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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of January 2023

Commission File Number: 001-41115

GENENTA SCIENCE S.P.A.
(Translation of registrant's name into English)

Via Olgettina No. 58
20132 Milan, Italy
(Address of 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): ☐

Other Events

Entry into Development and Manufacturing Services Agreement

Genenta Science S.p.A. (the "Company") is furnishing this Report on Form 6-K (this "Form 6-K") to report that on January 20, 2023 the Company and AGC Biologics S.p.A. ("AGC Biologics"), a contract development and manufacturing organization, have entered into a development and manufacturing services agreement (the "AGC Biologics MSA") pursuant to which AGC Biologics will provide lentivirus vector ("LVV") manufacture certain of the Company's drug products for its ongoing clinical programs (the "Services"). The AGC Biologics MSA establishes timelines for purchase order submissions and manufacturing date changes and cancellation. The AGC Biologics MSA also sets a timeline for the Services and for technology transfer if required and includes customary termination provisions, allowing for termination by a party upon the other party's uncured material breach or upon the other party's insolvency. The Company will render payment to AGC Biologics for each stage reached by AGC Biologics while providing the Services to the Company.

The Company has an existing manufacturing services agreement with Molecular Medicine S.p.A (which was subsequently acquired by AGC Biologics), dated March 6, 2019, pursuant to which AGC Biologics has agreed to manufacture the Company's LVV and drug product for the Company's ongoing clinical programs. The services provided under this existing agreement are in addition to the Services that will be provided under the AGC Biologics MSA.

The foregoing description of the AGC Biologics MSA does not purport to be complete and is qualified in its entirety by reference of the complete text thereof, a copy of which is filed as exhibit 10.1 to this Form 6-K.

Exhibits

Exhibit No.	Description
10.1	Development and Manufacturing Services Agreement dated January 20, 2023 between AGC Biologics S.p.A. and Genenta Science S.p.A.†

† Portions of this exhibit (indicated with markouts) have been redacted in accordance with Item 601(b)(10)(iv).

SIGNATURES

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

GENENTA SCIENCE S.P.A.

By: */s/ Richard B. Slansky*
Name: Richard B. Slansky
Title: Chief Financial Officer

Dated: February 1, 2023

Exhibit 10.1

Certain information in this document indicated with "[*]" has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Development and Manufacturing Services Agreement

This Development and Manufacturing Services Agreement (the "**Agreement**") is made and entered into by AGC and Customer as of the Effective Date, as each capitalized term is defined below.

This Agreement consists of the first 3 pages (the "**Cover Page**"), the General Terms and Conditions, Applicable Schedules, and Appendices (the "**Terms and Conditions**"), and each Exhibit as may be executed from time to time.

Background

AGC provides bioprocessing and gene therapy services to pharmaceutical and biotechnology companies;

Customer wishes to contract with AGC for the provision of the Services pursuant to one or more Work Statements that may be entered into from time to time during the Term; and

AGC is willing to perform the Services on the terms set out in this Agreement and the Quality Agreement, if applicable.

Agreement

In this Agreement, in addition to the defined terms in Appendix I, the following capitalized terms shall have the following meaning.

"**AGC**", "**We**" or "**Us**"	AGC Biologics S.p.A.
"AGC Address"	Via Meucci, 3 20091 Bresso, Italy For the attention of: Legal Department
"**Customer**", "**You**" or "**Your**"	Genenta Science S.p.A.
"Customer Address"	Via Olgettina 58, 20132 Milano, Italy For the attention of: Pierluigi Paracchi
"Project Team"	Genenta Science: Stefania Mazzoleni AGC Biologics:
"**Effective Date**"	January 20, 2023
"Currency"	Euro (€)
"Bank Account"	INTESA SANPAOLO S.p.A. Filiale 03665 - MILANO OSPEDALE SAN RAFFAELE Via Olgettina, 58, Account#: IBAN-IT84 Y030 6901 7651 0000 0000 242 | Beneficiary AGC Biologics S.p.A. | BIC Code: BDITITMM | Swift Code: BCITITMMXXX

"Cancellation Fees"	**Timing of Notice of Cancellation***	**Cancellation Fees**
	Notice served [*] the scheduled Commencement Date, or during a Batch.	[*] Price of the Cancelled Batch
	Notice served [*] before the scheduled Commencement Date or during a Batch.	[*] Price of the Cancelled Batch
	Notice served more than [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch
	Notice served [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch
	Notice served [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch
	Notice served [*] before the scheduled Commencement Date.	[*] Price of the Cancelled Batch
Schedules	Schedule 1A- Manufacturing service viral vectors	
Appendices	Appendix I – Definitions Appendix II - Work Statement No. 1	
Governing Law; Venue:	Italian law; Milan venue.	

The Parties hereby agree and contract with each other on the terms of this Agreement set forth in the General Terms, the applicable Schedules and the Appendices to this Agreement.

Signatures

THIS DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT has been executed by the parties on the date first written above.

AGC Biologics S.p.A.)
)
)
Signature: /s/ Luca Alberici)
)
Print Name: Luca Alberici)
)
Position: Managing director)

Genenta Science S.p.A.)
)
)
Signature: /s/ Pierluigi Paracchi)
)
Print Name: Pierluigi Paracchi)
)
Position: CEO)

AGC Biologics

GENERAL TERMS AND CONDITIONS

THE PARTIES AGREE AS FOLLOWS:

1. DEFINITIONS, CONSTRUCTION & INTERPRETATION

1.1 Capitalized terms used in this Agreement, subject to Section 1.3, shall have the meaning defined for such capitalized term in the Cover Page, Appendix I or in the main body of these Terms and Conditions.

1.2 In this Agreement (except where the context otherwise requires) (i) any reference to a recital, section, clause or appendix is to the relevant recital, section, clause or appendix of this Agreement, and clause headings are included for convenience only and shall not affect the interpretation of this Agreement; (ii) any phrase introduced or preceded by the terms "include", "including" or any similar expression shall be construed as illustrative, shall not limit the sense of the words preceding these terms unless expressly stated otherwise, and shall be deemed to be followed by "without limitation"; (iii) use of the singular includes the plural and vice versa, and use of any gender includes any other gender; (iv) any reference to a "**person**" includes an individual, firm, partnership, body corporate, corporation, association, organisation, government, state, foundation, trust or other legally recognised entity or person; (v) a period of time being specified which dates from a given day or the day of an act or event, shall be calculated exclusive of that day; and, (vi) uses of the word "**or**" shall be deemed to have the inclusive meaning of "**and/or**".

1.3 In the event of any conflict between the provisions of any of the Cover Page, the Terms and Conditions or the Work Statement, the conflicting terms of (i) the Cover Page will prevail over the conflicting terms of the Terms and Conditions and/or Work Statement, and (ii) the Terms and Conditions will prevail over the conflicting terms of the Work Statement. If any term of this Agreement conflicts with any term of the Quality Agreement, the conflicting term of this Agreement will prevail, except with respect to matters solely dealing with quality, in which case the Quality Agreement will prevail. This Agreement is written in English, and the English version of this Agreement will control.

2. PERFORMANCE OF THE SERVICES

2.1 Work Statements. As of the Effective Date, the Parties are entering into Work Statement No. 1 attached as Appendix II. From time to time during the Term, the Parties may, but are not obliged to, enter into additional Work Statements, each of which will form part of and be governed by this Agreement.

2.2 Standards. AGC shall perform the Services in accordance with its obligations under this Agreement. AGC shall use commercially reasonable efforts to (i) perform the Services to achieve the Objective; (ii) meet the Timeline for the Services; and, (iii) subject to Section 4.3, manufacture Product within the parameters of the Specification. Notwithstanding the foregoing, subject to the warranties and indemnities set forth below nothing in this Agreement guarantees that the Objective(s) will be achieved, that the Product will meet the Specification or the Services will deliver the results or output anticipated.

2.3 Totality of Services. AGC will not perform any Services other than those described in the Work Statement. Due to the nature of the Services, however, changes to the Services may be necessary to achieve the Objective.

2.4 Project Change Orders. The Parties acknowledge that changes to the Services, Timeline, Product or Objectives may be desirable or necessary from time to time. Either Party may notify the other Party of any such change considered desirable or necessary, whereupon the Parties will promptly meet to negotiate and seek to agree on any changes in writing in the form of a change order. Any changes agreed may affect the Price and Timeline, which will be agreed in the written change order. Until a written change order is signed by both Parties' signatories per Section 15.4, the existing Work Statements shall prevail and continue.

2.5 Project Team

2.5.1 Each party will name and notify the other party of its representatives who will form the project team and who will be responsible for planning, executing and discussing issues regarding the Services and communicating with the other party ("**Project Team**").

2.5.2 The Project Team will schedule meetings at regular intervals for the purpose of communicating updates on the performance of the Services and providing an initial forum for discussing and resolving any issues encountered with the Services. These meetings will be conducted by telephone or, if necessary, by face-to-face meetings. Each party is responsible for its own costs in attending these meetings.

2.5.3 Any decision by the Project Team that amends the Services will not be binding unless it is recorded in writing and signed by authorized representatives of both parties per Section 15.4.

2.6 Joint Steering Committee

2.6.1 The parties may establish a joint steering committee (the "**JSC**"). The JSC shall be comprised of two (2) named representatives of AGC and two (2) named representatives of Customer (or such other number as the parties may agree). A member of the Project Team may simultaneously serve as a member of the JSC. Each party may replace one or more of its representatives, in its sole discretion, effective upon written notice to the other party of such change. Either party may, from time to time, invite additional representatives or consultants to attend JSC meetings, subject to such representative's or consultant's written agreement to comply with confidentiality obligations substantially the same as those set forth in Section 9. The JSC shall meet once a calendar year or as needed either in person or by teleconference. Each party shall bear its own expenses related to the attendance at JSC meetings by its representatives. The JSC shall be co-chaired by a representative from each Party.

2.6.2 The JSC's responsibilities shall include: (i) coordinating the activities of the parties under this Agreement, including facilitating communications between the parties; (ii) approving updates and amendments to the Work Statement, in particular those that represent a substantial increase in risk to the timely completion of a material activity under the Work Statement; (iii) reviewing the Timeline; (iv) approving budgets to the Work Statement or proposed costs for conducting activities under this Agreement; (v) attempting to resolve issues presented to it by the Project Team; and (vi) considering and acting upon such other matters as specified in this Agreement. The JSC may delegate any responsibilities to the Project Team or require the Project Team to cede any of its responsibilities to the JSC.

3. CUSTOMER MATERIALS

3.1 Transfer. Customer must deliver and successfully transfer to the AGC Facility and AGC's personnel the Customer Materials and other information described in the Work Statement by the deadline in the Work Statement. If relevant, that information must include a full description of the Process and all Customer Know-How relevant to the Cell Line, Customer Materials, Drug Substance and Process. All information must be provided in written form and in English.

3.2 Raw Materials. AGC shall be solely responsible for procuring all raw materials or reagents necessary to perform the Services other than material supplied by Customer, its Affiliate or agent to AGC, or made available to AGC by Customer, at Customer's expense [*], as set forth in the applicable Work Statement. AGC shall confirm in writing by email to Customer at least on a monthly basis the availability of raw materials or reagents necessary to perform the Services agreed in the Work Statement or the PCO (as the case may be). In addition, AGC undertakes to promptly inform Customer in writing by email if it becomes aware of any risk of shortage or raw materials or reagents necessary to perform the Services agreed in the Work Statement or the PCO (as the case may be) and the Parties shall discuss in good faith any possible remedy. Without limiting the foregoing, if such shortage reasonably prevents AGC from manufacturing the applicable Batch(es) on the production date set forth in the Work Statement or the PCO (as the case may be), upon Customer's request AGC shall reschedule the affected manufacturing slot(s) as expeditiously as reasonably possible upon the applicable raw material or reagent becoming available, it being understood that AGC shall use commercially reasonable efforts to (a) procure such raw material or reagent as expeditiously as reasonably possible and (b) make available such manufacturing slot(s) to Customer within [*] from such production date. For clarity, the foregoing shall not be construed to limit AGC's liability for negligence or wilful misconduct in ordering raw materials and reagents.

3.3 Customer Assistance. Customer must reasonably promptly and, in any event, within seven (7) Business Days after the request, make available to AGC suitably qualified and skilled employees to assist in the successful transfer of the Customer Know-How, Customer Materials and Process to AGC. Availability may occur also by means of teleconference or videoconference.

3.4 MSDS. At least thirty (30) Business Days before the delivery of the Customer Materials (including, where applicable, the Cell Line) Customer must provide to AGC an accurate and complete written risk assessment (in English) for genetically modified organisms that details the hazards, storage and handling recommendations for the Customer Materials (**"Materials Safety Data Sheet"**).

3.5 Return of Customer Materials. Within thirty (30) days after completion of the Services under the Agreement, Customer must notify AGC whether it wants AGC to return the Customer Materials to Customer or a third party storage facility or if it wants AGC to dispose of the Customer Materials, in each case, at Customer's expense. If Customer does not provide the notice required by this Section 3.5, AGC will provide a written notice to the Customer informing that an answer is due with thirty (30) days, otherwise AGC will return them to the Customer in thirty (30) days, in each case at Customer's expense.

4. TIMELINE CHANGES, SPECIFICATION AND CGMP CHANGES

4.1 The parties may revise the Timeline by mutual agreement; provided, that the revised Timeline is in writing and agreed by the Project Team or the JSC.

4.2 In addition, AGC may revise the Timeline if a Non-Fault Delay occurs, keeping the revised Timeline as close as possible to the Timeline in effect immediately before the Non-Fault Delay. AGC is not liable for failure to meet the Timeline if any Non-Fault Delay contributes to the failure.

4.3 Specification and Quantities

4.3.1 AGC must use commercially reasonable efforts to manufacture Product to meet the Specification where required by the Work Statement.

4.3.2 For the avoidance of doubt, until the Process Performance Qualification (PPQ) has been completed at AGC, AGC will use commercially reasonable efforts to manufacture Product to meet the Specification by following the Process as defined in the Work Statement or as otherwise agreed in writing by the parties.

4.3.3 The Specification may be revised by the parties if agreed by the Project Team in writing and signed by both parties. If the parties cannot agree to a revised Specification, the previous agreed on Specification applies.

4.3.4 All quantities of Product are good faith estimates only.

4.4 Changes in cGMP. If there are any material and unforeseen changes in cGMP or manufacturing regulations issued under law that impact the Services and (i) are specific only to the Product (and not a general requirement for gene therapy or biologics contract manufacturing services); or (ii) require capital or other investment by AGC for the performance of the Services in excess of the total Price of the Services resulting in the financial returns under this Agreement being substantially affected to AGC's detriment, then AGC must notify Customer and the parties must in good faith discuss ways to continue the Services while overcoming the financial detriment by, for example, increasing the Price in an equitable and reasonable manner. If the parties do not reach an agreement within ninety (90) days after AGC's notice and AGC has substantiated the financial detriment, then AGC may terminate this Agreement or an applicable Work Statement upon thirty (30) days written notice to Customer, to be delivered to Customer within thirty (30) days following the expiration of such ninety (90)-day period.

5. MANUFACTURING CAPACITY AND CANCELLATION FEES

5.1 Reservations and Scheduling

AGC will reserve Slots in its Facility on the basis of the Customer requirements for the Product as set forth under the relevant Schedule.

5.2 Cancellation of cGMP Batches

5.2.1 Customer must pay AGC:

(a) the cancellation fees set forth on the Cover Page ("**Cancellation Fees"**)

(i) if any cGMP Batch or other Batch scheduled for manufacture in AGC's cGMP facility (e.g., an engineering batch) is delayed, vacated, or cancelled as a result of Customer terminating or postponing the Batch, Slot or terminating this Agreement except for termination of this Agreement under Section 12.2 ("**Termination for Default**") where AGC is the "Defaulting Party";

(ii) if any cGMP Batch or other Batch scheduled for manufacture in AGC's cGMP facility (e.g., an engineering batch) is delayed, vacated, or cancelled as a result of any of the events under [*];

(iii) if any cGMP Batch or other Batch scheduled for manufacture in AGC's cGMP facility (e.g., an engineering batch) is delayed, vacated, or cancelled due to the [*]

(each a "**Cancelled Batch**")

(b) [*] of the Cancellation Fees if any cGMP Batch or other Batch scheduled for manufacture in AGC's cGMP facility (e.g., an engineering batch) is delayed, vacated, or cancelled as a result [*];

(c) [*] of the Cancellation Fees [*].

5.2.2 For clarity, Customer will not pay any fee if the cancellation is due to shortage of raw materials which AGC is responsible for procuring as set forth in the applicable Work Statement as long as such shortage is due to AGC's negligence or wilful misconduct in ordering raw materials, and provided that AGC shall (a) use commercially reasonable efforts to maintain at all times adequate inventory levels of raw materials as necessary to manufacture the applicable Batch(es) in accordance with the applicable timelines as set forth herein, (b) keep Customer reasonably informed about the availability of such raw materials, and, without limiting the foregoing, promptly inform Customer about any delay in the supply of such raw materials that could reasonably be expected to affect AGC's ability to supply such Batch(es) to Customer in accordance with the applicable timelines as set forth herein, and (c) use commercially reasonable efforts to mitigate the effects of any such delay in consultation with Customer, including using any inventory that AGC is not contractually obligated to use for the benefit of other customers.

5.2.3 For purposes of Section 5.2.1, the date of service of notice of a Cancelled Batch is the earlier of (a) the date of the notice to terminate a Batch, Slot or this Agreement is given by the terminating party to the other party; (b) the date that the new Timeline has been agreed by the parties; or (c) the date on which AGC has given notice that the Timeline has been updated in accordance with Section 4.2. [*].

5.2.4 AGC will invoice the Cancellation Fees on the date of service of notice. Cancellation Fees are payable within thirty (30) days after an invoice is issued by AGC.

6. PACKAGING, DELIVERY, STORAGE, EXAMINATION, DEFECTS AND SAMPLES

6.1 Packaging. AGC will package all Cell Lines (only for biologics Services), Product and perishable Deliverables to be Delivered per AGC's applicable packaging SOPs and Regulatory Obligations.

6.2 Delivery

6.2.1 AGC will provide Customer with advance notice of the anticipated date of Delivery of Product. Notice will be provided at least ten (10) Business Days before AGC is to Deliver that Product.

6.2.2 Except as stated in Section 6.2.4 or in the Specifications, all Product that AGC manufactures under this Agreement will be released to Customer Ex Works (Incoterms 2020) at AGC's Facilities on the date and at the time specified in AGC's notice to Customer. Product will be considered "delivered" on the date Product is so released ("**Delivery**" or "**Delivered**"). Customer may arrange collection at any time during normal business hours on Business Days or other times as may be agreed by the parties.

6.2.3 AGC has no obligation to clear for export or import any Deliverables nor is AGC obligated to obtain, or assist Customer in obtaining, export or import licenses, consents or permissions.

6.2.4 Documentary deliverables will be delivered by electronic means or as otherwise agreed to by the parties.

6.3 Release for Further Processing. Subject to, and if permitted by, Regulatory Obligations, Customer may request that AGC Deliver Product to Customer before AGC issues a Certificate of Analysis ("**Release For Further Processing**"). Any Product that is the subject of Release For Further Processing must until the applicable Certificate of Analysis is issued by AGC.

6.3.1 not be administered to any living organism;

6.3.2 be handled by Customer with the utmost care as if it were an unknown substance; and

6.3.3 be accepted at Customer's sole risk and liability.

AGC is not liable for any loss or damage caused by Product that is the subject of Release For Further Processing.

6.4 Title and Risk. Title and risk of loss in the Deliverables transfer to Customer on Delivery.

6.5 Storage and Transport. If Customer elects to have a shipping company or other agent (**"Shipping Company"**) collect and transport the Product on Delivery, Customer must:

6.5.1 inform AGC of Customer's designated Shipping Company before the collection of the Product;

6.5.2 coordinate with the Shipping Company for the shipment of the Product; and

6.5.3 ensure that the Product is stored and transported in accordance with the Shipping Guidelines.

AGC is not responsible for any shipping costs of the Shipping Company.

6.6 Storage. If Customer or Customer's Shipping Company is unable to collect the Product at the time of Delivery, AGC will store the Product for a period [*] after Delivery. Storage of the Product at AGC's premises after Delivery is at [*]. If the Product has not been collected by Customer or Customer's Shipping Company within [*] after Delivery, AGC will notify Customer. If Customer or Customer's Shipping Company fails to collect the Product within [*] after the date of that notice, AGC may, without additional notification to Customer and without any liability to Customer, either, in its sole discretion, dispose of the Product or continue to store the Product at a cost to Customer in the amount stated in Appendix II. If AGC elects to continue to store the Product, then AGC may subsequently dispose of the Product if Customer or Customer's Shipping Company fails to collect the Product [*] after notice given in accordance with Section 15.9. If Product consists of viral vector to be used as an intermediate in the manufacturing process performed by AGC under this Agreement, then AGC shall be responsible for storing such Product in accordance with cGMP (and for any damage resulting from any AGC not compliance with cGMP) for the entire period in which AGC is supporting the Customer in the clinical trial relating to the Product (and provided that the clinical trial is ongoing and has not been suspended) and this Section 6.6 shall not apply to such Product. To this aim, the Customer undertakes to promptly inform AGC if the clinical trial has been suspended or terminated.

6.7 Samples. AGC must store regulatory reserve samples (e.g., GMP retention samples) of all cGMP Product released by AGC's quality department with a Certificate of Analysis for the period required by applicable Regulatory Obligations, which in the absence of a definitive time period is fifteen (15) years from the date of release or Delivery of the applicable Product. AGC is solely responsible for the maintenance and sample disposal only according to the purpose of these regulatory reserve samples. At the end of the retention period of the samples, AGC will notify the Customer to proceed with their destruction unless Customer contacts AGC in writing pursuant to Section 15.9 within the following five (5) days, and AGC and Customer then agree to an alternate plan in a written agreement signed by both parties within the following thirty (30) days from the Customer communication.

6.8 Shipping Guidelines. If Customer intends to test the Product and wants to reserve its right to make a claim against AGC under this Section 6 for defective Product, Customer must ensure that the Product since collection from AGC's Facility is always transported and stored in accordance with the Shipping Guidelines. Failure to comply with the Shipping Guidelines before or after serving a Customer Defect Notice (as defined below) will invalidate Customer's right to make any claim under this Agreement for defects in those Products.

6.9 Defective Products

6.9.1 Upon completion of the manufacturing of each Product, AGC shall perform quality control testing to confirm the absence of Defects (as defined below). If AGC ascertains [*] (a "**Defect**", and a Product affected by a Defect, "**Defective Product**"), AGC will promptly inform the Customer in accordance with the Quality Agreement ("**AGC Defect Notice**"). In addition, AGC will promptly investigate whether the Defect is due to AGC's negligence or failure to comply with its obligations under this Agreement and will report to Customer the results of such investigation in accordance with timeline set forth under the Quality Agreement. Product that is not specified in the Work Statement to meet cGMP and/or Specifications cannot be considered Defective Product.

6.9.2 Customer must notify AGC in writing ("**Customer Defect Notice**") within [*] after Delivery of the Product if any alleged Defect is identified. To be effective, a Customer Defect Notice must identify:

(a) the Batch;

(b) the date of Delivery and collection;

(c) reasonable detail of the Defect, including test results;

(d) where applicable full disclosure of the methodology of all analytical tests performed on the Product and the results of those tests;

(e) confirmation that the Products have been stored and transported in accordance with the applicable Shipping Guidelines; and

(f) where the Customer asserts that the Defect is due to AGC's fault, and not as a result of any third party (other than subcontractors) or Customer action or inaction, the reasons for that assertion.

6.9.3 In consultation with AGC, Customer must return samples of the Products that are subject to the Customer Defect Notice in accordance with the Shipping Guidelines to AGC within [*] after the date of the Customer Defect Notice.

6.9.4 If a Defect in any Product is not notified to AGC in accordance with the provisions and time limits stipulated in this Section 6.9, the Product will be considered accepted and free of Defects, and Customer will have no further remedy against AGC for that Batch of Product.

6.10 Consequences of Defective Product.

6.10.1 If Customer provides to AGC a reasonably documented finding of a Defective Product due to AGC's failure to comply with cGMP and its SOPs, and AGC accepts that finding, then AGC will replace any such Defective Product at no additional charge to Customer as soon as reasonably practicable.

6.10.2 If AGC disputes Customer's finding as per Section 6.10.1, ("**Disputed Product**"), then (a) analysts from both parties must directly communicate to determine that the parties' respective methods of analysis are the same and are being executed in the same manner and to attempt to determine whether any non-compliance may have been caused during the shipment of the sample from AGC's Facility, and (b) carefully controlled and split samples as agreed must be sent from one site to the other for testing. This process may involve Customer sending a representative and a sample of the Disputed Product to AGC, and the parties conducting jointly agreed on tests on the samples. The parties must use good faith efforts for a period of thirty (30) days after completing those tests to resolve whether the Disputed Product is Defective due to AGC's failure to manufacture in accordance with this Agreement.

6.10.3 If the parties cannot resolve their dispute in the manner described above as to whether a Disputed Product is a Defective Product due to AGC's failure to comply with cGMP and its SOPs, the parties must require an independent agreed on laboratory to test the Disputed Product. The costs of the independent laboratory will be shared by the parties equally; provided, however, that the party that is determined to be incorrect will be responsible for those reasonable costs and must reimburse the correct party for its share of the reasonable costs incurred. The decision of the independent laboratory must be in writing. The decision will be binding on the parties, unless there has been a manifest error, in which case, the parties will revert to the dispute resolution procedure in Section 15.11.

6.11 Rejected Product. Customer must segregate and must not use any Product for any human clinical testing or trials or any other purpose (other than compliance testing pursuant to this Section 6) after it becomes aware of a basis for rejection or a Defect Notice. On a final determination that any Product is Defective, the ultimate disposition of any Defective Product will be the responsibility of Customer, and AGC shall have no liability or responsibility with respect to such disposition, provided that, to the extent Defective Product consists of starting material for the manufacturing of drug product, then AGC shall destroy such Defective Product at AGC's cost or deliver such Defective Product at Customer's cost, as requested by Customer.

6.12 Exclusive Remedies. Subject to Article 11, the remedies and obligations under Section 6.10.1 are Customer's sole remedy for Defective Products and the relevant Documentary Deliverables.

7. PRICE AND PAYMENT TERMS

7.1 Amounts. All amounts stated in this Agreement are denominated, and must be paid in the currency specified on the Cover Page or as otherwise agreed in a Work Statement. The Price stated in the Work Statement is exclusive of (a) taxes, duties and other fees imposed by any government authority (other than taxes on AGC's income); (b) external analysis costs, (c) raw materials and (d) shipping and handling. Customer must pay these amounts in addition to the Price. Customer must also reimburse AGC for all travel costs requested by Customer.

7.2 Payment Schedule. Unless a different payment schedule is provided in the Work Statement, AGC will issue invoices for the Price of Stages as follows:

7.2.1 For all Stages other than those described in Section 7.2.2:

(a) [*] of the Price of each Stage on [*]; and

(b) [*] of the Price of the Stage on [*].

7.2.2 For all Stages where the Stage relates to the manufacture of cGMP Product or where the performance of the Stage takes place in AGC's GMP facility (in each case with respect to the relevant batch(es):

(a) [*] of the Price of the Stage on [*];

(b) [*] of the Price of the Stage upon [*];

(c) [*] of Price of the Stage [*] for both Product and drug product; and

(d) [*] of the Price of the Stage on [*].

For clarity, [*] will be invoiced separately under the Work Statement in accordance with Section 7.3.

All payments made by the Customer under this Section 7.2 are non-refundable, but may be creditable for future Services under the terms and conditions of this Agreement at AGC's discretion.

7.3 Incidental Costs

7.3.1 Raw Materials. The costs for raw materials and handling are described in the Work Statement.

7.3.2 External Analysis. The costs and handling for external analysis are described in the Work Statement.

7.3.3 Handling Fees. Customer must pay AGC a handling and processing fee for [*].

7.3.4 Other Fees. Customer must pay AGC the other fees as described in the Work Statement if relevant.

7.3.5 AGS shall inform the Customer once it becomes aware of a [*] as described in the Work Statement.

7.4 Payments. Unless otherwise directed by AGC in an applicable Work Statement, all invoices must be paid by wire transfer of immediately available funds to the account set forth on the Cover Page.

Unless otherwise stated on an invoice, Customer must pay all invoices in full without any deductions within [*] after issue by AGC.

7.5 Late Payments. If any undisputed amount is not paid in full when due under this Agreement, AGC may:

7.5.1 charge Customer interest at a rate of [*] on the overdue amount on a compounded basis until payment is received, and

7.5.2 suspend the performance of the Services. Where performance is suspended, AGC will have no liability to Customer for the suspension or delay in the Timeline.

7.6 Acceptance of Invoices. All invoices will be considered accepted by Customer unless Customer notifies AGC to the contrary within [*] after delivery of the applicable invoice.

8. INTELLECTUAL PROPERTY

8.1 Pre-Existing Intellectual Property. As between the parties, each party retains sole ownership of any Intellectual Property owned or Controlled by that party (i) as of the Effective Date or before the commencement of the Services; or (ii) as a consequence of any activities of that party or its Affiliates which are unconnected with the Services performed hereunder ("**Pre-Existing IPR**"). Nothing in this Agreement assigns or transfers a party's ownership of its Pre-Existing IPR to the other party.

8.2 Customer's Grant of License for the Services. During the Term, Customer hereby grants to AGC a non-exclusive, royalty-free, sublicensable (to Affiliates and subcontractors) license to exploit the Customer Intellectual Property Rights covering the Product (including its manufacture), any Customer Materials and/or Confidential Information solely to the extent necessary to perform the Services. For clarity, the foregoing license does not include the right to disclose any Confidential Information of the Customer or Customer's Know-How to any third party, except for the Approved Subcontractors and the Testing laboratories, without the express prior written consent of the Customer in each case. This license terminates automatically on the termination or expiry of this Agreement save to the extent required for any surviving obligations of AGC under this Agreement.

8.3 AGC License. AGC hereby grants to Customer a non-exclusive, perpetual (subject to termination in accordance with the last sentence of this Section 8.3), royalty-free, sublicensable (through multiple tiers), worldwide license to the AGC Intellectual Property Rights to the extent required to (i) only undertake activities necessary to support AGC in providing the Services; (ii) use, sell, offer to sell, import and otherwise exploit (excluding in any case to manufacture or have manufactured by third parties others than AGC) those Physical Deliverables delivered hereunder; and (iii) use, store and reproduce Documentary Deliverables in connection with the use of the Physical Deliverables. This license does not include the right to disclose any Confidential Information of AGC or AGC's Know-How to a third party without the express prior written consent of AGC other than to regulatory authorities in connection with the regulatory approval process for the Product. This license automatically terminates if AGC terminates the Agreement pursuant to Section 12.2 for a breach by Customer.

8.4 IPR Created during the Services. Without limiting Section 8.1, any Intellectual Property that is, as between the parties and their Affiliates, first generated, created or reduced to practice in connection with the performance of the Services under this Agreement ("**New IPR**") shall be:

8.4.1 owned solely by AGC to the extent the New IPR [*] (collectively being "**AGC New IPR**"); or

8.4.2 owned solely by Customer to the extent the New IPR [*] (collectively being "**Customer New IPR**").

[*].

8.5 Assignment of IPR. In accordance with the provisions of Section 8.4, to the extent (i) AGC created and owns any Customer New IPR, AGC hereby assigns, and shall execute those documents necessary to assign, such Customer New IPR to Customer; and, (ii) Customer created and owns any AGC New IPR, Customer hereby assigns, and shall execute those documents necessary to assign, such AGC New IPR to AGC.

8.6 Right to File for Protection. Each party may file patent protection on any Intellectual Property it owns in accordance with Section 8.1, 8.4 or 8.5 and the other party will reasonably cooperate at the requesting party's expense, with any requests to assist or enable the party's protection including signing and delivering documents and other information necessary for the valid application and prosecution of any patent.

8.7 Party's Name. Except as otherwise provided in this Agreement or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither party shall use the name of the other party or of the other party's Affiliates, directors, officers or employees in any advertising, news release or other publication except that AGC may identify Customer by name as a customer of AGC.

8.8 No Implied Licenses. Except for those licenses expressly granted in this Agreement (including those in the Schedules hereto), no other rights or licenses are granted by a party to the other, whether by implication, estoppel or otherwise.

8.9 Incorporation of AGC Platform Technology. AGC shall not incorporate any LVV Platform Technology into the Product unless expressly set forth in a Work Statement.

9. CONFIDENTIAL INFORMATION

9.1 The Recipient Party must:

9.1.1 use the Confidential Information of the Disclosing Party only during the Term as reasonably necessary to carry out this Agreement;

9.1.2 protect the Confidential Information of the Disclosing Party against unauthorized use or disclosure applying standards of care reasonably expected and no less stringent than the standards applied to protection of Recipient Party's own confidential information of a similar nature; and

9.1.3 not disclose any Confidential Information of the Disclosing Party to any person or entity except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9.

9.2 The obligations in Section 9.1 do not apply to information that:

9.2.1 at the time of its disclosure by the Disclosing Party, was available to the public and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence;

9.2.2 becomes generally available to the public other than by reason of a breach of this Agreement or any breaches of confidence by the Recipient Party or its Permitted Recipients;

9.2.3 at the time of disclosure and as evidenced by the Recipient Party's written records, was lawfully already within its possession; or

9.2.4 is independently developed by the Recipient Party without reference to the Confidential Information of the Disclosing Party.

9.3 The Recipient Party may disclose certain Confidential Information of the Disclosing Party, without violating the obligations of this Agreement, to the extent that disclosure is required by and in compliance with a valid order of a court or other governmental body having jurisdiction, provided that the Recipient Party provides the Disclosing Party with reasonable prior written notice, to the extent permitted by law, of the disclosure and makes a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure. For clarity, without limiting Section 8, in the event any of AGC's Confidential Information is incorporated into any Physical Deliverable or Product, Customer shall be allowed to use and disclose such Confidential Information (and to authorize such use and disclosure) in connection with the development, manufacturing and/or commercialization of such Physical Deliverable and/or Product.

9.4 If the Recipient Party or any of its Permitted Recipients becomes aware of any actual or potential unauthorized use or disclosure of the Confidential Information of the Disclosing Party, the Recipient Party must inform the Disclosing Party as soon as reasonably possible after it becomes aware of that actual or potential unauthorized use or disclosure. The Recipient Party must cooperate in any action that the Disclosing Party may decide to take.

9.5 Except as otherwise provided in this Agreement or otherwise required by law, neither Customer nor AGC will disclose any terms of this Agreement to any third party without the prior written consent of the other party except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9. Notwithstanding the above, each Party may disclose the terms of this in securities filings with the Securities Exchange Commission ("**SEC**") (or equivalent foreign agency) to the extent required by applicable laws, provided that the Party seeking such disclosure will prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no less than two (2) Business Days after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines proscribed by applicable SEC regulations. The Party seeking such disclosure shall exercise commercially reasonable efforts to obtain confidential treatment of the Agreement from the SEC as represented by the redacted version reviewed by the other Party.

9.6 On the termination of this Agreement or at the request of the Disclosing Party, the Recipient Party must promptly return to the Disclosing Party any Confidential Information of the Disclosing Party then in its possession or control except where that Confidential Information is covered under surviving license rights between the parties. However, each party may retain in its legal files a single copy of any document that contains the Disclosing Party's Confidential Information solely for the purpose of determining the scope of the obligations under this Agreement. Neither party is obligated to destroy electronic files securely archived in accordance with its customary data retention policies.

10. LIMITED WARRANTIES

10.1 Customer Warranties. Customer warrants and represents to AGC that:

10.1.1 Customer has all necessary rights to supply to AGC the Customer Materials (including the Cell Line if provided by Customer), the Customer Confidential Information and the Customer Intellectual Property Rights, and AGC has and will have the right to use those items for the performance of the Services and manufacture of the Product;

10.1.2 the Materials Safety Data Sheet is accurate and complete and the Customer Materials (including the Cell Line if provided by Customer) are free from all contaminants, including virus, bacteria (other than the Cell Line itself) and other vectors, and if handled and used in accordance with the Materials Safety Data Sheet supplied by Customer will not cause a health hazard or biohazard;

10.1.3 to its knowledge, the use of the Cell Line and Process, the Customer Materials, the Customer Confidential Information, the Customer Intellectual Property Rights and the manufacture of the Product does not and will not infringe any Intellectual Property rights of any third parties; and

10.1.4 (a) to its knowledge, the Cell Line and Process if provided by Customer and Customer Materials are viable, adequate and suitable for the effective performance of the Services and manufacture of the Product according to the Specification, (b) it knows of no reason (suspected or otherwise) why the Objective cannot be achieved or the Services successfully performed and (c) the information supplied to AGC regarding the Cell Line, the Customer Material provided by Customer and Process is accurate and complete.

10.2 AGC Warranties. AGC warrants and represents to Customer that:

10.2.1 it has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics/gene therapy contract manufacturer for the regular provision of manufacturing and development services of biologic material/ gene therapy products;

10.2.2 all Deliverables will be Delivered free of financial encumbrances or liens created by AGC but no warranty is given in this Section 10.2.2 as to (a) non-infringement of third party Intellectual Property rights, or (b) freedom to use;

10.2.3 to its knowledge, the AGC Intellectual Property Rights used in the Services do not infringe third party Intellectual Property rights except that no warranty is given to the extent that infringement arises from the combination of AGC Intellectual Property Rights with the Cell Line, Process, Customer Materials or Customer Intellectual Property Rights;

10.2.4 where Stages are to be performed according to cGMP, AGC will apply the appropriate cGMP standards to the performance of those Stages; and

10.2.5 where Product is released with a Certificate of Analysis by AGC, the Product at the time of release will comply with the criteria specified in that Certificate of Analysis.

10.3 Disclaimer of All Other Warranties. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT FOR THOSE EXPRESS WARRANTIES IN THIS SECTION 10, NEITHER PARTY MAKES OR GIVES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED (WHETHER BY STATUTE, CUSTOM, COURSE OF DEALING OR OTHERWISE) AND EACH PARTY HEREBY DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT AND TITLE.

11. INDEMNIFICATION

11.1 AGC's Indemnity. Customer must indemnify and defend AGC and its Affiliates and each of their respective directors and officers and Testing Laboratories, including Approved Subcontractors (**"AGC Parties"**) against any and all losses, demands, claims, liabilities, damages, costs and expenses (including court costs and reasonable attorneys' fees and expenses) (**"Claims"**) that the AGC Parties incur as a result of any:

11.1.1 alleged or actual infringement or misappropriation of any Intellectual Property rights of any third party arising from (i) AGC's use of the Cell Line, the Process (if provided, in full or in part, by the Customer), Customer Intellectual Property Rights, Customer Confidential Information or Customer Materials; or (ii) [*]; or (iii) the Product, including its manufacturing, provided that Customer shall not have any liability under this Section 11.1.1 with respect to the Process (except to the extent the Process is provided by the Customer).

11.1.2 Claims resulting from the administration, use, handling, storage or other disposition of the Product or Drug Substance in any form;

11.1.3 use, storage or holding by AGC of the Customer Materials except to the extent the Customer Materials were not handled in accordance with the Materials Safety Data Sheet;

11.1.4 use of any Product that was the subject of a Release for Further Processing in accordance with Section 6.3; and

11.1.5 any acts or omissions of any third party auditor of Customer.

11.2 Customer's Indemnity. AGC must indemnify and defend Customer and its Affiliates and each of their respective directors and officers (**"Customer Parties"**) against any and all Claims that the Customer Parties incur as a result of any:

11.2.1 material inaccuracy in a Certificate of Analysis such that the certified Product at the time of Delivery does not meet the Specification when certified to meet it;

11.2.2 failure of AGC to manufacture the Product according to cGMP when the Product is released by AGC at the time of Delivery as a cGMP Product;

11.2.3 actual or alleged infringement or misappropriation of any Intellectual Property rights of any third party to the extent that infringement or misappropriation is due to AGC's use of the AGC Intellectual Property Rights in the performance of the Services but excluding [*]; and

11.2.4 Any negligence or wilful misconduct by AGC or its subcontractors other that Approved Subcontractors in the performance of the Services under the Agreement.

11.3 Indemnification Procedure. The party (**"Indemnitee"**) that claims indemnification under this Section 11 must:

11.3.1 promptly, and in any event within fifteen (15) Business Days of it receiving notice of the Claim, notify the other party ("**Indemnitor**") in writing of the Claim; provided that failure to give that notice will not relieve the Indemnitor of its indemnification and defense obligations except to the extent the failure materially prejudices the ability of the Indemnitor to defend against the Claim;

11.3.2 permit the Indemnitor to control the defense of the Claim; and

11.3.3 have the right (at the Indemnitee's expense) to participate in the defense of the Claim.

11.4 Settlement. The Indemnitor must not settle or consent to an adverse judgment in any Claim indemnified by the Indemnitor that adversely affects the interests of the Indemnitee or imposes additional obligations on the Indemnitee, without the prior written consent of the Indemnitee.

11.5 IP Claims. Each party must promptly (and within five (5) Business Days if permissible under applicable law or stock exchange rules) notify the other party of any third party allegation of infringement or misappropriation of any third party Intellectual Property rights due to the handling, storage or use of the Cell Line, Customer Materials, Customer Intellectual Property Rights or AGC Intellectual Property Rights or the manufacture of the Product, in each case to the extent such allegation could reasonably be expected to affect the other party.

12. TERM AND TERMINATION

12.1 Term. The term of this Agreement commences on the Effective Date and terminates on the later of (a) the date that all Stages under all Work Statements have been completed and (b) ten (10) years from the Effective Date, unless sooner terminated in accordance with Sections 4.4, 12.2, 12.3, 12.4, 12.5 or 15.1, or extended or terminated by mutual written agreement of the parties (**"Term"**).

12.2 Termination for Default. Either party (**"Non-Defaulting Party"**) may terminate this Agreement on notice to the other party (**"Defaulting Party"**) if:

12.2.1 the Defaulting Party commits a material breach of its obligations under this Agreement and fails to remedy it during a period of thirty (30) days starting on the date of receipt of notice from the Non-Defaulting Party identifying the breach and requiring it to be remedied;

12.2.2 a petition is filed against the Defaulting Party for an involuntary proceeding under any applicable bankruptcy or other similar law and that petition has not been dismissed within sixty (60) days after filing or a court having jurisdiction has appointed a receiver, liquidator,

trustee or similar official of the Defaulting Party for any substantial portion of its property, or ordered the winding up or liquidation of its affairs; or

12.2.3 the Defaulting Party commences a voluntary proceeding under applicable bankruptcy or other similar law, has made any general assignment for the benefit of creditors, or has failed generally to pay its debts as they become due.

12.3 Termination for Convenience

12.3.1 Customer may terminate this Agreement or any Stage of the Services at any time before completion of the Services or Stage by giving no less than [*] notice in writing to AGC detailing the Stages of the Services that are to be terminated.

12.3.2 AGC may terminate this Agreement at any time after the completion of all Stages under all Work Statements by giving [*] written notice to Customer.

12.4 Termination for Scientific or Technical Difficulties. AGC may terminate this Agreement, a Work Statement or any Stage on [*] notice if AGC reasonably concludes that it cannot technically or scientifically deliver the Services contemplated by this Agreement or any Stage despite applying its commercially reasonable efforts. During the [*] notice period or when AGC notifies Customer that it has become aware that a technical or scientific problem has or may arise, the parties must in good faith discuss the difficulties and scientific and technical hurdles in an attempt to resolve those problems. If the parties agree during those discussions that the Services can be delivered then the notice to terminate will expire and this Agreement (or the Stage as the case may be) will continue in effect. If an agreement cannot be reached this Agreement or Stage, at AGC's election, will terminate on expiration of the [*] notice period.

12.5 Effect of Termination

12.5.1 Upon termination of this Agreement for any reason, Customer shall pay to AGC:

(a) payments due by Customer to AGC for Services performed up to and including the day of termination for all completed Stages and for partially completed Stages an amount calculated on a pro-rata basis taking into account the Price for the cancelled Stages (fairly determined by the Project Team taking into account FTE hours, materials, profit element and irreversible commitments incurred by AGC);

(b) payments due pursuant to Section 5.2; and

(c) payments due at the time of termination pursuant to Section 7 and also in accordance with the payment terms in the Work Statement.

12.5.2 Upon termination of this Agreement for any reason, provided that Customer has paid all amounts outstanding, AGC will, within thirty (30) Business Days of (a) those payments having been made or (b) the date of termination of this Agreement (whichever is the later) provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured and released, subject to Regulatory Obligations at Customer's sole risk.

12.6 Survival. Termination will not affect the accrued rights of AGC or Customer arising under this Agreement before the effective date of termination. The provisions of this Agreement which by their terms or nature would continue beyond any termination or expiration of this Agreement, including Sections 8, 9, 10, 11, 12.5, 12.6, 13 and 15 will survive any termination or expiration of this Agreement to the degree necessary in accordance with their terms.

13. TECHNOLOGY TRANSFER

13.1 Scope. Upon termination or during the notice period for termination of this Agreement other than where Customer is the Defaulting Party, Customer may seek assistance from AGC for the transfer to a third party qualified manufacturer [*] (**"Technology Transfer"**); provided that AGC is not obligated to transfer any [*] unless and until the parties enter into a separate license agreement for such technology. Following AGC's receipt of that request, the parties will use diligent efforts to establish [*] a plan for effecting the transfer and AGC will cooperate with Customer in starting the implementation of that plan within [*]. As part of the Technology Transfer AGC will make available for collection, subject to any Regulatory Obligations and rights of third parties and Section 12.5.2, all Customer Materials, Cell Line (only for biologics Services) and one copy of all documentation (to the extent not previously delivered to Customer) generated pursuant to the Services (exclusive of AGC's SOPs) up to the date of termination.

13.2 Limits. The obligations of AGC under Section 13.1 will only be exercisable by Customer within a period [*] after the date of termination and AGC is not obliged to commit any human resources greater than [*]. Customer must pay AGC's costs of cooperating with and providing the Technology Transfer [*] set forth in a Work Statement and [*]. Customer will not, and AGC will not be obliged to, transfer any AGC Intellectual Property Rights pursuant to this Technology Transfer until the contract manufacturer to whom the Process is transferred enters into a limited royalty-free license and confidentiality agreement acceptable to and with AGC in order to protect AGC's Confidential Information, AGC Intellectual Property Rights.

14. LIMITATIONS OF LIABILITY

14.1 Limitation of Liability.

14.1.1 AGC's aggregate liability to Customer for any loss or damage suffered by Customer as a result of breach of this Agreement or any other liability (including negligence, misrepresentation or Claims under the indemnities) under this Agreement or in connection with the Services is limited, in the aggregate, to [*] of (a) the total Price of the Services actually paid to AGC [*] preceding the occurrence of the event giving rise to the claim, and (b) [*].

14.1.2 Notwithstanding Section 14.1.1, AGC's aggregate liability under Section 11.2.3 of for violation of Section 9 is limited to the amount of euro [*].

14.2 Disclaimer of Certain Damages. EXCEPT AS PROVIDED IN SECTION 14.3, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL (INCLUDING LOST PROFITS) OR SPECIAL DAMAGES ARISING OUT OF ITS BREACH OF THIS AGREEMENT OR ANY OTHER LIABILITY (INCLUDING NEGLIGENCE, MISREPRESENTATION OR CLAIMS UNDER THE INDEMNITIES) ARISING IN CONNECTION WITH THIS AGREEMENT, EVEN IF THOSE DAMAGES WERE FORESEEABLE AND WHETHER THOSE DAMAGES ARISE IN TORT, IN CONTRACT OR OTHERWISE.

14.3 Exclusions. The limitations in Sections 14.1 and 14.2 do not apply to (a) claims arising from either party's gross negligence or wilful misconduct; (b) liability for any fraud or fraudulent misrepresentation; (c) amounts owing by a party under Section 7; or (d) claims indemnified by Customer under Section 11.1.

15. MISCELLANEOUS

15.1 Excused Performance. AGC will not be liable to Customer nor be considered to have breached this Agreement for failure or delay in performing to the extent, and for so long as, the failure or delay is caused by or results from causes beyond the reasonable control of AGC. AGC must notify Customer of any force majeure event that prevents AGC from performing the Services. If a force majeure event continues for more than [*] after AGC's notice, and is adversely affecting the performance of this Agreement, each party will have the right terminate this Agreement on thirty (30) days' notice. In that event, Customer will not have a right to reimbursement for any amounts paid under this Agreement or any claim for damages as a result of the termination or non-performance of the Services.

15.2 Insurance. During the Term, AGC must maintain a comprehensive general liability insurance against claims for bodily injury or property damage arising from AGC's activities in performing the Services, with insurance companies and in amounts as AGC customarily maintains for similar activities. Customer must during the Term and for the longer of (a) ten (10) years after the termination of this Agreement and (b) ten (10) years after the last use of the Product maintain comprehensive general liability insurance and product liability insurance (including clinical trials coverage) covering all liability and claims arising or that may arise from the use, supply, licensing or distribution of the Product with insurance companies and in amounts as customarily maintained.

15.3 Press Release. The parties may issue a joint press release to announce the collaboration under this Agreement only upon mutual written agreement.

15.4 Amendment. Other than as provided for elsewhere in this Agreement, any amendment of this Agreement (or any document entered into pursuant to this Agreement) will be valid only if it is in writing and signed by each party.

15.5 Assignment. Except as provided in this Section 15.5, Customer may not without the prior written consent of AGC (that consent not to be unreasonably withheld) assign this Agreement or any rights under this Agreement or subcontract any or all of its obligations under this Agreement. Any purported assignment in breach of this Section 15.5 is void and confers no rights on the purported assignee. Customer may on giving written notice to AGC assign its rights under this Agreement to an Affiliate of Customer provided that Customer must procure that the assignee must assign those rights to another Affiliate on ceasing to be an Affiliate of Customer. Notwithstanding the above, no consent shall be required for Customer to assign this Agreement in connection with any merger, acquisition or other change of control transaction involving Customer or sale by Customer of substantially all of the assets to which this Agreement relates; provided, that Customer notifies AGC of such transaction within five (5) Business Days after the earlier of the public announcement or closing of such transaction.

15.6 Subcontracting. AGC may subcontract to (a) its Affiliates, any of the Services provided that the Affiliate may not further subcontract those Services; (b) Testing Laboratories, only those parts of the Services identified in the Work Statement; and (c) any other third party, any of the Services with the prior written consent of Customer (that consent not to be unreasonably withheld, delayed or conditioned). AGC will remain responsible for the activities of its subcontractors except to the extent that Customer requires AGC to use a subcontractor that Customer selects over AGC's objection.

15.7 Waiver. In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this Agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.

15.8 Severability. If any provision of this Agreement is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, that invalidity or unenforceability will not affect the other provisions of this Agreement which shall remain in full force and effect. The parties must, in the circumstances referred to in this Section 15.8, attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision that achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.

15.9 Notices. Any notice or other communication given under this Agreement (including under Section 3.4 or 6.6) must be in writing and in English and signed by or on behalf of the party giving it and must be given by hand or by delivering it or sending it by prepaid post or overnight delivery service, to the address and for the attention of the relevant party set out on the Cover Page (or as otherwise notified by that party under this Section 15.9), with a copy to follow via email. Any notice will be deemed to have been received:

15.9.1 if hand delivered or sent by prepaid overnight delivery service, at the time of delivery; or

15.9.2 if sent by post with receipt confirmation, at the time of receipt indicated in the receipt confirmation.

15.9.3 if sent by e-mail with receipt of confirmation that such transmission has been received, within five (5) days from the receipt of

confirmation.

15.10 Governing Law. This Agreement will be interpreted and governed, and all rights and obligations of the parties determined, in accordance with the laws of the jurisdiction specified on the Cover Page (regardless of choice of law provisions to the contrary). The parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.

15.11 Dispute Resolution. Before resorting to litigation, unless emergency relief is required by either party when either party will be free to resort to litigation, the parties must use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate to this Agreement (or its construction, validity or termination) (a **"Dispute"**). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the parties, either party may give to the other a notice in writing (a **"Dispute Notice"**). Within seven (7) days of the Dispute Notice being given the parties must each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within thirty (30) days of the Dispute Notice (a) the Dispute is not settled by agreement in writing between the parties or (b) the parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled by the courts located in the jurisdiction specified on the Cover Page.

15.12 Relationship of the Parties. Nothing in this Agreement operates to create a partnership or joint venture between the parties or authorizes either party to act as agent for the other. Neither party has authority to act in the name of or otherwise to bind the other in any way.

15.13 Entire Agreement. This Agreement, and the documents referred to in it, constitutes the entire agreement and understanding of the parties and supersedes any previous agreement between the parties relating to the subject matter of this Agreement.

15.14 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one instrument. Signature of this Agreement, unless otherwise stipulated herein, may be by electronic means using digital signature technology (such as DocuSign) and will have the same validity and effect as a hand-written signature. Signed counterparts may be delivered by mail, facsimile or electronically in Portable Document Format (.pdf), each of which shall be binding when sent.

15.15 Privacy. In order to fulfil their obligations pursuant to this Agreement and, in particular, to (i) carry out any activity provided by law or regulations, (ii) handle bookkeeping, orders, invoicing and any disputes and (iii) store documents as required by applicable law, the parties confirm the receipt of adequate privacy notice with reference to their respective employees' personal data treatment, if any. The Customer declares it has acknowledged AGC's relevant privacy notice on AGC's website (www.agcbio.com). In the event that for the execution of this Agreement a party needs to process additional personal data of which the other party is the data controller, the parties hereby agree that said treatment can be done only after adequate appointment of such party by the data controller.

15.16 Code of Conduct. The Customer acknowledges that AGC has adopted a Code of Conduct available on AGC's website (www.agcbio.com). By signing this Agreement, the Customer declares it (i) has read the Code of Conduct; (ii) has understood the principles contained therein, and (iii) agrees to comply with the obligations and principles contained therein. The Customer hereby agrees to promptly notify AGC if, during the term of this Agreement, it becomes aware of any act or omission conflicting with, or any breach of the principles expressed in the Code of Conduct.

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SCHEDULE 1A

TERMS APPLICABLE TO MANUFACTURING SERVICES

VIRAL VECTOR PRODUCTION

1. MANUFACTURING TERMS & CONDITIONS

1.1 These manufacturing terms and conditions shall apply only to those manufacturing Services set forth under the Work Statement or PCO.

1.2 Capitalized terms used in this Schedule 1A, shall have the meaning defined for such capitalized term in the Cover Page and Appendix I.

2. SCOPE

2.1 This Schedule 1A sets out the terms and conditions under which, during the Term, and subject to the payment of the Price AGC shall manufacture and supply to Customer those non-commercial Product as forecasted and ordered from time to time in accordance with this Schedule. For the purpose of this Section 4.3 "Non-Commercial Product" means any Product manufactured by AGC which is intended for clinical use.

3. MANUFACTURING SERVICES

3.1 AGC's obligation to manufacture Products for Customer pursuant to this Schedule 1A shall cover non-commercial Product.

3.2 AGC will periodically keep Customer informed regarding the progress of the manufacturing Services in accordance with the Timelines agreed in writing by the parties.

3.3 AGC will perform the Services in accordance with (i) all applicable laws, including cGMP; and (ii) the provisions of the Quality Agreement.

4. ORDERS AND FORECASTS

4.1 Customer shall no later than [*], provide AGC with (or with access to) a rolling manufacturing forecast of volume requirements for viral vectors for the [*], or such shorter period as may then remain under the Term (the "**Forecast**"). The Forecast shall show estimates and desired delivery timings of required viral vectors for each month during the [*] period covered by the Forecast based on Customer's assumptions as to likely requirements for Batches of viral vectors. In preparing a Forecast Customer shall use its best efforts to provide a Forecast that accurately reflects its genuine and anticipated requirements for the period covered by the Forecast.

4.2 As soon as reasonably practicable following receipt of each Forecast and in any event within [*] from the receipt of the Forecast, AGC will provide Customer with the Forecast stating the Slot potentially allocated to Customer on the basis of the availability at the Facility. The reservation of the Slots potentilly allocated by AGC shall be finalised by the Parties within [*] by signing a Work Statement (or a PCO as the case may be).

4.3 Once signed the Purchase Order (or a PCO as the case may be), the Slots shall be definitely booked for Customer in the terms defined in the confirmed reservation, and if scheduled for manufacture in AGC's cGMP facility subject to Cancellation Fees as set forth in Section 5.2 of the general terms and conditions of the Agreement.

5. TESTING BY AGC

5.1 The Product manufactured under this Agreement will be manufactured in accordance with the Process, cGMP and the Specification (if expressly stated in the applicable Work Statement). Each Batch of Product will be sampled and tested by AGC against the Specifications (if applicable), and the quality assurance department of AGC will review the documentation relating to the manufacture of the Batch and will assess if the manufacture has taken place in compliance with cGMP and the Specification (if applicable) and the Process.

5.2 Upon commencement of the manufacturing of a Product, Customer will have the option to request AGC to prioritize the testing of a Product over the other products in order to reduce the standard timeline for testing ("**Fast Testing**"). If the request has been accepted by AGC, the Customer shall pay Fast Testing fee set forth under the Work Statement.

6. DELIVERABLE AND DOCUMENTATION

6.1 AGC shall (i) retain complete, accurate and authentic documents and records for each Product as required by cGMP and (ii) provide the Customer with the Deliverable listed in the Work Statement. For Product manufactured using LVV Platform Technology or AAV manufacturing processes and relevant QC testing belonging to the AGC Platform Technology AGC will supply Customer with (a) a Certificate of Analysis for such Batch; (b) a summary report regarding the manufacture of such Batch in AGC's standard form but in no event the Documentary Deliverable will include [*].

6.2 During audit, Customer will have access to any other documentation relating to the manufacture of the Product that is reasonably necessary to exercise Customer's auditing rights in accordance with the Quality Agreement. For avoidance of doubt, such documentation will be produced in the language it is maintained in at the AGC facility.

6.3 The Work Statement will specify the governing language of each Documentary Deliverable (Italian or English). Any further language translations shall be managed by Customer at its cost.

7. QUALIFIED PERSONS

7.1 AGC shall at all times employ a Qualified Person who shall be responsible, in accordance with applicable law, for confirming by his/her signature on the appropriate certificate that each Batch of Product conforms with the requirements of the Product Specification File and is manufactured in accordance with cGMP and applicable law (included but not limited to Legal Decree 219/2006).

8. QC SAMPLE

8.1 Within 30 days after the issuance of the Certificate of Analysis, Customer shall notify AGC whether it wants AGC to (i) make available for collection the QC sample to Customer or a third party storage facility or (ii) to dispose of the QC Sample, in each case, at Customer's expense. If Customer fails to give the notice required by this Section 8.1 within 30 days after the completion of the relevant Services, AGC may, without notifying Customer dispose of them or return them to the Customer in each case at Customer's expense, in its sole discretion and without liability to Customer.

9. REGULATORY COMPLIANCE

9.1 Without prejudice to AGC's obligation to maintain the regulatory and cGMP licences for its Facility, Customer shall otherwise have sole responsibility for all interactions with the relevant regulatory authorities, and shall be solely responsible for filing all regulatory documents required by such regulatory authorities, which in each case are specific to or required for the use or approval of the Product.

9.2 Prior to the submission in any communication or regulatory filing with a regulatory authority concerning the Product, the Services or the chemistry, manufacturing and controls (CMC) section of a regulatory application which discloses any information concerning the Facility or derived from the Services, Customer must first obtain AGC's consent for the inclusion of such information (such consent not to be unreasonably withheld). If AGC withholds its consent then AGC will provide reasons, and the parties will co-operate and work together to modify the communication or filing such that it is reasonably acceptable to AGC and accurately reflects data generated in the Services or concerning the Facility.

9.3 AGC shall use commercially reasonable efforts to respond promptly to those regulatory questions reasonably raised by Customer or by a regulatory authority concerning the Services undertaken by AGC under this Agreement.

9.4 Customer shall be entitled on a confidential basis to disclose AGC Confidential Information or AGC Know-How contained in a regulatory dossiers concerning a Product manufactured under this Agreement to any regulatory or governmental authority provided that it exercises commercially reasonable endeavours to seek the confidential treatment by the regulatory or governmental authority of such information or AGC Know-How.

9.5 Notwithstanding the foregoing, if Customer seeks AGC to provide any regulatory support services related to obtaining or maintaining regulatory approval for the Product manufactured hereunder, then such services shall be i) be limited to the provision by AGC of technical information and reports necessary for preparation of the regulatory dossier and ii) review of the regulatory section of the Customer's submission, all as set forth in a Work Statement.

APPENDIX I

Definitions

"**Affiliate**" means, with respect to any entity, any other entity that directly or indirectly controls, is controlled by or is under common control with that entity. For this definition, "control" means that more than 50% of the controlled entity's shares or ownership interests representing the right to make decisions for that entity are owned or controlled, directly or indirectly, by the controlling entity.

"**AGC Facility**" means AGC's then current facility at Milan and Bresso, Italy or any of AGC's or its Affiliates' facilities as specified in writing in a Work Statement.

"**AGC Intellectual Property Rights**" means Intellectual Property rights and AGC Know-How in (i) the applicable AGC Platform Technology which are owned or Controlled by AGC, and which are used in the Services; and (ii) the AGC New IPR.

"**AGC Know-How**" means all information, techniques and technical information known to AGC or developed pursuant to the Services that, in each case, are not of general public knowledge.

"**AGC Platform Technology**" means, as applicable, (i) AGC's Pre-Existing IPR (excluding that in the LVV Platform Technology and AAV manufacturing and relevant QC testing); (ii) LVV Platform Technology (where it is identified in the Work Statement as being used in, or for, the Services); (iii) AGC DP Technology; (iv) AAV manufacturing and relevant QC testing (where it is identified in the Work Statement as being used in, or for, the Services) and (v) the New IPR owned and Controlled by AGC from time to time pursuant to this Agreement.

"AGC DP Technology" means, as applicable,(i) analytical methods and know-how owned or Controlled by AGC and its Affiliates, including that applied for QC testing of Drug Product; (ii) process for manufacturing of genetically modified CD34+ stem cells; and (iii) any New IPR that is owned and Controlled by AGC and which is an improvement to (i) and (ii).

"**Approved Subcontractor**" means any subcontractor used by AGC for any part of the Services who is (i) selected by Customer, or otherwise directed or mandated by the Customer to be used for the Services and/or (ii) is the only viable subcontractor available at the time to provide such part of the Services where neither Party has been able to identify a viable alternative to perform such part of the Services, provided that each such subcontractor may only be engaged upon good faith consultation with Customer. The following entities shall be deemed Approved Subcontractors: Bioreliance Corp, Eurofins Biolab Srl.

"**Batch**" means a quantity of Product resulting from a single batch run as described in the Work Statement.

"**Business Day**" means any day that is not a Saturday, Sunday or a public holiday in the country where the Services are performed.

"Calendar Quarter" means a three (3) month period beginning on January 1, April 1, July 1, or October 1 of each year.

"Campaign" means a series of Batches manufactured consecutively in accordance with the Process.

"**Cell Line**" means the cell line described in the Work Statement provided by Customer or to be developed by AGC using Customer Materials as part of the Services, and any modified strains of that cell line constructed in accordance with the Services and any progeny clone of those cell lines.

"**Certificate of Analysis**" means AGC's standard form certificate of analysis confirming that Product to which the certificate relates meets the Specification and any other criteria identified on the certificate.

"**cGMP**" means (a) if the manufacturing site is within the European Union, the standards, rules, principles and guidelines set out in Directive EU 2017/1572 together with the guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human use contained in Volume 4 of "The Rules Governing Medicinal Products in the European Union"; (b) if the Manufacturing Site is in the United States of America the Current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 et seq.) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; and (c) the ICH guide Q7a "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" as applied to investigational drugs (Section 19).

"**cGMP Batch**" means a Batch that is stipulated in the Work Statement to be manufactured according to cGMP.

"**cGMP Product**" means Product manufactured under a cGMP Batch.

"**Commencement Date**" means, for vector with respect to a cGMP Batch the date on which a vial of cells is thawed for the cell culture for manufacture of the Product.

"**Confidential Information**" means information of a confidential nature and in any form (oral, written or otherwise) the use of which is governed according to the provisions of Section 9.

"**Controlled**" means, in the context of Intellectual Property rights and know-how, that such rights may be licensed or sub-licensed by the applicable party to the other party on the terms of the licenses set out herein without (i) breaching an obligation owed to a third party; or (ii) triggering any payment or other financial obligation of the licensing party purely by virtue of the grant of such license or sub-license.

"**Customer Intellectual Property Rights**" means Intellectual Property rights and Customer Know-How owned or Controlled by Customer covering any aspect of the Services and/or Product, and/or any materials, techniques or processes provided by or on behalf of the Customer to AGC for the performance of Services.

"**Customer Know-How**" means all information, techniques and technical information known to Customer in connection with the Product, Cell Line, Customer Materials or Process which is not known to AGC or of general public knowledge.

"**Customer Materials**" means the Cell Line, vectors, plasmids, human biological sample and all other materials (i) supplied by Customer, its Affiliate or agent to AGC, (ii) made available to AGC by Customer or (iii) procured by AGC on behalf of the Customer (in accordance with Section 3.2), including, without limitation, those described in the Work Statement.

"**Deliverables**" means on a Work Statement by Work Statement basis, the Documentary Deliverables and the Physical Deliverables applicable to the Services under such Work Statement.

"**Documentary Deliverables**" means the documentary deliverables to be provided by AGC to Customer pursuant to the applicable Services, as identified in the applicable Work Statement.

"**Drug Substance**" for biologics product means the biological or chemical entities described or classified in the Work Statement expressed by the Cell Line and harvested in bulk from a fermentation run pursuant to the applicable Process.

"**Intellectual Property**" means all intellectual property rights, including patent rights, supplementary protection certificates, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions.

"**LVV Platform Technology**" means (i) the lentiviral vector manufacturing process and know-how for use in cell factories (48L scale), packed bed bioreactors and/or bioreactors for cultivation in suspension, as owned or Controlled by AGC and its Affiliates as of the Effective Date; (ii) the packaging plasmids owned or Controlled by AGC or its Affiliates as of the Effective Date; and (iii) analytical methods and know-how owned or Controlled by AGC and its Affiliates, including that applied for QC testing of lentiviral vectors; (iv) any New IPR that is owned and Controlled by AGC and which is an improvement to (i), (ii) or (iii); and (v) all Intellectual Property rights in each of (i), (ii), (iii) and (iv).

"**Non-Fault Delay**" means [*]; or [*].

"**Objective**" means the desired outcome of the Services as described in the Work Statement.

"**Permitted Recipients**" means the directors, officers, employees, Testing Laboratories, Approved Subcontractors or professional advisers who are required, on a need-to-know basis, in the course of their duties to receive and consider the Confidential Information for the purpose of enabling the relevant party to perform its obligations under this Agreement; provided, that those persons are under obligations of confidence no less onerous than those set out in Section 9 imposed on the Recipient Party.

"**Physical Deliverables**" means the Product, Cell Line, physical samples and/or other physical materials to be provided by AGC to Customer pursuant to the applicable Services, each as identified in the applicable Work Statement.

"**Price**" means the price for the Services (or any part or Stage of the Services as context requires) as defined in the Work Statement and itemized on a Stage by Stage basis.

"**Process**" means the method for manufacture, harvesting, testing purification of the Product.

"**Product**" means the viral vector described in the Work Statement manufactured pursuant to the applicable Process and/or the drug product described in the Work Statement manufactured pursuant to the applicable Process.

"**Product Specification File**" means the document containing relevant information regarding production, testing and release of a Batch of Product (such as manufacturing flow chart, in process control and release tests and Specifications, critical raw materials and equipment, product packaging and labels, and shelf life).

"**Qualified Person**" means the person named in the Quality Agreement (or such replacement person as may be notified by AGC to Customer in writing from time to time) who is nominated by AGC and is suitably qualified to enable AGC to perform and discharge its quality management obligations required by GMP or other applicable law, including, without limitation, EC Directive 2001/83/EC (Articles 48 and 49).

"**Quality Agreement**" means the agreement between the parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services, to be entered into within sixty (60) days following execution of this Agreement.

"**QC Sample**" means the quality control sample, other than regulatory samples which AGC shall retain pursuant to Section 6.7 of the General Terms and Conditions, used to perform the testing of a GMP Product.

"**Regulatory Obligations**" means those mandatory regulatory requirements applicable in Europe and the U.S. (as applicable) to the manufacture of cGMP Product for human use.

"**Services**" means any or all parts of the development and/or manufacturing services to be conducted by AGC as exhaustively described in the relevant Work Statement.

"**Shipping Guidelines**" means the storage and transport guidelines for the Product that are determined by mutual written agreement of the parties.

"**Slot**" means, with respect to AGC's cGMP manufacturing suite, the period of time the suite is reserved in preparation for and the performance of a Batch.

"**Specification**" means the specification of the Product either as defined in the Work Statement or modified in accordance with Section 4.3.2.

"**Stage**" means a particular activity or series of conjoined activities that constitute a main step in the Services and that is more specifically identified in the Work Statement by the breakdown of the Services into numbered stages.

"**Standard Operating Procedures**" or "**SOPs**" means the standard operating procedures of AGC in place from time to time that define AGC's methods of performing activities applicable to the Services.

"**Testing Laboratories**" means any third party instructed by AGC, excluding an Approved Subcontractor, to carry out tests on the Cell Line, Customer Materials, Drug Substance or Product pursuant to the performance of the Services.

"**Timeline**" means the estimated timeline for performance of the Services as initially set out in the Work Statement and as may be amended from time to time by the Parties written agreement or otherwise in accordance with this Agreement.

"**Work Statement**" means, as applicable, a written work statement signed by each of the Parties which references that it is governed by the Agreement established under the Cover Page and Terms and Conditions, which may be revised by the mutual written agreement of each of the Parties from time to time.

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APPENDIX II

Work Statement

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