPPLIER incurs actual, reasonable costs and expenses related to its having to increase Manufacturing capacity (e.g., overtime or need for second shift) in order to accommodate NOVARTIS' requirements for Products in excess of the Forecast in accordance with this sub-clause (c), such costs and expenses shall be passed on to, and shall be payable by, NOVARTIS subject to SUPPLIER seeking advance written approval of NOVARTIS and providing documented evidence of such costs and expenses; and (ii) nothing in this sub-clause (c) shall require SUPPLIER to make any capital expenditures or additional investments outside of SUPPLIER's normal shift pattern (as it relates to the manufacture and supply of products generally at its Facility). If and to the extent SUPPLIER agrees to make any capital expenditures or additional investments that are required in order to accommodate NOVARTIS' requirements for Products in excess of the Forecast in accordance with this sub-clause (c), the cost of such capital expenditures or additional investments shall be passed on to, and shall be payable by, NOVARTIS subject to the terms of a separate written agreement between the parties.

(d) **Changes to Confirmed Orders Requested by SUPPLIER**. In the event that SUPPLIER anticipates that it will be unable to meet the Confirmed Delivery Dates and/or Confirmed Order Quantities, SUPPLIER shall promptly notify NOVARTIS (and in any event no later than [***] business days before the

Confirmed Delivery Date). In such case, any such change to the Confirmed Delivery Dates and/or Confirmed Order Quantities, whether or not accepted by NOVARTIS, are without prejudice to NOVARTIS' rights and remedies under this Agreement and/or governing law, including **Clause 5.7** (Late Delivery**); Clause 5.8** (Supply Failure), and **Clause 11.2** (KPIs).

(e) **Changes to Confirmed Orders Requested by NOVARTIS.** SUPPLIER shall use commercially reasonable efforts to comply with any unplanned changes to Confirmed Orders requested by NOVARTIS and shall confirm (or reasonably reject) any such changes within the timelines set forth in **Clause 5.2(a)**, and where SUPPLIER accepts such changes, SUPPLIER's supply related KPIs shall be deemed adjusted accordingly. SUPPLIER shall not implement such unplanned changes without the prior written consent of NOVARTIS if such changes result in supplementary costs for NOVARTIS. Notwithstanding the foregoing, (i) if SUPPLIER incurs actual costs and expenses related to its compliance with such unplanned changes to Confirmed Orders (e.g., overtime or need for a second shift) in order to accommodate NOVARTIS' requested changes to Confirmed Orders in accordance with this sub-clause (e), such costs and expenses shall be passed on to, and shall be payable by, NOVARTIS subject to SUPPLIER seeking advance written approval of NOVARTIS and providing documented evidence of such costs and expenses; and (ii) nothing in this sub-clause (e) shall require SUPPLIER to make any capital expenditures or additional investments outside of SUPPLIER's normal shift pattern (as it relates to the manufacture and supply of products generally at its Facility). If and to the extent SUPPLIER agrees to make any capital expenditures or additional investments in order to accommodate NOVARTIS' requested changes to Confirmed Orders in accordance with this sub-clause (e), the cost of such capital expenditures or additional investments shall be passed on to, and shall be payable by, NOVARTIS subject to the terms of a separate written agreement between the parties.

5.3 **Terms of Delivery**. SUPPLIER shall Deliver the Products FCA, 1300 Gould Drive, Gainesville, GA ("**Free Carrier**", INCOTERMS® 2010*)*. SUPPLIER shall ensure that Delivery of the Product fully complies with the TSP. SUPPLIER shall not be entitled to Deliver partial shipments of the Products unless expressly authorized by NOVARTIS in writing to do so. SUPPLIER shall provide the origin, either preferential or non-preferential, of the Product on the shipping documentation or a certificate of origin. If the Product qualifies for preferential origin under a Free Trade Agreement, SUPPLIER shall maintain all necessary documentation to prove qualification under the Free Trade Agreement. SUPPLIER shall also provide documents and assistance as requested by NOVARTIS to address customs or special shipping requirements relating to the Products, including to obtain any licenses, official authorizations, clearances, customs, or any other documents or information that NOVARTIS may require for export, import or transport of the Product to the final destination.

5.4 **Packaging**. SUPPLIER shall ensure that any packaging for transportation (if applicable), fully complies with the requirements set forth in this Agreement, the Quality Agreement and (as applicable) the TSP. SUPPLIER shall facilitate the orderly Delivery and the taking over by the selected carrier of any Product Delivered to NOVARTIS pursuant to **Clause 5.3** above.

5.5 **Residual Shelf Life**. Upon Delivery, the Products' residual shelf life must be at least [***] percent ([***]%) of the applicable Product's total shelf life (such residual shelf life (or any change thereto agreed in writing between the parties) to be referred to as "**Residual Shelf Life**"). The shipment of Product with less than the Residual Shelf Life requires the prior written approval of NOVARTIS.

5.6 **TSP**. SUPPLIER shall comply with the TSP, a copy of which is attached hereto as **ANNEX 5**.

5.7 [***].

5.8 **Supply Failure**. Without prejudice to any other rights or remedies available to NOVARTIS under this Agreement and/or governing law, in the event of a Supply Failure, SUPPLIER shall promptly notify NOVARTIS and NOVARTIS may, in its sole discretion:

(a) request SUPPLIER to use best efforts to supply to NOVARTIS at least the same quantity of a Product as the quantity of such Product purchased by NOVARTIS from SUPPLIER in the previous [***] months during the duration of such Supply Failure;

(b) for any Confirmed Order (or portion thereof) which cannot be satisfied or be reasonably expected to be satisfied within timelines acceptable to NOVARTIS, cancel such Confirmed Orders (or the relevant portions thereof) without any penalty to NOVARTIS; and/or

(c) terminate this Agreement in accordance with **Clause 20.1**.

The term "**Supply Failure**" shall mean [***].

6. PRICE AND PAYMENT TERMS

6.1 **Price**. The Price for the Product(s) is set forth in [***]. The Price shall be exclusive of any VAT. For purposes of this Agreement, "**VAT**" means within the European Union such taxation as may be levied in accordance with (but subject to derogation from) Council Directive 2006/112/EC and outside the European Union any taxation levied by reference to added value or sales.

6.2 **Price Changes**. [***]

6.3 **Payment Terms**. SUPPLIER shall provide NOVARTIS with an invoice setting forth the Price due and payable for each Delivery of Products made under this Agreement. Each such invoice shall, to the extent applicable, identify the Order number, Product numbers, Batch numbers, quantities of Products, shipping address, Price and the total amount to be remitted by NOVARTIS and the applicable VAT or other sales tax (if any) or such other information as may be required by the applicable tax laws. NOVARTIS shall pay all such invoices on or before [***] after the receipt of such invoice, unless otherwise agreed upon in writing by the parties.

6.4 **Disputed Invoices**. If NOVARTIS disputes in good faith its obligation to pay all or part of any invoice submitted by SUPPLIER under this Agreement, then non-payment of such invoice or part of such invoice pending resolution of such dispute shall not constitute a material breach of this Agreement by NOVARTIS, provided, that if any such dispute is resolved in SUPPLIER's favor, NOVARTIS shall be responsible for the payment of interest on the amount(s) that were in dispute.

7. QUALITY ASSURANCE

7.1 **Quality Agreement**. The mutual tasks and responsibilities of the parties (or their Affiliates who are a party to the Quality Agreement) with regard to Quality Assurance are in particular determined in the Quality Agreement entered into by the parties (including though an affiliate addendum to a frame Quality Agreement). SUPPLIER shall at all times during the Term fully comply (and shall cause its Affiliates and Approved Subcontractors to fully comply) with its obligations under the Quality Agreement. A breach of the Quality Agreement shall be considered a breach of this Agreement.

7.2 **Quality Control**. SUPPLIER shall maintain a quality assurance and quality control program in accordance with cGxP, Applicable Standards and the Quality Agreement.

7.3 **Quality Audits and Regulatory Inspections**. In accordance with the terms of the Quality Agreement and at no additional cost to NOVARTIS, SUPPLIER shall (and shall cause its Affiliates and Approved Subcontractors and suppliers to) permit (i) NOVARTIS, its Affiliates or its designated representatives to audit any facilities (including the Facility) used by SUPPLIER, its Affiliates, its Approved Subcontractors or its suppliers in relation to the performance of its obligations under this Agreement (including the Quality Agreement); and (ii) Regulatory Authorities to inspect any such facilities.

8. CHANGES TO PRODUCTS

8.1 Changes to the Products (including the API and Components), the Manufacturing or the Facility may only be made in accordance with the Quality Agreement.

8.2 SUPPLIER shall solely bear all actual and related costs resulting from:

(a) [***]

(b) [***]

(c) [***].

8.3 NOVARTIS shall solely bear all actual and related costs resulting from:

(a) [***]

(b) [***]

(c) [***].

9. EXCHANGE OF INFORMATION

Without prejudice to NOVARTIS' rights to information set forth in the Quality Agreement, the parties shall continually exchange information and experiences in all matters pertaining to the Manufacturing of the Product and Quality Assurance and shall inform each other promptly in writing regarding all matters which could jeopardize the Manufacturing of the Product, whether for scientific, legal, regulatory or other reasons.

10. DEFECTIVE PRODUCT

10.1 **Right of Rejection**. Within the timeframes mentioned in this **Clause 10**, NOVARTIS shall have, at its sole discretion, the right to reject any Defective Product or any Batch (or related Batch) which can reasonably be expected to contain any Defective Product (except to the extent due to a Defect in the API attributable to NOVARTIS). For the avoidance of doubt, it is expressly agreed that any acknowledgement of receipt of Product by NOVARTIS shall not constitute any acceptance of Product as free of Defects or any waiver of any rights by NOVARTIS.

10.2 **Notification**. NOVARTIS shall notify SUPPLIER of any claims of Defective Product within the following timelines:

(a) For Apparent Defects, NOVARTIS shall have the right to make a Defective Product claim under this **Clause 10,** provided that such claim is made in writing to SUPPLIER within [***] following receipt of the Defective Product by NOVARTIS at the NOVARTIS warehouse; and

(b) For Latent Defects of which it becomes aware during the Residual Shelf Life of a Product, NOVARTIS shall have the right to make a Defective Product claim under this **Clause 10,** provided that such claim is made in writing to SUPPLIER within [***] following discovery of the Defect.

Any Defect which has been notified within the above time periods shall be presumed to have been in existence at the time of Delivery, unless SUPPLIER can demonstrate that such presumption is incompatible with the nature of the Defect.

10.3 **Handling of Defective Products**. Without any prejudice to any other rights or remedies available to NOVARTIS under this Agreement and/or governing law**,** and except to the extent that the Defect in the Product is due to a Defect in the API attributable to NOVARTIS, in the event that NOVARTIS notifies SUPPLIER of any Defect in accordance with this **Clause 10**, SUPPLIER shall

(a) at NOVARTIS' sole discretion and direction either: [***]

(b) [***].

Further, and without prejudice to NOVARTIS' other rights hereunder and/or governing law, SUPPLIER shall promptly instruct NOVARTIS to either send back to SUPPLIER or dispose of any Defective Products (and, if applicable, Products from the same or related Batch(es)), at SUPPLIER's discretion. Any remedial action taken by SUPPLIER shall comply with the Quality Agreement and SUPPLIER shall not rework or reprocess any rejected Defective Products, unless expressly authorized in writing to do so by NOVARTIS.

11. CONTINUOUS IMPROVEMENT, KPI, RELATIONSHIP MANAGEMENT

11.1 **Continuous Improvement**. The parties agree to pursue a mutual continuous improvement strategy and shall confer on a regular basis (at least annually) to consider whether new technologies or manufacturing processes may exist which would likely improve the Manufacturing performance and Product cost. [***]

11.2 **KPIs Scoring and Reporting**. NOVARTIS wishes to create additional transparency regarding supplier performance by providing feedback on supplier performance [***].

11.3 **Relationship Management**. The parties shall establish a relationship management team and procedure as set forth in **ANNEX 4**.

12. RESPONSIBLE PROCUREMENT

NOVARTIS promotes the societal and environmental values of the United Nations Global Compact to its external suppliers and uses its influence where possible to encourage their adoption. SUPPLIER shall:

(a) comply with the Novartis Supplier Code (and any published updates) which can be viewed and downloaded from [***] (SUPPLIER may request a copy free of charge from NOVARTIS);

(b) having regard to Section 9.6 of the Novartis Supplier Code, provide information and documentation on reasonable request to NOVARTIS and its Affiliates to allow NOVARTIS and its Affiliates to verify compliance with the Novartis Supplier Code in the form requested;

(c) to rectify identified non-compliances with the Novartis Supplier Code (where capable of remedy) and report remediation progress to NOVARTIS on request; and

(d) ensure that where SUPPLIER, its Affiliates and/or Approved Subcontractors of SUPPLIER and its Affiliates have been pre-approved by NOVARTIS (in accordance with this Agreement) to provide services that such third parties also comply with the above requirements relating to the Novartis Supplier Code.

[***]

13. HSE, RISK MANAGEMENT AND BUSINESS CONTINUITY

13.1 **HSE Requirements**. SUPPLIER shall fully comply (and shall cause its Approved Subcontractors and suppliers to fully comply) with the HSE Requirements set forth in this Agreement, including without limitation (i) any Applicable Standards relating to HSE protection (including REACH (Regulation (EC) No. 1907/2006)); (ii) any terms of the Quality Agreement relating to HSE; and (iii) **ANNEX 8** (collectively, the "**HSE Requirements**").

13.2 **HSE Audits**. As further set out in **ANNEX 8** and at no additional cost to NOVARTIS, SUPPLIER shall (and shall cause its Affiliates, Approved Subcontractors and suppliers to) permit NOVARTIS, its Affiliates and/or its designated representatives no more frequently than once every [***] months (or more frequently solely "for cause") to audit any facilities (including the Facility) used by SUPPLIER, its Affiliates, its Approved Subcontractors and/or its suppliers in order to verify compliance with the HSE Requirements under this Agreement.

13.3 **Risk Management**. In order to ensure continuity of supply and in connection with diligent Risk Management (as defined below) practices, SUPPLIER will develop, implement and keep current a Risk Management program, including a Business Continuity Management (as defined below), of which a Business Continuity Plan (as defined below) is a key element and output. The Business Continuity Plan shall detail strategies for responses to and recovery from a range of potential disruptive incidents. Upon NOVARTIS' written request, SUPPLIER will promptly make a summary or abridged version of such Business Continuity Plan available to NOVARTIS, its Affiliates or their designated representatives for review. The Business Continuity Plan does not relieve SUPPLIER from any liability under this Agreement. Once per calendar year (or at any other frequency as NOVARTIS reasonably deems to be appropriate), SUPPLIER will conduct a test and evaluation of the Business Continuity Plan. The parties agree that any issues arising from the Risk Management and Business Continuity Management will be promptly communicated to the other party. In no event shall SUPPLIER increase the Price as a result of the development, existence or implementation of the Business Continuity Plan.

For purposes of this **Clause 13.3**:

(a) "**Risk Management**" means the identification, assessment, and prioritization of risks followed by coordinated application of resources to minimize, monitor, and control the probability and/or impact of undesired incidents or to maximize the realization of opportunities;

(b) "**Business Continuity Management**" means the holistic management process which identifies potential threats to an organization and the impacts to business operations those threats, if realized, might cause and which provides a framework for building organizational resilience with the capability of an effective response that safeguards the interests of its key stakeholders, reputation, brand and value-creating activities.

(c) "**Business Continuity Plan**" means a plan clearly defining and documenting a set of measures designed to (i) allow a quick response to a disruptive incident so that the key business processes are restored to a minimum required operational level, and (ii) recover the key business processes in a defined time frame; such plan shall cover all key personnel, resources, services and actions which are required to manage the Business Continuity Management process.

14. PRODUCT RECALLS AND RETURNS

14.1 **Recalls**. Upon discovery that a Product should be recalled or corrected, or may be required to be recalled or corrected, the discovering party shall give prompt written notice to the QA contact of the other party, all subject to the terms of the Quality Agreement. The decision to initiate a recall or to take some other corrective action, if any, shall be made and implemented by NOVARTIS. The recall procedure is set forth in the Quality Agreement. If a recall occurs, at NOVARTIS' request, SUPPLIER shall replace the recalled Products (regardless of whether or not such Products are Defective) with new Products in the same manner as set forth in **Clause 10**.

14.2 **Customer Complaints and Returns**. SUPPLIER shall fully comply with the provisions of the Quality Agreement relating to customer complaints and customer returns. NOVARTIS or its Affiliates shall have full responsibility for handling such customer complaints and returns. SUPPLIER shall provide NOVARTIS with such assistance as required under the terms of the Quality Agreement. If a return occurs, at NOVARTIS' request, SUPPLIER shall replace the returned Products (regardless of whether or not such Products are Defective) with new Products in the same manner as set forth in **Clause 10**.

15. INTELLECTUAL PROPERTY

15.1 **License Grant.** Subject to the terms and conditions of this Agreement, SUPPLIER hereby grants to NOVARTIS and its Affiliates a worldwide, exclusive, fully paid up and royalty free sub-licensable license to the Recro Patent Rights, including to make, have made, dispose of, have disposed of, offer to dispose of, sell, offer to sell, commercialize, use, import, or keep the Products.

15.2 **Sub-license Grant.** Subject to the terms and conditions of this Agreement, SUPPLIER hereby grants to NOVARTIS and its Affiliates a worldwide, exclusive, fully paid up and royalty free sub-licensable sub-license to the Alkermes Patent Rights, including to make, have made, dispose of, have disposed of, offer to dispose of, use, import, or keep the Products.

15.3 **Background IP**. Each party's background Intellectual Property, which are owned by or licensed to that party prior to the Effective Date, or which are not invented, discovered, generated or derived under or in connection with this Agreement are and shall remain owned by or licensed to that party. Except as expressly stated herein, nothing in this Agreement shall constitute or grant any implied license or ownership in proprietary rights or permission to file any patent, copyright or any other Intellectual Property rights to either party under the other party's background Intellectual Property.

15.4 IP Ownership.

(a) **Novartis IP**. All Intellectual Property solely invented, discovered, generated or derived by or on behalf of NOVARTIS or its Affiliates under or in connection with this Agreement shall be the exclusive property of NOVARTIS or its Affiliates. All Intellectual Property invented, discovered, generated or derived by or on behalf of SUPPLIER, whether solely or jointly with NOVARTIS or its Affiliates, under or in connection with this Agreement, shall be the exclusive property of NOVARTIS or its Affiliates if the Intellectual Property arises from or relates to Novartis Material or other Confidential Information of or disclosed by NOVARTIS. [***]

(b) **Supplier IP**. All Intellectual Property invented, discovered, generated or derived by SUPPLIER in connection with the Product which is not covered by **Clause 15.4(a)** and which is independently invented, discovered, generated or derived by or on behalf of SUPPLIER shall be the sole and exclusive property of SUPPLIER. NOVARTIS and its Affiliates shall have a worldwide, perpetual, non-exclusive, royalty free, fully paid-up license under such Intellectual Property, with the right to grant sub-licenses.

(c) **Notification by Supplier**. SUPPLIER shall promptly disclose in writing and make available to NOVARTIS in electronic form, and shall cause its Approved Subcontractors to disclose in writing and make available to NOVARTIS in electronic form, all results, inventions and improvements (whether patentable or not) which are invented, discovered, generated or derived under or in connection with this Agreement. NOVARTIS and its Affiliates shall have the first right but not the obligation, at NOVARTIS' costs, to prepare, file, prosecute, obtain and maintain patent applications and patents relating to inventions and improvements which are invented, discovered, generated or derived under or in connection with this Agreement.

(d) **Supplier Assistance**. SUPPLIER shall execute all documents and take all such other actions as may be reasonably requested by NOVARTIS or its Affiliates in order to permit NOVARTIS (or its Affiliates) to obtain the benefit of its rights (including Intellectual Property) under or in connection with this Agreement, and shall cause any employees, Approved Subcontractors, suppliers of Components or any other subcontractor to take such action, all at NOVARTIS' expense. SUPPLIER shall ensure that it has enforceable written agreements with its Approved Subcontractors granting to SUPPLIER rights (with the right to sub-license) to all results and Intellectual Property created by such Approved Subcontractors during the course of their engagement hereunder.

(e) **IP Infringement**. Should SUPPLIER become aware of any infringement of NOVARTIS' or its Affiliates' Intellectual Property relating to the Product or Manufacturing processes, SUPPLIER shall immediately notify NOVARTIS thereof.

15.5 IP Enforcement and Defense.

(a) Each party will promptly notify the other of any infringement by a third party of any of the Alkermes Patent Rights, Recro Patent Rights or Intellectual Property in connection with this Agreement of which it becomes aware, including any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions and of any request for declaratory judgment, opposition, nullity action, interference, inter-partes reexamination, inter-partes review, post-grant review, derivation proceeding, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Alkermes Patent Rights, Recro Patent Rights, Intellectual Property or Know-How in connection with this Agreement (collectively "**Third Party Infringement**"). Each party will provide the other with any available evidence of such Third Party Infringement.

(b) NOVARTIS will have the right to bring and control any legal action in connection with any Third Party Infringement of Recro Patent Rights at its own expense as it reasonably determines appropriate, and the SUPPLIER shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If NOVARTIS fails to bring or terminate any such action or proceeding with respect to such Third Party Infringement of Recro Patent Rights (i) within one hundred twenty (120) days following the notice of alleged infringement or (ii) prior to ten (10) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, SUPPLIER shall have the right, upon written approval of NOVARTIS (such approval not to be unreasonably withheld or delayed), to bring and control any such action at its own expense and by counsel of its own choice, and NOVARTIS shall have the right, at its own expense, to be represented in any such action by counsel of its own choice; provided, however, that if NOVARTIS notifies SUPPLIER in writing prior to ten (10) days before such time limit for the filing of any such action that NOVARTIS intends to file such action before the time limit, then NOVARTIS shall be obligated to file such action before the time limit, and SUPPLIER will not have the right to bring and control such action.

(c) At the request of NOVARTIS, SUPPLIER shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, access to SUPPLIER'S premises and employees, cooperating reasonably in discovery and joining as a party to the action if required.

(d) In connection with any such proceeding, NOVARTIS shall not enter into any settlement admitting the invalidity of, or otherwise impairing SUPPLIER'S rights in, the Recro Patent Rights and/or the Alkermes Patent Rights without the prior written consent of SUPPLIER, which will not be unreasonably withheld or delayed.

(e) Any recoveries resulting from such an action relating to a Claim of Third Party Infringement of Recro Patent Rights shall be first applied against payment of each party's costs and expenses in connection therewith. In the event that NOVARTIS brought such action, any remainder will be retained by (or if received by SUPPLIER, paid to) NOVARTIS. In the event that SUPPLIER brought such action, any remainder shall be divided equally between SUPPLIER and NOVARTIS.

15.6 **Trademarks**. NOVARTIS shall have the right to brand the Products using NOVARTIS related trademarks and any other trademarks and trade names it determines appropriate for the Product, which may vary by country or within a country ("**Product Marks**"). NOVARTIS or its Affiliates shall own all rights in the Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary.

15.7 **Representations and Warranties of SUPPLIER**. SUPPLIER represents and warrants to NOVARTIS as of the Effective Date that:

(a) **ANNEX 10** sets forth a complete and accurate list of all Patent Rights owned by SUPPLIER covering the Product in existence as of the Effective Date, indicating the owner, and/or co-owner(s) thereof if such Patent Rights are not solely owned by SUPPLIER;

(b) SUPPLIER is the sole and exclusive owner of all of the Recro Patent Rights, free from encumbrances (except for security interests), and is listed in the records of the appropriate governmental agencies as the sole and exclusive owner of record for each registration, grant and application included in the Recro Patent Rights;

(c) **ANNEX 9** sets forth a complete and accurate list of all Patent Rights owned by Alkermes and its Affiliates covering the Product in existence as of the Effective Date, indicating the owner, and/or co-owner(s) thereof if such Patent Rights are not solely owned by Alkermes;

(d) SUPPLIER has the right to grant to Novartis and its Affiliates the licenses under the Recro Patent Rights and Alkermes Patent Rights that it purports to grant hereunder;

(e) to SUPPLIER's knowledge, the issued patents in the Recro Patent Rights and Alkermes Patent Rights are valid and enforceable without any Claims, challenges, oppositions, nullity actions, interferences, inter-partes reexaminations, inter-partes reviews, post-grant reviews, derivation proceedings, or other proceedings pending or threatened;

(f) to SUPPLIER's knowledge, SUPPLIER has not committed any act, or omitted to commit any act, that may cause the Recro Patent Rights or Alkermes Patent Rights to expire prematurely or be declared invalid or unenforceable; and

(g) all applications, registrations, maintenance and renewal fees for which there is a maximum payment deadline prior to the Effective Date in respect of the Alkermes Patent Rights listed in **ANNEX 9** and the Recro Patent Rights listed in **ANNEX 10** have been paid. All applications, registrations, maintenance and renewal fees in respect of the Recro Patent Rights and Alkermes Patent Rights will be maintained by SUPPLIER until the respective patent expiry dates. To SUPPLIER's knowledge, all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining the Recro Patent Rights and Alkermes Patent Rights.

16. INDEMNIFICATION AND LIABILITIES

16.1 **Supplier Indemnification**. SUPPLIER shall defend, indemnify and hold NOVARTIS and its Affiliates harmless against any and all Claims to the extent arising out of: (i) any breach of this Agreement by SUPPLIER or its Affiliates; (ii) any Defect in the Products; (iii) any negligence or willful misconduct of SUPPLIER or its Affiliates; or (iv) any patent infringement or infringement of any other Intellectual Property with respect to the Products and/or SUPPLIER's manufacturing processes, except to the extent that such Claims arise out of: (A) any breach of this Agreement by NOVARTIS or its Affiliates; (B) any negligence or willful misconduct of NOVARTIS or its Affiliates; or (C) any Claim otherwise covered by the indemnity in **Clause 16.2**.

16.2 **Novartis Indemnification**. NOVARTIS shall defend, indemnify and hold SUPPLIER and its Affiliates harmless against any and all Claims to the extent arising out of: (i) the use of the Products in a NOVARTIS pharmaceutical proprietary product by any person, (ii) any breach of this Agreement by NOVARTIS or its Affiliates; or (iii) any negligence or willful misconduct of NOVARTIS or its Affiliates, except to the extent that such Claims arise out of: (A) any breach of this Agreement by SUPPLIER or its Affiliates; (B) any Defect in the Products; (C) any negligence or willful misconduct of SUPPLIER or its Affiliates; or (D) any Claim otherwise covered by the indemnity in **Clause 16.1**.

16.3 **Indemnification Process**. The indemnification obligations of NOVARTIS and SUPPLIER, as the case may be, shall apply only if:

(a) the party asserting its rights ("**Indemnitee**") promptly notifies the other party ("**Indemnitor**") in writing after Indemnitee receives notice of any Claims;

(b) Indemnitee has refrained and continues to refrain from making any admission of liability or any attempt to settle any such Claims without Indemnitor's written consent;

(c) Indemnitor is given the opportunity to manage and control the defense or settlement of such Claims;

(d) Indemnitee reasonably co-operates with Indemnitor in the defense of any such Claims; and

(e) Indemnitee takes all such reasonable steps and actions as are necessary or as the Indemnitor may reasonably require or request in order to mitigate any Claims.

16.4 Nothing in this Agreement shall exclude or limit any liability for (i) willful misconduct or omission; (ii) fraud; (iii) intentional breach; (iv) gross negligence; (v) personal injury or death caused by the negligence of a party; or (vi) any other liability that cannot be limited or excluded by law.

17. INSURANCE

17.1 Each party (or its Affiliate on behalf of such party) shall maintain in full force and effect, at its sole cost and expense, and at all times during the Term hereof, a policy of commercial general liability insurance, including contractual liability, with limits of not less than [***] in the aggregate. Notwithstanding the foregoing, SUPPLIER (or its Affiliate on behalf of SUPPLIER) shall maintain throughout the term of this Agreement products/completed operations liability coverage in an amount not less than [***]. Both parties shall also maintain such other policies of insurance or programs of self-insurance of the types and in the amounts customarily carried by their respective businesses to fulfill their respective obligations stated within this Agreement.

17.2 Each party warrants that neither its program of self-insurance, if any, nor its (or its Affiliate's) insurance policy(ies) as described in the foregoing paragraph will affect or limit its liability or indemnity obligations stated elsewhere in this Agreement or as required by law. By requiring SUPPLIER to maintain products/completed operations liability insurances, Novartis does not represent that SUPPLIER's insurance program will be adequate to fund all losses for which SUPPLIER may be liable hereunder. Upon execution of this Agreement and annually thereafter upon request, each party shall provide the other with evidence of its (or its Affiliate's) liability insurance as described in the foregoing paragraphs. NOVARTIS shall evidence its general commercial and products/completed operations liability insurance to SUPPLIER using a Memorandum of Insurance (MOI) website link. Each party shall be given thirty (30) days' prior written notice of any cancellation, termination or non-renewal of any of the insurance policies described herein by the other party.

18. CONFIDENTIALITY

18.1 **Confidential Information**. Neither party shall disclose to any third party nor use for any purpose outside of the scope of this Agreement any information which is not in the public domain and which was disclosed in connection with this Agreement: (i) by a party or any of its Affiliates; or (ii) any unaffiliated third party at the request of such disclosing party ("**Confidential Information**"). The receiving party may only provide the disclosing party's Confidential Information to its and its Affiliates' directors, officers, employees, advisors, and consultants ("**Representatives**") who are informed of the confidential nature of the Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive than those contained herein and provided that the receiving party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by the receiving party. The obligations of confidentiality and non-use shall expire for Confidential Information which:

(a) is or becomes part of the public domain without a violation of this Agreement;

(b) was already in its possession at the time of receipt from the disclosing party, as shown by documentary evidence; or

(c) after the date of this Agreement is received from a third party whose direct or indirect source is not the disclosing party.

18.2 **Disclosure of Confidential Information**. The parties may disclose Confidential Information where reasonably required under applicable law (including any securities law or regulation or the rules of a securities exchange): (i) to competent Regulatory Authorities for Registration or other regulatory purposes, including the U.S. Securities and Exchange Commission (the "**SEC**") or a securities exchange, and, when required by such applicable law, to the public; and (ii) to competent court or governmental agencies, in which case the disclosing party (to the extent permissible under applicable law) shall inform the other party of such disclosure in writing and shall use commercially reasonable efforts to limit the scope of such disclosure to obtain confidential treatment by the court or governmental agency. Except as expressly permitted herein, this **Clause 18.2** shall not be interpreted as relieving the receiving party of its confidentiality obligations under this **Clause 18**. In addition, NOVARTIS and/or its Affiliates may disclose Confidential Information to any purchaser interested in acquiring all or part of NOVARTIS' business or assets relating to the Products (including without limitation by asset purchase, divestment, out-licensing, merger, consolidation or reorganization), provided that such potential purchaser (x) has submitted an offer for such business or assets, and (y) has entered into a confidentiality agreement with NOVARTIS and/or its Affiliates on terms and conditions not less stringent than those foreseen herein. The parties acknowledge that either or both parties may be obligated to make filings (including, but not limited to, filing a copy of this Agreement) with the SEC or other governmental entity. Each party shall be entitled to make such required filings, provided that it requests confidential treatment of sensitive terms of this Agreement (including any Annex hereto) to the extent such confidential treatment is reasonably available to such party. In the event of any such filing of this Agreement, the party making such filing shall provide notice to the other party with a copy of such disclosure and, if applicable, a copy of this Agreement (including the Annexes hereto) marked to show provisions for which such party intends to seek confidential treatment not less than five (5) business days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), and shall give consideration to the other party's comments thereon to the extent consistent with legal requirements. No such notice shall be required under this **Clause 18.2** if the substance of the description of or reference to this Agreement contained

in the proposed filing has been previously included in or is substantially similar to any filing previously made by a party pursuant to the terms of this **Clause 18.2** or that has otherwise been previously approved in writing by the other party.

18.3 **Survival**. The obligations of confidentiality and non-use contained in this **Clause 18** shall survive the expiration or termination of this Agreement for a period of [***] years.

18.4 **Return of Confidential Information**. Upon termination or expiration of this Agreement for any reason, the receiving party will promptly return to the disclosing party all Confidential Information received from the disclosing party in connection with this Agreement.

19. TERM AND TERMINATION FOR CONVENIENCE

19.1 **Effective Date**. This Agreement shall come into force on the Effective Date.

19.2 **Term**. This Agreement shall have an initial fixed term of five (5) years from the Effective Date (the "**Initial Term**"). Thereafter, unless terminated in accordance with **Clause 19.3** or **Clause 20**, it shall renew automatically for successive periods of twelve (12) months ("**Renewal Term**"). The Initial Term and any Renewal Term(s) are collectively referred to as the "**Term**".

19.3 **Termination for Convenience**. NOVARTIS may terminate this Agreement without cause upon written notice to SUPPLIER at least twenty-four (24) months prior to the end of the Initial Term or any Renewal Term. SUPPLIER may terminate this Agreement without cause upon written notice to NOVARTIS at least twenty-four (24) months prior to the end of the Initial Term or any Renewal Term. For clarity, the earliest termination effective date shall be 31 December 2023, and in the event either party wishes to terminate this Agreement at the end of the Initial Term, such party shall be required to provide written notice to the other party no later than 31 December 2021. SUPPLIER acknowledges and agrees that this notice period is necessary in order to allow NOVARTIS sufficient time to identify, approve and transfer the Manufacturing of the Product to a new supplier.

20. EXTRAORDINARY TERMINATION; DIVESTMENT

Without prejudice to any grounds for extraordinary termination available to a party under applicable law, the parties agree that this Agreement may be terminated in accordance with the terms set forth in this **Clause 20**.

20.1 **Termination due to Material Breach**. Upon failure of any party to remedy its material breach of any of its obligations under this Agreement (where remediable) on or before ninety (90) days after receipt of written notice of said breach from the other party, the party giving such notice shall have the right but not the obligation to terminate this Agreement immediately (or such longer period of time as such party shall determine) by written notice. In respect of a material breach which is not capable of remedy, the non-defaulting party shall have the right, but not the obligation, to terminate this Agreement immediately by written notice to the defaulting party.

20.2 **Termination due to Liquidation**. SUPPLIER or NOVARTIS at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party upon the liquidation, dissolution, winding-up, insolvency, bankruptcy, assignment for the benefit of creditors, or filing of any petition therefor, appointment of a receiver, custodian or trustee, or any other similar proceeding, by or of the other party where such petition, assignment or similar proceeding is not dismissed or vacated within ninety (90) days.

20.3 **Termination due to Regulatory Authority**. NOVARTIS may terminate this Agreement immediately (in whole or in part on either a country-by-country basis or a Product-by-Product basis) if any Regulatory Authority takes any action, or raises any objection, that prevents NOVARTIS from supplying API (as applicable) and/or exporting, purchasing or selling a Product in its bulk or finished packaged form. Additionally, NOVARTIS shall have the right to terminate this Agreement immediately (in whole or in part) if any Product (or, as applicable, the pharmaceutical product comprised of the Product) cannot be reasonably commercialized for medical, scientific or legal reasons.

20.4 **Termination for Divestment**. In the event of a sale, divestiture, out-license or other disposition of all or part of the business or assets relating to the Product (or, as applicable, the pharmaceutical product comprised of the Product) supplied under this Agreement, NOVARTIS shall have the right to unilaterally terminate this Agreement in whole or in part upon twelve (12) months prior written notice to SUPPLIER, provided, however, that neither NOVARTIS nor any assignee of NOVARTIS pursuant to **Clause 24.9** may unilaterally terminate this Agreement pursuant to this Clause 20.4 during the Initial Term.

20.5 **Termination due to Non-Compliance with HSE Requirements**. NOVARTIS may terminate this Agreement upon sixty (60) days' written notice to SUPPLIER if SUPPLIER fails to comply with Applicable Standards relating to HSE and does not cure such failure during such sixty (60) day period.

20.6 **Compensation for Termination**. [***]

21. EFFECTS OF TERMINATION OR EXPIRATION

21.1 **Return of Novartis Material**. Upon expiration or termination of this Agreement for any reason, SUPPLIER shall, and shall cause its Approved Subcontractors to, promptly Deliver to NOVARTIS or destroy at NOVARTIS' direction, all Novartis Material. For Product, NOVARTIS shall pay the Price in effect at the time the relevant Order was placed; for partially-Manufactured Product, the parties shall agree on a mutually agreed price, which shall consider whether the partially-Manufactured Product can be finished and, if so, NOVARTIS' costs to complete such Manufacturing.

21.2 **Survival**. Except as otherwise expressly provided herein, the termination or expiration of this Agreement will not affect any rights and obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement, nor shall it prejudice any other remedies that the parties may have under this Agreement. Upon expiration or termination of this Agreement, all outstanding unpaid invoices shall become payable immediately in place of the payment terms previously agreed by the parties.

21.3 **Bridging Stock**. Prior to expiration of this Agreement or upon notice of termination, NOVARTIS will have the option (valid until the effective date of such expiration or termination) to place Orders for an additional quantity of the Products of up to [***] demand based on [***] percent ([***]%) of the quantity forecasted by NOVARTIS for the year in which the contract expires or is terminated ("**Bridging Stock**") at the price equal to the Price in force for the Product at the time of expiration or termination of this Agreement. NOVARTIS shall exercise its option for the Bridging Stock by providing SUPPLIER with an Order for the desired quantities of the Bridging Stock, which shall be Manufactured or packaged pursuant to a Confirmed Order and shall meet the Specifications and be subject to the terms of this Agreement. The parties shall agree in good faith on the Delivery dates of such Bridging Stock, provided, however, that SUPPLIER shall accept Requested Delivery Dates falling within the [***] period following the expiration or termination effective date, and the parties hereby agree that terms of this Agreement shall apply to such Bridging Stock.

22. **Technical Transfer**. Upon the expiration or termination of this Agreement, at NOVARTIS' written request, in NOVARTIS' sole discretion, and provided the reason for such termination is not NOVARTIS' material breach of this Agreement, SUPPLIER shall (and shall cause its Affiliates and Approved Subcontractors to) implement the transfer of all know-how necessary for the Manufacture of the Products and related analytical testing methods from SUPPLIER, its Affiliates and/or Approved Subcontractors to NOVARTIS, its Affiliates and/or a designated third party. SUPPLIER (or its Affiliates) shall cooperate with NOVARTIS (or its Affiliates or designated third party) with regard to such transfer and provide all reasonably required and customary assistance to NOVARTIS (or its Affiliates or designated contract manufacturer) to enable NOVARTIS (or its Affiliates or designated contract manufacturer) to complete such transfer in a timely and effective manner. [***]

23. GOVERNING LAW AND JURISDICTION

23.1 **Governing Law**. This Agreement and the legal relations between the parties in connection herewith shall be governed by, and construed in accordance with, the laws of the State of New York, USA, without regard to its conflict of laws principles.

23.2 **Jurisdiction**. For the purpose of any dispute arising out of or in connection with this Agreement which cannot be resolved amicably, the parties hereby irrevocably submit to the exclusive jurisdiction of the Federal courts located in New York.

23.3 **Dispute Resolution through Independent Laboratory**. The following shall apply in relation to any unresolved dispute as to the existence and root cause of any non-conforming or Defective Product:

(a) either party may request in writing for such unresolved dispute to be determined by an independent first-class laboratory ("**Laboratory**");

(b) upon receipt of such request, the parties shall jointly appoint the Laboratory within twenty (20) days. If the choice of the Laboratory cannot be agreed by the parties within the timeframe stated, each party shall be entitled to appoint one independent laboratory and the two independent laboratories so selected by the parties shall jointly select the Laboratory. The Laboratory (and any laboratories appointed by the parties in order to jointly select the Laboratory) shall be bound to the parties by obligations of confidentiality no less exacting than those applying between the parties pursuant to this Agreement;

(c) the Laboratory shall within forty (40) days of its appointment determine the root cause of the non-conformity or Defect and its findings shall be conclusive and binding upon the parties; and

(d) all fees and expenses of the Laboratory shall be borne solely by the unsuccessful party.

23.4 **Remedy for Breach**. The parties understand and agree that monetary damages may not be a sufficient remedy for breach of this Agreement and that the injured party will be entitled to seek equitable relief, including injunction and specific performance, for any such breach.

24. MISCELLANEOUS

24.1 **Relationship of the Parties**. For the purposes of this Agreement, each party shall be an independent contractor and not an agent or employee of the other party. Neither party shall have authority or power to make any statements, representations or commitments of any kind, or to take any action which is binding on the other party, unless expressly so authorized to do so by an instrument in writing signed by authorized representatives of such other party.

24.2 **Notices**. Any notices which either party may be required or shall desire to give under this Agreement shall be deemed to be duly given when in writing and delivered personally, mailed by registered mail or courier service to the party to whom notice is to be given, at the address specified below (which may be amended upon at least seven (7) days prior written notice to the other party), or for any notices which either party may be required or shall desire to give under any Annex to this Agreement, shall be given at the address specified in such Annex.

RECRO GAINESVILLE LLC
1300 Gould Drive
Gainesville, GA 30504
Attn: Scott Rizzo (General Manager)

With a copy to:
Pepper Hamilton LLC
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799
Attn: Rachael Bushey
Attn: Jennifer Porter

NOVARTIS PHARMA AG
Lichtstrasse 35
CH-4056 Basel
Switzerland
Attn: Head of External Supply Operations, Novartis Technical Operations
Copy: Head of Legal Novartis Technical Operations

24.3 **No license**. No license or right is granted by implication or otherwise with respect to any know-how, patent application or patent owned by NOVARTIS or any of its Affiliates or SUPPLIER or any of its Approved Subcontractors, except as and if specifically set forth herein.

24.4 **Annexes**. All Annexes (and any amendments to such Annexes) and their enclosures form an integral part of this Agreement and are incorporated herein by reference.

24.5 **Order of Priority**. In the event of any conflict, inconsistency or discrepancy between this Agreement, the Annexes or the terms and conditions referenced or incorporated in this Agreement or the Appendices, the following order of priority shall apply: (i) the Quality Agreement (solely in respect of Quality Assurance, quality management and compliance with the Applicable Standards), (ii) this Agreement, (iii) any Annexes, and (iv) individual Orders.

24.6 **Standard Terms**. Except as expressly otherwise agreed in writing by the parties, the provisions of this Agreement (including its Annexes) shall apply to any Order for the Product as well as any activity within the scope of this Agreement to the exclusion of any standard terms and conditions of either party, even if reference is made to such standard terms and conditions by either party in any Order, or any other document.

24.7 **Force Majeure**. Failure of any party to perform its obligations under this Agreement (other than obligations to make any payments or of confidentiality) shall not subject such party to any liability or place them in breach of any term or condition of this Agreement to the other party if, and solely to the extent, such failure is caused by Force Majeure. The corresponding obligations of the other party will be suspended to the same extent. "**Force Majeure**" shall mean any unanticipated event beyond a party's (and/or its subcontractors') reasonable control that could not be avoided by due care of such non-performing party (and/or its subcontractors), including without limitation, acts of God, fire, explosion, flood, earthquake, drought, war, hostility, revolution, riot, civil disturbance, national emergency, sabotage, or embargo; provided, however, that the party affected shall promptly notify the other party of the condition constituting Force Majeure as defined herein and shall exert commercially reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed. If a condition constituting Force Majeure as defined herein prevents, or would likely prevent, a party from performing its obligations under this Agreement for more than ninety (90) days, the parties shall meet to negotiate a mutually satisfactory solution to the problem, if practicable, including the use of a third party to fulfil the obligations hereunder of the party invoking Force Majeure at the expense of the party invoking Force Majeure.

24.8 **Entire Agreement**. This Agreement (including the Annexes hereto) constitutes the entire agreement between the parties related to the subject matter covered by this Agreement, and shall supersede and prevail over any other prior or contemporaneous arrangements regarding this subject matter, whether written or oral, and is binding upon the parties hereto and their successors. No modification of this Agreement will be binding upon either party unless made in writing and signed by both parties.

24.9 **Assignment**. Unless otherwise provided for herein, this Agreement and the rights and obligations hereunder may not be assigned or transferred by either party hereto without the prior written consent of the other party, provided however, that NOVARTIS may assign this Agreement (in whole or in part) upon written notice to, but without the prior approval of, SUPPLIER to: (i) an Affiliate of NOVARTIS; (ii) a third party in connection with the sale or disposal of all or part of the assets of NOVARTIS; or (iii) if NOVARTIS divests, out-licenses or otherwise disposes of the Product or the business or assets relating to the Product.

24.10 **Delegation**. NOVARTIS may delegate any of the activities under this Agreement to any of its Affiliates, including without limitation Quality Assurance, regulatory ordering process, invoicing, artwork approval process, or supply chain related activities. In such case, NOVARTIS shall remain fully responsible for the performance of its obligations under this Agreement by its Affiliate and SUPPLIER shall have no recourse against such Affiliate but shall address any claims or demands to NOVARTIS.

24.11 **Severability**. If any provision of this Agreement is held to be invalid or unenforceable, then the offending provision (or the relevant part thereof) shall not render any other provision of this Agreement invalid or unenforceable, and the Agreement shall remain in full force and effect and shall be enforceable, and the invalid one shall be replaced by a new provision which meets the original economic intent of the invalid provision as far as legally possible.

24.12 **Waiver**. No delay or omission on the part of either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any complete or partial waiver on the part of either party of any right, power or privilege hereunder, nor shall any single or partial exercise or any right, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder. Any provision of this Agreement may be waived if, and only if, such waiver is in writing and signed by the party against whom the waiver is to be effective.

24.13 **Survivorship**. Any of the provisions of this Agreement, including the Annexes, that are expressed or implied to survive the expiration or termination of this Agreement, shall remain in full force and effect.

24.14 **Execution**. This Agreement may be executed in two or more counterparts and by facsimile or pdf electronic signature, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts shall together constitute one and the same instrument.

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Signed by the duly authorized representatives of each of the parties hereto as of the Effective Date.

NOVARTIS PHARMA AG

By: /s/ Stefan Amberg
Name: Stefan Amberg
Title: Head External Supply Organisation Europe

By: /s/ Sarah Thomae
Name: Sarah Thomae
Title: Senior Legal Counsel

RECRO GAINESVILLE LLC

By: /s/ M. Scott Rizzo
Name: M. Scott Rizzo
Title: SVP & General Manager, Recro Gainesville, LLC

NOVARTIS PHARMACEUTICALS CORPORATION (solely with respect to termination of the Development, License and Supply Agreement pursuant to **Clause 2.9**)

By: /s/ John McKenna
Name: John McKenna
Title: Chief Financial Officer, NPC

[***] CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THIS OMITTED INFORMATION.

ANNEX 1

PRODUCT & PRICING

Ritalin LA

Pricing/M	[***] capsules	[***] capsules	[***] capsules	[***] capsules	[***] capsules +
Ritalin LA [***](Bulk)	[***]	[***]	[***]	[***]	[***]
Ritalin LA [***](Bulk)	[***]	[***]	[***]	[***]	[***]
Ritalin LA [***](Bulk)	[***]	[***]	[***]	[***]	[***]
Ritalin LA [***](Bulk)	[***]	[***]	[***]	[***]	[***]
Ritalin LA [***](Bulk)	[***]	[***]	[***]	[***]	[***]

Focalin XR

Pricing/M	[***] capsules	[***] capsules	[***] capsules	[***] capsules +
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]
Focalin XR [***](Bulk)	[***]	[***]	[***]	[***]

ANNEX 2

SAFETY STOCK REQUIREMENTS

[***]

[***]

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ANNEX 3

Part A – KEY PERFORMANCE INDICATORS

[***]

[***]

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KPI	Definition	Critical KPIs (Yes/No)
Number of Deviations	All deviations non-critical or critical decided/approved by Novartis QA in the reporting period.	
Number of Deviations overdue	Number of all deviations considered by NOVARTIS to be overdue (at the agreed reporting period)	
Complaint Rate	All complaints (justified and not justified, critical and non-critical) per units shipped externally ('units shipped'). To be reported separately as a justified and not justified complaints rate	
Number of Complaints overdue	Definition imminent (during the agreed reporting period). In order to prevent double counting the Number has to be provided by the Organization (i.e. NOVARTIS or SUPPLIER) which investigates the complaint (not which received the complaint)	
Number of Complaints	All complaints non-critical or critical decided/approved by Novartis QA in the reporting period.	
Number of Recalls	Total number of (decided) recalls presented as Year-to-date total	
SDP (Supply Delivery Performance)	SDP (formerly OTIF) measures the number of orders delivered and available to use (quality approved) within the time tolerance and within the quantity tolerance. An order is considered a HIT if both data points (time and quantity) are met. An order is considered a MISS if: [***] [***]	Yes
Savings as a percentage of spend last 12 months	Evaluated as (Price Previous Year-Price Current Year) * Quantity invoiced in Current Year. For multiple deliveries and invoices of the same item throughout the period, the weighted average price concept (weighted average price of all supplier invoices during the current year compared with the weighted average price of the previous year) is normally applied.	

Collaboration (subjective measurement by NOVARTIS)	**Cooperation Mindset:** This supplier has a generally cooperative spirit and approach to work with NOVARTIS, is willing to make compromises when needed (i.e., no opportunistic behavior); there are concrete examples of joint collaboration initiatives with this supplier
	1. Openness: This supplier is generally open to sharing data and information (e.g., on quality, cost, etc.) beyond traditional silos and is openly communicating any internal problems (e.g., deviations)
	2. Improvement Drive: This supplier is aspiring to truly bring their performance to the next level, going beyond requirements, across key functional performance areas (e.g., Quality, Service)
	3. Responsiveness: This supplier always responds to any arising issues timely, both in terms of finding a short-term fix and a long-term solution; communication with this supplier is generally easy and smooth (i.e., no/little need for follow-up, reminders, etc.)
	4. Proactiveness: This supplier proactively identifies, flags, and resolves issues and pushes for the implementation of their resolution
Innovation (subjective measurement by Novartis)	**1. Culture:** This supplier is open to innovation, to new ways of working, and to change (whether it comes from Novartis or elsewhere)
	2. Idea Generation & Implementation: This supplier proactively generates improvement ideas themselves, has drive and perseverance to implement them, is willing to invest in innovation and take risks
	3. Track Record: There are concrete examples of key innovation or co-development projects with this supplier over the last year

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Part B - KPI Targets & Scoring Mechanism

Area	KPI	Scoring mechanism: Performance Points to be allocated 1	3	5	Performance	Score
Quality ([***]%)	No. of deviations overdue	[***]	[***]	[***]		
	APR/ PQR overdue	[***]	[***]	[***]		
	No. of complaints overdue	[***]	[***]	[***]		
	Complaint rate	[***]	[***]	[***]		
	No. of recalls	[***]	[***]	[***]		
	Quality overall					
Service ([***]%)	SDP	[***]	[***]	[***]		
	Service overall					
Cost ([***]%)	Savings as share of spend, last 18 months	[***]	[***]	[***]		
	Cost overall					
Collaboration ([***]%)	Collaboration score overall by SRT	[***]	[***]	[***]		
	Collaboration overall					
Innovation ([***]%)	Innovation score overall by SRT	[***]	[***]	[***]		
	Innovation overall					
Overall score						

ANNEX 4

RELATIONSHIP MANAGEMENT

1. **Supplier Representatives.** SUPPLIER shall establish a customer interface team headed by a dedicated key account manager as primary point of contact to NOVARTIS.

2. **Joint Supply Team.** The parties shall establish a joint supply team (the "***Joint Supply Team***") which shall be composed of an equal number of employees from NOVARTIS' and SUPPLIER's operational team responsible for performance under this Agreement. Either Party may replace any or all of its representatives at any time by written or electronic notice to the other Party.

3. **Meetings.** The Joint Supply Team shall meet at least once per calendar month, or as otherwise agreed by the Joint Supply Team. Meetings shall occur by teleconference, videoconference or in person.

4. **Responsibilities.** The Joint Supply Team shall supervise and coordinate the collaboration of the parties under this Agreement, including technical aspects, logistics and planning, Quality Assurance, quality control, regulatory aspects and compliance and shall serve as a point of escalation for all issues that arise during the performance of this Agreement. In particular, the Joint Supply Team shall:

(a) regularly discuss projected demand requirements and supply plans (S&OP) for the Products;

(b) discuss any proposed Manufacturing changes;

(c) review and discuss a mutual continuous improvement and competitive best practices strategy;

(d) review and discuss the KPIs; and

(e) carry out any other duties that are allocated to it under this Agreement.

The Joint Supply Team shall not have any authority to modify the terms of this Agreement.

Minutes. Joint Supply Team meetings shall be chaired by a Joint Supply Team member of NOVARTIS. The chair shall be responsible to keep reasonably detailed minutes of the relevant meetings. Minutes of Joint Supply Team meetings shall be sent to all Joint Supply Team members, for review and approval within ten (10) business days. Minutes shall be deemed approved unless any Joint Supply Team member objects to the accuracy of such minutes within ten (10) business days of receipt.

ANNEX 5

TRADING SERVICES PROCEDURE

(As attached, immediately following this page, and the remainder of this page is left blank intentionally.)

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[***] [Twenty-four pages omitted in their entirety]

ANNEX 6

QUALITY AGREEMENT

(As attached, immediately following this page, and the remainder of this page is left blank intentionally.)

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[***] [Eighty-three pages omitted in their entirety]

ANNEX 7

ADDITIONAL HSE REQUIREMENTS

During the Term, SUPPLIER shall comply with the additional HSE requirements set forth in this ANNEX and shall procure that its Approved Subcontractors and suppliers similarly comply with each of these additional HSE requirements, in each case solely as it relates to the Product and/or any Novartis procedures applicable thereto.

1. HSE Audit Rights

a. SUPPLIER shall establish and maintain a HSE audit program for its Approved Subcontractors, its suppliers and its supply chain generally in order to ensure SUPPLIER's compliance with the HSE Requirements. Upon request, SUPPLIER shall provide any audit reports related thereto to NOVARTIS.

b. SUPPLIER shall (and shall cause its Approved Subcontractors and suppliers to) grant NOVARTIS, its Affiliates and its designated representatives access to the Facility and to any other facilities where any activities falling within the scope of this Agreement are being performed. This includes access to equipment, as well as to any documents, records, reports, data, procedures, regulatory submissions, and any other information required to be maintained under the HSE Requirements, for the purposes of auditing compliance with the HSE Requirements.

c. SUPPLIER shall enable (and shall cause its Approved Subcontractors and suppliers to enable) NOVARTIS, its Affiliates and designated representatives to take sufficient quantities of samples in order to reasonably verify compliance with the HSE Requirements.

2. **HSE Training.** SUPPLIER shall ensure that any persons engaged in activities falling within the scope of this Agreement have adequate HSE training, including training in handling hazardous materials (as defined under Applicable Standards).

3. **Incident Reporting.** SUPPLIER shall immediately report to NOVARTIS any serious HSE incident (including fatalities, loss of body parts, spills beyond facility boundaries, etc.) representing a failure to comply with Applicable Standards relating to HSE as it relates to the Product and/or any Novartis procedures applicable thereto. This includes, without limitation, any incident resulting in involvement of Regulatory Authorities or other governmental authorities or any HSE related incidents with actual or potential impact on supply continuity.

4. **Contact information.** For each Facility or location where any of the activities falling within the scope of this Agreement are being performed, SUPPLIER shall communicate to NOVARTIS the name and contact information (including telephone and e-mail address) of at least one responsible and qualified contact person for HSE related topics.

5. **HSE Management System.** SUPPLIER shall, for each Facility or location where any activities falling within the scope of this Agreement are being performed, ensure that HSE management systems are in place and maintained throughout the Term in accordance with Applicable Standards as well as with the following:

(a) EMAS

(b) OHSAS 18001

If, on the Effective Date, SUPPLIER does not have a HSE management system in place which meets the above criteria, then SUPPLIER shall promptly so notify NOVARTIS, provided, however, that on such date, SUPPLIER shall have in place and maintain throughout the Term the following minimum elements:

(a) HSE policy;

(b) adequate documentation on the effects of any Facility, services and activities on the environment;

(c) HSE risk assessment(s); and

(d) general and detailed HSE targets and HSE requirements for SUPPLIER's own suppliers.

ANNEX 8

Toll Materials

A. Yield Loss Rates and Reimbursement Value

Toll Material	Toll Material Yield Loss Rate	Toll Material Reimbursement Value
[***]	[***] percent ([***]%)	$ [***]/KG
[***]		$ [***]/KG

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ANNEX 8

B. Stock Count Procedure for Toll Materials

Reporting SUPPLIER		Reporting Month:		Date:	

1. Toll Materials (free of charge Toll Materials)

Product Name	Novartis Product Code	Unit of Measure	Quantity on Stock (a)	Quantity Work in Progress (WIP) (b)	Quantity of Toll Materials contained in finished Products, ex Section 2 (c)	Total Stock (a)+(b)+(c)	Last order number received from Novartis, batch number and delivery date

2. Finished Products

Product Name	Novartis Product Code	Unit of Measure	Quantity on Stock	Last lot number of shipped finished Product	Novartis Product Code of starting material	UoM	Quantity of starting material, to be reported in Section 1 (c)

3. Inventory differences, write-offs and extraordinary consumption of Toll Materials (in quantity of free of charge Toll Material)

Product Name	Novartis Product Code	Unit of Measure	Quantities			Reason / Explanation please indicate batch number of finished product or of free of charge Toll Material
			Write-offs	Slow/Non-Movers	Extra-ordinary consum-ption of Toll Materials	

4. Reconciliation Statement of physical count result and quantities reported to Novartis (at least once per year)

SUPPLIER hereby confirms that the result of the physical stock count that has been carried out in accordance to local law and generally accepted accounting rules correspond to the quantities reported under this report. NOVARTIS may request a stock take, attend to it or ask for more supporting documentation.

Date of physical count (or indication of inventory method) _____

Date of next physical count _____

Signature _____

_____

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ANNEX 9

ALKERMES PATENT RIGHTS

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ANNEX 10

RECRO PATENT RIGHTS

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ANNEX 11

LIST OF OPEN ORDERS

SHIPMENTS AND INVOICES RECEIVED AS OF FEBRUARY 4, 2019

Description	PO	Quantity	Posting Date	Invoice $	Invoice No.
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]	[***]

PURCHASE ORDERS PLACED IN 2018 AND DELIVERING IN 2019

Sales Document	Purchase Order	Materials	Description	Batch	Order Quantity	Delivery Date
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
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