UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

Date of Report: April 14, 2023

Commission File Number: 001-39307

Legend Biotech Corporation
(Exact Name of Registrant as Specified in its Charter)

2101 Cottontail Lane
Somerset, New Jersey 08873
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Legend Biotech USA Inc. Enters into Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement with Novartis Pharmaceuticals Corporation

On April 12, 2023, Legend Biotech USA Inc. ("**Legend**") together with Janssen Research & Development, LLC ("**Janssen**" and together with Legend, the "**Collaboration Partners**") and Novartis Pharmaceuticals Corporation ("**Novartis**") entered into a Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product (the "**Agreement**"), pursuant to which the Collaboration Partners and Novartis will initiate technology transfer activities necessary for Novartis to perform the Collaboration Partners' process for manufacturing ciltacabtagene autoleucel (cilta-cel) to supplement the Collaboration Partners' own manufacturing capabilities.

The Agreement is effective as of April 12, 2023 and continues for a period of three years.

This Form 6-K, including Exhibit 99.1 hereto, is hereby incorporated by reference into the Registration Statements of Legend Biotech Corporation (the "**Company**") on Form F-3 (File Nos. 333-257625 and 333-257609) and the Company's Registration Statement on Form S-8 (File No. 333-239478).

Cautionary Note Regarding Forward-Looking Statements

Statements in this report on Form 6-K about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the Company's strategies and objectives; and statements relating to CARVYKTI® (ciltacabtagene autoleucel), including the Company's expectations for CARVYKTI®, such as the Company's manufacturing and commercialization expectations for CARVYKTI® and statements related to contracting with and engaging third-parties, including contract manufacturers. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. the Company's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to the Company's patent or other proprietary intellectual property protection, including the uncertainties involved in the U.S. litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 30, 2023. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Form 6-K as anticipated, believed, estimated or expected. Any forward-looking statements contained in this Form 6-K speak only as of the date of this Form 6-K. The Company specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

EXHIBIT INDEX

Exhibit	Title
99.1	Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product, dated as of April 14, 2023

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.

LEGEND BIOTECH CORPORATION

Date: April 14, 2023

By: /s/ Ying Huang
Name: Ying Huang, Ph.D.
Title: Chief Executive Officer

[***] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

MASTER TECHNOLOGY TRANSFER, MANUFACTURING AND CLINICAL SUPPLY SERVICES AGREEMENT FOR BCMA CAR-T PRODUCT

This Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product is effective as of the date of last signature hereto (the **"Effective Date**"), by and among **Janssen Research & Development, LLC**, having a business address at 920 US Route 202, Raritan, NJ 08869 (hereinafter referred to as "**Company**"), **Legend Biotech USA Inc.**, having a business address at 2101 Cottontail Lane, Somerset, NJ 08873 (hereinafter referred to individually as "**Legend**" and collectively with Company as "**Collaboration Partners**") and **Novartis Pharmaceuticals Corporation,** having a business address at One Health Plaza, East Hanover, NJ 07936 (hereinafter referred to as "**Provider**"). Company, Legend and Provider may be hereinafter referred to collectively as the "**Parties**" and individually as a "**Party**". For the avoidance of doubt, each reference herein to the Collaboration Partners shall refer to each of Legend and Company, and not either Party on behalf of both Legend and Company, unless the Agreement expressly provides otherwise.

WHEREAS, Company's Affiliates, Janssen Biotech, Inc. and Janssen Pharmaceutica NV, together with Legend and Legend Biotech Ireland Limited, are parties to a Collaboration and License Agreement effective December 21, 2017, as amended ("**Collaboration and License Agreement**"), related to an autologous BCMA CAR-T cell therapy product in the oncology field; and

WHEREAS, Provider has facilities and capabilities related to the development and manufacturing of cell and gene therapy products for use in clinical and/or non-clinical research and is interested in performing contract manufacturing services for Collaboration Partners related to their BCMA CAR-T Product, and Collaboration Partners wish to engage Provider to perform such services. In furtherance of the foregoing, Company and Provider have entered into the Technology Transfer Agreement and the Parties have entered into the Equipment Letter Agreement; and

WHEREAS, Collaboration Partners have assigned Company to be the lead contact for the management and operational execution of this Agreement with Provider.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, the Parties, intending to be legally bound, hereby agree as follows:

1 Definitions

1.1 "**Affiliate**" of a Party means any entity that directly or indirectly Controls, is Controlled by or is under common Control with such Party. "**Control**," "**Controls**" or "**Controlled by**" with respect to an entity shall mean the possession of at least fifty percent (50%) of the voting stock or other ownership interest of such entity, or the power to direct or cause the direction of the management and policies of such entity or the power to elect or appoint at least 50% of the members of the governing body of such entity through the ownership of the outstanding voting securities or by contract or otherwise.

1.2 "**Agreement**" means this Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product, as it may be amended from time to time in accordance with its terms, and the Exhibits and attachments hereto, including without limitation all Work Orders, all of which are an integral part of this agreement and are deemed incorporated by reference herein.

1.3 "**Anti-Corruption Laws**" has the meaning set forth in Section 30.11 (Anti-Corruption Laws).

1.4 "**Apheresis Material**" means material collected from patients which may be used in the Manufacture of the Product.

1.5 "**Applicable Law**" means any and all national, federal, state or local or foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution, guidance or promulgation, or any Government Order, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law, in each case, as in effect at a given time, including, but not limited to, cGMP and Good Tissue Practice Regulations.

1.6 **[***]**.

1.7 **[***]**.

1.8 "**Background IP**" means, with respect to a Party, any Intellectual Property Right that such Party (together with its Affiliates) controls, owns or has the right to use, and that (i) existed on or prior to the Effective Date, or (ii) is developed or acquired by such Party after the Effective Date, outside of and unrelated to the performance of the activities contemplated under this Agreement.

1.9 "**Batch**" means a Product Manufactured for an individual patient from Apheresis Material collected from such patient.

1.10 "**Batch Documentation**" means all completed batch records, batch deviations, raw data, reports, authorizations, certificates, raw material specifications, standard test methods, and other documentation in the possession or under the control of a Party (or its vendors) relating exclusively to the Manufacture of each Batch.

1.11 "**BCP**" has the meaning set forth in Section 15 (Business Continuity).

1.12 "**Bill of Materials**" means **[***]**.

1.13 "**BLA**" means a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder, including all amendments and Supplemental Applications with respect thereto.

1.14 "**Business Day**" or "**Business Days**" means a day on which banking institutions in **[***]** and Raritan, New Jersey, USA are open for business.

1.15 "**Certificate of Analysis**" means a document, signed by an authorized representative of Provider, describing Process Specifications for, and testing methods applied to, a Product, and the results thereof.

1.16 "**Certificate of Compliance**" means a document, signed by an authorized representative of Provider, certifying that a particular Batch was Manufactured in accordance with cGMP (if applicable), all other Applicable Law, the Batch Documentation, the Process Specifications and the Product Specifications.

1.17 "**cGMP**", "**Good Manufacturing Practice**" or "**GMP**" means the part of quality assurance which ensures that Products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. § 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16, and applicable United States, European Union, Canadian and ICH Guidance, regulatory requirements for each Product, applicable USP, NF, JP and Ph. Eur. requirements and/or any equivalent Applicable Law in any jurisdiction applicable to the Services, as in effect from time-to-time.

1.18 "**Change**" has the meaning set forth in Section 3.6.2 (Non-Regulatory Changes).

1.19 "**Change Control**" means a system that enables the evaluation, approval and documentation of changes pertaining to, but not limited to, the Manufacturing and control of Product. The system will allow the determination and assurance that such changes are evaluated, approved, and tracked to assure compliance with applicable regulatory and internal requirements of Company and Provider and ensure timely updates to applicable regulatory filings.

1.20 "**Change of Control**" means the sale of all or substantially all the assets of a Party; any merger, consolidation or acquisition of a Party with, by or into another corporation, entity or person; or any change in the beneficial ownership of more than fifty percent (50%) of the voting capital stock of such Party, in each case, in one or more related transactions.

1.21 "**Change Order**" means an approved and signed document between Company, Legend and Provider detailing a change in a Work Order as set forth in Section 3.6 (Changes to Services). Change Orders will be in the form substantially similar to the document attached as Exhibit C (Form of Change Order) to this Agreement.

1.22 "**Claim Notice**" has the meaning set forth in Section 37.2 (Meeting of Senior Officers).

1.23 "**Collaboration Partner Foreground IP**" has the meaning set forth in Section 13.3 (Collaboration Partner Foreground IP).

1.24 "**Collaboration Partners Equipment**" means the Equipment identified as Collaboration Partners Equipment in Exhibit M (Project Execution Plan).

1.25 "**Collaboration Partners Indemnitee**" or "**Collaboration Partners Indemnitees**" has the meaning set forth in Section 17.1 (Indemnification by Provider).

1.26 "**Collaboration Partner Works**" has the meaning set forth in Section 13.7 (Copyrightable Works).

1.27 **[***]**.

1.28 **[***]**.

1.29 **[***]**.

1.30 **[***]**.

1.31 **[***]**.

1.32 "**Company Material(s)"** means any and all biological and/or chemical materials (including, by way of example, **[***]**, Apheresis Material, Raw Materials, molecules, compounds, Product candidates and samples) that are transferred by or on behalf of Company, Legend and/or their respective Affiliates to Provider for use in the performance of the Services.

1.33 "**Company's Records and Information**" has the meaning set forth in Section 16.1 (Company's Records and Information).

1.34 "**Confidential Information**" has the meaning set forth in Section 12.1 (Confidential Information).

1.35 "**Confidentiality Violation**" has the meaning set forth in Section 12.5 (Breach of Confidentiality Obligations).

1.36 "**Corrective Action Plan**" or "**CAP**" has the meaning set forth in Section 6.11 (Corrective Action Plans).

1.37 "**Corrective and Prevention Action**" or "**CAPA**" shall mean action(s) taken to resolve a deviation or observation and eliminate the cause of a deviation or observation related to the Services.

1.38 **[***]**.

1.39 **[***]**.

1.40 "**C-TPAT**" has the meaning set forth in Section 31 (Supply Chain Security).

1.41 "**Deliverables**" means **[***]**.

1.42 "**Dispute**" has the meaning set forth in Section 37.2 (Meeting of Senior Officers).

1.43 "**Equipment**" means any equipment or machinery used in the Manufacturing of a Product.

1.44 "**Equipment Letter Agreement**" means **[***]**.

1.45 "**Facility**" or "**Facilities**" means the **[***]** facility of Provider used for the Manufacture of Product.

1.46 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.47 "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §321 et seq., the Public Health Act, each as amended, and the regulations promulgated thereunder.

1.48 **[***]**.

1.49 "**Force Majeure Event**" has the meaning set forth in Section 33 (Force Majeure).

1.50 "**Force Majeure Party**" has the meaning set forth in Section 33 (Force Majeure).

1.51 "**GMP Readiness**" means **[***]**.

1.52 "**Good Tissue Practice Regulations**" means the then-current good tissue practice regulations of the FDA, under subparts C and D of 21 CFR part 1271, and all applicable rules, regulations, orders, and guidances, and requirements that govern the methods used in, and the facilities and controls used for, the manufacture of human cell, tissue, and cellular and tissue-based products, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution, including those of the FDA and all applicable EU and EMEA regulations, directives and guidelines.

1.53 "**Government Order**" means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any governmental authority or Regulatory Authority.

1.54 "**Head of Quality**" means the highest ranking person in the quality department of each of **[***]** (or authorized appointees) with substantial knowledge of, and direct responsibility pertinent to, a Product.

1.55 "**ICH**" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which includes quality, safety, efficacy, and multidisciplinary joint safety/efficacy guidelines.

1.56 "**Income Taxes**" has the meaning set forth in Section 43.1 (Responsibility for Own Taxes).

1.57 "**Indirect Taxes**" has the meaning set forth in Section 43.3 (Indirect Taxes).

1.58 "**Insolvency Event**" has the meaning set forth in Section 11.1.5 (Termination Rights).

1.59 "**Insolvent Party**" has the meaning set forth in Section 11.1.5 (Termination Rights).

1.60 "**Intellectual Property Rights**" means any and all rights, anywhere in the world, pertaining to intellectual property, including, but not limited to, patent applications, patents, trade secret rights, copyrights, trademark applications, trademark registrations, know-how, trade names, business names, get-up, logos and trade dress, and all other similar rights in the nature of proprietary rights (whether registered or unregistered) similar to the foregoing, licenses, immunities, covenants not to sue and the like relating to any of the foregoing, any claims or causes of action arising out of or related to any infringement, misuse or misappropriation of any of the foregoing, and all applications and rights to apply for any of the foregoing, in each case for their full term and any extension thereto.

1.61 "**JGC**" has the meaning set forth in Section 2.1 (Purpose; Formation; Composition).

1.62 "**JJNET**" has the meaning set forth in Section 16.4 (Training).

1.63 "**Losses**" has the meaning set forth in Section 17.1 (Indemnification by Provider).

1.64 "**Manufacturing**" or "**Manufacture**" or "**Manufactured**" means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, in process testing, quality assurance testing and release, and storage of a Product.

1.65 "**Manufacturing Process**" means **[***].**

1.66 "**Manufacturing Representative**" has the meaning set forth in Section 5.5.2 (Person-in-Plant).

1.67 "**Manufacturing Requirements**" has the meaning set forth in Section 5.1 (Manufacture of Product).

1.68 **[***]**.

1.69 **[***]**.

1.70 **[***]**

1.71 **[***]**.

1.72 "**Non-Conforming Product**" has the meaning set forth in Section 6.3 (Batch Failure).

1.73 "**Pallet Policy**" has the meaning set forth in Section 32 (Policy for Wood Pallets).

1.74 "**Personal Information**" (or "**Personal Data**") means data that identifies, can be used to identify, relates to, or is capable of being associated with, or could reasonably be linked, directly or indirectly, with an individual or household, as defined by Applicable Law.

1.75 "**Process Specifications**" means **[***]**.

1.76 "**Product**" or "**Products**" means the BCMA CAR-T Product, as more fully described in Exhibit L (Description of Product).

1.77 "**Product Specifications**" means **[***]**.

1.78 "**Project Documentation**" means **[***]**.

1.79 "**Project Execution Plan**" or "**PEP**" means the technology transfer project execution plan. The initial PEP is attached hereto as Exhibit M (Project Execution Plan) and will be incorporated by the Parties into a Work Order.

1.80 **[***]**.

1.81 "**Provider Foreground IP**" has the meaning set forth in Section 13.4 (Provider Foreground IP).

1.82 "**Provider Indemnitee**" or "**Provider Indemnitees**" has the meaning set forth in Section 17.2 (Indemnification by Company and Legend).

1.83 "**Provider Operating Documents**" means **[***]**.

1.84 "**Provider Personnel**" means the employees, agents and contractors of Provider, and the employees, agents and contractors of Provider's Affiliates and Subcontracted Parties, in each case, that are involved in the management or provision of the Services under this Agreement or any Work Order, or the performance of Provider's obligations under a Quality Agreement.

1.85 "**Purchase Order**" has the meaning set forth in Section 5.8.1 (Purchase Orders).

1.86 "**Quality Agreement**" has the meaning set forth in Section 6.1 (Quality Agreement).

1.87 "**Raw Materials**" means all chemicals, solvents, reagents, media, excipients, components, packaging materials and other physical materials (including but not limited to shipping components) required to be used in order to Manufacture Product in accordance with the Process Specifications.

1.88 "**Regulatory Approval**" means the technical, medical and scientific licenses, registrations, authorizations and approvals of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the Manufacture, use, import, and export of Products in a regulatory jurisdiction.

1.89 "**Regulatory Authority**" means any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Agency for the Evaluation of Medicinal Products), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the granting of Regulatory Approval for a Product.

1.90 "**Relief Event**" means **[***]**.

1.91 "**Reservation Fee**" has the meaning set forth in Section 9.1.1 (Pricing and Payment).

1.92 "**RIM Requirements**" has the meaning set forth in Section 16 (Records and Information Management Requirements).

1.93 "**Rolling Forecast**" has the meaning set forth Section 5.8.3 (Forecasting).

1.94 "**Services**" means any Manufacturing and/or other services to be performed by Provider as set forth in this Agreement, the Technology Transfer Agreement or each Work Order entered into by Company, Legend and Provider during the Term.

1.95 "**SOPs**" means, with respect to a Party, the then-current, standard operating procedures of such Party.

1.96 "**Subcontracted Party**" or "**Subcontracted Parties**" has the meaning set forth in Section 23.1 (Subcontractors).

1.97 "**Technology Transfer Agreement**" means **[***]**.

1.98 "**Technology Transfer Manager**" has the meaning set forth in Section 4.1.1 (Technology Transfer).

1.99 "**Technology Transfer Services**" has the meaning set forth in Section 4.1 (Technology Transfer).

1.100 "**Term**" has the meaning set forth in Section 10 (Term).

1.101 "**Third Party**" or "**Third Parties**" means any person other than a Party or any of its Affiliates.

1.102 "**Third-Party Request**" has the meaning set forth in Section 16.3 (Third Party Requests).

1.103 "**TTS Representative**" has the meaning set forth in Section 5.5.1 (Person-in-Plant).

1.104 "**Work Order**" means a written and fully executed agreement, between Provider and Collaboration Partners, detailing the Services to be provided by Provider (other than Manufacture of Product) as described more fully in Section 3.1 (Work Orders), as such agreement may be amended from time to time by one or more Change Orders. Work Orders will be in the form attached as Exhibit A (Form of Work Order) to this Agreement.

2 Joint Governance Committee

2.1 **Purpose; Formation; Composition**. Promptly following execution of this Agreement, the Parties shall establish a joint governance committee ("**JGC**") with representation from Company, Legend and Provider. The JGC shall be co-chaired by **[***]** and shall convene monthly or at such intervals as may otherwise be agreed to by Company, Legend and Provider. Company, Legend and Provider will each ensure that production, quality, planning and process engineering lead representatives will attend and participate in the JGC meetings as, and to the extent, required. Each member of the JGC shall have the appropriate experience, knowledge and ongoing familiarity with the Services. Company, Legend and Provider shall dedicate appropriate resources to the establishment and operation of the JGC and to the development and implementation of processes related to the performance of Services related to Manufacturing.

2.2 **Role of the JGC.** The JGC shall facilitate timely communication of matters affecting the Services, including but not limited to the Technology Transfer Services, provide strategic oversight of the activities under this Agreement, and provide informal resolution of issues that may arise. The JGC's responsibilities include, but are not limited to:

2.2.1 [***].

2.3 **Limits on JGC**. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JGC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JGC and each sub-team will only have the roles assigned to them under this Agreement and will not have any power to amend, modify or waive compliance with this Agreement, or to impose additional obligations on a Party beyond those provided in this Agreement.

2.4 **Information Sharing**. Whenever Provider is providing data, information or documents to Collaboration Partners hereunder, it will do so in compliance with the sharing procedures mutually agreed upon by the Parties in their reasonable discretion. **[***].**

3 Performance of Services

3.1 **Work Orders**. All Services will be contracted pursuant to a Work Order (other than Manufacture of Product). Each Work Order will set out, at a minimum, the scope of Services to be performed, including a timeline for performance, the cost and fees associated with the Services, and any Subcontracted Parties approved by Company to perform the Services.

3.2 **Performance of Services; Provider Affiliates**. Provider shall perform all Services, including, but not limited to, delivering any Deliverables, in compliance with the terms and conditions of this Agreement, each applicable Work Order and Quality Agreement, and all Applicable Law. Provider may use one or more of its Affiliates or Subcontracted Parties in accordance with Section 23 (Subcontracting) to perform its obligations and duties under this Agreement, a Work Order or Quality Agreement, provided that Provider shall be responsible (i) for ensuring that such Affiliates or Subcontracted Parties comply with this Agreement, each applicable Work Order and each applicable Quality Agreement and (ii) for all actions of such Affiliates or Subcontracted Parties in connection with this Agreement, each applicable Work Order and each applicable Quality Agreement, including but not limited to any actions or omissions that would be in breach of this Agreement, the applicable Work Order or the applicable Quality Agreement if performed or omitted by Provider. Provider shall warrant and solely be responsible for the performance of such Affiliates and Subcontracted Parties, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by Provider itself under this Agreement and any applicable Work Order or Quality Agreement. Provider shall cause each such Affiliate or Subcontracted Party to be bound by, and to comply with, the terms of this Agreement and any applicable Work Order and Quality Agreement, including without limitation, all confidentiality, quality assurance, record keeping, audit, regulatory, government funding and other obligations of, and requirements applicable to, Provider set forth in this Agreement and any applicable Work Order and Quality Agreement.

3.3 **Deliverables**. **[***]**.

3.4 **Provider Personnel**. All Provider Personnel shall be qualified to perform the Services and shall provide the management and oversight necessary to deliver the Services consistent with the timelines set forth in this Agreement and each applicable Work Order and Quality Agreement. Provider shall be solely responsible for any compensation due to any Provider Personnel performing Services under this Agreement, the Quality Agreement and each applicable Work Order, including (without limitation) any compensation due by operation of law to any of Provider Personnel **[***]**. Under no circumstances shall Provider use Provider Personnel in **[***]** to perform any Services under this Agreement or any Work Orderor Quality Agreement; *provided, however*, that **[***]**; *provided further*, that **[***]**.

3.5 **Reporting**. Provider shall provide Collaboration Partners with written reports of the progress of the Services as reasonably agreed in writing by Company and Provider. All such reports shall be Company's Records and Information, and shall be subject to Section 16 (Records and Information Management Requirements).

3.6 **Changes to Services**.

3.6.1 **Regulatory Changes**. If a law or regulation is enacted or amended, or if any agency, body, or court of competent jurisdiction adopts or amends an interpretation of a law or regulation, that requires additional provisions to be included in this Agreement or a Work Order in order to implement a requirement that is applicable to this Agreement ("**Regulatory Change**"), Provider will implement such Regulatory Change in accordance with Applicable Law. **[***]**.

3.6.2 **Non-Regulatory Changes**. In the event either Company or Provider requests a change (other than a Regulatory Change) **[***]**. Provider shall have no obligation to perform, and Company shall have no obligation to pay for, any additional or modified Services absent written agreement with respect thereto in a Work Order or one or more Change Orders agreed to and executed by Company, Legend and Provider as set forth in this Agreement.

3.7 **Non-Conformance.** Company reserves the right to refuse any Services and/or Deliverables if Provider does not, or the Services and/or Deliverables do not, conform to the obligations of this Agreement, the applicable Work Order and/or all Applicable Law. Acceptance of any part of the Services and/or Deliverables under this Agreement or a Work Order shall not bind Company to accept any non-conforming Services and/or Deliverables simultaneously provided by Provider, nor deprive Company of the right to reject any previous or future non-conforming Services and/or Deliverables. In the event that all or any portion of the Services and/or Deliverables provided to Company by or on behalf of Provider do not conform with Provider's obligations under this Agreement and/or the subject Work Order, Company shall notify Provider in writing of the deficiency and **[***].** Notwithstanding the foregoing, this Section will not be applicable to non-conforming Batches of Product, which are covered under Section 6.7 (Disputes Regarding Conformity), and Section 6.9 (Product Disposition for Non-Conforming Product).

3.8 **Company Materials.**

3.8.1 The Collaboration Partners will provide to Provider, either directly or indirectly through an Affiliate or a Third Party working on behalf of the Collaboration Partners, those Company Materials that are required for Provider to perform the Services as detailed in this Agreement, a Work Order and/or the Quality Agreement. Except as otherwise expressly set forth in this Agreement, Provider is not granted any right to or any license under any Intellectual Property Rights embodied in such Company Materials.

3.8.2 Provider shall inspect the Company Materials upon receipt according to procedures agreed in writing by Company and Provider and otherwise in accordance with Provider's SOPs. Without limitation to the foregoing, **[***]**. Provider will not attempt to analyze the Company Material for its chemical or physical composition except as required in connection with the Manufacturing Requirements, or with Company's prior written consent. The responsibilities of the Parties with regards to testing and release of the Company Materials will be detailed further in the Quality Agreement.

3.8.3 Provider shall not be liable for any delays under this Agreement or a Purchase Order to the extent that such delays are caused by the late or insufficient delivery of Company Materials. Provider agrees to maintain control over all Company Materials that are received hereunder and acknowledges that Company Materials may not be transferred, distributed or released to any person or entity other than the Collaboration Partners, or an entity designated in writing by Company. Provider agrees to identify Company Materials as such, and to store Company Materials in a secured location within the Facility that is designated for the storage of materials provided by customers of Provider. Access to such secure location within the Facility shall be limited to those Provider Personnel whose responsibilities require such access. **[***]**.

3.8.4 The Company Materials will be stored by Provider in accordance with its SOPs at such temperatures and conditions as specified in this Agreement, including the Manufacturing Requirements.

3.8.5 All Company Materials, (a) will be used by Provider only in furtherance of the Services in accordance with this Agreement, the applicable Work Order, the applicable Quality Agreement and the health and safety procedures outlined in Section 3.9 (Health and Safety Procedures), (b) **[***]**, and (c) will not be used or delivered to or for the benefit of any Third Party without the prior written consent of Company.

3.8.6 As between the Parties, Company Materials (including, without limitation, as modified into a Product) will remain the sole property of Collaboration Partners and all right, title and interest in and to Company Materials will remain with Collaboration Partners at all times.

3.9 **Health and Safety Procedures**. Provider will be responsible for implementing and maintaining health and safety procedures for its performance of Services and for the handling of any materials or hazardous waste used in or generated by the Services in accordance with Applicable Law. Company, in consultation with Provider, will develop safety and handling procedures for each Product (including but not limited to preparation and issuance of material safety data sheets) and Provider shall ensure that it and Provider Personnel comply with such safety and handling procedures; provided, however, that Company will not have decision-making power or responsibility for Provider's health and safety programs.

4 Technology Transfer

4.1 Promptly after the Effective Date, Provider will initiate activities necessary to perform the Manufacturing Process at its Facility and to Manufacture Product in accordance with the Work Order executed in connection therewith which incorporates the Project Execution Plan ("**Technology Transfer Services**"). The Collaboration Partners will work with Provider to facilitate the exchange of information necessary for Provider to perform the Technology Transfer Services. The Collaboration Partners will provide to Provider all Manufacturing and process/analytical development information that Provider may reasonably require in order to Manufacture Product, including but not limited to, the information set forth in the Project Execution Plan.

4.1.1 Each Party will identify a "**Technology Transfer Manager**" to be such Party's primary contact person responsible for interactions regarding the Technology Transfer Services; provided, that **[***]. Each Technology Transfer Manager will have sufficient and appropriate expertise and status to fulfill his/her responsibilities. Each Technology Transfer Manager will be available to its counterparts from each other Party as reasonably required for consultation during the course of the Technology Transfer Services and each Party's Technology Transfer Manager shall have a reasonable opportunity to be involved in any such consultation. For the avoidance of doubt, a Technology Transfer Manager may not amend or modify the terms of this Agreement or any Work Order or Change Order, or waive any rights afforded to such Party herein or therein.

4.1.2 The Collaboration Partners and Provider will cooperate in good faith to complete the Technology Transfer Services as soon as reasonably practicable to establish the Facility as a new manufacturing site for Manufacturing the Product by Provider.

4.1.3 The Technology Transfer Services to be provided by Provider, the milestones, timelines and the resource plan will be set forth in a Work Order. Provider may invoice Collaboration Partners for costs incurred by Provider **[***]**.

4.1.4 The Technology Transfer Services will be deemed complete when **[***]**; *provided*, that following such achievement and notwithstanding such completion, Provider will support Collaboration Partners to answer any questions received from Regulatory Authorities in connection with receiving Regulatory Approval.

4.1.5 Failure to Achieve **[***]**.

(i) **[***]**.

(ii) **[***]**.

(iii) **[***]**.

5 Manufacture and Supply of Product

5.1 **Manufacture of Product**. Provider will Manufacture Product in accordance with the applicable Purchase Order, Process Specifications, Manufacturing Process, Quality Agreement and in accordance with all Applicable Law (the "**Manufacturing Requirements**").

5.2 **Facility**. Provider will ensure all Services related to Manufacture and supply of Product are performed only at the Facility and in accordance with the Manufacturing Requirements. Provider will not change the location of the Facility or use any additional facility for the performance of Services under this Agreement or the Quality Agreement without Company's prior written approval. If there is a change in location of a Facility or use of any additional facility that is approved by Company in writing, Provider will continue to have affected Products Manufactured at the existing Facility until the new facility is fully qualified for such purpose. Upon full qualification, such changed location or additional facility that has been approved by Company in writing will be deemed a Facility. Provider will maintain the Facility in a state of repair and operating efficiency consistent with the Manufacturing Requirements. **[***]**.

5.3 **Facility Qualification**. Provider will be responsible for performing or overseeing the performance of all initial and ongoing qualification of the Facility in accordance with the Manufacturing Requirements.

5.4 **Licenses and Permits**. Provider will be responsible for obtaining and maintaining, at its expense, any Facility or other licenses, permits and/or certifications, and any regulatory and/or government approvals necessary for the performance of Services by it under this Agreement and any Work Order that do not arise specifically out of the Product, and shall ensure that all Services are performed in accordance with such licenses, permits, certifications and approvals. At Company's reasonable request, Provider will provide Collaboration Partners with (i) copies of, or other similar evidence of its receipt of, all such approvals, Facility licenses, certificates and permits necessary for Manufacturing at the Facility, and (ii) **[***]**. **[***]**.

5.5 **Person-in-Plant**.

5.5.1 Provider shall allow Legend's and Company's employees and authorized representatives reasonable access to Provider's Facility, as reasonably necessary during Provider's provision of the Technology Transfer Services. In connection with the foregoing, Legend and/or Company will notify Provider of the names of the employees and authorized representatives (each being a "**TTS Representative**") who will require access to Provider's Facility, the dates and times on which they require access to Provider's Facility, the purpose of their visit and any other relevant information. Provider shall inform Legend and/or Company (as applicable) within **[***]** days of receipt of such notice if there is a scheduling conflict that would make the TTS Representative's presence at Provider's Facility disruptive to Provider's operations and Provider shall propose alternative dates. The Parties shall work together in good faith to agree upon an alternative date for such TTS Representative to access Provider's Facility. Each TTS Representative will have access **[***].** Each TTS Representative will coordinate closely with Provider in order to minimize the impact of the TTS Representative's presence on operations and will comply with all policies and procedures regarding their presence in the Facilities that have been provided by Provider. **[***].**

5.5.2 Provider will permit, upon reasonable advance notice and during normal operating hours, Company's and Legend's personnel or duly authorized representatives (including, for the avoidance of doubt, quality personnel) to observe and consult during the performance of Services under this Agreement and/or any Work Order, including without limitation the Manufacturing of any Batch (each such employee or agent a "**Manufacturing Representative**"). Provider will allow each Manufacturing Representative reasonable access to **[***]**. Each Manufacturing Representative will have access **[***]**. In no event will any Manufacturing Representative interfere with the Services provided under this Agreement and/or each applicable Work Order, and Provider will remain fully responsible for the Services it is providing pursuant to this Agreement and each applicable Work Order. Each Manufacturing Representative will coordinate closely with the Provider in order to minimize the impact of his/her presence on operations and will comply with all the Provider's policies and procedures regarding their presence in the Facilities including any training requirements, and will be required to be escorted by Provider Personnel during any observation of Manufacturing activities. Unless otherwise approved in writing by Provider, Collaboration Partners shall schedule visits by their Manufacturing Representatives at the same time, so as to minimize disruption to Provider. **[***]**.

5.6 **Raw Materials**. Except for Company Materials, which shall be delivered to Provider **[***]** (Incoterms 2020), Provider will purchase all Raw Materials, excipients, packaging materials and components to be used by Provider in the performance of Services, including any such materials as specified in a Work Order. Where possible, all Raw Materials and excipients will meet the standards of major pharmacopeial conventions, including United States Pharmacopeia (USP), European Pharmacopeia (Ph. Eur), and Japanese Pharmacopeia (JP). Provider will ensure that all suppliers of Raw Materials, excipients, packaging materials and components are fully qualified and approved pursuant to the applicable Quality Agreement. Provider will obtain Raw Materials listed on the Bill of Materials using suppliers listed on the Bill of Materials. In relation to Raw Materials not listed on the Bill of Materials or specified in a Regulatory Approval, **[***]**. Provider will ensure there is a sufficient inventory of Raw Materials to satisfy its obligations under this Agreement consistent with **[***]**.

5.7 **Chain of Custody and Identity.** Provider shall provide trained Provider Personnel and use systems, mutually agreed upon by Company and Provider, to maintain chain of custody and identity of Apheresis Material and Product within the Facility, from receipt of Apheresis Material at the Facility through supply of Product to Company in accordance with Section 8 (Shipping and Delivery). Company shall provide trained employees and use systems designated by Company, to maintain chain of custody and identity of Apheresis Material from collection at each qualified treatment center to delivery of Apheresis Material to the Facility and to maintain chain of custody and identity of Product from delivery of Product to Company through delivery of Product to each qualified treatment center. Provider shall provide **[***]** with access to information regarding the chain of custody and identity of Apheresis Material and Product for improved planning purposes. **[***]**.

5.8 **Ordering; Forecast; [***]**.

5.8.1 **Purchase Orders**. Company shall place each order for a Batch of the Product in writing to Provider (each such order for **[***]** being a "**Purchase Order**"). Company shall submit each Purchase Order either electronically or by such other means that the Parties shall mutually determine and to such location as is mutually agreed by the Parties. Purchase Orders shall be in a form agreed by the Parties and shall specify the date the Purchase Order was issued, and the requested delivery date.

5.8.2 **[***]**:

(i) **[***]**; and

(ii) **[***]**.

5.8.3 **Forecasting**. **[***]**.

5.9 **Forecast Changes or Cancellations**. **[***]**.

5.10 **Inability to Perform; Failure to Supply**.

5.10.1 **Notice to JGC**. Other than **[***]**, if at any time during the Term Provider has reason to believe that it will be unable to Manufacture or have Manufactured **[***]** Product in accordance with **[***]**, it will promptly notify the JGC of the issue, **[***]**.

5.10.2 **Failure to Supply**. If Provider, at any time during the Term, notifies Company that **[***]** (a "**Failure to Supply**"), then:

(i) Provider will promptly notify the JGC regarding the issue;

(ii) **[***]**; and

(iii) **[***]**.

5.10.3 **Restoration Plan**. If Provider provides notice to the JGC pursuant to Section 5.10.1 (Notice to JGC) or Section 5.10.2(i) (Failure to Supply), Company may request that Provider provide a plan to the Collaboration Partners to fully ensure and/or restore the supply of the Products. Within **[***]** Business Days after receipt of such notice by the Collaboration Partners, Provider shall propose a plan to restore the supply of Products in accordance with this Agreement by production at a Facility (or Facilities). The JGC shall meet, within **[***]** Business Days following receipt of the proposed restoration plan, and in good faith discuss and attempt to agree on the restoration plan.

5.10.4 Intentionally Omitted.

5.10.5 **[***]**.

5.10.6 **[***]**.

5.11 **[***]**.

6 Testing and Quality Assurance

6.1 **Quality Agreement**. **[***]** will enter into a quality agreement reflecting the quality obligations for **[***]** with respect to the Product (the "**Quality Agreement**") prior to **[***]**. The Quality Agreement will be signed by **[***]**. The Quality Agreement will be reviewed **[***]** on a periodic basis (as defined in the Quality Agreement) and amended as necessary to be an accurate reflection of the quality obligations for **[***]** regarding Product.

6.2 **Sampling**. Provider will, in accordance with the Quality Agreement and/or any applicable Work Order, (i) sample and test each Batch of Product against the applicable Product Specifications to determine whether it complies with the Product Specifications and (ii) review the Records relating to the Manufacture of such Batch of Product to determine whether the Manufacture of such Batch of Product was in accordance with the Manufacturing Requirements and whether the Product meets the Product Specifications. **[***]**.

6.3 **Batch Failure**. If a Batch fails to conform to **[***]** ("**Non-Conforming Product**") then Provider shall notify Collaboration Partners as soon as reasonably practicable after such Non-Conforming Product is identified, and in any event, within the time set forth in the Quality Agreement, in which case Provider and Company shall comply with their respective obligations under Section 6.6 (Root Cause Analysis).

6.4 **Technical Release.** Where Provider determines, in accordance with Section 6.2 (Sampling), that a Batch of Product (or the relevant portion thereof) conforms to the applicable Product Specifications and was Manufactured according to the Manufacturing Requirements then:

6.4.1 the quality assurance department of Provider will complete and issue a Certificate of Analysis, a Certificate of Compliance, Batch Documentation and any other required documents listed in the Quality Agreement (the "**Technical Release Documents**") to Company in accordance with the Quality Agreement; and

6.4.2 following receipt of such Technical Release Documents by Company pursuant to Section 6.4.1 (Technical Release), within the time set forth in the Quality Agreement, Company shall notify Provider in writing:

(i) that Company agrees that such Batch of Product complies with the Product Specifications and the Manufacturing Requirements ("**Final Release**"), in which case Provider shall comply with its obligations under Section 6.5 (Product Disposition); or

(ii) that Company does not agree that such Batch of Product (or portion thereof) complies with the Product Specifications and/or the Manufacturing Requirements based on the Technical Release Documents, in which case Provider and Company shall comply with their respective obligations under Section 6.6 (Root Cause Analysis).

6.5 **Product Disposition**. Where Company issues a Final Release in accordance with Section 6.4.2(i), Company will notify Provider of Batch disposition.

6.6 **Root Cause Analysis**. Where (a) Provider determines, in accordance with Section 6.2 (Sampling) or Section 6.3 (Batch Failure), that a Batch of Product (or the relevant portion thereof) does not conform to the applicable Product Specifications and/or was not Manufactured according to the Manufacturing Requirements or (b) Company notifies Provider, in accordance with Section 6.4.2(ii), that it does not agree with Provider's determination that a Batch of Product (or the relevant portion thereof) complies with the Product Specifications and/or the Manufacturing Requirements based on the Technical Release Documents, Provider shall perform a root cause analysis on the relevant Batch of Non-Conforming Product within the time set forth in the Quality Agreement to determine the reasons why the relevant Batch does not conform to the applicable Product Specifications and/or was not Manufactured according to the Manufacturing Requirements. Provider shall notify Company of the results of such assessment after completing such analysis as set forth in the Quality Agreement.

6.7 **Disputes Regarding Conformity.** In the event of any disagreement between Company and Provider concerning whether a Batch was Manufactured in accordance with the Manufacturing Requirements and/or the event that Company does not agree with the analysis performed by Provider pursuant to Section 6.6 (Root Cause Analysis), the quality assurance representatives of **[***]** will attempt in good faith to resolve any such disagreement. If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed **[***]**), the matter shall be referred to **[***]** by providing written notice to the appropriate contact person specified in the Quality Agreement. If the discussions between **[***]** do not resolve the disagreement in a reasonable time (which will not exceed **[***]**) then **[***]**.

6.8 Intentionally Omitted.

6.9 **Product Disposition for Non-Conforming Product**. Provider shall, at Company's sole option and discretion, (a) deliver such Batch of Non-Conforming Product to Company, and/or destroy such Batch of Non-Conforming Product, and (b) produce a new Batch of Product as soon as reasonably possible (subject to the Collaboration Partners providing the required Company Materials). **[***]**.

6.10 **Review of Batch Documentation and Records**. The Collaboration Partners will have the right to receive copies of and review the Batch Documentation. The standard documentation to be created and maintained by Provider related to the packaging, Manufacturing and testing of each Product shall be set forth in the Quality Agreement. **[***]**.

6.11 **Corrective Action Plans**. Where (i) there is a Batch failure pursuant to Section 6.3 (Batch Failure), (ii) it is agreed between the Parties pursuant to Section 6.7 (Disputes Regarding Conformity) or (iii) it is determined by a Third Party laboratory pursuant to Section 6.7 (Disputes Regarding Conformity) that a Batch of Product did not comply with the Manufacturing Requirements or the Product Specifications, **[***]** will meet to discuss and mutually agree in writing the scope of a corrective and preventative action plan ("**CAP**"). **[***]**.

6.12 **Complaint Investigation**. Provider shall cooperate fully and promptly in the investigation of complaints involving any Product supplied under this Agreement. All complaints should be investigated, and Provider shall provide a written response to Company's quality assurance team within **[***]** days of receipt, or such other timeline set forth in the Quality Agreement. In the event that corrective actions are deemed warranted by Company as the result of complaints for the supplied Product, these corrective actions shall be incorporated and tracked as part of the corrective action system specified in the applicable Quality Agreement **[***]**.

6.13 **Quality Assurance Management Notification**. If a problem that potentially affects the safety, efficacy or reliability of a Product is identified by **[***]**, the problem and all known facts shall be brought to the attention of each Party's quality assurance management as soon as possible, but in any event, within **[***]** (or such other timeframe set forth in the Quality Agreement) after the identification of the problem. Provider shall reasonably cooperate in the implementation of any corrective action agreed between the Parties, **[***]**.

6.14 **Stability**. If **[***]** Provider will implement a stability program appropriate to the state of development of each Product. Thereafter, the Provider will conduct stability studies and maintain the agreed upon stability program in accordance with ICH guidelines, **[***]**. Provider shall perform stability testing, if any, in accordance with the applicable stability protocol and such other applicable Manufacturing Requirements,.

6.15 **Change Control**.

6.15.1 Provider may propose changes or modifications to the Manufacturing Process, Process Specifications, Product testing, storage of the Product or Product Specifications. Any proposed changes will be provided in writing to the Collaboration Partners for their review and consent, which may be provided or withheld in their sole discretion and as communicated by Company to Provider in writing, prior to the implementation of any such changes and in accordance with the Change Control provisions of the relevant Quality Agreement.

6.15.2 Provider may propose changes or modifications to the Facility and Equipment that relate to the Product (other than any changes that would require a modification to the BLA or other Regulatory Approval). Any proposed changes will be provided in writing to the Collaboration Partners for their review prior to the implementation of any such changes and in accordance with the Change Control provisions of the relevant Quality Agreement.

6.16 **Records and Sample Retention.**

Provider will keep complete and accurate records in their original or validated format, the scope of which is defined in the applicable Quality Agreement **[***]** (collectively, the "**Records**"). Records will be available at reasonable times for inspection, examination and copying by or on behalf of the Collaboration Partners upon **[***]** Business Days' prior written notice; *provided, however*, that in the event of a regulatory inspection, audit or request from a Regulatory Authority, such Records will be available upon **[***]** Business Days' notice. Collaboration Partners and Provider will each retain and archive all of its respective original Records of the Manufacture of each Product under this Agreement in accordance with the timelines and requirements set forth in the applicable Quality Agreement and all Applicable Law, but in no case for less than a period of **[***]** years following delivery of such Product. Upon Company's request, Provider will promptly provide copies of such Records to the Collaboration Partners. Provider will not destroy any Records without prior written notification to Collaboration Partners and, if requested by Company, will provide such Records to Collaboration Partners in lieu of such destruction. **[***]**.

6.17 **Timelines**. Standard times for supply of documentation required for a Product release, deviations, change controls, complaints and any other relevant quality systems will be outlined in the applicable Quality Agreement.

6.18 **Company Audits.**

6.18.1 Company or Company's authorized representative (including authorized Legend personnel) and any Regulatory Authority that regulates the Collaboration Partners may, **[***]** inspect and audit the Records of Provider with respect to the Deliverables or Services (including the Provider Operating Documents) for the purpose of evaluating compliance with this Agreement, each Work Order, the Quality Agreement, and any Applicable Law. Routine audits by the Company shall be scheduled no more frequently than **[***]** per calendar year, on reasonable notice to Provider, while "for cause" audits may occur as needed. Company shall reasonably cooperate with the Provider's audit procedures. Audits shall not include access or review of any information relating to any other customer of Provider.

6.18.2 Provider hereby authorizes the Collaboration Partners to, and shall provide Collaboration Partners with the ability to, remote audit of Records so long as such audit otherwise complies with the requirements of Section 6.18.1, including audit frequency. Company and Provider will ensure that (a) remote access is restricted to identified and authorized employees only (including, for the avoidance of doubt, authorized employees of Legend); (b) remote access is used for verifying compliance with the terms and conditions of this Agreement and each applicable Work Order and Quality Agreement; (c) remote access as determined by Provider will be restricted to access that is directly related to the performance of obligations under the terms and conditions of this Agreement and each applicable Work Order and Quality Agreement; (d) remote access to documentation will be provided only in accordance with the terms and conditions of this Agreement and each applicable Work Order and Quality Agreement during the agreed timeframe and in a manner requested by Company, which may include, without limitation, secure electronic transmission, as further determined by Provider and finalized by Company and Provider, and (e) remote access shall comply with all Applicable Law and policies. **[***].**

6.18.3 If any findings arising out of an audit require a CAP, including a determination of the appropriate CAPAs for implementation, **[***]**. To the extent Provider's responsibility, Provider will share such CAP and CAPAs with the JGC and will consult with the JGC in good faith with respect to the preparation and the implementation of the CAP and the associated CAPAs. Provider will update the JGC on its progress on the CAP and the implementation of such CAPAs. If there is any disagreement regarding audit findings, proposed CAPAs and/or implemented CAPAs, or whether a CAPA is required or whether a proposed CAPA adequately addresses an audit finding, the quality assurance representatives of **[***]** will attempt in good faith to resolve any such disagreement. If the foregoing discussions do not resolve the disagreement in a reasonable time the matter shall be referred to the **[***]**, for resolution, by providing written notice to the appropriate contact person specified in the relevant Quality Agreement **[***]**. **[***]**.

6.18.4 Should Provider or any Third Party conduct any audit or inspection of any Facility, Provider shall promptly notify the JGC of any critical findings relating, directly or indirectly, to the Services **[***]**.

6.18.5 Collaboration Partners' rights under this Section are in addition to, and not in limitation of, the rights granted in Section 7.2 (Regulatory Inspections) and Section 9.11 (Financial Audit).

7 Regulatory Matters

7.1 **Regulatory Approvals**. Collaboration Partners will be responsible for obtaining and maintaining all Regulatory Approvals required for the Product, except to the extent such Regulatory Approvals are the responsibility of Provider pursuant to Section 5.4 (Licenses and Permits). Provider will be responsible for providing Collaboration Partners with all supporting data and information relating exclusively to the Manufacture of Product at the Facility that is necessary for regulatory submissions by Company, including, without limitation, all Records, raw data, reports, authorizations, certificates, methodologies, Batch Documentation, Raw Material specifications, Process Specifications, Product Specifications, SOPs, standard test methods, Certificates of Analysis, Certificates of Compliance and other documentation in its possession or under its control relating to the Manufacture of Products; *provided, however*, that **[***]**.

7.2 **Regulatory Inspections**. Provider will permit Legend and Company or their respective agents to be present at any visit or inspection by any Regulatory Authority, **[***]**. Provider will notify the Collaboration Partners within **[***]** Business Days (or within such other time period set forth in the Quality Agreement) of becoming aware of any planned inspection. The Parties shall agree in advance of any such inspection the number of personnel who will be permitted to attend that inspection; provided, however, **[***]**. Provider will notify the Collaboration Partners within **[***]** (or within such other time period set forth in the Quality Agreement) of any unplanned inspection or ongoing inspection. Legend and Company or their respective agents present at a visit or inspection by a Regulatory Authority may attend solely for observational purposes and shall not interact with such Regulatory Authorities, except as agreed in writing by Provider. Provider will provide the Collaboration Partners with copies of all regulatory reports of inspection, copies of all regulatory correspondence from Regulatory Authorities, **[***]**. Reports and communications may be reasonably redacted by Provider to the extent they contain competitively sensitive information or information relating to products and services other than the Products and Services under this Agreement. If any Party receives notification of GMP deficiencies, such as inspectional observations or written correspondence, from any Regulatory Authority relating to any of the Products or the portion of the Facility used to Manufacture the Product, it shall, within **[***]** Business Days of the date of such observations or warning, remedy or cause the remedy of the issues identified in such notice or warning or, if any such issues cannot reasonably be remedied within such **[***]** Business Days period, the Parties will agree on a plan to resolve such issues within a mutually agreed time period. If the Parties cannot agree, the matter will be referred to the **[***]** for resolution, by providing written notice to the appropriate contact person specified in the relevant Quality Agreement **[***]**.

7.3 **Clinical Holds**. Provider will assist, as Company may reasonably request, Legend and Company with any lawful action taken by either of them or their respective Affiliates (in each of their sole discretion) for health or safety reasons, including (but not limited to) in response to complaints regarding a Product. Provider and Company will have written procedures for implementing a clinical hold of the Products in accordance with the applicable Quality Agreement. Company will make a determination (in its sole discretion) of whether a clinical hold is required.

7.4 **Notification of Quality Event**. Provider will inform Collaboration Partners within **[***]** (or such other timeframe set forth in the Quality Agreement) of discovery of any quality event which could potentially impact the quality of Product already released, in transit, or in process including but not limited to aseptic simulation failures, potential microbial or cross-contamination and nonconforming raw materials.

8 Shipping and Delivery

8.1 **Storage and Handling**. Provider will ensure that effective controls are established for the storage and handling of Products as provided in this Agreement, the Quality Agreement or Work Orders.

8.2 **Production**. With respect to each Batch of Product, **[***]** will be produced: (a) the **[***]** will be shipped to Company or its designee in accordance with the procedures outlined in Section 8.3 (Shipping) and (b) the **[***]** will be stored by Provider at the Facility in accordance with the handling requirements in this Agreement, the Quality Agreement or a Work Order until such **[***]** is shipped in accordance with Section 8.3 (Shipping), **[***]**.

8.3 **Shipping**. Provider agrees to deliver each shipment of Products to Company or its designee (as designated in writing) **[***]** (INCOTERMS 2020) **[***]**. **[***].** Each shipment shall be packed, marked and sealed in accordance with reasonable packaging and labeling practices as detailed in the Manufacturing Requirements and/or Quality Agreement. The shipment shall be labeled with a traceable Batch number. The bill of lading shall list the gross weight and net weight of the shipment. Before the shipment of Products and in addition to the documents to be provided by Provider as described in Section 6.17 (Timelines), Provider shall provide Company with an electronic copy of the Certificate of Analysis confirming that such Batch meets the applicable Product Specifications. No Batch shall ship without the express release and coordination of transportation by the Company; *provided, however*, **[***]**. Upon shipment, Provider shall provide Company with notice that the shipment has been shipped. **[***]**.

9 Price and Payment

9.1 **Pricing and Payment**.

9.1.1 [***].

9.1.2 Pricing for any and all Services shall be as detailed in Exhibit D (Pricing and Discounting) and the applicable Work Order.

9.1.3 Company shall pay to Provider during the Term and any applicable Work Order term, a fixed or non-fixed fee determined for each assignment, to be agreed upon by Company and Provider and specified in the applicable Work Order. Provider shall not, without prior written agreement, send any invoices or claims for payment, including any amount for fees or expenses, for any work done by Provider prior to the full execution of a Work Order and, solely with respect to the Manufacture of the Product, Company issuing a Purchase Order to Provider. After a Work Order is fully executed, and if applicable, Company issues a Purchase Order, Provider may not make any claim for additional payment on the grounds of Provider's misinterpretation of any Product Specifications or Process Specifications, requirements or other matter relating to a Work Order or Purchase Order, unless Company and Provider agree in writing to change the applicable Work Order in accordance with the Change Order process set forth in Section 3.6 (Changes to Services) or issue a new Purchase Order (as applicable).

9.1.4 Unless otherwise agreed in writing in a Work Order, in no instance will Company make advance payments to Provider. This includes **[***]**.

9.1.5 No out-of-pocket expenses can be billed except as detailed in an applicable Work Order and are subject to the Johnson & Johnson Travel, Meetings, and Expense Policy attached hereto as Exhibit E (Johnson & Johnson Travel, Meetings, and Expense Policy). **[***]**.

9.2 **Other Services**. Provider shall invoice Company (i) **[***]** for Technology Transfer Services, (ii) **[***]** for Product Manufacture and (iii) **[***]** for all other Services, except to the extent set forth otherwise in the applicable Work Order. Provider shall include on all invoices a reference to the applicable Work Order, a valid Purchase Order number, and an itemized cost breakdown with a description of the Services to which the invoice relates.

9.3 **Fixed-priced or Unit-priced Services**. For the purposes of this Agreement only, for Services performed on a fixed-price or unit-price basis, **[***]**. Provider is expected to manage the performance of Services within the budget limit if the scope of work remains the same as outlined in this Agreement, the applicable Work Order or Change Order.

9.4 **Time and Materials Basis Services**. For Services performed on a time and materials basis, Company shall reimburse Provider at the regular hourly rate, including work performed after hours or on weekends or holidays.

9.5 **Records and Budget Limit Notification**. Provider shall keep records of hours worked and costs of materials used, as well as other reasonable out-of-pocket expenses. Provider shall notify Company immediately upon learning that the cost of performing Services, if any, is expected to exceed the budget limit or if the agreed schedule will not be met. **[***]**.

9.6 **Reimbursement of Expenses**. Subject to Section 9.1.5, Company shall reimburse Provider for reasonable, pre-approved out-of-pocket expenses incurred in connection with the Services. Unless otherwise provided in Exhibit D (Pricing and Discounting) or a Work Order, Provider shall invoice out-of-pocket expenses to Company on a **[***]** basis as incurred. Invoices for out-of-pocket expenses shall be accompanied by supporting documentation.

9.7 **Invoices**. Invoices shall be provided to Company no more than **[***]** after the date the applicable payment is earned. Payment terms for (i) **[***]** and (ii) all other payments will be net **[***]** days after Company's receipt of an undisputed invoice from Provider, provided however, **[***]**. Company may contest any invoice or portion thereof if it reasonably believes that the charges do not conform to the agreed costs and charging mechanisms set forth herein or in any applicable Work Order or Purchase Order for the applicable Services. Once the matter is resolved, Company shall pay the appropriate charges. **[***]**. If an invoice is disputed in part, Provider may issue a new invoice in compliance with this Section reflecting solely the undisputed charges, and any such invoice is payable within **[***]** days after receipt, provided however, **[***]**.

9.8 **Restrictions on Invoices**. Provider shall not invoice Company for Services, and no claim for payment (including any expenses) will be considered with respect to such Services prior to Company's and Provider's duly authorized representatives signing this Agreement and the applicable Work Order under which the Services are being delivered and Company issuing a Purchase Order number to Provider with respect to such Services in a timely manner before the start of the Services.

9.9 **Restrictions on Charges and Expenses**. Except for charges or expenses of Provider expressly set forth in this Agreement or an applicable Work Order, Company shall not be responsible for any charges or expenses of Provider or any mark-ups on any expenses of Provider.

9.10 **Business Travel Expenses**. All business travel expenses of Provider charged to Company shall be pre-approved by Company and documented in a Work Order and incurred in strict compliance with the Johnson & Johnson Travel, Meetings, and Expense Policy attached hereto as Exhibit E (Johnson & Johnson Travel, Meetings, and Expense Policy), as updated from time to time by Company.

9.11 **Financial Audit**. During the Term and the term of each Work Order, and for **[***]** thereafter, Provider agrees to make, keep and maintain, in accordance with generally accepted accounting principles and practices, consistently applied from year to year, complete books, invoices, records of payments, correspondence, instructions, specifications, plans, drawings, receipts, manuals, contracts, Purchase Orders, tax returns, memoranda and other records relating to this Agreement and the Services and/or Deliverables provided under each Work Order. **[***]** shall have the right to audit and/or examine all such items (except to the extent they contain internal Provider financials, which Provider shall be permitted to withhold or redact), **[***]**, during regular business hours and upon reasonable prior notice. Such examinations may not (a) be conducted **[***]**, (b) be conducted more than **[***]** or (c) **[***]**. The auditor shall disclose only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared with the Collaboration Partners. **[***]**. If any audit or examination reveals that Provider collected more from Company than it was entitled to collect under the Agreement and/or any Work Order, Provider shall promptly reimburse Company for the amount of any overcharges. If any audit or examination reveals that Provider collected less from Company than it was entitled to collect under the Agreement and/or any Work Order, Company shall promptly pay Provider for the amount of any undercharges. **[***]**.

10 Term

The term of this Agreement will begin on the Effective Date and end **[***]** years thereafter, unless sooner terminated in accordance with the terms of this Agreement (the "**Term**"). This Agreement will remain in effect after any expiration of the Term for the sole purpose of and until the completion of all Work Orders hereunder and the performance of all of Provider's duties with respect to all Services being conducted pursuant to Work Orders entered into or Purchase Orders issued during the Term.

11 Termination

11.1 **Termination Rights.**

11.1.1 Company, on behalf of the Collaboration Partners may terminate this Agreement at any time for convenience upon Company providing **[***]** prior written notice to Provider. Company, on behalf of the Collaboration Partners may terminate any Work Order at any time for convenience upon Company providing **[***]** prior written notice to Provider. Termination of a Work Order for convenience shall constitute termination of such Work Order only and shall not affect this Agreement or any other outstanding Work Orders hereunder.

11.1.2 **[***]**.

11.1.3 Intentionally Omitted.

11.1.4 If any Party is in breach of any of its material obligations under this Agreement or any Work Order, then Company, on behalf of the Collaboration Partners (if Provider is the breaching Party) or Provider (if either Legend or Company is the breaching Party) may terminate this Agreement and/or the relevant Work Order(s), in whole or in part, after providing **[***]** days' written notice to the breaching Party (provided that, (i) if Provider is the breaching Party, such written notice will be delivered by Company, and (ii) if either Legend or Company is the breaching Party, such written notice must be delivered to both Legend and Company) of its intent to terminate, stating the grounds therefor, unless the breaching Party is able to satisfactorily cure such default within such **[***]** day period or such longer period as agreed in writing by Company and Provider. Notwithstanding the foregoing, **[***]**. Notwithstanding any termination of this Agreement or any Work Order as a result of a breach, a non-breaching Party shall be entitled, in accordance with Applicable Law and this Agreement, to exercise any other remedies available to it at law or in equity.

11.1.5 In the event of the insolvency of, assignment for the benefit of creditors or the initiation of bankruptcy proceedings (each, an "**Insolvency Event**") by or against, Company or Provider (such Party experiencing an Insolvency Event, an "**Insolvent Party**") occurs, then Company (where Provider is the Insolvent Party) and Provider (where Company is the Insolvent Party) will each have the right to terminate this Agreement and any Work Order with immediate effect by way of written notice to each other Party.

11.1.6 Any notice of termination of this Agreement or any Work Order by a Party as set forth herein shall be provided as set forth in Section 14.4 (Notice).

11.2 **Rights and Obligations upon Termination.**

11.2.1 Upon termination of this Agreement or any Work Order for any reason, Provider shall cease all work under all Work Orders or Purchase Orders then in effect immediately. Following that, Provider will conduct an orderly wind-down of the affected Services and will return, transfer to a Third Party, or destroy (in each case, at Company's instructions), all affected Products, all Deliverables, including any work-in-progress and all full and partial copies thereof, and any Company Materials or Equipment belonging to Company, Legend or their respective Affiliates, **[***]**. In addition, Provider shall deliver to Collaboration Partners all information supplied by or on behalf of the Collaboration Partners, including, but not limited to any technology, processes, methodology and related know-how and information transferred by or on behalf of Collaboration Partners and/or any of their Affiliates to Provider for use in the performance of the Services, and all results, documentation, materials and Deliverables acquired or generated as a result of the applicable Services. Notwithstanding the foregoing, upon termination of this Agreement, Company may, in its sole discretion, direct Provider to either cancel or fulfill pending Purchase Orders and Work Orders.

11.2.2 Upon termination of this Agreement or any Work Order, Provider shall submit a final reconciliation (to be followed within **[***]** days approval of the final reconciliation by a final invoice) to the Collaboration Partners in accordance with the pricing set forth in this Agreement for all work done by Provider in accordance with the applicable Work Order(s) and Purchase Orders prior to termination.

11.2.3 Upon any Party's receipt of a notice of termination as provided herein, the Parties shall cooperate with each other and use all commercially reasonable efforts to affect a smooth transition. Upon delivery of a notice of termination by any Party, Provider shall use all reasonable efforts to avoid incurring additional costs and expenses.

11.3 **Liability and Survival of Rights**. No termination or expiration of this Agreement or any Work Order shall release any Party from any liability which at such time had already accrued, and no such termination or expiration shall affect the survival of any right, duty or obligation of any Party that is stated to survive or that by its nature survives termination or expiration, including (without limitation) the following Sections (in each case, in accordance with the terms thereof, and including any Exhibits that are referenced therein): **[***]**.

11.4 **Payment upon Termination**.

11.4.1 **[***]**.

11.4.2 **[***]**.

(i) **[***]**.

(ii) **[***]**.

12 Confidentiality

12.1 **Confidential Information**. As used herein, "**Confidential Information**" means all information provided or otherwise disclosed to or obtained by a Party or its Affiliates (a "**Receiving Party**") from another Party or its Affiliates (a "**Disclosing Party**"), in connection with this Agreement and each Work Order, and all information derived or generated therefrom. For the avoidance of doubt, for purposes of this Agreement the Collaboration Partners and their Affiliates shall not be severable in their designations as a Disclosing Party or a Receiving Party, as the case may be. A Disclosing Party's Confidential Information will include, without limitation, all of that Party's past, present, and future (i) research, development, business activities, products (and with respect to Collaboration Partners, the Product), services, unpatented inventions, know-how, data, methods, apparatus, systems, protocols, procedures, works, compositions of matter, technical data, information data, and information regarding intellectual property rights, (ii) costs, productivity or technological advances, and (iii) customers or suppliers. Further, the terms and conditions of this Agreement, each Work Order, each Purchase Order and each Change Order shall be deemed to be the Confidential Information of each Party.

12.2 **Exclusions from Confidential Information**. Notwithstanding the foregoing, Confidential Information does not include the following: (i) information that is known by the Receiving Party without an associated obligation of confidentiality at the time of its receipt, (ii) information received by a Receiving Party from a Third Party that has the right to disclose the information to Receiving Party without breaching any applicable confidentiality obligations; (iii) information that is or becomes publicly available other than as the result of any breach of confidentiality obligations by the Receiving Party, or (iv) information developed independently by the Receiving Party without use of or reference to Confidential Information of the Disclosing Party.

12.3 **Use of Confidential Information**. A Receiving Party shall not, except as otherwise permitted by this Section 12 (Confidentiality) (i) use or reproduce the Confidential Information of a Disclosing Party for any purpose other than as required to provide or receive the Services, or (ii) disclose the Confidential Information of a Disclosing Party to any Third Party, without the prior written approval of the Disclosing Party. Notwithstanding the foregoing, Confidential Information of a Disclosing Party may be disclosed to the extent required by Applicable Law or regulations or as ordered by a court or other regulatory body having competent jurisdiction*; provided, however*, (a) that the Receiving Party uses commercially reasonable efforts to limit the disclosure to only that which is required to be disclosed and maintains confidentiality, to the extent possible and (b) provides the Disclosing Party, unless legally prohibited, with sufficient prior written notice of any such disclosure to permit the Disclosing Party to take appropriate steps, including obtaining a protective order or confidential treatment requiring that the information be held in confidence or intervening, to protect the confidentiality of the subject Confidential Information. These obligations of confidentiality and nondisclosure shall survive any termination or expiration of this Agreement or any Work Order.

12.4 **Protection Obligations**. The Receiving Party shall (i) use at least the same degree of care that it uses to protect its own proprietary information of a similar nature and value, but no less than reasonable care, to protect and maintain the Confidential Information of a Disclosing Party, (ii) restrict disclosure of the Confidential Information of a Disclosing Party to those personnel and representatives of Receiving Party who have a need to know such information, (iii) cause such persons to not disclose or use such Confidential Information other than as authorized in this Agreement, and (iv) be responsible for any actions of such persons that would be in breach of this Agreement if done by Receiving Party. The Receiving Party may retain one copy thereof to the extent required by Applicable Law or required to enable the Receiving Party to perform its obligations or exercise its rights under this Agreement, and the foregoing shall not require the Receiving Party to destroy copies of the subject Confidential Information that are then-located on IT data backups that were undertaken in the ordinary course of the Receiving Party's IT business operations, it being understood that Receiving Party shall continue to comply with its confidentiality obligations hereunder for as long as it retains such Confidential Information in its IT data backups and such Confidential Information will be promptly destroyed in the event that the subject backups are later restored. **[***].**

12.5 **Breach of Confidentiality Obligations**. A breach by a Receiving Party of its obligations under this Section 12 (Confidentiality) (a "**Confidentiality Violation**"), may cause immediate and irreparable injury, loss and/or damage to the Disclosing Party, for which an adequate remedy at law may not exist. Therefore, in the event of an actual or threatened Confidentiality Violation by a Receiving Party, the Disclosing Party may seek from a court of competent jurisdiction specific performance and/or temporary or permanent injunctive relief to prevent such Confidentiality Violation without the necessity of showing irreparable harm or posting a bond.

12.6 **No Implied Rights**. Nothing in this Section 12 (Confidentiality) shall be construed as an obligation for a Party to disclose its Confidential Information to any other Party, or as granting any right, title, interest or license to a Party under any Intellectual Property Right by the disclosure of Confidential Information hereunder. Disclosing Party shall, as between that Party and the other Parties, be and remain the exclusive owner of and have all rights to its Confidential Information.

13 Intellectual Property Rights

13.1 **Background IP.** Each of Company, Legend and Provider (in each case, together with its respective Affiliates) owns all right, title and interest in and to its Background IP. For the avoidance of doubt, as between the Parties, (i) the Manufacturing Process and the Product shall be deemed to be the Background IP of the Collaboration Partners and (ii) Provider Operating Documents will be deemed to be the Background IP of Provider.

13.2 **Limited License.** Company and Legend (in each case, together with its respective Affiliates) each hereby grants Provider and its Affiliates a non-exclusive, worldwide, royalty-free, limited license, with the right to grant sublicenses solely to Subcontracted Parties, under the applicable Intellectual Property Rights, to use each of their respective Background IP and the Collaboration Partner Foreground IP (as defined below) solely to the extent necessary for Provider and its Affiliates to perform the Services and the obligations set forth hereunder.

13.3 **Collaboration Partner Foreground IP.** As among the Parties, the Collaboration Partners shall jointly own **[***]** ("**Collaboration Partner Foreground IP**"). Provider, on its own behalf and on behalf of its Affiliates, hereby absolutely, irrevocably, and in perpetuity assigns to Collaboration Partners or their designee, all Collaboration Partner Foreground IP, including all Intellectual Property Rights therein. In the event the assignment of any such rights cannot be made or is not enforceable by operation of Applicable Law, Provider, on its own behalf and on behalf of its Affiliates, hereby grants Collaboration Partners an irrevocable, paid-up, royalty-free, exclusive (even as to Provider and its Affiliates) transferable license, with the right to sublicense (through multiple tiers), to develop, make, use, offer for sale, sell and import throughout the world, all such Collaboration Partner Foreground IP.

13.4 **Provider Foreground IP.** Provider shall own **[***]** ("**Provider Foreground IP**"). The foregoing shall not be deemed to include any right or license to use any Company Background IP, Legend Background IP, Collaboration Partner Foreground IP, Confidential Information, the Product or the Manufacturing Process. Provider hereby grants the Collaboration Partners a non-exclusive, worldwide, royalty-free, limited license, under the applicable Intellectual Property Rights, to use the Provider Foreground IP in connection with **[***]**.

13.5 **Assignment of Intellectual Property Rights**. Each Party shall ensure that all individuals performing services under this Agreement are obligated to assign to the respective Party all rights in inventions made under this Agreement, either by written agreement or by the terms of their employment. Each Party shall cooperate and cause its personnel and those of its Affiliates to cooperate, and to execute all applications, assignments or other instruments reasonably requested by a Party in order to give effect to the ownership of Intellectual Property Rights set forth hereunder.

13.6 **No Implied License or Transfer.** Except for any rights expressly granted herein, nothing in this Agreement shall, or shall be construed to, grant or otherwise convey any license, release, authorization or other right, express or implied, directly or by implication, exhaustion, estoppel or otherwise, under any Intellectual Property Right.

13.7 **Copyrightable Works.** All copyrightable works, whether published or unpublished, that are deemed to be owned by the Collaboration Partners pursuant to the operation of Sections 13.1 (Background IP) through Section 13.6 (No Implied License or Transfer) ("**Collaboration Partner Works**") shall be considered a "work made for hire" for Collaboration Partners to the fullest extent permitted by law. Collaboration Partners shall be considered the author of the Collaboration Partner Works for purposes of copyright and all right, title and interest therein, including the worldwide copyrights, shall be the property of Collaboration Partners as the Party specially commissioning such Collaboration Partner Works. In the event that any such copyrightable Collaboration Partner Works or any portion thereof does not legally qualify as a work made for hire, or is subsequently held by a court or other body of competent jurisdiction to not be a work made for hire, Provider and its Affiliates shall assign, and does hereby irrevocably and in perpetuity assign, and Provider shall cause Provider Personnel and Provider's Affiliates and Subcontracted Parties to assign, to Collaboration Partners or its designee, all right, title, and interest in and to such Collaboration Partner Works or portions thereof, including but not limited to the worldwide copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted Collaboration Partner Works, to prepare derivative works based on the copyrighted Collaboration Partner Works, to distribute copies of the copyrighted Collaboration Partner Works, to perform the copyrighted Collaboration Partner Works publicly, to display the copyrighted Collaboration Partner Works publicly, and to register the claim of copyright therein. At Collaboration Partners' request and without charge to the Collaboration Partners, Provider shall, and shall cause its Provider Personnel and Provider's Affiliates and Subcontracted Parties to, execute and deliver to the Collaboration Partners or its designee all such further papers, including confirmatory assignments and applications for copyright registration or renewal, as may be necessary to enable Collaboration Partners or its designee to publish or protect the Collaboration Partner Works by copyright or otherwise in any and all countries, and to vest title to the Collaboration Partner Works in Collaboration Partners or its designee, and its nominees, successors or assigns.

13.8 **Breach**. Each Party agrees that a breach of any of the provisions of Section 13 (Intellectual Property Rights) of this Agreement could cause immediate and irreparable injury, loss and/or damage to a non-breaching Party for which an adequate remedy at law may not exist and that damages arising from such breach may be difficult or impossible to ascertain. Accordingly, in the event of any breach or threatened breach by a Party of any provision of Section 13 (Intellectual Property Rights), the non-breaching Party **[***]** shall be entitled to institute and prosecute proceedings in any court of competent jurisdiction to enjoin the breaching Party from such breach or to seek specific performance of this Agreement or any Work Order without the necessity of showing irreparable harm or posting a bond. Nothing contained herein shall preclude a non-breaching Party from pursuing any other remedy for any breach or threatened breach of this Agreement or any Work Order, and all of such remedies shall be cumulative.

14 Compliance with Applicable Law

14.1 **Healthcare Compliance**. Provider represents and warrants that the Services will be performed in compliance with all Applicable Law, including without limitation, the FD&C Act, as amended, and applicable regulations, the Medicare/Medicaid Anti-kickback Statute, Health Insurance Portability and Accountability Act of 1996 (HIPAA), the False Claims Act, applicable state fraud and abuse laws, the AMA Guidelines on Gifts to Physicians from Industry, the Economic Espionage Act of 1996 and Applicable Laws and government regulations relating to the Services and the privacy, professional confidentiality and security thereof.

14.2 **Disbarment and Disqualification**. Each Party represents and warrants that:

14.2.1 Neither it nor any of its Affiliates is excluded, debarred, suspended or otherwise been made ineligible from participation in any state or federal healthcare program, as defined in 42 U.S.C. §1320a-7b(f) for the provision of items or services for which payment may be made by a federal healthcare program;

14.2.2 Neither it nor any of its Affiliates has been debarred, or is subject to a pending debarment, or will use in any capacity in connection with the Services any person who has been debarred pursuant to section 306 of the FD&C Act, 21 U.S.C. § 355a;

14.2.3 Neither it nor any of its Affiliates has been convicted of a criminal offense related to the provision of healthcare items or services which could lead to debarment or is subject to any such pending action, or is the subject of a conviction or pending action described in Section 14 (Compliance with Applicable Law);

14.2.4 It has not contracted with any employee, contractor, agent, vendor or vendor's affiliate knowing that the contracting party is excluded from participation in any state or federal healthcare program; and

14.2.5 No final adverse action or exclusion, as described in 42 U.S.C. § 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g), has occurred or is pending against it or its Affiliates or contractors.

14.3 **Compliance**. No Party shall violate the statutes, regulations and written directives of the Medicare, Medicaid and all other United States federal health care programs (as defined in 42 U.S.C. §1320a-7b(b)-(f)) or the statutes, regulations and written directives of the FDA, with respect to the performance of its obligations under this Agreement and each Work Order.

14.4 **Notice**. Provider shall promptly notify Collaboration Partners, and each of Legend and Company shall promptly notify Provider, in writing, of any adverse action, discovery of contract with an excluded entity or individual, or exclusion, or if such Party or any Affiliate, or Provider Personnel, or employees, agents and contractors of Legend or Company, or their Affiliates, as applicable, is debarred, excluded or otherwise disqualified or if any action or investigation is pending or threatened relating to the debarment, exclusion of such Party or any person involved in the performance of such Party's obligations under this Agreement or if any other aspect of Section 14.2 (Disbarment and Disqualification) becomes untrue at any time. In the event that a Party, or any of its Affiliates or employees, agents or contractors becomes debarred, excluded or otherwise disqualified, Company, on behalf of Collaboration Partners (if Provider is debarred, excluded or otherwise disqualified), or Provider (if Legend or Company is debarred, excluded or otherwise disqualified) will have the option to terminate this Agreement and/or any Work Order executed hereunder upon Company's written notice to Provider, or Provider's written notice to Collaboration Partners, as applicable.

15 Business Continuity

During the Term and the term of each applicable Work Order, and notwithstanding Provider's compliance with the Johnson & Johnson Policy on Data Safeguards attached hereto as Exhibit H (Data Safeguards) and the Cybersecurity Requirements attached hereto as Exhibit I (Cybersecurity Requirements), Provider has developed, implemented and maintains a business continuity plan (as updated from time to time) for the Facility (the "**BCP**"), **[***]**. With respect to Records, such BCP requires Provider to, and Provider shall, use all commercially reasonable and appropriate industry standard measures and processes to ensure that all data collected and stored by Provider in the course of providing the Services is safeguarded against loss, damage and destruction arising from any cause, including, but not limited to, theft, fire, flood, earthquake, lightening and electrical disruption. Such measures and processes shall include, but not be limited to **[***]**. With respect to the supply of Product, **[***]**. **[***]**.

16 Records and Information Management Requirements ("RIM Requirements")

16.1 **Company's Records and Information**. All records and information (or any portions thereof), in any format, that Provider creates or generates that relate to the performance of the Services, or receives on behalf of Company or its Affiliates or Legend or its Affiliates in connection with the Services or pursuant to this Agreement and each Work Order, will be referred to herein as "**Company's Records and Information**." For the avoidance of doubt, **[***]**.

16.1.1 Provider shall maintain, manage and protect Company's Records and Information (i) in accordance with Company's records retention requirements; and (ii) in accordance with Applicable Law.

16.1.2 Provider shall not transfer Company's Records and Information to any Third Party unless directed by Company.

16.1.3 Provider shall manage Company's Records and Information such that Company's Records and Information is not intermingled with records and information managed by Provider for other customers.

16.1.4 Provider shall retain electronic data backups of Company's Records and Information for disaster recovery, record retention requirements, or delivery of Services, in each case in accordance with Company's record retention requirements.

16.2 **Preservation and Production**. Provider shall comply with any reasonable written request from Company to preserve Company's Records and Information (or parts thereof). Upon reasonable written request, Provider shall deliver as soon as reasonably practicable Company's Records and Information requested all as part of the Services and in accordance with Section 16.8 (Format of Company's Records and Information).

16.3 **Third Party Requests**. Within **[***]** Business Days after Provider receives from any Third Party a request, demand, notice, subpoena, order, or other legal request ("**Third-Party Request**") for Company's Records and Information, Provider shall (in each case, unless legally prohibited): (i) notify Collaboration Partners and provide Collaboration Partners with a copy of the Third-Party Request; and (ii) confer with Collaboration Partners to identify, document, and implement procedures to comply with the request. Provider shall take reasonable steps to protect the Collaboration Patners' legal rights when responding to a Third-Party Request.

16.4 **Training**. All employees and contractors of Provider with access to the Johnson & Johnson Enterprise Network ("**JJNET**") shall annually complete reasonable Records and Information Management training as specified and provided by Company.

16.5 **Destruction**. Provider shall not destroy or permanently delete Company's Records and Information without Company's written approval or instruction. Prior to any such destruction or deletion, Company shall confirm that the subject Company's Records and Information is not subject to any pending preservation obligation or retention requirement. Following the completion of any such destruction or deletion, Provider shall certify in writing that the subject Company's Records and Information has been destroyed or permanently deleted as reasonably specified by Company in writing, subject, in any case, to the retention and deletion provisions of Section 12.4 (Protection Obligations). **[***]**.

16.6 **Transfer**. When a transfer of Company's Records and Information from Provider is required, Provider shall (i) transfer Company's Records and Information to the Collaboration Partners or an entity specified by Company in accordance with Section 16.8 (Format of Company's Records and Information), (ii) take no action on Company's Records and Information until written notification from Company confirming accurate and complete transfer is received, and (iii) only destroy or permanently delete Company's Records and Information in accordance with Section 16.5 (Destruction). **[***]**.

16.7 **Termination**. Upon termination of this Agreement and at Company's direction, Provider shall (i) transfer Company's Records and Information to the Collaboration Partners or an entity specified by Company in accordance with Section 16.6 (Transfer), or (ii) only destroy or permanently delete Company's Records and Information in accordance with Section 16.5 (Destruction).

16.8 **Format of Company's Records and Information**. In consultation with Company, Provider shall identify Company's Records and Information and Deliverables and implement mutually-agreed upon procedures to deliver to the Collaboration Partners or an entity specified by Company, Company's Records Information, Deliverables and supporting documentation in the format reasonably directed by Company.

16.9 **Product Records**. Provider acknowledges and agrees that this Section 16 (Records and Information Management Requirements) is in addition to, and not in limitation of, the requirements related to Records reflected in Section 6.16 (Records and Sample Retention); *provided*, that the Parties acknowledge that the scope of documents subject to such Sections may overlap, and do not represent independent and unrelated sets of documents.

17 Indemnification

17.1 **Indemnification by Provider**. **[***]**.

17.2 **Indemnification by Company and Legend**. **[***]**.

17.3 **Indemnification Claims by Provider**. Provider shall give the relevant Collaboration Partner Indemnitor as soon as reasonably practicable written notice of any matter upon which a Provider Indemnitee intends to base a claim for indemnification under Section 17.2 (Indemnification by Company and Legend); *provided, however*, that no delay on the part of Provider in notifying the relevant Collaboration Partner Indemnitor shall relieve such Collaboration Partner Indemnitor of any indemnity liability or obligations hereunder except to the extent the relevant Collaboration Partner Indemnitor has been materially prejudiced by such delay. The indemnification obligations of a Collaboration Partner Indemnitor hereunder shall apply only if the relevant Provider Indemnitee permits the relevant Collaboration Partner Indemnitor and its attorneys and personnel to handle and control the defense of such indemnified claims or suits, including pretrial, trial or settlement, and the relevant Provider Indemnitee fully cooperates and assists in such defense. Provider shall have the right to assume control of the defense, settlement, negotiations or litigation relating to such indemnified claim at its own expense. **[***]**. The Parties agree to cooperate with one another in the defense and disposition of any indemnity claim.

17.4 **Indemnification Claims by Collaboration Partners**. Company shall give Provider as soon as reasonably practicable written notice of any matter upon which any Collaboration Partners Indemnitee intends to base a claim for indemnification under Section 17.1 (Indemnification by Provider); *provided, however*, that no delay on the part of Company in notifying Provider shall relieve Provider of any indemnity liability or obligations hereunder except to the extent Provider has been materially prejudiced by such delay. The indemnification obligations of Provider hereunder shall apply only if the relevant Collaboration Partners Indemnitee permits Provider and its attorneys and personnel to handle and control the defense of such claims or suits, including pretrial, trial or settlement, and the relevant Collaboration Partners Indemnitee fully cooperates and assists in such defense. Collaboration Partners shall have the right to assume control of the defense, settlement, negotiations or litigation relating to such indemnified claim at their own expense. **[***]**. The Parties agree to cooperate with one another in the defense and disposition of any indemnity claim.

18 Liability

18.1 **No Exclusion or Limitation**. NOTHING IN THIS AGREEMENT LIMITS OR EXCLUDES THE LIABILITIES OF A PARTY PURSUANT TO **[***]**.

18.2 **Excluded Types of Loss**. EXCEPT FOR **[***]**, NO PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE TO THE OTHERS IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, REMOTE, EXEMPLARY, MULTIPLIED OR SPECULATIVE DAMAGES, INCLUDING LOSS OF PROFITS (TO THE EXTENT IT IS AN INDIRECT LOSS).

18.3 **[***]**.

18.4 **[***]**.

18.5 **[***]**.

18.6 **[***]**.

19 Privacy

Prior to Provider processing any Personal Information under this Agreement, the Parties shall finalize and document a policy regarding the protection of such Personal Information. Once finalized, the Parties shall attach such policy to this Agreement as Exhibit F (Protection of Personal Data), and Provider shall comply with such policy.

20 Insurance

Provider shall maintain in full force and effect valid and collectible insurance policies in connection with the Services, which policies shall be in compliance with Exhibit G (Insurance Requirements) attached to this Agreement.

21 Financial Reconciliation

If reasonably requested by Company (such requests to be limited to once per calendar year), Provider shall provide Collaboration Partners, with a financial reconciliation of funds paid by Company for Services performed by Provider.

22 Non-Employment

Provider, or where applicable, its Subcontracted Parties, shall at all times be and remain the sole employer of persons assigned to the performance of the Services hereunder and shall assume any and all obligations, responsibilities and risks related to such employment and the possible termination thereof. No Party shall have any responsibility for the hiring, firing or compensation of any other Party's employees or for any employee benefits.

23 **Subcontracting**

23.1 **Subcontractors**. **[***]**. Provider shall ensure that any subcontractor (the "**Subcontracted Party**" or "**Subcontracted Parties**") provides at least the same quality of Services as are expected from Provider. **[***]**, Provider shall only engage a Third Party that has been qualified pursuant to Provider's policies and procedures. Provider shall be responsible (i) for ensuring that any permitted Subcontracted Parties comply with the provisions of this Agreement pertinent to their engagement, each applicable Work Order and each applicable Quality Agreement and (ii) for all actions of such Subcontracted Parties in connection with this Agreement, each applicable Work Order and each applicable Quality Agreement, including any actions that would be in breach of this Agreement, the applicable Work Order or the applicable Quality Agreement if performed by Provider. Provider shall warrant and solely be responsible for the performance of each Subcontracted Party, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by Provider itself under this Agreement and any applicable Work Order or Quality Agreement. Provider shall cause each Subcontracted Party to be bound by, and to comply with, the terms of this Agreement and any applicable Work Order and Quality Agreement, including without limitation, all confidentiality, quality assurance, record keeping, audit, regulatory, government funding and other obligations of and requirements applicable to Provider set forth in this Agreement and any applicable Work Order and Quality Agreement.

23.2 **No Contractual Relationship**. **[***]** subcontracting of Services shall not create any kind of contractual relationship between Company or Legend and the Subcontracted Party unless otherwise provided by Applicable Law. Provider shall ensure that each subcontract with a Subcontracted Party contains provisions that (i) prohibit any further subcontracting and (ii) with respect to agreements with Subcontracted Parties, provides for performance of Services in compliance with all relevant provisions of the Agreement, each applicable Work Order and each applicable Quality Agreement and provide for rights exercisable by the Collaboration Partners consistent with those afforded to them under this Agreement, each applicable Work Order and each applicable Quality Agreement, including, in each case, without limitation, provisions related to record retention, audits, confidentiality and ownership of Intellectual Property Rights.

23.3 **Intentionally Omitted**.

24 **Equipment**.

24.1 **Equipment Supply**. Except as set forth in the PEP with respect to Collaboration Partners Equipment, Provider shall provide such tooling and equipment as is needed to perform the Services (the "**Dedicated Suite Items**"), **[***]**.

24.2 **Equipment Purchase**. Provider shall procure the Collaboration Partners Equipment identified in the PEP by the delivery dates set forth in the PEP and shall install the Collaboration Partners Equipment in the Facility in accordance with the requirements and specifications set forth in the PEP. **[***]**. Provider shall obtain the Collaboration Partners' prior approval for the terms and conditions of purchase before issuing a purchase order for any Collaboration Partners Equipment, which approval shall not be unreasonably withheld, conditioned or delayed. **[***]**.

24.3 **License to use Collaboration Partners Equipment**. Collaboration Partners grant Provider the right to use the Collaboration Partners Equipment for exclusive use by Provider in Manufacturing the Product during the Term and not for the benefit of Provider, its Affiliates or any Third Party or for any other purpose.

24.4 **Maintenance**.

24.4.1 During the use of the Collaboration Partners Equipment, Provider shall (a) be responsible for any damage to the Collaboration Partners Equipment (normal wear and tear excepted), (b) keep the Collaboration Partners Equipment free of all liens or other claims that could affect title to the Collaboration Partners Equipment or a Collaboration Partner's interest therein, (c) not modify or alter the Collaboration Partners Equipment in any way, except as otherwise permitted herein, (d) not remove or cause or permit to be removed, the Collaboration Partners Equipment from the Facility for other than approved maintenance or repair, and (e) not remove, conceal or deface any tags, stickers or other items affixed to the Collaboration Partners Equipment that indicate a Collaboration Partner's status as owner thereof.

24.4.2 Provider shall service, repair and maintain (collectively "**Maintenance**") all Equipment used in the provision of Services, and provide supplies and consumable items and accessories, as may be necessary to keep the Equipment (including Collaboration Partners Equipment) in good working order **[***]**. Upon request, Provider shall update the Collaboration Partners on the condition of the Collaboration Partners Equipment and the expected remaining life thereof. Upon the end of the useful life of the Collaboration Partners Equipment, Provider shall be responsible for decommissioning (and disposal, if applicable) of the Collaboration Partners Equipment in accordance with applicable laws and regulations. **[***]**.

24.4.3 Without prejudice to anything set forth in this Agreement, **[***].**

24.5 **Return of Collaboration Partners Equipment**. In case of termination or expiry of Provider's right to use the Collaboration Partners Equipment, Provider shall return the Collaboration Partners Equipment to the Collaboration Partner identified by Company in writing, in the same condition as when Provider took delivery of the Collaboration Partners Equipment, ordinary wear and tear excepted. **[***]**. Provider shall prepare the Collaboration Partners Equipment for transport and shall put the Collaboration Partners Equipment at the disposal of the applicable Collaboration Partner (together with all accessories, documents and records) by the date agreed-to by the Parties for review by such Collaboration Partner, and shall deliver the Collaboration Partners Equipment **[***]** (Incoterms 2020) and, **[***]**, make available to the Collaboration Partner or its designee access to all information, know-how, as well as any other technical guidance, necessary or helpful for the operation by the Collaboration Partner or its designee of the Collaboration Partners Equipment. The Parties shall work in good faith to complete the transportation of the Collaboration Partners Equipment within **[***]** from the date of expiry or termination of Provider's right to use the Collaboration Partners Equipment.

25 Premises

25.1 **Compliance with Company and Governmental Rules and Regulations**. While on the premises of a Party or any of its Affiliates at any time, Provider Personnel (in respect of Provider) and employees, agents and contractors of each Collaboration Partner (in respect of the Collaboration Partners) shall comply with all rules and regulations of the premises Party, as applicable, and all federal, state and local laws, ordinances and regulations applicable to such Party's premises. Provider shall be responsible for Provider Personnel and the Collaboration Partners shall be responsible for their employees, agents and contractors while on another Party's premises, whether or not the actions of such Provider Personnel or Collaboration Partner employees, agents and contractors, as applicable, fall outside the scope of their employment or engagement by the applicable Party. Provider shall ensure that Provider Personnel, and Collaboration Partners shall ensure that their employees, agents and contractors, proceed directly to the site where the Services will be performed and do not enter any other part of another Party's premises.

25.2 **COVID-19 Requirements**. While on the premises of Company or Legend or any of their respective Affiliates, Provider represents and warrants that it shall comply and shall ensure Provider Personnel and permitted Subcontracted Parties comply with the COVID-19 requirements of Company, Legend or any of their respective Affiliates applicable to such premises, as provided to Provider from time to time. While on the premises of Provider or any of their respective Affiliates, Company and Legend, as applicable, represents and warrants that it shall comply and shall ensure Collaboration Partner employees, agents and contractors comply with the COVID-19 requirements of Provider or any of their respective Affiliates applicable to such premises, as provided to Company and Legend from time to time.

26 No Exclusivity

Neither this Agreement nor any Work Order implies an exclusive undertaking on the part of Collaboration Partners or Provider. **[***]**, nothing contained herein shall be interpreted as an obligation of the Collaboration Partners to commit to a certain volume, value or frequency of services to be assigned to Provider, and the Collaboration Partners may contract with other provider(s) for the procurement of comparable services. Without limiting the foregoing, Provider agrees that the Collaboration Partners have the right to benchmark, formally or informally, any services offered by Provider or any terms of this Agreement or Work Order and to competitively bid any projects it may have.

27 [***]

28 Publicity

28.1 **Non-Disclosure**. Provider shall keep in strict confidence and not disclose to any Third Party the interest or participation of Collaboration Partners in the subject matter of this Agreement, each Work Order and/or Quality Agreement and the relationship of the Parties, or the terms of engagement hereunder except as necessary for the performance of or otherwise permitted under this Agreement and as agreed in writing with Collaboration Partners in advance of any such disclosure. Each Collaboration Partner shall keep in strict confidence and not disclose to any Third Party the interest or participation of Provider in the subject matter of this Agreement, each Work Order and/or Quality Agreement and the relationship of the Parties, or the terms of engagement hereunder except as necessary for the performance of or otherwise permitted under this Agreement and as agreed in writing with Provider in advance of any such disclosure.

28.2 **Limitations on Publicity**. No Party shall generate any publicity, news release or other announcement or use any names, trademarks or logos of the other Parties, in each case, relating to this Agreement, any Work Order or to the Services provided hereunder without the prior written consent of the other Parties; *provided, however*, that Company and Legend may acknowledge the participation or support of Provider in the Services or otherwise make such disclosure to the extent required by Applicable Laws or stock exchange rules, without consent, but subject to the terms of this Section 28.2 (Limitations on Publicity). In the event a Party is required by Applicable Law or the rules of a stock exchange to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and if possible at least **[***]** Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon, and the disclosing Party shall in good faith reasonably consider and incorporate any comments from the non-disclosing Party which are received in advance of the anticipated date of disclosure, including any request for confidential treatment of commercial terms and sensitive technical terms, to the extent such confidential treatment is reasonably available to the disclosing Party.

29 Assignment

No Party may assign any of its rights or obligations under this Agreement, any Work Order or the Quality Agreement without the prior written consent of, **[***]**. Notwithstanding the foregoing, this Agreement, any Work Order, or any Quality Agreement (if applicable) may be assigned, in whole or in part, **[***]**. Any attempted assignment by a Party in violation of this Section shall be null and void *ab initio*. This Agreement shall bind and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

30 Representations and Warranties

30.1 **Good Standing**. Provider represents and warrants that it is a corporation or limited liability company duly organized, validly existing and in good standing under the laws of the State of New Jersey. Company represents and warrants that it is a limited liability company duly organized, validly existing and in good standing under the laws of the State of New Jersey. Legend represents and warrants that it is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware.

30.2 **Performance of Services**. Provider represents and warrants that it shall comply with, and that the Services shall be performed in accordance with (i) this Agreement, (ii) any applicable industry standards and practices, and (iii) if applicable, Manufacturing Requirements, including all Applicable Law, including, but not limited to, those of the United States or any other country or jurisdiction applicable to the performance of the Services, including, without limitation, those set forth by the National Institutes of Health (NIH), U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA), the U.S. Federal Trade Commission (FTC), the U.S. Occupational Safety and Health Administration (OSHA), European Medicines Agency (EMA), Central Drugs Standard Control Organization (CDSCO) and any other governmental or supra-governmental agencies, as applicable, and applicable environmental regulations and labor standards.

30.3 **Personnel**. Provider represents and warrants that the Services shall be provided by Provider Personnel who are suitably skilled and trained in the performance of the Services, and that Provider Personnel shall perform the Services in a diligent and professional manner. Provider shall ensure that any Provider Personnel providing Services under this Agreement and/or any Work Order obtain and maintain any permits, licenses and certifications that such Provider Personnel are required to have to provide the Services in accordance with this Agreement. Provider agrees to ensure that Provider Personnel, and any other individuals performing Provider's obligations in the United States are authorized to work in the U.S., as required under the Immigration Reform and Control Act of 1986.

30.4 **Necessary Resources**. Provider represents and warrants that it has the necessary Facilities and Equipment (other than Collaboration Partners Equipment), Dedicated Suite Items and Provider Personnel with the requisite expertise, experience and skill to render the Services.

30.5 **Authority to Contract**. Each Party represents and warrants that it has the full power and right to enter into this Agreement.

30.6 **No Conflict with Third Parties**. Provider represents and warrants that it has not entered into and will not enter into any agreement or understanding with a Third Party, which could conflict or interfere with this Agreement or any Work Order. Provider represents and warrants that it has the right to perform its duties and obligations as provided in this Agreement and any Work Order without conflict of interest to others and without violating any confidentiality obligations it may have to others. Provider represents and warrants that it has obtained, in writing, all Third Party consents which are necessary or appropriate for the performance of the Services.

30.7 **Products**. Provider represents and warrants that at the time of shipment by Provider, each Batch of Product (i) will have been Manufactured in accordance with the Manufacturing Requirements, (ii) will not be adulterated or misbranded under FD&C Act or other Applicable Law **[***]** and (iii) will be free of liens and encumbrances.

30.8 **Sanctions, Restrictions or Embargoes**. Each Party represents and warrants that no transactions or dealings under this Agreement and/or any Work Order shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom or the United States of America.

30.9 **Software System**. If Provider uses software or a software system to provide the Services, Provider represents and warrants that either (i) it is the lawful owner of such system and any software which may be used in providing the Services hereunder, or (ii) such software has been lawfully licensed to or otherwise acquired by Provider and Provider is authorized to use such software in providing the Services hereunder. Provider shall use commercially reasonable efforts to maintain the functionality and data integrity of any system used in performing the Services during the Term. Provider shall technically support and maintain any system used in performing the Services during the Term. Provider represents and warrants that it shall use commercially reasonable efforts to ensure that any Third Party software used in performing the Services shall remain functional during the Term. Provider shall maintain current during the Term any Third Party software used in performing the Services using supported releases from the applicable Third Party software provider.

30.10 **Policy on Data Safeguards**. Provider shall protect each of Company's and Legend's Confidential Information in its possession or under its control from disclosure to or use by unauthorized Third Parties as provided in the Johnson & Johnson Policy on Data Safeguards attached hereto as Exhibit H (Data Safeguards). Provider represents and warrants that it shall comply with (i) such policy attached hereto as Exhibit H (Data Safeguards), as updated from time to time by Company (to the extent that such update is generally applicable to Company's service providers) and (ii) the Cybersecurity Requirements, attached hereto as Exhibit I (Cybersecurity Requirements). **[***]**.

30.11 **Anti-Corruption Laws**. Each Party represents and warrants that it shall not perform any actions that are prohibited by any local or other anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (collectively, "**Anti-Corruption Laws**"). Without limiting the foregoing, no Party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other Third Party in a manner that would violate Anti-Corruption Laws.

30.12 **Responsibility Standards for Suppliers**. In performing under this Agreement and any Work Order, **[***]**.

30.13 **[***]**.

30.14 **[***]**.

30.15 **DISCLAIMER OF WARRANTIES**. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. **[***]**.

31 Supply Chain Security

Provider is a certified member of the Customs-Trade Partnership Against Terrorism ("**C-TPAT**") program of the U.S. Bureau of Customs and Border Protection. As such, Provider has reviewed its supply chain security procedures and these procedures and their implementation are, and shall remain during the Term, in accordance with the importer security criteria set forth by C-TPAT.

32 Policy for Wood Pallets

Provider and its officers have read and understand the Johnson & Johnson Policy for Wood Pallets ("**Pallet Policy**") in effect as of the Effective Date and set out in Exhibit K (Johnson & Johnson Policy for Wood Pallets), as updated from time to time by Company (to the extent that such update is generally applicable to Company's service providers), and Provider agrees that it shall comply with the Pallet Policy. Provider shall certify compliance with such Pallet Policy at least annually. Such certification shall be sent to Company pursuant to the notice provisions set forth herein. Company has the right to reject any Products or materials that fail to comply with this Pallet Policy.

33 Force Majeure

If any Party is affected by any event beyond its reasonable control, including fires, floods, earthquakes, hurricanes, embargoes, war, acts of war (whether war is declared or not), terrorist acts, civil commotion, strikes, lockouts, or other labor disturbances, or acts of God (a "**Force Majeure Event**"), such Party shall not be liable in connection with this Agreement, any Work Order or any Quality Agreement to the extent affected by such Force Majeure Event; provided that such affected Party (the "**Force Majeure Party**") gives written notice as soon as reasonably practicable, to the other Parties of the Force Majeure Event and that Force Majeure Party exercises commercially reasonable efforts to eliminate the effects of the Force Majeure Event on the Services, this Agreement, a Work Order or the Quality Agreement as soon as and to the extent practicable. If any Force Majeure Event affecting Provider continues for a period longer than **[***]**, then Company may terminate this Agreement and/or the applicable Work Order upon written notice to Provider. This Section does not limit or alter a Party's right to terminate this Agreement, or any Work Order as set forth in Section 11 (Termination) or Section 14.4 (Notice). A performance failure of a Subcontracted Party of Provider will not be a Force Majeure Event for Provider unless the Subcontracted Party's performance failure was caused by a Force Majeure Event.

34 Independent Contractors; No Agency

No employee or representative of a Party shall have any authority to bind or obligate any other Party to this Agreement, each Quality Agreement or any Work Order for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on any other Party without said other Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement, any Work Order or any Quality Agreement to the contrary, each Party's legal relationship with one another under this Agreement, each Work Order and each Quality Agreement (as applicable) shall be that of independent contractor.

35 Severability

In the event that a court of competent jurisdiction holds any provision of the Agreement, any Work Order or any Quality Agreement to be invalid, such holding shall have no effect on the remaining provisions of the Agreement, the applicable Work Order and/or the applicable Quality Agreement and they shall continue in full force and effect.

36 No Waivers

The failure of any Party to require performance by another Party of any of such other Party's obligations hereunder shall in no manner affect the right of the first Party to enforce the same at a later time. No waiver by any Party hereto of any condition, or of the breach of any provision, term, representation or warranty contained in the Agreement shall be deemed to be or construed as a further or continuing waiver of any such condition or breach, or of any other condition or of the breach of any other provision, term, representation, or warranty in this Agreement. The remedies provided in this Agreement are not exclusive and the Party suffering from a breach or default of this Agreement may pursue all other remedies, both legal and equitable, alternatively or cumulatively.

37 Governing Law and Dispute Resolution

37.1 **Governing Law**. This Agreement and each Work Order and Quality Agreement are governed by and will be construed in accordance with the laws of the State of New York, excluding any conflicts of law provisions.

37.2 **Meeting of Senior Officers**. If a Party wishes to raise or initiate any dispute, controversy or claim arising out of or related to this Agreement, the Quality Agreement or any Work Order or the interpretation, application, breach, termination or validity thereof, including any claim of inducement by fraud or otherwise, (a "**Dispute**"), such Party shall provide the other Parties with detailed written notice of the Dispute ("**Claim Notice**"), provided that **[***]**. Within **[***]** of the Claim Notice being provided, the senior officers of each Party shall meet and undertake to reasonably resolve the issues described in the Claim Notice. If the Parties are not able to resolve any Dispute described in a Claim Notice **[***]**, unless extended by written mutual agreement of the Parties, from the date of the Claim Notice being provided, **[***]**.

37.3 **[***]**.

37.4 **Jurisdiction**. The Parties consent to the jurisdiction of the United States District Court for **[***]**. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.

37.5 **[***]**.

37.6 **Confidentiality**. All aspects of the dispute resolution process shall be treated as confidential except **[***]**.

37.7 **Waivers**. EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, EACH PARTY HERETO WAIVES: (1) ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY AND (2) ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST.

38 Notices

38.1 All notices hereunder shall be in writing and shall be deemed to have been duly given when delivered personally or by overnight courier or mailed by certified mail (postage prepaid) to the other Party at its address designated in or pursuant to this Section 38 (Notices). The address and/or contact person may be changed by any Party by providing notice to the other Parties in the manner provided in this Section 38 (Notices).

If to Provider:

Novartis Pharmaceuticals Corporation
Attention: **[***]**
[***]
[***]
[***]
With a copy to (which does not constitute notice):

Novartis Pharmaceutical Manufacturing GmbH
Attention: **[***]**
[***][***][***]

If to Company:

Janssen Research & Development, LLC
920 US Route 202
Raritan, NJ 08869
Attention: Head, Discovery, Product Development, and Supply

With a copy to:

Office of General Counsel
Johnson & Johnson
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: General Counsel, Pharmaceuticals

If to Legend:

Legend Biotech USA Inc.
2101 Cottontail Lane
Somerset, NJ 08873
Attention: Senior Vice President, Technical Operations

With a copy to (which does not constitute notice):

Legend Biotech USA Inc.
2101 Cottontail Lane
Somerset, NJ 08873
Attention: General Counsel

39 Entire Agreement

This Agreement, the Technology Transfer Agreement, the Equipment Letter Agreement, each Work Order and each Quality Agreement represents the entire and integrated agreement between the Parties with respect to the subject matter herein and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the performance of the Services. All services performed by Provider under the Technology Transfer Agreement shall be considered performed under this Agreement. No additional or different terms or conditions, whether set forth in an invoice, or other document shall be effective to bind any Party. No amendment, change or modification of this Agreement will be effective unless in writing and signed by the Parties. No amendment, change or modification of any Work Order or any Quality Agreement will be effective unless in writing and signed by the Parties thereto.

40 Conflict Between Documents

If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement, the Technology Transfer Agreement, the Equipment Letter Agreement and any Quality Agreement, this Agreement will govern. In the event of a conflict between this Agreement and any Work Order, this Agreement will govern unless this Agreement provides that the Work Order governs for that specific matter.

41 Headings

This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement and should not be used in the construction of this Agreement.

42 No Benefit to Third Parties

Except as provided under Section 17 (Indemnification), the representations, warranties, covenants and agreements set forth in this Agreement, each Work Order and each Quality Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons.

43 Taxes

43.1 **Responsibility for Own Taxes**. All fees are exclusive of sales, use, gross receipts, excise, value-added, business, consumption, and other taxes, and Company agrees to make all payments of fees to Provider under this Agreement and each Work Order without deduction or withholding for any tax, unless such deduction or withholding is required by Applicable Law. Each Party shall be responsible for taxes based on its own income ("**Income Taxes**"), for franchise and privilege taxes on its business, for employment taxes of its employees, and for taxes on any property it owns or leases. In addition, Provider will not be entitled to pass on to Company or Legend any taxes that Provider incurs in subcontracting the performance of the Services except to the extent such taxes were included in the fees negotiated by the Parties. Each Party and their respective Affiliates will reasonably cooperate with each other to more accurately determine a Party's tax liability and to minimize such liability, to the extent legally permissible.

43.2 **Withholding Taxes**. In the event Applicable Law requires Company to withhold any Income Taxes from any payments made to Provider, then Company shall withhold such taxes, pay the full amount withheld to the relevant taxing authority, and provide Provider with proof of such payment. Any such tax required to be withheld shall be an expense of and borne by Provider and any amounts paid, deducted or withheld by Company shall be treated for all purposes of this Agreement as paid to Provider.

43.3 **Indirect Taxes**. All fees are exclusive of any value added, sales, use, goods and services, transfer, services, consumption, business, or transaction taxes ("**Indirect Taxes**"). As long as the amount of Indirect Taxes are specified in a valid invoice compliant with Applicable Law, Company shall either pay such amount or supply valid exemption documentation. If Provider does not provide Company with a valid invoice (including separate identification of Indirect Taxes where required by Applicable Law), Provider shall assume responsibility for such non-compliance, including payment of any tax-related interest and penalties. Provider and Company shall reasonably cooperate to segregate fees for taxable Services from fees for nontaxable Services.

43.4 **[***]**.

44 Compliance with Anti-Trust Laws

The Parties shall not collude on commercial strategies, neither expressly nor tacitly, aimed at directly or indirectly influencing prices or allocating customers or geographic territories. The Parties agree to adhere to all competition laws, as applicable, prohibiting any discussion, understanding or agreement, however informal, or the exchange of information on: product pricing; costs of production or distribution; projected or actual sales or marketing strategies; projected or actual market shares; terms and conditions of purchases or sales; confidential research and development projects, budgets, spend, or priorities; bids or intentions to bid for particular products; or refusals to do business with particular suppliers, vendors, customers or competitors, or the suggestion that such a refusal or boycott might be appropriate or desirable.

45 **[***]**

45.1 Small, Disadvantaged and Woman-Owned Business Enterprises

Company has a policy of maximizing opportunities for small, disadvantaged and women-owned businesses where appropriate when working with suppliers who offer further subcontracting opportunities. When these conditions exist, Provider shall carry out this policy in good faith in connection with the award of permitted subcontracts to the fullest extent consistent with its efficient performance of this Agreement.

46 **Intentionally Omitted**

47 **Counterparts**

This Agreement may be executed in counterparts where execution in counterparts is valid and enforceable, and each such counterpart shall be an original and all such counterparts together shall constitute the entire Agreement. Facsimile signatures and photocopied signatures transmitted by email shall be deemed to be originals for all purposes under this Agreement where facsimile and photocopied signatures are valid and enforceable. This Agreement, each Work Order, each Quality Agreement and any amendment to this Agreement, a Work Order or a Quality Agreement may be signed electronically as long as (a) electronic signatures are valid and effective in the jurisdiction in which such instrument is signed, and (b) electronic signatures are permitted by Company's policies as in effect from time to time and authenticated in accordance with such policies.

[*Signature page follows*]

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representatives, on the date set forth below. The Parties agree to execute this Agreement by way of an electronic signature and agree this shall constitute a valid and enforceable agreement among the Parties. The present Agreement is made in pdf-version which is signed electronically by each Party.

Janssen Research & Development, LLC

By: _____
Name: _____
Title: _____
Date: _____

Novartis Pharmaceuticals Corporation

By: _____
Name: _____
Title: _____
Date: _____

Legend Biotech USA Inc.

By: _____
Name: _____
Title: _____
Date: _____

Exhibits:
Exhibit A – Form of Work Order
Exhibit B – Intentionally Omitted
Exhibit C – Form of Change Order
Exhibit D – Pricing and Discounting
Exhibit E – Johnson & Johnson Travel, Meetings, and Expense Policy
Exhibit F – Protection of Personal Data
Exhibit G – Insurance Requirements
Exhibit H - Data Safeguards
Exhibit I – Cybersecurity Requirements
Exhibit J – **[***]**
Exhibit K – Johnson & Johnson Policy for Wood Pallets
Exhibit L – Description of Product
Exhibit M – Project Execution Plan
Exhibit N – **[***]**
Exhibit O - **[***]**
Exhibit P – Bill of Materials

Exhibit A
Form of Work Order

[***]

Exhibit B
Intentionally Omitted

Exhibit C
Form of Change Order

[***]

Exhibit D
Pricing and Discounting

[***]

[***]

Exhibit F
Protection of Personal Data

[***]

Exhibit G
Insurance Requirements

[***]

Exhibit H
Data Safeguards

[***]

Exhibit I
Cybersecurity Requirements

[***]

Exhibit J
[***]

[***]

Exhibit K
Johnson & Johnson Policy for Wood Pallets

[***]

Exhibit L
Description of Product

[***]

Exhibit M
Project Execution Plan

[***]

Exhibit N
[***]

[***]

Exhibit O
[***]

[***]

Exhibit P
Bill of Materials

[***]