# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM (	5-K
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REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13A-16 OR 15D-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Dated March 9, 2017

Commission File Number 001-36421

# AURINIA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

 $\label{eq:NA} N/A \end{tabular}$  (Translation of Registrant's Name)

#1203-4464 Markham Street
Victoria, British Columbia
V8Z7X8
(250) 708-4272
(Address and telephone number of registrant's principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.			
Form 20-F □ Form 40-F ⊠			
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (1):			
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (7):			
Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.			
Yes ⊠ No □			
This Form 6-K is hereby filed and incorporated by reference into the Registrant's Registration Statement on Form F-10 (File No. 333-206994).			

# **SIGNATURES**

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

Dated: March 9, 2017.

# Aurinia Pharmaceuticals Inc.

By: /s/ Dennis Bourgeault

Name: Dennis Bourgeault Title: Chief Financial Officer

# EXHIBIT INDEX

# Exhibit Description of Exhibit

99.1 Manufacturing Collaboration and Services Agreement dated November 22, 2016 between Lonza Ltd. and Aurinia Pharmaceuticals Inc.

Exhibit 99.1 included with this report on Form 6-K is hereby incorporated by reference as an exhibit to the Registrant's Registration Statement on Form F-10 (File No. 333-206994), as amended or supplemented.

# **Manufacturing Collaboration and Services Agreement**

(the "Agreement")

by and between

Lonza Ltd Münchensteinerstrasse 38 CH-4002 Basel Switzerland

- hereinafter "Lonza" -

and

Aurinia Pharmaceuticals Inc. 1203-4464 Markham Street Victoria BC V8Z 7X8 Canada

- hereinafter "Customer' -

Effective as of 22 November 2016 (the "Effective Date")

# CONFIDENTIAL

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#### CONFIDENTIAL

#### Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of its proprietary product voclosporin;

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** "Affiliate" means, as of any point in time and for as long as such relationship continues to exist, 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. means this agreement incorporating all Appendices, as amended "Agreement" from time to time by written agreement of the Parties. "Applicable Laws" means all relevant U.S., Japanese, Canadian and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to a Party's activities hereunder, including 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.

"Background Intellectual Property"

"Batch"

"Batch Price"

"Campaign"

"Cancellation Fee"

"Capital Equipment"

"Certificate of Analysis"

means, subject to Clause 10.2, 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.

means the Product derived from a single run of the Manufacturing Process.

means the Price of each Batch.

means a series of no less than three (3) cGMP Batches manufactured consecutively.

has the meaning given in Clause 6.5.

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 the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment.

means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specifications and test results.

means those laws and regulations applicable in the U.S., Japan, Canada and Europe, relating to the manufacture of medicinal products for human use, including current good manufacturing practices as specified in the ICH guidelines, including ICH Q7A "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", US Federal Food Drug and Cosmetic Act at 21CFR (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.

means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.

means any change to the Services, pricing or Scope of Work incorporated into a written amendment to the Agreement in accordance with Clause 16.2 or effected in accordance with the Quality Agreement.

means the date of commencement of manufacturing activities for a Batch hereunder.

means Customer Information and Lonza Information, as the context requires.

means all technical and other information not known to Lonza (excluding information known to Lonza pursuant to the Isotechnika Agreements) or in the public domain relating to the Manufacturing Process or the Product disclosed from time to time by the Customer to Lonza, including any materials supplied by Customer to Lonza in accordance with the Project Plan.

means any Raw Materials, components of Product, or other materials of any nature provided by or on behalf of Customer under this Agreement.

means the European Medicines Agency, or any successor agency thereto.

means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility.

means any Third Party instructed by Lonza, with Customer's prior consent, which is to conduct activities required to complete the Services.

means Lonza's manufacturing facilities in Visp, Switzerland or such other Lonza facility as may be agreed upon by the Parties.

means the United States Food and Drug Administration, or any successor agency thereto.



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., Japan, Canada or European Union

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 clause (i) and (iii) and all rights and applications that are similar or equivalent to the rights and application described in the foregoing clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.

Isotechnika Lona Toll Manufacturing Agreement of March 4, 2008 and June 7, 2004 between Isotechnika Inc. and Lonza.

means all technical and other information not known to Customer or in the public domain that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement.

means the production process provided by Customer for the manufacture of Product, as such process may be improved or modified from time to time by agreement of the Parties in writing.

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.

has the meaning given in Clause 10.2.

"New General Application Intellectual Property"
"Party"
"Price"

"Process Validation Batch"

"Product"

"Project Plan"

"Quality Agreement"

"Raw Materials"

"Raw Materials Fee"

"Regulatory Authority"

has the meaning given in Clause 10.3.

means each of Lonza and Customer and, together, the "Parties".

means the price for the Services and Products as set out in Appendix A.

means a Batch that is produced with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.

means the proprietary molecule identified by Customer as Voclosporin, to be manufactured using the Manufacturing Process by Lonza for Customer as specified in the 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 is attached hereto as Appendix A.

means the quality agreement, attached hereto as Appendix B, or if not attached hereto, as agreed between the Parties, acting reasonably, as soon as possible after the Effective Date, setting out the responsibilities of the Parties in relation to quality as required for compliance with cGMP.

means all ingredients, solvents and other components of the Product required to perform the Manufacturing Process or Services set forth in the bill of materials detailing the same (but excluding any consumables or wearables).

means the procurement and handling fee of the acquisition cost of Raw Materials by Lonza that is charged to the Customer in addition to the cost of such Raw Materials.

means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.

"Release" has the meaning given in Clause 7.1.

"Services" means all or any part of the services to be performed by Lonza under this Agreement (including process and analytical method

transfer, process development, process optimization, validation, clinical and commercial manufacturing, as well as quality control and quality assurance activities), particulars of which are set out in a

Project Plan.

"Specifications" means the specifications of the Product as specified in Appendix C, which may be amended from time to time in accordance with this

Agreement.

"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**

- 2.1 Performance of Services. Subject to Clause 2.2, Lonza shall itself and through its Affiliates, diligently carry out the Services as provided in the Project Plan and use commercially reasonable efforts to perform the Services without any material defect and according to the estimated timelines as set forth in the Project Plan. 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 to External Laboratories any of its rights or obligations under this Agreement to perform the Services; provided, that any External Laboratories shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan. Lonza shall be responsible to Customer for analytical lab services performed by External Laboratories.
- 2.2 Engineering Batches. Lonza shall manufacture Engineering Batches as necessary 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. Regardless of whether any Engineering Batch meets cGMP or the Specifications, Customer shall pay to Lonza the Price for such Engineering Batch plus the Raw Materials Fee associated with such Engineering Batches.

- 2.3 <u>cGMP Batches</u>. Lonza will, in accordance with the terms of this Agreement and Quality Agreement, manufacture at the Facility and Release to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications, together with a Certificate of Analysis; provided, however, that cGMP manufacture shall not commence until at least one (1) successful Engineering Batch(es) has been manufactured in compliance with cGMP and Specifications. Prior to commencement of cGMP manufacturing, Lonza shall review the process assumptions. 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 whether or not a revision to the Batch Price is necessary to reflect such difference.
- 2.4 <u>Process Validation Batches</u>. Lonza shall manufacture and deliver Process Validation Batches as necessary as mutually agreed by Parties sufficient to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the necessary regulatory documents.
  - 2.4.1 Prior to commencement of Process Validation Batches, Lonza and Customer shall agree in writing on 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.
  - 2.4.2 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.
- 2.5 Supply of Customer Information and Customer Materials. Customer shall supply to Lonza within a reasonable period all additional Customer Information and Customer Materials and other information or materials in the possession or control of Customer 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 such Customer Information, Customer Materials, or other information or materials reasonably required to perform the Services to Lonza, and Customer shall be responsible for all additional out-of-pocket costs arising out of such failure, including, if applicable, any idle Facility capacity costs, provided that: (i) Lonza has made diligent efforts to fill such idle capacity; and (ii) Lonza has provided Customer reasonable notice in writing in advance of incurring any idle Facility capacity costs.
- 2.6 <u>Raw Materials</u>. Lonza shall procure all required Raw Materials as well as consumables other than those Raw Materials that are Customer Materials. Upon advance payment by Customer, Lonza shall purchase and hold a minimum of one (1) extra Batch's requirements of Raw Materials to serve as safety stock Customer shall be responsible

for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder. Upon cancellation of any Batch or termination of the Agreement, all unused Raw Materials 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, or (c) disposed of by Lonza.

- 2.7 <u>Reference Standards</u>. Lonza shall maintain all required reference standards. Customer shall provide Lonza a list of minimum inventories that must be maintained for each reference standard and update that list on an annual basis. Lonza shall maintain an inventory sufficient to meet the foregoing minimum inventories of each reference standard. Lonza shall notify customer 60 days before the reference standards exceed retest date. Customer shall provide purchase order for analytical services required to complete reference standard retesting. Customer shall be invoiced upon completion of retest. In the event additional inventory of reference standards are needed customer shall be invoiced for the synthesis of reference standards. Customer shall be invoiced 50% upon initiation of synthesis of reference standards and invoiced remaining 50% upon completion of synthesis of reference standards.
- 2.8 <u>Specifications.</u> The Parties acknowledge that during the course of the performance of the Services, the Specifications may change and Lonza will make all reasonable attempts to accommodate Customer's request(s) for changes to the Specifications, provided that corresponding reasonable adjustments to the timing and pricing for material changes to the Services are made by the Parties, acting reasonably.

#### 3 Project Management / Steering Committee

- 3.1 <u>Project Plans</u>. With respect to a new project to be governed by this Agreement, a new Project Plan shall be added by agreement in a writing signed by the Parties and appended to Appendix A. 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.
- 3.2 <u>Project Management</u>. With respect to each Project Plan, each Party will appoint a project manager who will be the representative responsible for overseeing the Project Plan.
- 3.3 <u>Steering Committee</u>. 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, such dispute shall be escalated to a senior executive of each of Customer and Lonza.

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 deadlines and milestones for the Services; and
- 3.3.3 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).
- Person in Plant. Customer shall be permitted to have, at no additional cost, one (1) employee or designate at the Facility as reasonably requested by Customer, at any time during the Manufacturing Process of engineering batches, cGMP batches or process validation batches for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such employee or designate 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 employee agrees to comply with all instructions of Lonza's employees at the Facility. Customer may request on its own costs the presence of more than one employee or designate to be present at the Facility with the consent of Lonza, such consent not to be unreasonably withheld.

# 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. 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.
- 4.3 During the Term, Lonza shall provide Customer with reasonable assistance and cooperation, at the expense of Customer, to support Customer in obtaining regulatory approvals for the Product, or any product containing the Product for any indications in any country. On request in writing from Customer, Lonza shall provide all original documents or copies of original documents and any other materials, data and information that are reasonably requested by Customer for submission, or for use in the preparation of applications to be submitted, to any Regulatory Authority for the purpose of seeking, obtaining or maintaining such regulatory approvals for the Product or a product containing the Product in any country, in accordance within timelines mutually agreed upon between the Parties.
- Lonza shall ensure that the results of its work pursuant to its performance of the Services are accurately recorded and accessible to Customer (or its respective designees), including all documentation and data generated therefrom. In addition to the reports required in connection with the Services, Lonza shall regularly update Customer on its progress in performing the Services by attending meetings and/or conference calls at places and times to be mutually determined by the Parties or upon the reasonable additional request of Customer. If Customer requests any Services from Lonza pursuant to this Clause 4.4 beyond those performed by Lonza in accordance with its usual procedures, then Lonza will advise Customer of same and Customer will bear the cost of the performance of such Services.

#### 5 Insurance

Each Party shall, during the Term and for five (5) years 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 product liability coverage in the amount of at least ten (10) million USD 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 Forecasting and Ordering. No later than the first (1st) day of each calendar year, Customer shall supply Lonza with a written forecast showing Customer's good faith non-binding estimated quarterly requirements for Batches for the following thirty-six (36) month period (the "Forecast"). No later than thirty (30) days following Lonza's receipt of a Forecast, Lonza shall provide written notice to Customer of whether it has (as of the date of receipt of the Forecast) capacity available to manufacture the number of Batches forecasted therein and shall provide Customer with an estimated production schedule showing the estimated Commencement Date and delivery date of each Batch. The first year of any Forecast shall be binding ("Binding Forecast"). Binding purchase orders ("Purchase Orders") for the entire one (1) year period shall be submitted by Customer on the basis of the Binding Forecast within five (5) days of submission of the Forecast. No Forecast shall amend any previous Binding Forecast. In order to ensure optimal production planning Customer will use good faith efforts to reach an accuracy of +50%/-15% of the non-binding portion of any Forecast.
- Order Confirmation. Lonza shall confirm the delivery date(s) and quantity of Product to be delivered as set out in each Purchase Order within ten (10) business days of receipt from Customer of the relevant Purchase Order. Upon confirmation, each Purchase Order will be regarded by the Parties as a binding commitment by Lonza to manufacture and to deliver to Customer the relevant quantity of Product according to the requirements set out in such Purchase Order. If Lonza fails to confirm a Purchase Order within the period for doing so, Customer shall have no obligation to purchase the quantity of Product set out in the Purchase Order from Lonza. Lonza shall use reasonable efforts to deliver the Product on the delivery date set forth in Lonza's written confirmation of a purchase order. All ordered Batches shall be scheduled in a single Campaign in each calendar year unless otherwise agreed by Lonza. Any additional or inconsistent terms or conditions of any Customer purchase order, Lonza confirmation, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected. If, in first two years after commercial launch of the Product, the Binding Forecast materially underestimates the actual quantity Product required by Customer will advise Lonza and Lonza will make commercially reasonable efforts to supply Customer with the actual quantity of Product required by Customer, with Customer bearing any incremental costs of such additional efforts, provided that such costs have been agreed-to in advance.
- 6.3 <u>Rescheduling</u>. Lonza shall have the right to reschedule a Commencement Date of any Batch or Campaign upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date is no earlier or no later than forty-five (45) days from the Commencement Date originally estimated at the time of Lonza's acceptance of the

binding 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, manufacture of the Customer's Batch or Campaign may be delayed until an adequate time period is available in the Facility schedule. Any such change requested by Customer in the Commencement Date may result in a rescheduling fee. Any delay requested by Customer of more than ninety (90) days shall be considered a cancellation pursuant to Clause 6.6.

- Minimum Quantity. Subject to the following, Customer has no obligation to purchase from Lonza any minimum of Batches or Services from Lonza. Customer undertakes to purchase from Lonza 100% of Customer's annual demand of Product prior to regulatory approval. Prior to commencement of the manufacture of Process Validation Batches and Commercial Batches, but in any event before the end of 2018, the Parties will seek to agree in good faith on the following, which shall then be set out in Appendix A:
  - 6.4.1 an annual minimum supply quantity (kilograms) Customer undertakes to purchase from Lonza,
  - 6.4.2 a minimum % of Customer's annual demand that Customer undertakes to purchase from Lonza, and
  - 6.4.3 the option for Lonza to produce the Product in a dedicated manufacturing asset.
- 6.5 <u>Cancellation of a Binding Purchase Order.</u> Cancellation of a Binding Purchase Order above the minimum required quantity shall be cancellable under these terms. Customer may cancel a binding purchase order upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):
  - 6.5.1 In the event that Customer provides written notice of cancellation to Lonza less than or equal to six (6) months prior to the Commencement Date of one or more Batches, then one hundred percent (100%) of the Batch Price of each such Batch cancelled is payable;
  - 6.5.2 In the event Customer provides written notice of cancellation to Lonza more than six (6) months but less than or equal to twelve (12) months prior to the Commencement Date of one or more Batches, then seventy-five percent (75%) of the Batch Price of each such Batch cancelled is payable; and
  - 6.5.3 In the event Customer provides written notice of cancellation to Lonza more than twelve (12) months prior to the Commencement Date of a Batch, then no Cancellation Fee is payable.
  - 6.5.4 Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to mitigate its loss suffered in connection with the cancellation of any purchase order and the amount payable pursuant to Clauses 6.5.1 or 6.5.2 shall be reduced to the extent that Lonza is able to mitigate its loss in this regard, including where Lonza is able to cancel any costs or commitments incurred by Lonza in connection with such purchase order or Lonza is able to fill the manufacturing capacity with a replacement project as contemplated by Clause 6.7 and Lonza shall promptly notify Customer of any such mitigation.

- 6.6 <u>Payment of Cancellation Fee</u>. Any Cancellation Fee shall be payable within thirty (30) days following the written notice of cancellation associated with the cancelled Batch. Any Cancellation Fee shall include all costs associated with the cancelled Batch, including any Raw Materials. All amounts paid in advance by Customer for the cancelled Batch or Service shall be creditable against any Cancellation Fee for such Batch or Service.
- 6.7 Replacement Project. Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new project 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 each Batch cancelled that is replaced by a Batch of the new project shall be reduced by an amount equal to one hundred percent (100%) of the production fees associated with such replacement Batch.

#### 7 Delivery and Acceptance

- 7.1 <u>Delivery.</u> All Product shall be delivered FCA (as defined by Incoterms<sup>®</sup> 2010) the Facility. Lonza shall deliver to Customer the Certificate of Analysis and such other documentation as is reasonably required to meet all applicable regulatory requirements of the Governmental Authorities not later than the date of delivery of Batches (the "Release"). With respect to any Customer Materials, title and risk of loss shall remain with the Customer, provided however that Lonza shall be responsible for any loss that is the result of Lonza's negligence or wilful misconduct. With respect to Product, title and risk of loss shall transfer to Customer upon Release in accordance with this provision.
- 5.2 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at Customer's expense, within thirty (30) days after Release or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to thirty (30) days; provided that any additional storage beyond thirty (30) 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 8.2, Customer shall be responsible for all value 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 one hundred and eighty (180) calendar days after Release. Within five (5) days following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

# 7.3 <u>Acceptance/Rejection of Product.</u>

7.3.1 Promptly following Release of 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 Batch based on any claim that it fails to meet Specifications, Applicable Law or any warranty given by Lonza herein with respect to Product within forty-five (45) days of Release, after which time all unrejected Batches shall be deemed accepted. Customer shall inform Lonza in writing in case of concealed or latent defects (i.e. not discovered by routine quality control means), promptly upon discovery of such defects but no later than one (1) year after delivery of the Product.

- 7.3.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within 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 analyses on samples of the Product that allegedly fails to conform to 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 If allowable under cGMP, Lonza shall reprocess any Batch or, if reprocessing is not possible, replace any Batch that failed to conform with the Specifications, Applicable Law or any warranty given by Lonza herein with respect to Product (a "Failed Batch"), in the event that it is determined (by the Parties or the independent laboratory) that such failure was solely due to Lonza's material breach of its obligations hereunder, negligence or intentional misconduct ("Lonza Responsibility"). Such reprocessing or replacement shall be made as promptly as practicable, in light of available manufacturing capacity, after the confirmation of Lonza Responsibility, and in any case as soon as reasonably possible after confirmation of Lonza Responsibility. Where possible, any replacement Batch shall be manufactured with the next scheduled cGMP Batch or Campaign. Customer acknowledges and agrees that its sole remedy with respect to a Failed Batch that is a Lonza Responsibility is as set forth in this Clause 7.3.3, and in furtherance thereof, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims. If a Failed Batch is a Lonza Responsibility, then Lonza shall be responsible for the cost of Raw Materials and Customer Materials used in any replacement Batch provided hereunder.
- 7.4 [Redacted provisions relating to Lonza acting as exclusive supplier.]

#### 8 Price and Payment

- 8.1 Pricing for the Services 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.
- 8.2 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.
- 8.3 Lonza shall issue invoices to Customer for fifty percent (50%) of the Price for Products or Services upon ordering of raw material with longest lead time and fifty percent (50%) upon Release of applicable Batches or completion of applicable Services, unless otherwise stated in the Project Plan. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch, provided, that any

Raw Materials required to be ordered more than six (6) months in advance shall be invoiced fifty percent (50%) at the time of order by Lonza and fifty percent (50%) upon Release of the Batch. All invoices are strictly net and payment must be made within thirty (30) days of date of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim.

If in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) rate of two percent (2%) per month above the London Interbank Offered Rate (LIBOR) 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.

#### 8.5 Price adjustments.

- 8.5.1 Not more than once per calendar year, Lonza may adjust the Price in accordance with the European Union Manufacturing Producer Prices Index (or any successor index) increase for the previous calendar year. The new Price reflecting such Batch Price adjustment shall be effective for any Batch for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment.
- 8.5.2 In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect only the additional cost incurred by Lonza resulting from (i) an increase in variable costs (such as energy or Raw Materials) by more than ten percent (10%) (based on the initial Price or any previously amended Price), or for a required process adjustment or assumption changes, and (ii) any material change in an environmental, safety or regulatory standard that causes Lonza's cost to perform the Services to increase by more than ten percent (10%).
- 8.5.3 The Prices outlined in the Project Plan are based on the currency exchange rate of the Swiss Franc (CHF) to the United States Dollars (USD) at the Effective Date. Lonza shall bear the risk of any increase or decrease of the CHF/USD exchange rate up to +/- five percent (5%) from the base currency exchange rate. If the CHF/USD exchange rate is more than five percent (5%) higher or lower than the base currency exchange rate at the date on which the Prices become due for payment, then the Prices will be adjusted to compensate all exchange rate differences greater than five percent (5%). The currency adjustments to be made, if any, shall be based on the market rate of exchange as published by Bloomberg.

# 9 Capital Equipment

9.1 Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties and incorporated into each iteration of the Project Plan 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. In the case of Customer, such Background Intellectual Property shall include the voclosporin intellectual property of Isotechnika's assignee, Customer, and the process for the manufacture of Product as it exists as of the Effective Date. In the case of Lonza, such Background Intellectual Property shall include, but not be limited to, the intellectual property related with the [technological methods relating to product production].
- Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer or others, develops, conceives, invents, first reduces to practice or makes in the course of performance of the Services, that is (i) applicable to the development or manufacture of the Product or Product components or (ii) is a derivative of or improvement of or requires use of or relates specifically to Customer Information or Customer Background Intellectual Property (collectively, the "New Customer Intellectual Property"), and may obtain patent, copyright and other proprietary protection therein at its own discretion and cost. For avoidance of doubt, "New Customer 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, but excluding any New General Application Intellectual Property.
- 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 its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer or others, develops, conceives, invents, first reduces to practice or makes in the course of performance of the Services that is generally applicable to the development or manufacture of chemical or biological products or product components, and does not include, require use of or relate specifically to, any Customer Background Intellectual Property, Customer Information, and/or Product ("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. Lonza agrees that, on a country-by-country basis, until the expiration of the later of: Customer's voclosporin composition of matter patent, and any regulatory exclusivity for the Product; any New General Application Intellectual Property will not be used for the production of Product for third parties.
- 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. Upon Customer's request and at Customer's expense, and at no cost to Lonza, Lonza shall use reasonable efforts to assist Customer to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property.

- Subject to the terms and conditions set forth herein, 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 make, have made, use, sell, offer for sale and import the Product.
- 10.6 Customer hereby grants Lonza the non-exclusive right to use the Customer Information, Customer Background Intellectual Property and New Customer Intellectual Property during the Term solely for the purpose of fulfilling its obligations under this Agreement.
- 10.7 Customer herewith grants to Lonza a non-exclusive, world-wide, fully paid-up, transferable license, including the right to grant sublicenses to all New Customer Intellectual Property for use outside the field of Product's application.
- In addition to the license granted pursuant to Clause 10.5 above, Customer shall have the option, exercisable on written notice to Lonza, to obtain from Lonza, to the extent that such is necessary to manufacture the Product, a non-exclusive, world-wide, transferable license, including the right to grant sublicenses, under Lonza Information and Lonza Background Intellectual Property used in the production of Product by Lonza, to make, have made, use, sell, offer for sale and import Product. In the event of any exercise of such option by Customer, Customer shall pay to Lonza a reasonable royalty to be agreed upon by the Parties. This license from Lonza to Customer does not include a license to the Continuous Flow/Microreactor technology intellectual property and equipment (collectively, "MRT") owned or licensed by Ehrfeld Mikrotechnik BTS. In case Customer wishes to use such MRT, Customer needs to enter into an agreement to procure the MRT separately from this Agreement either through Ehrfeld Mikrotechnik BTS or directly through Lonza for use outside of Lonza's premises.
- 10.9 Upon the written request of Customer, Lonza shall use its reasonable commercial efforts to assist and cooperate with Customer in the transition of the manufacture and supply of Product from Lonza to Customer or a new Third Party supplier selected by Customer, including the provision of documents, samples, process-related know-how, and other information and assistance with the timely validation and qualification of such Third Party supplier; provided that Customer agree to compensate Lonza for the reasonable costs and expenses incurred by Lonza for the assistance provided by Lonza hereunder. Lonza shall carry out such technology transfer within four (4) months of the written request of Customer.
- As of the Effective Date, no royalty or licensing fee is payable for the use of the Lonza Information or Lonza Background Intellectual Property under any license contemplated to be granted in accordance with Clause 10.5 or 10.8.
- 10.11 Lonza shall not use any Lonza Intellectual Property (including Lonza Information or Lonza Background Intellectual Property) other than as specified in the Project Plan in performing the Services without the prior written consent of Customer. Lonza will, at the time of seeking such consent, propose commercially reasonable terms for the commercial use of such Lonza Intellectual Property under any license to be granted in accordance with Clause 10.8.

#### 11 Warranties

- 11.1 Lonza warrants and agrees that:
  - 11.1.1 the Services shall be performed in accordance with the terms of this Agreement and all Applicable Laws;
  - 11.1.2 as of the Effective Date, to the best of Lonza's knowledge and belief, the use by Lonza of the any Lonza Intellectual Property used in performing the Services (including Lonza Information or Lonza Background Intellectual Property), if any, for the performance of the Services as provided herein shall not infringe any Third Party Intellectual Property rights;
  - 11.1.3 Lonza will promptly notify Customer in writing if it receives or is notified of a formal written claim from a Third Party that Lonza Information, Lonza Background Intellectual Property, New Customer Intellectual Property or New General Application Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property or other rights of any Third Party;
  - except with respect to any development services and Engineering Batches or any other special batch circumstances mutually agreed to by the parties, the manufacture of Product shall be performed in accordance with cGMP and the Quality Agreement and will meet the Specifications at the date of delivery;
  - 11.1.5 it or its Affiliate performing Services holds all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility; and
  - 11.1.6 it has the necessary corporate authorizations to enter into and perform this Agreement.
- 11.2 Customer warrants and agrees that:
  - 11.2.1 as of the Effective Date, to the best of its knowledge and belief, the use by Lonza of the Customer Information,
    Customer Materials and Customer Background Intellectual Property for the Services (including the manufacture of the Product) 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, New Customer Intellectual Property or New General Application Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property or other rights of any Third Party; and
  - 11.2.3 Customer has the necessary corporate authorizations to enter into this Agreement.
- 11.3 <u>DISCLAIMER</u>: 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 ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

#### 12 Indemnification and Liability

- 12.1 <u>Indemnification by Lonza</u>. Lonza shall indemnify the Customer, its Affiliates, and their respective directors, officers, employees and agents ("Customer Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising out of (i) any material breach of the warranties given by Lonza in Clause 11.1 above or (ii) any claims alleging that the Services (excluding use by Lonza of Customer Information and Customer Background Intellectual Property) infringe any Intellectual Property rights of a Third Party or (iii) the negligence or intentional misconduct of Lonza; 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 <u>Indemnification by Customer</u>. Customer shall indemnify Lonza, its Affiliates, and their respective directors, officers, employees and agents ("Lonza Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third Party claim arising out of (i) any material breach of the warranties given by Customer in Clause 11.2 above; or (ii) any claims alleging that the performance of Services infringes any Intellectual Property rights of a Third Party, only as respects Customer Information, Customer Materials and/or Customer Background Intellectual Property, provided to Lonza; or (iii) the manufacture, use, sale, or distribution of any Product, including any claims of product liability; 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 <u>Indemnification Procedure</u>. 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 settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents, shall reasonably cooperate with 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, 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 <u>DISCLAIMER OF CONSEQUENTIAL DAMAGES.</u> IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR LOST REVENUES ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM 1. FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT; 2) BREACH OF ANY OBLIGATION OF CONFIDENTIALITY OR LIMITED USE OR INFRINGEMENT OF THE OTHER PARTY'S INTELLECTUAL PROPERTY.
- 12.5 <u>LIMITATION OF LIABILITY</u>. EACH PARTY'S LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED, IN THE AGGREGATE, THE TOTAL AMOUNTS TO BE PAID BY CUSTOMER TO LONZA HEREUNDER IN THE TWELVE (12) MONTH PERIOD FOLLOWING THE EFFECTIVE DATE, OR IF THE FIRST CLAIM FOR

DAMAGES OCCURS AGFTER SUCH PERIOD, THE TWELVE (12) MONTH PERIOD PRECEDING THE FIRST CLAIM FOR DAMAGES, EXCEPT TO THE EXTENT RESULTING FROM SUCH PARTY'S FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

#### 13 Confidentiality

- 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") 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.
- 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. In such case the Receiving Party will, to the extent legally permitted, inform the other Party promptly in writing and 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 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:
  - 13.3.1 at the time of disclosure was publicly available; or
  - is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party; or
  - 13.3.3 as 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
  - 13.3.4 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
  - 13.3.5 is developed by the Receiving Party independently from and without use of the Confidential Information, as evidenced by contemporaneous written records.
- The Receiving Party will use Confidential Information 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, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party's request 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.

- Each Party will restrict the disclosure of 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 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.
- 13.6 The Receiving Party shall at any time be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the employees, consultants and representatives of itself or its Affiliates.
- 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 Disclosing 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 Disclosing Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the Disclosing Party.
- 13.8 Notwithstanding the foregoing, Customer may use and disclose the Lonza Information, to the extent incorporated into the manufacturing process, as necessary to exploit Customer's rights under any license to be granted in accordance with Clause 10.5 or 10.8

#### 14 Term and Termination

- 14.1 <u>Term.</u> This Agreement shall commence on the Effective Date and shall end on December 31, 2029 unless terminated earlier or extended as provided herein or extended by mutual written consent of the Parties (the "Term"); provided that the terms and conditions shall survive and apply with respect to any active Project Plan that was initiated prior to the expiration of this Agreement. Notwithstanding the foregoing, each Project Plan may have separate term and termination provisions so long as the Commencement Date of such Project Plan is not after the expiration of this Agreement.
- 14.2 <u>Termination</u>. This Agreement may be terminated as follows:
  - by either Party for any reason after the 5 year anniversary of the Effective Date upon 24 months prior written notice to the other Party;
  - by either Party if the other Party or its Affiliate breaches a material provision of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within sixty (60) days (thirty (30) days for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such sixty (60) day period shall be extended as agreed by the Parties if the identified breach is

incapable of cure 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). In the event Customer terminates this Agreement under this Clause 14.2.2, then no Cancellation Payments shall be due by Customer for the affected Services and Batches and all amounts paid in advance by Customer for such Services and Batches shall be promptly refunded;

- 14.2.3 by either Party, immediately, if the other Party 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 a receiver appointed for a substantial part of its assets; or
- 14.2.4 by either Party pursuant to Clause 15; or
- 14.2.5 Customer may, in its sole discretion, terminate this Agreement at any time by giving not less than ninety (90) days' notice in writing to Lonza in the event that the Product fails in any clinical trial or fails to achieve regulatory approval.
- Consequences of Termination. Except in the case this Agreement is terminated by Customer for Lonza or its Affiliate's material breach, in the event of termination hereunder, Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process; (ii) 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; (iii) all Capital Equipment and related charges agreed-to pursuant to Clause 9; (iv) all amounts due under binding Purchase Orders under Clause 6.1, provided that Lonza performs in accordance with same; and (v) any applicable Cancellation Fees. In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the date of written notice of termination. Upon the termination of the Agreement for whatever reason: (i) Lonza shall promptly return to Customer all Customer Information and shall dispose of or return to Customer all Customer Materials and any materials therefrom, as directed by Customer; and Lonza and Customer shall do all such acts and things and shall sign and execute all such deeds and documents as the other may reasonably require to evidence compliance with this Clause 14.3; (ii) at the request of Customer, Customer will have the right to transfer the Manufacturing Process in accordance with Clause 10.9; (ii) at the option of Customer, unless otherwise provided herein, binding Purchase Orders under Clause 6.1 shall survive, and Lonza shall use commercially reasonable efforts to perform the Services for up to two years from the date of termination.
- 14.4 <u>Survival</u>. 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 1, 5 (in accordance with its terms), 10 13 and 16 (to the extent relevant).

## 15 Force Majeure

15.1 If a Party is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to the other Party

specifying the matters constituting Force Majeure together with such evidence as the Party reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, such Party shall be excused from the performance or the 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, if such Force Majeure persists for a period of sixty (60) days or more, either Party may terminate this Agreement by delivering written notice to the other Party; and in the case of either Party terminating for the other Party's failed performance under this Clause 15.1, the consequences of termination shall be as if this Agreement were terminated for default of the Party that claimed the benefit of this Clause 15.

- 15.2 "Force Majeure" shall be deemed to include any reason or cause beyond a Party's reasonable control affecting the performance by such Party 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 such Party to obtain any required raw material, energy source, equipment, labor or transportation, at prices and on terms deemed by such Party to be reasonably practicable, from such Party's usual sources of supply.
- With regard to each Party, 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

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.

- 16.2.1 Modifications and/or amendments of this Agreement must be in writing and signed by the Parties.
- 16.2.2 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) each Party may assign this Agreement, without the other Party's consent, to (i) any Affiliate 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, the Services or the Product, and (b) Lonza shall be entitled to sell, assign 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 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. 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. The assigning Party shall have no obligation to the other Party arising after the assignment, provided that the assigning Party's assignee expressly assumes, for the benefit of the other Party, the obligations of the assigning Party hereunder.

- 16.2.4 Notwithstanding Clause 16.2.3, Customer may provide Lonza with a notice of the identity of any sublicensee of rights to the Product. If Lonza receives a written request from Customer or, with Customer's prior consent, from such sublicensee, for a new Manufacturing Collaboration and Services Agreement for the Product with such sublicensee, then, to the extent of its legal right to do so, Lonza shall offer to enter into a Manufacturing Collaboration and Services Agreement having the same terms and conditions as the terms and conditions of this Agreement (and no more onerous to Lonza or no less favourable to Lonza, than the terms and conditions of this Agreement). On request by Customer and any such sublicensee, Lonza shall provide such sublicensee with a letter confirming the rights of such sublicensee under this Clause 16.2.4.
- Notice. All notices must be written and sent to the address of the Party first set forth above. 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 <u>Governing Law/Jurisdiction</u>. This Agreement is governed in all respects by the laws of the State of New York, without regard to its conflicts of laws principles. Subject to Clause 16.5, the Parties agree to submit to the jurisdiction of the courts of the State of New York, USA and the courts of the United State of America located in the City of New York, NY.
- Disputes. Any disputes relating to issues arising from this Agreement shall, in the absence of resolution within thirty (30) days of the dispute arising, be referred to the Chief Executive Officers or Presidents (as the case may be) of each of the Parties, who shall discuss the matter and attempt to resolve it by mutual consent. If the dispute has not been settled within sixty (60) days of referral to the Chief Executive Officers and Presidents of the Parties, such dispute shall be exclusively and finally settled according to Clause 16.4.
- The relationship between the Parties created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, amalgamation, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Nothing herein shall be deemed to constitute any Party as the agent or representative of the other Party, or all Parties as joint venturers or partners for any purpose. No Party shall be responsible for the acts or omissions of the other Party, and no Party will have authority to speak for or represent the other Party or assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party, for any purpose whatsoever, in any way without

prior written authority from such other Party. Each Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under 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.

#### CONFIDENTIAL

**IN WITNESS WHEREOF**, each of the Parties hereto has caused this Manufacturing Services Agreement to be executed by its duly authorized representative effective as of the date written above.

# LONZA LTD

By: (signed) "Bart A.M. Aarnhem"

Name Bart A.M. Aarnhem Title Senior Legal Counsel

By: (signed) "Marie Leblanc"

Name Marie Leblanc Title Director, Strategic Marketing

# Aurinia Pharmaceuticals Inc.

By: (signed) "Michael R. Martin"

Name Michael R. Martin Title Chief Operating Officer