Exhibit 10.39  
\*\*\*Text Omitted and Filed Separately  
with the Securities and Exchange Commission.  
Confidential Treatment Requested  
Under 17 C.F.R. Sections 200.80(b)(4) and Rule 406 of the  
Securities Act of 1933, as amended.  
Manufacturing Agreement  
(the “Agreement”)  
by and between  
Lonza Biologics Tuas Pte Ltd  
00 Xxxx Xxxxx Xxxxxx 0,  
XX-Xxxxxxxxx,  
000000  
- hereinafter “Lonza” -  
and  
TRACON Pharmaceuticals Inc.  
0000 Xxxxxxxxxx Xxxxxx Xxxx,  
Xxxxx 000,  
Xxx Xxxxx,  
XX 00000  
- hereinafter “Customer” -  
Effective as of 22 February, 2017 (the “Effective Date”)  
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Recitals  
WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of product;  
WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;  
WHEREAS, Customer wishes to engage Lonza for Services relating to the development and manufacture of the Product as described in this Agreement; and  
WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.  
NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:  
 1 Definitions and Interpretation  
 “Additional Batches”  
 shall have the meaning set out in Clause 6.2.  
“Affiliate”  
 means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. “Control” means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party.  
“Agreement”  
 means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.  
“Alternate Product”  
 means such product which the Parties agree may be substituted in place of the Product in accordance with Clause 6.1, and after such substitution all references in this Agreement to “Product” shall be deemed to apply to such Alternate Product.  
“Applicable Laws”  
 means all relevant U.S. and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to a Party’s activities hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority and all applicable cGMP together with amendments thereto.  
“Approval”  
 means the first marketing approval by the FDA or EMA of Product from the Facility for commercial supply and the date of first Approval  
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 shall be the date on which the first such approval occurs.  
“Background Intellectual Property”  
 means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder during the Term of this Agreement.  
“Batch”  
 means the Product derived from a single run of the Manufacturing Process at the Facility at […\*\*\*…] litre scale.  
“Batch Price”  
 means the Price of each Batch as set out in Appendix A and as may be adjusted from time to time in accordance with this Agreement.  
“Campaign”  
 means a series of no less than […\*\*\*…] cGMP Batches manufactured consecutively.  
“Cancellation Fee”  
 has the meaning given in Clause 6.7.  
“Capital Equipment”  
 means those certain pieces of equipment described in the Project Plan used to produce the Product that are purchased by Customer or for which Customer reimburses Lonza, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment.  
“Cell Line”  
 means the Customer’s cell line, the particulars of which are set out in Appendix B.  
“Certificate of Analysis”  
 means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specifications and test results.  
“Certificate of Compliance”  
 means a document prepared by Lonza: (i) listing the manufacturing date, unique Batch number, and concentration of Product in such Batch; and (ii) certifying that such Batch was manufactured in accordance with the Master Batch Record and cGMP, if applicable.  
“cGMP”  
 means those laws and regulations applicable in the U.S. and European Union, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR  
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 (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents.  
“cGMP Batches”  
 means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.  
“Commencement Date”  
 means the date of removal of the vial of cells from frozen storage for the production of a Batch.  
“Confidential Information”  
 means Customer Information and/or Lonza Information, as the context requires.  
“Customer Information”  
 means all technical and other information not previously known to Lonza or in the public domain that is: (a) from time to time (including prior to the date of this Agreement) supplied by or on behalf of the Customer to Lonza, including any materials supplied by Customer to Lonza in accordance with the Project Plan; or (b) New Customer Intellectual Property.  
“Customer Materials”  
 means any Raw Materials, components of Product, or other materials of any nature provided by Customer.  
“Customer Withdrawal”  
 means a good-faith determination by the Customer’s board of directors, as a result of regulatory, safety and/or efficacy concerns regarding the Product, to completely and permanently cease development and promotion of the Product for all indications anywhere in the world and not to seek any marketing approvals anywhere in the world therefor.  
“EMA”  
 means the European Medicines Agency, or any successor agency thereto.  
“Engineering Batches”  
 means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility.  
“External Laboratories”  
 means any Third Party instructed by Lonza, with Customer’s prior consent, which is to conduct activities required to complete the Services.  
“Facility”  
 means Lonza’s […\*\*\*…] manufacturing facilities in Singapore.  
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“Failed Batch”  
 shall have the meaning set out in Clause 7.3.3.  
“Failed Engineering Batch”  
 shall have the meaning set out in Clause 7.3.3.  
“FDA”  
 means the United States Food and Drug Administration, or any successor agency thereto.  
“Governmental Authority”  
 means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in the U.S. or European Union.  
“GS”  
 means the glutamine synthetase expression system of which Lonza is the proprietor.  
“GS Licence”  
 means a licence granted by Lonza in respect of the use of GS.  
“Intellectual Property”  
 means: (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in Confidential Information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered; (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing sub-clause (i); and (iii) all rights and applications that are similar or equivalent to the rights and applications described in the foregoing sub-clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.  
“Lonza Information”  
 means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is from time to time (at any time including prior to the date of this Agreement) disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including without limitation, any and all Lonza know-how and trade secrets.  
“Lonza Responsibility”  
 has the meaning given in Clause 7.3.3.  
“Manufacturing Process”  
 means the production process for the manufacture of Product which may include Background Intellectual Property of Customer and Background Intellectual Property of Lonza, as such process may be improved or modified  
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 from time to time by agreement of the Parties in writing.  
“Master Batch Record”  
 means the document, proposed by Lonza and approved by Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product.  
“MO Year”  
 means a period of twelve (12) calendar months beginning on the date of first Approval and subsequent MO Years shall commence on each anniversary of the date of first Approval throughout the Term.  
“Minimum Order” or “MO”  
 shall have the meaning set out in Clause 6.3.  
“New Customer Intellectual Property”  
 has the meaning given in Clause 10.2.  
“New General Application Intellectual Property”  
 has the meaning given in Clause 10.3.  
“Operational Failure”  
 means the suspension by Lonza of production of Product for more than […\*\*\*…] consecutive days or […\*\*\*…] non-consecutive days within a […\*\*\*…] period due to the occurrence of a failure at the Facility or in the equipment used to manufacture Product (and where such failure is not attributable to […\*\*\*…]. Operational Failure would include, without limitation, such a suspension by Lonza due to […\*\*\*…].  
“Party”  
 means each of Lonza and Customer and, together, the “Parties”.  
“Persistent Supply Failure”  
 means the Delivery by Lonza of less than […\*\*\*…] percent ([…\*\*\*…]%) of the Minimum Order over a period comprising at least […\*\*\*…] consecutive Campaigns.  
“Pilot Batch”  
 means a Batch of Product designated as a pilot Batch which shall not comply with cGMP and is not required to meet the Specifications.  
“Price”  
 means the price for the Services and Products as set out in Appendix A.  
“Process Validation Batch”  
 means a Batch that is produced with the intent to show reproducibility of the  
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 Manufacturing Process and is required to complete process validation studies.  
“Product”  
 means the product known as TRC-105, to be manufactured using the Manufacturing Process by Lonza for Customer as specified in the Project Plan, or the Alternate Product.  
“Project Plan”  
 means the plan(s) describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time. The initial Project Plan shall be agreed between the Parties in accordance with Clause 3.1.  
“Quality Agreement”  
 means the quality agreement executed by both Parties, setting out the responsibilities of the Parties in relation to quality as required for compliance with cGMP.  
“Raw Materials”  
 means all ingredients, solvents and other components of the Product required to perform the Manufacturing Process or Services set forth in the xxxx of materials detailing the same (including Resins but excluding any wearables).  
“Raw Materials Fee”  
 means the procurement and handling fee of […\*\*\*…] percent ([…\*\*\*…]%) of the acquisition cost of Raw Materials by Lonza that is charged to the Customer in addition to the cost of such Raw Materials, except for […\*\*\*…] which shall not be subject to a procurement and handling fee.  
“Regulatory Authority”  
 means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.  
“Resin”  
 means the chromatographic media and/or UF membranes intended to refine or purify the Product, as specified in the Master Batch Record.  
“Safety Stock”  
 has the meaning set out in Clause 2.7.  
“Services”  
 means all or any part of the services to be performed by Lonza under this Agreement, particulars of which are set out in a Project Plan.  
“Shortfall Notice”  
 shall have the meaning set out in Clause 6.5.  
“Specifications”  
 means the specifications of the Product as specified in Appendix B, which may be  
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 amended from time to time in accordance with this Agreement.  
“Steering Committee”  
 shall have the meaning set out in Clause 3.3.  
“Term”  
 has the meaning given in Clause 14.1.  
“Third Party”  
 means any party other than Customer, Lonza and their respective Affiliates.  
In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word “including” are to be construed without limitation.  
 2 Performance of Services and Exclusivity  
 2.1 Performance of Services. Subject to Customer fulfilling its obligations under Clause 2.2, Lonza shall itself and through its Affiliates, diligently and consistent with industry standards, carry out the Services as provided in the Project Plan and in accordance with the terms and conditions of this Agreement and use commercially reasonable efforts to perform the Services according to the estimated timelines as set forth in the Project Plan (owing to the unpredictable nature of the biological processes involved in the Services, the timescales set down for the performance of the Services are estimated only); provided that Lonza shall remain fully responsible for its Affiliates’ performance of all obligations delegated to such Affiliates. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract or delegate any of its rights or obligations under this Agreement to perform the Services to Third Parties with Customer’s prior written consent, which consent shall not be unreasonably withheld, or to External Laboratories to provide some of the Services; provided that […\*\*\*…].  
 2.2 Technology Transfer. The Parties expressly agree that they shall work together to transfer the Manufacturing Process into the Facility, including implementing the technology transfer plan set forth in the Project Plan. The Parties shall use their commercially reasonable efforts to complete such technology transfer according to the Project Plan according to the estimated timelines set forth therein, and Customer shall fully support such technology transfer as reasonably requested by Lonza. The price for such technology transfer and process validation activities shall be as set out in Appendix A.  
 2.2A  
Pilot Batches. Lonza shall manufacture Pilot Batches in accordance with the Project Plan, but shall have no obligation to, and makes no warranty, that Pilot Batches will meet Specification or be manufactured in accordance with cGMP. Customer shall have the right to make whatever use of the Pilot Batches as it  
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 shall determine, provided that Customer pays Lonza the Price for such Pilot Batches, and such use is not for human use and does not violate any Applicable Laws.  
 2.3 Engineering Batches. Lonza shall manufacture, and Customer shall pay for, Engineering Batches in accordance with the Project Plan. Customer shall have the right to make whatever further use of the non-cGMP Engineering Batches as it shall determine, provided that Customer pays for such Batches, such use is not for human use and does not violate any Applicable Laws. Lonza makes no warranty that Engineering Batches will meet cGMP or the Specifications. If Lonza determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch. Nothing in this Clause 2.3 shall be construed to limit Customer’s remedies set forth in Clause 7.3.3. Notwithstanding anything to the contrary, no Engineering Batches shall commence until Lonza has completed a Pilot Batch at the Facility. In the event that there is a material difference in the process assumptions as compared with the process results demonstrated during the manufacture of Engineering Batches, the Parties shall meet to discuss in good faith the consequences of such changes.  
 2.4 cGMP Batches. Lonza will, in accordance with the terms of this Agreement and the Quality Agreement, manufacture at the Facility and release to Customer, cGMP Batches that comply with the Manufacturing Process, the Quality Agreement, cGMP and the Specifications, together with a Certificate of Analysis; provided, however, that cGMP manufacture shall not commence until at least […\*\*\*…]. Prior to commencement of cGMP manufacturing, the Parties shall jointly review the process assumptions.  
 2.5 Process Validation Batches. Lonza shall manufacture and deliver Process Validation Batches as mutually agreed by the Parties sufficient to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the necessary regulatory documents.  
 2.5.1 Prior to commencement of Process Validation Batches, Lonza and Customer shall agree to a process validation plan identifying the validation requirements of the Manufacturing Process. All process validation activities are excluded from the Price of Process Validation Batches, shall be approved by the Customer in advance, and shall be paid for by the Customer at the Price set out in the applicable Project Plan.  
 2.5.2 Any regulatory support activities (including pre-Approval inspection) required and agreed to by Customer to support the Approval of the Product from the Facility shall be performed and supported by Lonza as reasonably requested by Customer. All such regulatory support activities are excluded from the Price of Process Validation Batches, shall be approved by the Customer in advance, and shall be paid for by the Customer at the Price set out in the applicable Project Plan.  
 2.6  
Supply of Customer Information and Customer Materials. Customer shall supply to Lonza all Customer Information and Customer Materials, the Cell Line, and other information or materials that may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer’s failure to provide Lonza with such Customer Information, Customer Materials, the Cell Line, or other information or materials reasonably  
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 required to perform the Services, and Customer shall be responsible for all additional costs and expenses arising out of such delay, including, if applicable, any idle Facility capacity costs.  
 2.7 Raw Materials. Lonza shall procure all required Raw Materials as well as consumables other than those Raw Materials that are Customer Materials. Subject to agreement between the Parties, Lonza shall purchase additional Raw Materials and Resins in accordance with Lonza’s standard policy (“Safety Stock”). Except as otherwise provided in Appendix A, Customer shall be responsible for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder (including Safety Stock) in accordance with Clause 8.6. Upon cancellation of any Batch by Customer (whether a Pilot Batch, an Engineering Batch, a cGMP Batch or a Process Validation Batch or otherwise) or termination of the Agreement, all unused Raw Materials and Resins shall be paid for by Customer within thirty (30) days of invoice and at Customer’s option will either be: (a) held by Lonza for future use for the production of Product; (b) delivered to Customer; (c) disposed of by Lonza; or (d) returned to the supplier, to the extent permitted by the supplier. Lonza will credit Customer for any credits received by Lonza directly in connection with the return of Raw Materials for which Customer has already paid Lonza. Lonza shall manage any Safety Stock in accordance with its standard Safety Stock policy and the Quality Agreement. Customer shall own all consumables and Raw Materials (including Safety Stock) which Customer has paid for or reimbursed Lonza pursuant to this Section 2.7, and Lonza shall not subject any such consumables and Raw materials to any liens or encumbrances and shall use reasonable care to store and safeguard such consumables and Raw Materials while in Lonza’s possession or control.  
 2.8 Immediately following the Effective Date the Customer shall supply to Lonza the Customer Information reasonably required by Lonza to perform the Services, together with full details of any hazards relating to the Cell Line, and the Customer Materials, their storage and use. On review and approval by Lonza’s safety committee of this Customer Information, the Cell Line, the Customer Materials, Customer Background Intellectual Property, and any other necessary Intellectual Property shall be provided to Lonza at Lonza’s request.  
 2.9 Where the Cell Line uses GS, the Customer acknowledges that it will require a GS Licence from Lonza prior to in vivo clinical studies or any other commercial use or sale of the Product.  
 3 Project Management / Steering Committee / Future Scale-Up  
 3.1 Project Plans. With respect to a new project to be governed by this Agreement, a new Project Plan shall be added by agreement in writing signed by the Parties and appended to this Agreement. Each Project Plan shall include a description of the Services to be provided, the Product to be manufactured, Specifications, a schedule for completion of the Project Plan, pricing details, and such other information as is necessary for relevant Services. In the event of a conflict between the terms of a Project Plan and this Agreement, the terms of this Agreement will govern.  
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 3.2 Project Management. With respect to each Project Plan, each party will appoint a project manager who will be the party responsible for overseeing the Project Plan.  
 3.3 Steering Committee. Promptly after execution of this Agreement, the Parties shall establish a steering committee to oversee, review and coordinate the activities of the Parties under this Agreement and facilitate communications between the Parties with respect to such activities (the “Steering Committee”). Each Party shall name a mutually agreed upon equal number of representatives for the Steering Committee, which shall meet twice per calendar year, or as otherwise mutually agreed by the Parties. In the event that a Steering Committee dispute cannot be resolved within […\*\*\*…] days, such dispute shall be escalated to a senior executive of each of Customer and Lonza. If such senior executives are unable to resolve such dispute within […\*\*\*…] days of such escalation, then either Party may pursue any and all remedies available at law in accordance with Clause 16.  
The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall also take on the following responsibilities:  
 3.3.1 discuss and seek resolution of issues around management of the Services;  
 3.3.2 agree and monitor the Facility construction and start-up plan, deadlines and milestones for the Services;  
 3.3.3 discuss and seek resolution for any Batch failures and/or unreleased Batches;  
 3.3.4 discuss and recommend any changes to the Services (although such changes will not take effect until they have been incorporated into a written amendment to the Project Plan which has been signed by the Parties); and  
 3.3.5 discuss and seek resolution for any dispute regarding the terms of a technology transfer pursuant to Clause 10.7.  
 3.4 Person in Plant. Customer shall be permitted to have, […\*\*\*…] employees or consultants (provided that such consultants enter into an appropriate confidentiality and non-use agreement with Lonza) at the Facility as reasonably requested by Customer, at any time during the Manufacturing Process for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such employees or consultants shall be subject to and agree to abide by confidentiality obligations to Third Parties and Lonza’s customary practices and operating procedures regarding persons in plant, and such employees or consultants shall agree to comply with all instructions of Lonza’s employees at the Facility.  
 3.5 In the event Customer wishes to transition production of the Product from the Facility to another asset or facility within the Lonza network the Parties shall enter into good faith discussions to agree upon the terms of such transition.  
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4 Quality  
 4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement and in Lonza standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail, with the exception that the Quality Agreement shall control for matters directly relating to the quality and disposition of the Product and Raw Materials and the matters referenced in Clause 4.2. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing.  
 4.2 Provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement.  
 5 Insurance  
 5.1 Each Party shall, during the Term and for […\*\*\*…] after Delivery of the last Product manufactured or Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to, contractual liability coverage and product liability coverage in the amount of at least […\*\*\*…] per claim. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.  
 6 Forecasting, Ordering and Cancellation  
 6.1 Alternate Product. Customer may request Lonza to manufacture an Alternate Product in place of the Product subject to Lonza’s agreement and subject to a suitable amendment to the Agreement to be completed between Parties that shall set out the terms for the transfer of the Alternate Product into the Facility and for payment of all such additional costs as reasonably incurred by Lonza in the completion of such transfer, as well as the price and terms on which Lonza shall manufacture the Alternate Product.  
 6.2  
Forecasting. No later than […\*\*\*…] of each […\*\*\*…], Customer shall supply Lonza with a written forecast showing Customer’s good faith estimated quarterly requirements for […\*\*\*…] Batches to be manufactured by Lonza in the following […\*\*\*…] month period, which shall include the Batches comprising the Minimum Order and any Additional Batches (as defined below) (the “Forecast”). No later than […\*\*\*…] days following Lonza’s receipt of a Forecast, Lonza shall deliver written notice to Customer stating: (i) whether it has (at the date of receipt of the Forecast) capacity available to manufacture any Batches in excess of the Minimum Order (including any cGMP Batches covered by purchase orders submitted prior to Approval) forecast in Customer’s Forecast (“Additional Batches”); (ii) an estimated production schedule showing the estimated Commencement Date and Delivery date of each Batch within the Minimum Order requirement; and (iii) an estimated production schedule showing the estimated Commencement Date and Delivery date for any Additional Batches Forecast by Customer that Lonza has capacity to manufacture. Lonza’s response to the Forecast (including (i), (ii) and (iii)) being the “Response”. For the avoidance of any doubt, Lonza shall not have any obligation to fulfil any  
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 demand Forecast by Customer for Additional Batches except to the extent, and solely in its discretion, Lonza accepts purchase orders for any Additional Batches. Except as provided in Clauses 6.3 and 6.4, the Forecast and Response shall not be binding on either Customer or Lonza.  
 6.3 Minimum Order.  
 6.3.1 Customer undertakes to purchase from Lonza, and Lonza undertakes to manufacture, a minimum of […\*\*\*…] cGMP Batches in each MO Year (the “Minimum Order”). Pilot Batches and/or Engineering Batches and/or Process Validation Batches shall not form part of the Minimum Order, unless the Parties agree otherwise. This shall be regarded as a “take or pay” obligation, meaning that if Customer fails to purchase such Minimum Order, Customer shall pay the Batch Price for the number of Batches below the minimum by the date which would have been the Commencement Date for the first such Batch; provided that Customer shall not be obligated to pay for any portion of such […\*\*\*…] cGMP Batches that Lonza is unable to Deliver.  
 6.3.2 If at any time during any MO Year, Lonza provides a Shortfall Notice to Customer, Customer’s obligations under Clause 6.3.1 shall be […\*\*\*…].  
 6.3.3 As at the date of this Agreement, Customer hereby irrevocably commits to purchase […\*\*\*…] Batches.  
 6.4 Purchase Orders for Pilot Batches, Engineering Batches, Process Validation Batches and/or cGMP Batches.  
 6.4.1 With regard to the […\*\*\*…] Batches referenced in Section 6.3.3: Customer shall, within […\*\*\*…] days of the date of this Agreement place purchase orders binding on Customer for such Batches which it is obliged to purchase in accordance with Clause 6.3.3. Each binding purchase order shall be signed by Customer and shall authorise Lonza to manufacture such Batches of the Product as are set forth therein. Lonza shall promptly accept such purchase order and shall set forth an estimated Delivery date for each ordered Batch. For clarity, Clause 6.3.3 creates the legally binding commitment in respect of such […\*\*\*…] Batches.  
 6.4.2 With regard to Batches in the Minimum Order: Customer shall within […\*\*\*…] of first Approval in the first MO Year, and thereafter within each subsequent MO year, in each case at least […\*\*\*…] prior to the Commencement Date of a Campaign place purchase orders binding on Customer for the number of Batches that comprises the Minimum Order for the applicable MO Year which it is obligated to purchase in accordance with Clause 6.3.1. Each binding purchase order shall be signed by Customer and shall authorise Lonza to manufacture such Batches of the Product as are set forth therein. Lonza shall promptly accept such purchase order and shall set forth an estimated Delivery date for each ordered Batch. For clarity, Clause 6.3.1 creates the legally binding commitment in respect of such Batches in the Minimum Order.  
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 6.4.3 With regard to any Additional Batches which Customer included in its Forecast and which Lonza indicated that, at the time of its Response it had capacity for at the Facility, Customer may place purchase orders and Lonza may (at its discretion), if at the time of receipt of such purchase order Lonza still has capacity at the Facility to manufacture such Additional Batches, accept such purchase order for such Additional Batches within […\*\*\*…] business days of receipt. Lonza shall have no obligation to accept such purchase order. If Lonza accepts such purchase order, in its written confirmation of such purchase order for Additional Batches, Lonza shall set forth an estimated Delivery date for each ordered Batch and such confirmation shall create a legally binding commitment from both parties to manufacture, Deliver and purchase (as applicable) such Additional Batches. Any Delivery date set forth in Lonza’s written confirmation of a purchase order or in any Project Plan shall be an estimated Delivery date.  
 6.4.4 All Batches shall be scheduled in a single Campaign in each calendar year unless otherwise agreed by Lonza and Customer. Any additional or inconsistent terms or conditions of any Customer purchase order, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected.  
 6.5 Shortfall Notice. If at any time during any MO Year: (a) Lonza believes that […\*\*\*…]; or (b) […\*\*\*…] occurs, Lonza shall promptly provide written notice thereof to Customer, which notice shall include: (i) the number of Batches that Lonza believes it will be unable to Deliver; (ii) the reasons for Lonza’s inability to Deliver such number of Batches; and (iii) Lonza’s anticipated timeline for being able to Deliver such number of Batches (such notice, a “Shortfall Notice”). Following delivery of a Shortfall Notice, Lonza shall be obligated to provide written notice(s) to Customer promptly in the event there are subsequent changes in the details covered by a particular Shortfall Notice. For clarity, the provisions of this Clause 6.5 and Clause 6.6 and other provisions relating to mechanisms addressing Lonza’s inability to deliver Batches set forth in purchase orders under this Agreement shall not limit or otherwise affect Lonza’s obligations to continue efforts to manufacture and deliver Products in accordance with Clause 2.1.  
 6.6 Rescheduling. Lonza shall have the right to reschedule the start of any Batch or Campaign in any calendar year upon reasonable prior written notice to Customer (such notice to be sent to Customer as soon as reasonably practicable), provided that the rescheduled Commencement Date of such Batch or Campaign is no earlier or no later than […\*\*\*…] days from the date originally estimated at the time of Lonza’s acceptance of the purchase order. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites at the Facility, manufacture of the Customer’s Batch or Campaign may be delayed until […\*\*\*…]. Any such change requested by Customer may result in a reasonable rescheduling fee. Any delay requested by Customer of more than […\*\*\*…] days shall be considered a cancellation pursuant to Clause 6.7.  
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 6.7 Cancellation. If Customer cancels any Batch to which it is committed to purchase under Clause 6.3.1, 6.3.3 or 6.4.3 (whether in whole or in part) for any Engineering Batch, Process Validation Batches and/or cGMP Batches (whether such Batches are part of the Minimum Order or are Additional Batches) it shall pay Lonza […\*\*\*…]% of the Batch Price for each such cancelled Batch (the “Cancelation Fee”). Such Cancellation Fee shall be payable within […\*\*\*…] days following the written notice of cancellation associated with the cancelled Batch. In addition to the Cancellation Fee, the Customer shall pay for all costs associated with the cancelled Batch that Lonza has incurred, or is irrevocably committed to pay, including the costs of Raw Materials and the Raw Materials Fee, except as otherwise provided in Appendix A.  
 6.8 Replacement Product. Lonza will use reasonable efforts to secure a new project or additional batches under an existing project with a Third Party (excluding any batches with regard to which another customer is then under contractual obligation or binding purchase orders with Lonza to manufacture) for the cGMP manufacturing space and for the same dates and duration that would have been occupied by Customer, and then, in such case, the Cancellation Fee for a cancelled Batch that is replaced by a batch for the replacement project or expanded existing project shall be reduced by an amount equal to the production fees associated with such replacement batch.  
 6.9 Additional Work. In the event that the parties agree for any additional work to be added to the Project Plan (“Additional Work”), the prices for such Additional Work shall be calculated based on Lonza’s standard pricing at the time of agreement of such Additional Work. Once the Additional Work has been added into this Agreement, the pricing for such Additional Work shall be subject to review in accordance with the provisions of Clause 8.8.  
 6.10 Process Change Requests. Lonza shall communicate the lock down dates by which any request process changes can be accepted under purchase orders, change orders or statements of work. Should changes be requested outside of the lock down date prior to a Campaign, Customer may present a request for an expedited consideration of the change. Lonza will use commercially reasonable efforts to evaluate, however, Lonza will retain the right to adhere to lock down dates.  
 7 Delivery and Acceptance  
 7.1 Delivery. All Product shall be delivered EXW (as defined by Incoterms® 2010) the Facility and Lonza shall deliver to Customer the Certificate of Analysis, the Certificate of Compliance and such other documentation as may be required by the Quality Agreement not later than the date of the EXW delivery of Batches (the “Delivery”). With respect to any Customer Materials, title and risk of loss shall remain with the Customer and shall not transfer to Lonza. With respect to Product, title and risk of loss shall transfer to Customer upon Delivery in accordance with this provision.  
 7.2  
Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at Customer’s expense, within […\*\*\*…] days after Delivery or pay applicable storage costs. Lonza shall provide storage on a xxxx and hold basis for such Batch(es) at no charge for up to […\*\*\*…] days; provided that any additional storage beyond […\*\*\*…] days will be subject to availability and, if available, will be charged to Customer and will be subject to a separate agreement. In addition to Clause 8.5, Customer shall be responsible for all value  
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 added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Batch for more than […\*\*\*…] days after Delivery. Within […\*\*\*…] days following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the xxxx and hold status of each stored Batch.  
 7.3 Acceptance/Rejection of Product.  
 7.3.1 Promptly following Delivery of cGMP Batches and Process Validation Batches (but not Pilot Batches or Engineering Batches), Customer shall inspect such Batches and shall have the right to test such Batches to determine compliance with the Specifications. Customer shall notify Lonza in writing of any rejection of a cGMP Batch or Process Validation Batch based on any claim that it fails to conform to cGMP and the Specifications or was not manufactured in accordance with the Quality Agreement within […\*\*\*…] days of Delivery (the “Rejection Notice”), after which time all unrejected cGMP Batches or Process Validation Batches shall be deemed accepted; provided, however, that in the case of a Batch having a defect that causes a Batch to fail to comply with the Specifications and such defect is not discoverable upon reasonable physical inspection and testing performed pursuant to this Clause 7.3.1 but is discovered at a later time (e.g., in the course or as a result of long-term stability studies), but in any event within […\*\*\*…] months of Delivery, Customer will have […\*\*\*…] days from the discovery of such defect to provide a Rejection Notice to Lonza, in which case such Batch shall no longer be deemed accepted, provided always that the stability studies do not indicate that the Product would have degraded or deteriorated in any way within this period, in which case there would be no such right of rejection. Following receipt of a Rejection Notice, the Parties shall use their reasonable endeavours to reach a resolution, subject to Clause 7.3.2.  
 7.3.2 In the event that Lonza believes that a cGMP Batch or Process Validation Batch has been incorrectly rejected, Lonza may require that Customer provide to it cGMP Batch or Process Validation Batch samples for testing. Lonza may retain and test the samples of such cGMP Batch or Process Validation Batch. In the event of a discrepancy between Customer’s and Lonza’s test results such that Lonza’s test results fall within the relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and/or analyses on samples of the Product that allegedly fails to conform to the Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory’s results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.  
 7.3.3  
In the event that it is determined (by the Parties or the independent laboratory) that any cGMP Batch or Process Validation Batch failed to conform with the Specifications or was not manufactured in accordance  
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 with cGMP and the Quality Agreement (a “Failed Batch”), and such failure or non-conformity: (a) is primarily and materially attributable to Lonza’s breach of its obligations hereunder or Lonza’s negligence or intentional misconduct; or (b) results from a critical failure at the Facility or in the performance of the Manufacturing Process or the equipment used to manufacture Product which in each case, is primarily and materially attributable to Lonza’s breach of its obligations hereunder or Lonza’s negligence or intentional misconduct (collectively, “Lonza Responsibility”), or in the event any Engineering Batch fails to demonstrate the successful transfer of the Manufacturing Process to the Facility and such failure was primarily and materially attributable to Lonza’s breach of its obligations hereunder or negligence in following the Manufacturing Process or other written instructions in cGMP documentation (a “Failed Engineering Batch”); then Lonza shall replace such Batch as promptly as practicable (subject always to Lonza’s contractual commitments to Third Parties). Customer shall pay for such replacement Batch and the Raw Materials and Resins used therein (and any money Customer paid towards the Failed Batch or Failed Engineering Batch (including Raw Materials and Resins) shall be credited to the cost of the replacement Batch and related Raw Materials and Resins used in the replacement Batch). Customer acknowledges and agrees that, except in the case of Persistent Supply Failure (for which Customer shall have the rights and remedies expressly provided in this Agreement) and Lonza’s indemnity obligations pursuant to Clause 12.1 its sole remedy with respect to a Failed Batch that is a Lonza Responsibility or a Failed Engineering Batch is as set forth in this Clause 7.3.3 (notwithstanding any remedies which would otherwise be available at law or in equity). Lonza shall not be responsible for the cost of Raw Materials or Customer Materials consumed in any Failed Batch or Failed Engineering Batch except to the extent set forth in this Clause 7.3.3.  
 7.3.4 Lonza shall investigate, and cooperate reasonably with Customer in investigating, any Failed Batch or Failed Engineering Batch. Lonza shall keep Customer informed of the status of any investigation and, upon completion of the investigation, shall provide Customer with a final written report describing the cause of the failure and summarizing the results of the investigation.  
 8 Price and Payment  
 8.1 Other Services. Pricing for the Services (other than the manufacture of Batches) provided by Lonza are set out in, and based on the assumptions and information set out in, the applicable Project Plan. In the event of changes to the Services based on Customer’s request, Customer shall bear all additional costs. Lonza shall present such additional costs to Customer for approval prior to engaging in such modified Services.  
 8.2 Process Transfer and Validation, and Batches. In addition to the prices payable under Clause 8.1, Customer shall pay for the process transfer and process validation services, […\*\*\*…] Batches (except as otherwise provided in this Agreement or the applicable Project Plan). The details of all of which are set out in Appendix A.  
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 8.3 Raw Materials, Resins, Raw Materials Fees and Safety Stock. In addition to the fee due under Clauses 8.1 and 8.2, Customer shall pay for all Raw Materials, Resins, Safety Stock and the Raw Materials Fee (except as otherwise provided in this Agreement). The Prices for all of which are set out in Appendix A.  
 8.4 Milestone Payment.  
Customer shall pay a milestone payment of […\*\*\*…] US Dollars ($[…\*\*\*…]) on the first to occur of: (a) Approval of the Product; or (b) the Company’s receipt of a complete response letter or non-approvability letter from the FDA or equivalent written communication from the EMA with respect to a biologics license application or marketing authorization application for the Product in which the FDA or EMA, as applicable, does not identify a deficiency related to the Facility, the Manufacturing Process, Process Validation Batches or the Services as a reason for not approving the biologics license application or marketing authorization application, as applicable.  
 8.5 Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer. When sending payment to Lonza, the Customer shall quote the relevant invoice number in its remittance advice.  
 8.6 Payment Terms.  
 8.6.1 Lonza shall issue all invoices to Customer for […\*\*\*…] percent ([…\*\*\*…]%) of the Price for Batches or Services upon commencement thereof and […\*\*\*…] percent ([…\*\*\*…]%) upon Delivery of applicable Batches or completion of applicable Services, unless otherwise stated in the Project Plan. If Lonza fails to Deliver a Batch or a Batch is canceled and Customer is not otherwise obligated to pay for such cancelled Batch pursuant to this Agreement, then Lonza shall promptly refund to Customer any portion of the Price for such Batches that Customer previously paid.  
 8.6.2 Charges for Raw Materials (including media and feeds) and the Raw Materials Fee for each Batch shall be invoiced […\*\*\*…] percent ([…\*\*\*…]%) upon the Delivery of each Batch. Charges for Resins and membranes with no handling fee thereon shall be invoiced by Lonza upon placement of purchase orders for such Resins and membranes, media and feeds by Lonza. The price of the Safety Stock and the Raw Materials Fee in respect thereof shall be invoiced on use of such safety stock or upon its expiry. Charges for external testing shall be invoiced on Delivery.  
 8.6.3 All invoices are strictly net and payment must be made within […\*\*\*…] days of the date of invoice. Notwithstanding the foregoing, if any portion of an invoice is the subject of a bona fide dispute, then Customer shall pay the undisputed amounts and the Parties shall use good-faith efforts to reconcile the disputed amount as soon as practicable. Lonza shall not suspend performance of the Services or delivery of Product or seek to terminate this Agreement on account of non-payment of any invoiced amount that is the subject of a good-faith dispute; provided that Customer timely pays all non-disputed amounts. Payment shall be made without deduction, deferment, set-off, lien or counterclaim except  
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as set forth above with respect to disputed amounts.  
 8.7 If Customer is in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of: (i) the rate of […\*\*\*…] percent ([…\*\*\*…]%) per month […\*\*\*…]; or (ii) the maximum rate allowable by applicable law, interest to accrue on a day to day basis until full payment; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and/or delivery of Product until all overdue amounts have been paid in full including interest for late payments.  
 8.8 Price adjustments  
 8.8.1 With effect from […\*\*\*…], and not more than […\*\*\*…] per […\*\*\*…], Lonza may adjust the Price in accordance with the […\*\*\*…] Index […\*\*\*…] (or any successor index) increase for the previous calendar year. The new Price reflecting such Price adjustment shall be effective for any Services and/or Batches for which a binding purchase order is entered into by Customer after the date of Lonza’s notice to Customer of the Price adjustment.  
 8.8.2 In addition to the above, the Price may be changed by Lonza with respect to any Batches for which Customer has not yet delivered a purchase order, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect any material change in an environmental, safety or regulatory standard that substantially impacts Lonza’s cost and ability to perform the Services and Lonza shall use reasonable endeavours to provide any additional information regarding such changes reasonably requested by Customer.  
 9 Capital Equipment  
Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to commencement of the relevant Services.  
 10 Intellectual Property  
 10.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party or any of its Affiliates.  
 10.2  
Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all: (a) Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes, solely or jointly with Customer or others, to the extent that it: (i) is a direct derivative of or improvement to, or uses or incorporates, Customer Information and/or Customer Background Intellectual Property; and (ii) is severable from, and does not utilise, disclose or reveal any Lonza Background Intellectual Property and/or Lonza Information; and (b) information and documentation developed by Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza during the course of performing the Services to the extent that it: (i) relates specifically to the TRC-105 molecule or the Product; and (ii) is severable from, and does not disclose or  
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 reveal, any Lonza Background Intellectual Property (such new Customer Intellectual Property, information and documentation, collectively being the “New Customer Intellectual Property”). For the avoidance of doubt, “New Customer Intellectual Property” shall include any material, processes or other items to the extent that they embody, or are claimed or covered by, any of the foregoing Intellectual Property, data within batch release documentation, comparability data, structure elucidation data, stability data, results of viral clearance testing, and results of cell bank testing, but excluding any New General Application Intellectual Property.  
 10.3 Notwithstanding Clause 10.2, and subject to the license granted in Clause 10.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services to the extent that it: (i) is generally applicable to the development or manufacture of chemical or biological products or product components; or (ii) is an improvement of, or direct derivative of, any Lonza Background Intellectual Property and/or Lonza Information (collectively the “New General Application Intellectual Property”). For avoidance of doubt, “New General Application Intellectual Property” shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property.  
 10.4 Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer’s ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property.  
 10.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property, to use, sell and import the Product manufactured under this Agreement (but no other product).  
 10.6 Customer hereby grants Lonza and its Affiliates the non-exclusive right to use the Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and any and all other intellectual property supplied by or on behalf of the Customer, during the Term solely for the purpose of fulfilling its obligations under this Agreement.  
 10.7  
Provided that Customer is not in breach of any of its obligations under this Agreement and further provided Lonza has not terminated this Agreement pursuant to Clauses 14.2.3 and/or 14.2.4, Customer will have the right to transfer the Manufacturing Process to itself (provided that if Customer assigns this Agreement to a Third Party pursuant to Clause 16.2, such Third Party’s / assignee’s right to request a transfer of the Manufacturing Process to itself or a Third Party of such assignee shall be subject to Lonza’s prior written consent, and such Third Party / assignee shall not have an automatic right to such a transfer) and/or any Third Party approved in writing by Lonza operating at such location approved by Lonza (provided that Lonza shall approve a requested  
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 transfer to any Third Party or Affiliate thereof listed on Appendix C and shall not unreasonably withhold consent for a requested transfer to any other Third Party or Affiliate thereof with a principal place of business outside of the restricted territories listed on Appendix C), It is agreed between the Parties that Lonza shall be considered to be reasonably withholding its consent if it […\*\*\*…] on the basis that such transfer shall be for the manufacture of that Product (and no other product); provided, however, to the extent such technology transfer includes Lonza Confidential Information, Lonza Background Intellectual Property, or New General Application Intellectual Property (which shall at all times remain the sole and absolute property of Lonza), such technology transfer shall be subject to a reasonable one-time licensing fee (a “Technology Fee”) and reasonable terms (both to be agreed upon by the Parties), subject to the following:  
 10.7.1 If a Technology Fee is applicable, the amount shall not be greater than $[…\*\*\*…]. For the avoidance of doubt, the fee referred to in this Clause 10.7 shall be in addition to the fees and royalties due under the terms of any license for Lonza’s GS system.  
 10.7.2 If there has been a […\*\*\*…], or if such transfer of the Manufacturing Process is in connection with a  
[…\*\*\*…], then no Technology Fee shall be due.  
 10.7.3 For the avoidance of doubt, Customer may, in its sole discretion, elect not to have transferred or disclosed to it any Lonza Confidential Information, Lonza Background Intellectual Property and New General Application Intellectual Property, in which case Customer’s sole payment obligation with respect to exercise of its technology transfer right under this Clause 10.7 shall be as set forth in Clause 10.10.  
 10.8 Should Customer wish to sub-licence any or all of the Lonza Confidential Information, Lonza Background Intellectual Property or New General Application Intellectual Property to any Third Party that is not in connection with a transfer under Clause 10.7, Customer shall obtain Lonza’s prior written consent (not to be unreasonably withheld) to such sub-licensing.  
 10.9 Lonza shall not introduce into the Manufacturing Process any royalty-bearing Intellectual Property or Intellectual Property requiring other payments for license without the prior written consent of Customer.  
 10.10 If Customer exercises its technology transfer right under Clause 10.7, Lonza shall provide reasonably necessary services and documents to complete such technology transfer as promptly as practical, and Customer shall reimburse Lonza for any reasonable costs (based on a full-time employee rate for such support) and expenses incurred in providing such services and documents, subject to Clause 10.7.  
 11 Warranties  
 11.1 Lonza warrants that:  
 11.1.1 the Services shall be performed in accordance with all Applicable Laws  
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and in a workmanlike manner consistent with industry standards;  
 11.1.2 except with respect to any development services, Pilot Batches and/or Engineering Batches, the manufacture of Product shall be performed in accordance with cGMP and will meet the Specifications at the date of Delivery;  
 11.1.3 all Product delivered by Lonza hereunder shall: (a) conform to the applicable Specifications at the date of Delivery; (b) be manufactured and delivered in accordance with the Quality Agreement and cGMP; (c) not be adulterated within the meaning of the United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder; and (d) be free and clear of any lien, encumbrance; provided, however, that this warranty shall not apply in respect of any Pilot Batch or Engineering Batch;  
 11.1.4 it has not been debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions;  
 11.1.5 to the best of its reasonable ability and knowledge it will not use in the performance of Services hereunder, any personnel, Affiliate or Third Party that has been debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions;  
 11.1.6 it will not use or disclose any Customer Information or Customer Background Intellectual Property in violation of its obligations under this Agreement;  
 11.1.7 as of the date of this Agreement, to the best of Lonza’s knowledge and belief, the Lonza Confidential Information and Lonza Background Intellectual Property are owned by Lonza or Lonza is otherwise entitled to use them for the purposes of providing Services under this Agreement and, during the Term of this Agreement, Lonza shall not do or cause anything to be done which would adversely affect its ownership or entitlement to use Lonza Confidential Information, Lonza Background Intellectual Property or New General Application Intellectual Property for the purposes of providing Services under this Agreement;  
 11.1.8 as of the date of this Agreement, to the best of Lonza’s knowledge and belief, the use by Lonza of those parts of the Manufacturing Process that constitute Lonza Background Intellectual Property (excluding any modifications or steps made or developed by Customer the Customer Materials, Customer Information and Customer Background Intellectual Property) and Lonza Confidential Information for the performance of the Services as provided herein will not infringe any rights (including without limitation any intellectual or industrial property rights) vested in any Third Party;  
 11.1.9 Lonza will notify Customer in writing immediately if it receives or is notified of a claim from a Third Party that the use by Lonza of the Manufacturing Process and/or the Lonza Confidential Information, Lonza Background Intellectual Property or New General Application Intellectual Property for performance of the Services infringes any Intellectual Property rights vested in such Third Party;  
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 11.1.10 it or its Affiliate holds all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility (subject always to Clause 11.2.3); and  
 11.1.11 it has the necessary corporate authorizations to enter into and perform this Agreement.  
 11.2 Customer warrants that:  
 11.2.1 To the best of Customer’s knowledge as of the Effective Date, Customer has all the rights necessary to permit Lonza (and its relevant Affiliates) to perform the Services without infringing the Intellectual Property rights of any Third Party and the performance of the Services shall not infringe any Third Party Intellectual Property rights;  
 11.2.2 Customer will promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and/or any and all other information, materials and Intellectual Property supplied by or on behalf of the Customer, or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property or other rights of any Third Party;  
 11.2.3 Customer has all the rights necessary to provide, and permit Lonza and its Affiliates and any Lonza sub-contractors and the External Laboratories to use for the purposes of this Agreement, the Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and any and all other information, materials and Intellectual Property supplied by or on behalf of the Customer, and that the use of anything referred to in this clause 11.2.3 will not infringe the Intellectual Property rights of any Third Party; and  
 11.2.4 Customer has the necessary corporate authorizations to enter into this Agreement.  
 11.3 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.  
 12 Indemnification and Liability  
 12.1  
Indemnification by Lonza. Lonza shall indemnify the Customer, its Affiliates, and their respective officers, employees and agents (“Customer Indemnitees”) for any loss, damage, costs, liability and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of: (i) any material breach of the warranties given in this Agreement by Lonza; (ii) any claims alleging that the Services (excluding use by Lonza, Lonza’s Affiliates, contractors or the External Labs of the Cell Line, Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, and/or any and all information, materials and other Intellectual Property supplied by or on behalf of the  
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 Customer) infringe any Intellectual Property rights of a Third Party; and/or (iii) Lonza’s negligence or intentional misconduct; except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Customer Indemnitees.  
 12.2 Indemnification by Customer. Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents (“Lonza Indemnitees”) from and against any loss, damage, costs, liability and expenses (including reasonable attorney fees) that any Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of: (i) any material breach of warranties given in this Agreement by Customer; (ii) the manufacture, use, sale, or distribution of any Product, including any claims of product liability; (iii) any claims alleging that the use by Lonza, any of Lonza’s Affiliates, any Lonza sub-contractors, any External Laboratory or any Third Party of the Cell Line, Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, and/or any and all information, materials and other Intellectual Property supplied by or on behalf of the Customer, for the purposes of this Agreement, infringes any Intellectual Property rights of Third Parties; and/or (iv) Customer’s negligence or intentional misconduct; except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Lonza Indemnitees.  
 12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, it shall promptly notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and/or settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee shall not settle any indemnifiable claim without the prior written consent of the indemnitor, such consent not to be unreasonably withheld. The indemnitee, its employees and agents, shall reasonably cooperate with the indemnitor (at the expense of the indemnitor) in the investigation of any liability covered by this Clause 12. The failure to deliver prompt written notice to the indemnitor of any claim, solely to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 12.  
 12.4 DISCLAIMER OF CERTAIN DAMAGES. SUBJECT ALWAYS TO CLAUSE 12.6, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY AND/OR ANY OF THE OTHER PARTY’S AFFILIATES AND/OR ANY OF THE OTHER PARTY’S INDEMNITEES (IN EACH CASE WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, UNDER ANY INDEMNITY OR OTHERWISE HOWSOEVER ARISING) FOR ANY LOSS OF PROFITS, LOSS OF REVENUES, LOSS OF GOODWILL, LOSS OF REPUTATION, OR FOR ANY INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL LOSSES, COSTS, EXPENSES OR DAMAGES, ARISING FROM OR RELATED TO THIS AGREEMENT.  
 12.5  
LIMITATION OF LIABILITY. SUBJECT ALWAYS TO CLAUSE 12.6, THE AGGREGATE LIABILITY OF LONZA AND ITS AFFILIATES WITH RESPECT TO ANY CLAIM OR RELATED SET OF CLAIMS UNDER OR IN RELATION TO THIS AGREEMENT (WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, UNDER ANY INDEMNITY OR OTHERWISE HOWSOEVER ARISING) SHALL NOT EXCEED, IN THE AGGREGATE, […\*\*\*…] IN THE […\*\*\*…] PERIOD OF THIS AGREEMENT PRIOR TO THE APPLICABLE  
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 CLAIM, LESS ANY AMOUNT PREVIOUSLY PAID BY LONZA WITH RESPECT TO LIABILITY CLAIMS. THE FOREGOING SENTENCE SHALL NOT APPLY TO ANY CLAIM OR RELATED SET OF CLAIMS WHICH LONZA IS OBLIGED TO INDEMNIFY CUSTOMER FROM IN ACCORDANCE WITH CLAUSE […\*\*\*…]. THE AGGREGATE LIABILITY OF LONZA AND ITS AFFILIATES WITH RESPECT TO ANY CLAIM OR RELATED SET OF CLAIMS WHICH LONZA IS OBLIGED TO INDEMNIFY CUSTOMER FROM IN ACCORDANCE WITH CLAUSE […\*\*\*…] AND THE AGGREGATE LIABILITY OF CUSTOMER AND ITS AFFILIATES WITH RESPECT TO ANY CLAIM OR RELATED SET OF CLAIMS WHICH CUSTOMER IS OBLIGED TO INDEMNIFY LONZA FROM IN ACCORDANCE WITH CLAUSE […\*\*\*…] SHALL NOT EXCEED, IN EACH INSTANCE, […\*\*\*…] IN THE […\*\*\*…] PERIOD OF THIS AGREEMENT PRIOR TO SUCH INDEMNITY CLAIM, LESS ANY AMOUNT PREVOUSLY PAID BY THE APPLICABLE PARTY WITH RESPECT TO SUCH INDEMNITY CLAIMS.  
 12.6 NOTHING IN THIS AGREEMENT SHALL OPERATE SO AS TO EXCLUDE OR IN ANY WAY LIMIT ANY LIABILITY FOR FRAUD, OR FOR DEATH OR PERSONAL INJURY, OR TO THE EXTENT RESULTING FROM GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, A BREACH OF CONFIDENTIALITY, OR FOR ANY OTHER LIABILITY THAT MAY NOT BE EXCLUDED OR LIMITED AS A MATTER OF APPLICABLE LAW. NOTHING IN THIS AGREEMENT SHALL EXCLUDE OR LIMIT CUSTOMER’S LIABILITY TO PAY INVOICES AND/OR CANCELLATION FEES EXCEPT AS EXPRESSLY PROVIDED IN CLAUSES 14.3.3, 14.3.5 AND 14.3.6.  
 13 Confidentiality  
 13.1 A Party receiving Confidential Information (the “Receiving Party”) agrees to strictly keep secret any and all Confidential Information received during the Term from or on behalf of the other Party (the “Disclosing Party”) as well as the terms of this Agreement using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party, observed by the Receiving Party or its employees, agents, consultants, or representatives, or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary. For clarity, all “Customer Information” disclosed or made available by or on behalf of one Party to the other Party or any of its Affiliates or representatives shall be deemed the Confidential Information of Customer for purposes of this Agreement and all “Lonza Information,” disclosed or made available by or on behalf of one Party to the other Party or any of its Affiliates or representatives shall be deemed the Confidential Information of Lonza for purposes of this Agreement.  
 13.2 Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other authorities Confidential Information which is or will be required pursuant to applicable governmental or administrative or public law, rule, regulation or order, including, without limitation requirements of the Securities and Exchange Commission or any national securities exchange on which a Party’s equity securities are traded. In such case the Party that received the Confidential Information will, to the extent legally permitted, inform the other  
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Party promptly in writing and reasonably cooperate with the Disclosing Party in seeking to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.  
 13.3 In the case of Customer as the Receiving Party: (a) Customer may disclose the terms of this Agreement to actual and prospective Third Party licensees, collaborators, acquirers, investors and strategic partners who: (i) have been informed of the confidential nature of such terms; (ii) have a need to know such terms; and (iii) are bound by confidentiality and non-use obligations no less stringent than those set forth herein; and (b) Lonza will not unreasonably withhold its consent to Customer’s disclosure of other Confidential Information as is reasonably required for (i) actual and prospective Third Party licensees, collaborators, acquirers, investors and strategic partners to conduct due diligence evaluations of Customer and TRC105 (provided that Customer complies with clauses (a)(i) – (iii) above), or (ii) regulatory filings related to the Product, including a biologics license application or marketing authorization application.  
 13.4 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:  
 13.4.1 at the time of disclosure was publicly available;  
 13.4.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party;  
 13.4.3 the Receiving Party can establish by competent proof, was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party (or anyone for whom it is responsible);  
 13.4.4 is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party; or  
 13.4.5 is developed by the Receiving Party independently from and without use of the Confidential Information, as evidenced by contemporaneous written records.  
 13.5 The Receiving Party will use Confidential Information of the Disclosing Party only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including, without limitation, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy, as directed by Disclosing Party, promptly (and certify such destruction) on Disclosing Party’s request, or upon expiration or termination of this Agreement, all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only, provided that during the period of such retention the confidentiality obligations in Clause 13 shall continue to apply.  
 13.6  
Each Party will restrict the disclosure of the other Party’s Confidential Information to such officers, employees, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the  
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 purpose of this Agreement. Prior to disclosure to such persons, the Receiving Party shall bind its and its Affiliates’ officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information. Lonza may disclose the Customer’s Confidential Information to Lonza’s Affiliates, contractors and the External Laboratories, in each case to the extent reasonably necessary for Lonza to perform the Services under this Agreement.  
 13.7 The Receiving Party shall at all times be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or subcontractors or the employees, consultants and representatives of itself or its Affiliates or subcontractors, or by any other third party to which it is permitted to disclose the other Party’s Confidential Information.  
 13.8 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 13 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.  
 14 Term and Termination  
 14.1 Term. This Agreement shall commence on the Effective Date and shall end on the seventh (7th) anniversary of the date of first Approval unless terminated earlier as provided herein or extended by mutual written consent of the Parties (the “Term”). The Term may be extended on the written agreement of the Parties for a further three (3) years, provided such extension shall be made no later than the fifth anniversary of the date of first Approval.  
 14.2 Termination. This Agreement may be terminated as follows:  
 14.2.1 before first Approval, Customer shall have the right to terminate this Agreement upon sixty (60) days’ written notice to Lonza in the event that: (a) Customer receives a complete response letter from a Governmental Authority indicating that Customer’s application for approval to market the Product cannot be approved and a Customer Withdrawal subsequently occurs; or (b) a Customer Withdrawal occurs;  
 14.2.2 after first Approval, Customer shall have the right to terminate this Agreement upon sixty (60) days’ written notice to Lonza in the event that: (a) Approval is withdrawn by a Governmental Authority and a Customer Withdrawal subsequently occurs; or (b) a Customer Withdrawal occurs;  
 14.2.3  
by either Party if the other Party commits a material breach of this Agreement and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within thirty (30) days (or ten (10) days for non-payment or amounts not subject to good-faith dispute) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such thirty (30) day period  
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 shall be extended as agreed by the Parties if the identified breach is incapable of cure within thirty (30) days but is curable within sixty (60) days and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment), or by Customer in the event of a Persistent Supply Failure;  
 14.2.4 by either Party, immediately, if the other Party enters into administration, becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has an administrator or receiver appointed for a substantial part of its assets;  
 14.2.5 by either Party pursuant to Clause 15; or  
 14.2.6 by either Party prior to the execution of the initial Project Plan if, despite good faith efforts to agree on the initial Project Plan, the Parties have not agreed on the initial Project Plan within ninety (90) days of the Effective Date; provided, however, that such ninety (90) day period may be extended upon mutual agreement of the Parties.  
 14.3 Consequences of Termination.  
In the event of termination hereunder:  
 14.3.1 Under any right of termination set out in this Agreement: all Batches shall be deemed to have been cancelled, except pursuant to Clause 14.3.3, all obligations of Customer to purchase Batches shall be terminated (subject to the termination fees set forth in this Clause 14.3) and Lonza shall be compensated for:  
 (a) all Services and Batches rendered up to the date of termination, including in respect of any Product in-process;  
 (b) all costs incurred through the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used or purchased for use in connection with the Project Plan, except as otherwise provided in Appendix A; and  
 (c) all unreimbursed Capital Equipment and related decommissioning charges incurred pursuant to Clause 9, solely to the extent agreed to by the Company as part of the acquisition of Capital Equipment.  
 14.3.2  
Additional Consequences for Termination by Lonza pursuant to Clauses 14.2.3 or 14.2.4: in the event of termination by Lonza pursuant to Clauses 14.2.3 or 14.2.4, then in addition to Clause 14.3.1, all binding purchase orders shall be deemed cancelled and Customer shall pay a Cancellation Fee of […\*\*\*…]% in respect thereof, and Customer shall pay for all Minimum Orders for which it would have been required to submit purchase orders during the MO Year in which termination occurs (if such purchase orders have not already been submitted for such MO Year) and all Minimum Orders for which it would have been required to submit purchase orders during either […\*\*\*…]; provided, that  
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 Lonza shall use reasonable efforts to secure a new project or additional batches under an existing project with a Third Party (excluding any batches with regard to which another customer is then under contractual obligation or binding purchase orders with Lonza to manufacture) for the cGMP manufacturing space and for the period for which Customer is obligated to pay for Minimum Orders under this Clause 14.3.2, and then, in such case, the termination fees due under this Clause 14.3.2 that is replaced by a batch for the replacement project or expanded existing project shall be reduced by an amount equal to the production fees associated with such replacement batch.  
 14.3.3 Additional Consequences for Termination by Customer pursuant to Clause 14.2.3 or 14.2.4 or by either Party pursuant to Clause 14.2.5: in the event of termination by Customer in accordance with Clause 14.2.3 or 14.2.4 then in addition to Clause 14.3.1, Customer shall have the option to cancel without any Cancellation Fee any or all binding purchase orders then in effect or to continue with any or all binding purchase orders then in effect, in which case Customer shall be obligated to purchase and Lonza shall be obligated to Deliver such non-cancelled Batches pursuant to the terms of this Agreement. In the event of termination by either Party in accordance with Clause 14.2.5, all binding purchase orders then in effect shall be cancelled without any Cancellation Fee.  
 14.3.4 Additional Consequences for Termination pursuant to Clause 14.2.1 In the event of Customer’s termination of this Agreement pursuant to Clause 14.2.1, then all binding purchase orders shall be deemed cancelled and Customer shall pay a Cancellation Fee of […\*\*\*…]% in respect of binding purchase orders to the extent the manufacture thereof was scheduled to commence within […\*\*\*…] months of the termination of this Agreement.  
 14.3.5 Additional Consequences for Termination pursuant to Clause 14.2.2. In the event of Customer’s termination of this Agreement pursuant to Clause 14.2.2, then all binding purchase orders shall be deemed cancelled and in lieu of any Cancellation Fee in respect thereof (Clause 6.7 notwithstanding), Customer shall pay an amount equal to the aggregate purchase price of Batches constituting the Minimum Order for […\*\*\*…].  
 14.3.6 Additional Consequences for Termination by either Party pursuant to Clause 14.2.6: In the event this Agreement is terminated by either Party pursuant to Clause 14.2.6 and, Clause 6.7 notwithstanding, no Cancellation Fees shall be owed by Customer.  
 14.4 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Clauses 5, 10-14 (inclusive) and 16 (to the extent relevant).  
 15 Force Majeure  
 15.1 If Lonza is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such  
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evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue; provided that Lonza uses commercially reasonable efforts to cure or mitigate such Force Majeure and the effects thereof throughout such time. If such Force Majeure persists for a period of […\*\*\*…] months or more, either Party may terminate this Agreement by delivering written notice to the other.  
 15.2 “Force Majeure” shall be deemed to include any reason or cause beyond Lonza’s reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labour or transportation due to a general shortage of such materials, energy, equipment, labor or transportation or an inability to obtain them at reasonable commercial terms.  
 15.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.  
 16 Miscellaneous  
 16.1 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the purpose.  
 16.2  
Amendments/Assignment. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza’s obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations. Subject thereto, neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that: (a) Lonza may assign this Agreement to: (i) any Affiliate of Lonza (provided that such Affiliate is of sufficient financial standing to be able to meet its obligations under the Agreement); or (ii) any Third Party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to the Facility or providing the Services, provided, in each case, that Xxxxx xxxxx, transfers or otherwise provides all necessary licenses and Intellectual Property to such assignee to allow such assignee to perform under this Agreement; (b) Customer may assign this Agreement to any Third Party (provided that such Third Party is not less credit-worthy than Customer and is not engaged primarily in the business of manufacturing pharmaceutical or biological products on a contract basis) in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of Customer, a merger, consolidation or acquisition of the Customer, or a sale or transfer of, or grant of an exclusive license for, all or substantially all of the line of business or Product to which this Agreement relates; and (c) Lonza shall be entitled to sell, assign  
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 and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer. For purposes of this Clause 16.2, the terms “assign” and “assignment” shall include, without limitation: (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person; (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates; and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment. This Agreement shall be binding on the successors and permitted assignees of each Party.  
 16.3 Notice. All notices must be written and sent to the address of the Party first set forth above or to such other address as either Party may designate hereafter by written notice to the other Party. All notices must be given: (a) by personal delivery, with receipt acknowledged; (b) by facsimile followed by hard copy delivered by the methods under (c) or (d); (c) by prepaid certified or registered mail, return receipt requested; or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.  
 16.4 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of the State of New York, without regard to its conflicts of laws principles. The Parties agree to submit to the jurisdiction of the courts of New York.  
 16.5 Third Parties. No Third Parties shall have the right to enforce any of the provisions of this Agreement or be beneficiaries of this Agreement of either Party’s rights or obligations hereunder, save that Affiliates of Lonza and Affiliates of Customer respectively may rely on the indemnities granted to them and limitations and exclusions of liability contained herein. The Parties may amend this Agreement without the consent of the Affiliates of either Party.  
 16.6 Announcements / Press Releases. Neither Party shall make any press release or announcement regarding the subject matter of this Agreement without the prior written consent of the other. On execution of this Agreement the Parties may issue a joint press release regarding the entry into this Agreement.  
 16.7 Entire Agreement. This Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for purposes of this Agreement.  
 16.8 Independent Contractors. Each Party is an independent contractor, and the relationship between the Parties shall not be deemed to constitute a partnership, joint venture, distributorship, agency, employee-employer or similar business relationship between the Parties. Neither Party is a legal representative of the other Party; and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.  
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 16.9 Waiver. No waiver by any Party of any term, provision or condition contained in this Agreement or any Project Plan, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement or any Project Plan.  
IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed by its duly authorised representative effective as of the date written above.  
 LONZA BIOLOGICS TUAS PTE LTD  
By: /s/ Xxxxxx Xxxxxx  
 Name: Xxxxxx Xxxxxx  
 Title: General Manager, Singapore  
By:   
 Name:  
 Title:  
TRACON PHARMACEUTICALS, INC.  
By: /s/ Xxxxxxx Xxxxxx  
 Name: Xxxxxxx Xxxxxx  
 Title: CEO  
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