As confidentially submitted to the Securities and Exchange Commission on July 10, 2020 as Amendment No. 4 to the draft registration statement submitted on May 6, 2020. This Amendment No. 4 to the draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Freeline Therapeutics Holdings Limited[1]

(Exact name of Registrant as specified in its charter)

England and Wales	**2836**	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

Stevenage Bioscience Catalyst
Gunnels Wood Road
Stevenage, Hertfordshire SG1 2FX
United Kingdom
+44 (0)1438 906870
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Freeline Therapeutics Inc.
c/o Corporation Service Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19808
(302) 636-5401
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Richard D. Truesdell, Jr., Esq.	**Mitchell S. Bloom, Esq.**
Marcel R. Fausten, Esq.	**Edwin M. O'Connor, Esq.**
Davis Polk & Wardwell LLP	**Goodwin Procter LLP**
450 Lexington Avenue	**100 Northern Avenue**
New York, NY 10017	**Boston, MA 02210**
(212) 450-4000	**(617) 570-1000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

1 We intend to alter the legal status of our company under English law from a private limited company by re-registering as a public limited company and changing our name from Freeline Therapeutics Holdings Limited to Freeline Therapeutics Holdings plc prior to the completion of this offering. See the section titled "Corporate Reorganization" in the prospectus which forms a part of this registration statement. The term Freeline Therapeutics Holdings plc in the prospectus which forms a part of this registration statement refers to Freeline Therapeutics Holdings Limited.

Explanatory Note

The sole purpose of this Amendment No. 4 to the Draft Registration Statement on Form F-1 of Freeline Therapeutics Holdings Limited (the "Company") is to file exhibit 10.12 and to re-file exhibits 10.8 and 10.11, which were originally filed with the Securities and Exchange Commission on June 29, 2020. Accordingly, this Amendment No. 4 consists only of the facing page, this explanatory note, Part II, including the signature page and the exhibit index, and the exhibits filed herewith. This Amendment No. 4 does not contain a copy of the prospectus that was included in Amendment No. 3 to the Company's Draft Registration Statement on Form F-1 confidentially submitted to the U.S. Securities and Exchange Commission on July 6, 2020, and is not intended to amend or delete any part of the prospectus.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 6. Indemnification of Directors and Officers

Subject to the Companies Act 2006, members of the registrant's board of directors and its officers (excluding auditors) have the benefit of the following indemnification provisions in the registrant's articles of association:

Current and former members of the registrant's board of directors or officers shall be reimbursed for:

(i) all costs, charges, losses, expenses and liabilities sustained or incurred in relation to his or her actual or purported execution of his or her duties in relation to the registrant, including any liability incurred in defending any criminal or civil proceedings; and

(ii) expenses incurred or to be incurred in defending any criminal or civil proceedings, in an investigation by a regulatory authority or against a proposed action to be taken by a regulatory authority, or in connection with any application for relief under the statutes of the United Kingdom and any other statutes that concern and affect the registrant as a company, or collectively the Statutes, arising in relation to the registrant or an associated company, by virtue of the actual or purposed execution of the duties of his or her office or the exercise of his or her powers.

In the case of current or former members of the registrant's board of directors, there shall be no entitlement to reimbursement as referred to above for (i) any liability incurred to the registrant or any associated company, (ii) the payment of a fine imposed in any criminal proceeding or a penalty imposed by a regulatory authority for non-compliance with any requirement of a regulatory nature, (iii) the defense of any criminal proceeding if the member of the registrant's board of directors is convicted, (iv) the defense of any civil proceeding brought by the registrant or an associated company in which judgment is given against the director, and (v) any application for relief under the Statutes in which the court refuses to grant relief to the director.

In addition, members of the registrant's board of directors and its officers who have received payment from the registrant under these indemnification provisions must repay the amount they received in accordance with the Statutes or in any other circumstances that the registrant may prescribe or where the registrant has reserved the right to require repayment.

The underwriting agreement the registrant will enter into in connection with the offering of ordinary shares being registered hereby provides that the underwriters will indemnify, under certain conditions, the registrant's board of directors and its officers against certain liabilities arising in connection with this offering.

Item 7. Recent Sales of Unregistered Securities

Issuances of Share Capital

The following list sets forth information regarding all unregistered securities sold by us or Freeline Therapeutics Limited since April 1, 2017, through the date of the prospectus that forms a part of this registration statement. In April 2020, Freeline Therapeutics Holdings Limited was incorporated in England and Wales with nominal assets and liabilities for the purpose of consummating a corporate reorganization by which it acquired the outstanding share capital of Freeline Therapeutics Limited. Following the share exchange by which the outstanding shares of Freeline Therapeutics Limited will be exchanged for the same number and class of newly issued ordinary shares of Freeline Therapeutics Holdings Limited, our ordinary shares will be redenominated as ordinary shares with a nominal value of £ per share. All share and per share information presented in this "Issuances of Share Capital" section do not reflect the -to- conversion that will occur as part of our corporate reorganization.

Set forth below is information regarding all securities issued by Freeline Therapeutics Limited without registration under the Securities Act since April 1, 2017.

On July 25, 2017, Freeline Therapeutics Limited issued 13,000,000 series A preferred shares to Syncona Portfolio Limited for aggregate consideration of £13,000,000.

On August 8, 2017, Freeline Therapeutics Limited issued 520,000 series A preferred shares to UTF General Partner LLP for aggregate consideration of £520,000.

On August 22, 2017, Freeline Therapeutics Limited issued 11,000,000 series A preferred shares to Syncona Portfolio Limited for aggregate consideration of £11,000,000.

On May 9, 2018, Freeline Therapeutics Limited issued 100,000 series A preferred shares to UTF General Partner LLP for aggregate consideration of £100,000.

On May 10, 2018, Freeline Therapeutics Limited issued 2,500,000 series A preferred shares to Syncona Portfolio Limited for aggregate consideration of £2,500,000.

On June 18, 2018, Freeline Therapeutics Limited issued:

- 20,000,000 series B preferred shares to Syncona Portfolio Limited for aggregate consideration of £30,000,000.
- 800,034 series B preferred shares to UTF General Partner LLP for aggregate consideration of £1,200,051.

On March 4, 2019, Freeline Therapeutics Limited issued:

- 20,000,000 series B preferred shares to Syncona Portfolio Limited for aggregate consideration of £30,000,000.
- 800,033 series B preferred shares to UTF General Partner LLP for aggregate consideration of £1,200,050.

On June 21, 2019, Freeline Therapeutics Limited issued:

- 16,666,667 series B preferred shares to Syncona Portfolio Limited for aggregate consideration of £25,000,000.
- 666,599 series B preferred shares to UTF General Partner LLP for aggregate consideration of £999,899.

On December 19, 2019, Freeline Therapeutics Limited issued 12,307,692 series C preferred shares to Syncona Portfolio Limited for aggregate consideration of $39,999,999.

On March 12, 2020, Freeline Therapeutics Limited issued 721,120 A ordinary shares to Rentschler Biotechnologie Beteiligungs GmbH upon an exercise of 721,120 warrants at a strike price of £0.01 per share, resulting in aggregate proceeds of £7,211.20 to us.

On March 26, 2020, Freeline Therapeutics Limited issued;

- 230,249 series A preferred shares to Rentschler Biotechnologie Beteiligungs GmbH for aggregate consideration of £230,249.
- 448,631 series B preferred shares to Rentschler Biotechnologie Beteiligungs GmbH for aggregate consideration of £672,947.

On June 29, 2020, Freeline Therapeutics Holdings Limited issued:

- 7,300,151 series C preferred shares to Syncona Portfolio Limited for aggregate consideration of £73.

- 10,661,764 series C preferred shares to Novo Holdings A/S for aggregate consideration of $21,750,000.
- 7,720,588 series C preferred shares to Eventide Healthcare & Life Sciences Fund for aggregate consideration of $15,750,000.
- 7,352,941 series C preferred shares to Wellington Biomedical Innovation Master Investors (Cayman) I L.P. for aggregate consideration of $15,000,000.
- 5,960,486 series C preferred shares to Cowen Healthcare Investments III LP for aggregate consideration of $12,159,392.
- 166,964 series C preferred shares to CHI EF III LP for aggregate consideration of $340,608.
- 4,901,960 series C preferred shares to Acorn Bioventures, L.P. for aggregate consideration of $10,000,000.
- 2,450,980 series C preferred shares to Ample Plus Fund Limited Partnership for aggregate consideration of $5,000,000.

Share Grants

Since April 1, 2017 through the date of the prospectus that forms a part of this registration statement, we and Freeline Therapeutics Limited have granted shares to employees, directors, consultants and service providers covering an aggregate of 12,047,440 ordinary shares with a nominal value of £0.00001 per share.

We believe that each of such issuances was exempt from registration under the Securities Act in reliance on (i) Section 4(a)(2) of the Securities Act or Rule 506 promulgated thereunder as transactions by an issuer not involving a public offering, (ii) under Rule 701 promulgated under the Securities Act in that transactions were under compensatory benefit plans and contracts relating to compensation or (iii) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was either an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act or was our employee, director or consultant and received the securities under our equity incentive plans. None of these transactions involved any underwriters, underwriting discounts or commissions or any public offering. All recipients had adequate access, through their relationships with us to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 8. Exhibits

(a) The following documents are filed as part of this registration statement:

1.1	Form of Underwriting Agreement.*
3.1	Form of Articles of Association of Freeline Therapeutics Holdings plc.*
4.1	Form of Deposit Agreement.*
4.2	Form of American Depositary Receipt (included in Exhibit 4.1).*
5.1	Form of opinion of Davis Polk & Wardwell London LLP.*
10.1	License Agreement, dated as of May 22, 2015, by and between Freeline Therapeutics Limited and UCL Business plc.**#
10.2	Deed of Variation, dated as of January 24, 2017, to License Agreement, dated as of May 22, 2015, by and between Freeline Therapeutics Limited and UCL Business plc.**#

10.3	Second Deed of Amendment, dated as of May 24, 2018, to the License Agreement, dated as of May 22, 2015, by and between Freeline Therapeutics Limited and UCL Business plc.**#
10.4	Collaboration Agreement, dated as of April 10, 2018, by and between Freeline Therapeutics Limited and Cell Therapy Catapult Limited.**#
10.5	Third Deed of Amendment and Termination, dated as of December 18, 2019, by and between Freeline Therapeutics Limited and UCL Business Ltd.**#
10.6	Service Agreement, dated as of May 14, 2018, by and between Freeline Therapeutics Limited and Aldevron, LLC.**#
10.7	Biopharma Services Agreement, dated as of June 5, 2016, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group).**#
10.8	Services Agreement, dated as of October 11, 2016, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group).#
10.9	Amendment No. 2, dated as of September 7, 2018, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group), to Services Agreement, dated as of October 11, 2016.**#
10.10	Amendment No. 3, dated as of April 9, 2020, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group), to Services Agreement, dated as of October 11, 2016.**#
10.11	Development and Manufacturing Services Agreement, dated as of October 6, 2017, by and between Freeline Therapeutics Limited and Brammer Bio MA, LLC.#
10.12	Dedicated Manufacturing and Commercial Supply Agreement, dated as of June 30, 2020, by and between Freeline Therapeutics Limited and Brammer Bio MA, LLC. #
10.13	License Agreement, dated as of March 24, 2017, by and between Freeline Therapeutics Limited and St. Jude Children's Research Hospital.**#
10.14	Amendment, dated as of February 28, 2020, to License Agreement, dated as of March 25, 2017, by and between Freeline Therapeutics Limited and St. Jude Children's Research Hospital.**#
10.15	Freeline Therapeutic Holdings Limited 2020 Option Plan.*+
10.16	Form of Freeline Therapeutics Holdings plc 2020 Omnibus Incentive Plan.*+
10.17	Form of Deed of Indemnity between the registrant and each of its members of senior management and directors.*
10.18	Form of Registration Rights Agreement between the registrant and the shareholders listed therein.*
21.1	List of subsidiaries.*
23.1	Consent of Deloitte LLP.*
23.2	Consent of Davis Polk & Wardwell London LLP (included in Exhibit 5.1).*
24.1	Powers of attorney (included on signature page to the registration statement).*

* To be filed by amendment.
** Previously filed.
\+ Indicates management contract or compensatory plan.
\# Portions of this exhibit (indicated by asterisks) have been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the registrant it disclosed.

(b) Financial Statement Schedules

None.

Item 9. Undertakings

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York on , 2020.

Freeline Therapeutics Holdings Limited

By: _____
Name: Theresa Heggie
Title: Chief Executive Officer

By: _____
Name: Brian Silver
Title: Chief Financial Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Theresa Heggie and Brian Silver and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on , 2020 in the capacities indicated:

Name	Title
Theresa Heggie	Chief Executive Officer and Director (principal executive officer)
Brian Silver	Chief Financial Officer (principal financial officer and principal accounting officer)
Chris Hollowood, Ph.D.	Chairman of the Board of Directors
Amit Nathwani, M.D.	Director
Martin Andrews	Director
Jeffrey Chodakewitz, M.D.	Director
Julia P. Gregory	Director

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Freeline Therapeutics Holdings Limited has signed this registration statement on , 2020.

FREELINE THERAPEUTICS, INC.

By: _____

Name: Brian Silver
Title: Chief Financial Officer

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Exhibit 10.8

Services Agreement

This services agreement, hereafter referred to as the **"Agreement"**, is entered into on 11th OCT. 2016 (the **"Effective Date"**) by and between

FREELINE THERAPEUTICS LIMITED, a company incorporated in England (Company No. 09500073) with registered office address at 215 Euston Road, London NW12BE, United Kingdom

hereafter referred to as **"FREELINE THERAPEUTICS"** or **"CUSTOMER",**

and

HENOGEN SA (a subsidiary of the NOVASEP group), a Belgian corporation having its registered address at 12 rue des Professeurs Jeener et Brachet, B-6041 Gosselies, BELGIUM,

hereafter referred as "**NOVASEP**".

CUSTOMER and NOVASEP will be hereafter be referred to separately as a "**Party**" and jointly as the "**Parties**".

WHEREAS:

(i) FREELINE THERAPEUTICS wishes to engage NOVASEP to conduct Work on the development and production of clinical trial supplies of therapeutic products owned by FREELINE THERAPEUTICS using an rAAV vector (each, as applicable, a "Product");

(ii) NOVASEP provides contract manufacturing services including process development, process scale-up, validation, production, quality assurance, regulatory support, analytical development and quality control analysis to pharmaceutical and biotechnology companies including in cell culture, fermentation, synthesis, purification and fill & finish processes;

(iii) NOVASEP has the professional skills and knowledge to, and is willing to, perform the Works detailed in each Work Plan on the terms and conditions set forth herein and in exchange for which the CUSTOMER agrees to pay NOVASEP the Price as set out in the relevant Work Plan in respect of the Work; and

(iv) The Parties are willing to explore (but without obligation or commitment of either Party) the feasibility of entering into a more substantial and long lasting agreement in relation with the Product(s) for the potential commercial production of the Product(s) including without limitation the Parties' respective investment in a facility for such potential future commercial production.

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the adequacy of which is acknowledged by each of the Parties, the Parties hereto agree as follows:

Part 1: Definitions

In this Agreement, unless the context otherwise requires, the following expressions shall have the following meanings:

"Affiliates" means any company, corporation; firm, partnership or other entity which is directly or indirectly controlled by, or under the same control of any of the Parties, where control means the power, direct or indirect, to direct or cause the direction of the management and policies of such entity, whether by contract, through the by-laws of the aforementioned entitles or otherwise;

"Agreement" means the present Agreement and all its Appendix(es) including all Work Plans and Quality Agreements agreed between the Parties during the Term and any amendments to any of the foregoing made in accordance with this Agreement;

"Batch" means the total quantity of Product obtained from one manufacturing run using the process at a specified scale, the purification of the Product, and the analytical activities as further described in the applicable Work Plan;

"Batch Records" means all of the documentation associated with the production and testing of a given Batch, including without limitation production records (including-the master production record). Raw Materials certificates of release, sampling documentation, out of specification and deviation reports, test results, investigative and corrective action reports. all applicable manufacturing process data (including any pertinent output from instrumentation), facility cGMP compliance verifications for the duration of the Batch's production (including without limitation for Water For Injections (WFI) production system, Heating and Ventilation Air Conditioning ("HVAC") system and clean room classification attainment at the time that the Batches are produced), the Certificate of Analysis, the Certificate of Compliance and any additional quality review and approval documentation, If applicable. To the extent such documentation has been disclosed by CUSTOMER to NOVASEP, or includes CUSTOMER Background Data, CUSTOMER Pre-Existing IPR, or constitutes CUSTOMER Foreground IPR, or has been developed specifically in relation to a Product, It shall be deemed to be CUSTOMER's Confidential Information disclosed to NOVASEP pursuant to this Agreement. Otherwise such documentation (other than where It relates to Jointly Owned Foreground IPR) shall be deemed to be the Confidential information of the Party developing or generating the same. To the extent that such documentation relates to Jointly Owned Foreground IPR, it shall be deemed to be the Confidential Information of both Parties jointly In respect of which each Party shall be considered a Receiving Party and shall act in accordance with the confidentiality obligations on a Receiving Party as set out in this Agreement;

"Certificate of Analysis" means a certificate of analysis listing in relation to each Batch the tests performed by NOVASEP or a sub-contractor of NOVASEP (as permitted under this Agreement and agreed between the Parties), the Specification and the test results and confirming that the Product meets the Specification and such other criteria as identified on the certificate of analysis;

"cGMP" means current Good Manufacturing Practices as promulgated in ICH Q7A (Guideline on Good Manufacturing Practice for Active Pharmaceutical Ingredients) as relevant to each stage of Product development and/or manufacture; EU and US GMP requirements as defined In Eudralex Vol 4 and In EC Directives 2003/94/EC and 2005/28/EC, and in 21 CFR Parts 210, 211, 600 and 610 and Part 11 for activities directly related to final Drug Product manufacture and control as any of the foregoing may be amended from time to time; and anything which replaces or supersedes the same from time to time;

"cGMP Batch" means a Batch which is manufactured, or is stipulated in a Work Plan to be manufactured, according to cGMP;

"cGMP Product" means a Product manufactured (or to be manufactured, as the context requires) under cGMP conditions;

"Competitor" means any pharmaceutical or biotechnology company with (i) an active Adeno-associated virus based programme of research or clinical development, or (ii) one or more products, whether in development or available on the market, which compete with those of CUSTOMER as may be the case from time to time during the Term;

"Confidential information" means any and all commercial and technical information, and whether patented or unpatented, including but not limited to documents, strategies, methods, procedures, know-how, trade secrets, pre-clinical and clinical test-data, or technical or marketing information regardless of method of storage, and copies thereof, disclosed by or on behalf of one Party ("**the Disclosing Party**") to the other Party ("**the Receiving Party**") pursuant to this Agreement. The Product and (save to the extent containing Confidential information of NOVASEP) Work Plans shall be deemed the Confidential information of CUSTOMER;

"Customer Background Data" means all data, CUSTOMER's Confidential Information, methods, substances, samples and Materials provided to NOVASEP by or on behalf of CUSTOMER pursuant to this Agreement;

"Delivered"/"Delivery" has the meaning given in Section 3.3 of this Agreement;

"Drug Product" means the formulated Drug Substance in association with none, one or more other ingredients sterile filtered and aseptically filled into vials suitable for use as a medicinal product;

"Drug Substance" means the active component in solution in bulk form in a suitable container for frozen storage;

"Effective Date" means the date mentioned on top of the first page of this Agreement;

"Equipment" means those pieces of equipment described in a Work Plan and required or used by NOVASEP to produce the Product, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment. Components of the Equipment shall also be deemed Equipment. "**Customer Equipment**" and "**Novasep Equipment**" shall be as defined in Section 2.4 of this Agreement;

"Facility" shall mean NOVASEP's development and manufacturing facility(ies) where the Work will be carried out, as agreed between the Parties and set out in the relevant Work Plan;

"Field" means any and all uses of Adeno-associated virus constructs;

"Force Majeure" has the meaning given in Section 14 of this Agreement;

"Foreground IPR" means the Novasep Foreground IPR, the CUSTOMER Foreground IPR and/or the Jointly Owned Foreground IPR as the case may be;

"Good Industry Practice" means the degree of skill, care prudence, knowledge and foresight which would reasonably and ordinarily be expected of a skilled, professional, competent and experienced contract manufacturing organisation engaged in the development of manufacturing processes for, and the cGMP manufacture of products at a similar or equivalent stage of development or approval to the Product;

[**]

"Intellectual Property Rights" means all Intellectual property rights, including (without limitation) patents, rights in patents, supplementary protection certificates, petty patents, utility models, trade marks, 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, rights in Confidential Information and other proprietary knowledge and 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;

"Master Production Record" means the document, proposed by NOVASEP and subsequently approved in writing by CUSTOMER and which specifies the Raw Materials with their quantities and the packaging materials, together with a detailed description of the procedures and precautions required to produce a specified quantity of an intermediate, bulk or finished product as well as the processing instructions, including the in-process controls;

"Materials" means materials, Raw Materials, compounds or Intermediates supplied by or on behalf of CUSTOMER to NOVASEP or its Affiliates under Section 2.7 of this Agreement or procured by NOVASEP in accordance with Section 2.6 of this Agreement;

"Permitted Sub-contractor" has the meaning given in Section 2.1 of this Agreement;

"Price" has the meaning given in Section 2.1 of this Agreement;

"Product" has the meaning given in Recital (i) to this Agreement;

"Production Records" has the meaning given in Section 2.4 of this Agreement;

"Project Team" means the team established by the Parties per Work Plan, in advance of commencement of the Work, and detailed in a Work Plan, responsible for (without limitation) the management of the Work on a day-to-day basis and which will consist of include one project manager from each of NOVASEP and CUSTOMER to act as the primary day-to-day point of contact for the Parties in respect of a Work Plan (each a "Project Manager");

"Quality Agreement" means the agreement between the Parties, to be entered into on or within thirty (30) calendar days of the Effective Date, defining (without limitation) the quality and cGMP responsibilities regarding the performance of the Work and quality aspects of the manufacture of the Product, and **"Quality Agreements**" will include any further quality agreements to be entered into between the Parties in respect of any other Work Plan; in the format of the template quality agreement at Part 4 of this Agreement;

"Raw Materials" media, resins, catalysts, raw materials, solvents, filters, membranes, disposable analytical test kits, disposable bags, and other items consumed during or for the performance of the Work;

"Reasonable Endeavours" shall mean using all reasonable care and skill and resources but having regard to the fact that the Work, including without limitation the method of manufacture of the Product, is experimental in nature and NOVASEP cannot be considered liable for issues (including without limitation those causing delays) arising for causes which could not reasonably have been known to NOVASEP at the relevant time;

"Regulatory Filings" means any or all applications, submitted to regulatory authorities for the purpose of seeking and obtaining marketing approval for the Product, and/or of the method of production of the Product as required by statute and any amendments or supplements thereto, and any other filings required by the regulatory authorities relating to the manufacture, testing, sale or distribution of any Product, including, without limitation, an NDA or BLA;

"Results" means any and all data, methods, procedures, processes, substances and materials arising from Work undertaken by NOVASEP or its Affiliates (or any Permitted Sub-contractor) and pursuant to a Work Plan, and any and all documentation thereof. Results which relate to the upstream process, including cell culture, transfection, viral vector release and viral vector harvest shall be defined as "**Upstream Results**" and Results which relate to the downstream process, including clarification, chromatography, membrane filtration, formulation and fill & finish steps shall be defined as **"Downstream Results"**:

"Specification" means the specification of the Product (in Drug Product or Drug Substance form as applicable) as defined in the relevant Work Plan or as otherwise agreed in writing between the Parties;

"Steering Group" means the three (3) senior representatives of each Party identified in Part 5 responsible for (without limitation) overseeing the relationship between the parties under this Agreement, the progress of the Work and for attempting to resolve any disputes not resolved by the Project Team(s);

"Work" means the work and services to be conducted by NOVASEP or its Affiliates (or any Permitted Sub-contractor) pursuant to this Agreement and as more particularly described in all of the Work Plans;

"Work Package" means a work package as set out in the Work Plan.

"Work Plan" means, in respect of each of the Work to be provided to CUSTOMER, a document signed by the Parties in advance of commencement of the Work and which sets out, without limitation, the Specification, each Party's activities, roles and responsibilities, the timeline for performance of the Work and completion of the Work, key decision points, training, budget, payment terms and the Project Team; and any amendments to a Work Plan agreed between the Parties during the conduct of the relevant Work (such as, without Limitation, to confirm the Specification once known) will be deemed part of that Work Plan. To the extent that the Parties agree that any timelines or Specifications are to be binding, these will be identified as such by mutual consent of the Parties in the Work Plan. For the avoidance of doubt, all other timelines and the Specifications will be deemed to be indicative and non-binding;

"Work Plan IP" means any intellectual Property Rights generated, acquired or otherwise arising from or as a result of the Work carried out pursuant to the applicable Work Plan;

"Written" or **"in writing"** means either paper hardcopy or facsimile signed by both Parties or mail confirmed by both Parties.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 2: Legal Terms

1 Integral Parts of this Agreement

The present Agreement contains the following parts, each of which is an integral part thereof;

- Part 1: Definitions
- Part 2: Legal Terms
- Part 3: Work' Plans (to include Price and any variation to pricing terms)
- Part 4: Quality Agreements
- Part 5: The Steering Group
- Part 6: Customer Pre-Existing IPR
- Part 7: NOVASEP Pre-Existing IPR
- Part 8: Cancellation Fees

2 Work

2.1 **Scope of Work**. NOVASEP will conduct the Work (i) in accordance with the relevant Work Plan(s), (ii) having regard to the timeline set out in that Work Plan, (iii) at the rates or for all sums set out in the relevant Work Plan, inclusive of any subcontracted analytical testing performed by any third party instructed by NOVASEP to cary out tests on the Product pursuant to the performance of the Work (the "Price") (subject to any withholdings or deductions as otherwise provided for in this Agreement); (iv) using Reasonable Endeavors and in accordance with Good Industry Practice, and (v) otherwise upon the terms of this Agreement, Any work or services not expressly described as being included in the Work as set forth in a Work Plan (as may be amended from time to time by the Parties) will be considered to be outside NOVASEP's scope of Work and will be charged to CUSTOMER at NOVASEP's then applicable rates provided that such services and charges have been pre-approved by CUSTOMER in writing prior to such services being undertaken and additional charges being incurred, CUSTOMER will not be liable for any charges which are not the subject of a Work Plan or that it has not pre-approved in writing prior to such charges being incurred. All Product to be manufactured for CUSTOMER pursuant to a Work Plan will be manufactured solely by NOVASEP at the Facility unless CUSTOMER agrees, by prior written consent (not to be unreasonably withheld, delayed or conditioned), that NOVASEP may subcontract certain of its obligations under a Work Plan to a third party (a **"Permitted Sub-contractor"**), or that some or all of the Work may take place at a different NOVASEP facility Where NOVASEP sub contracts any part of the Work to be performed by an Affiliate or a Permitted Sub-contractor, NOVASEP shall continue to be responsible to CUSTOMER for the performance (or non-performance) of such Work and the acts and omissions of such Affiliate or Permitted Sub-contractor.

2.2 **Change of scope**. Any change of scope of a Work Plan requested in writing by CUSTOMER or recommended in writing by NOVASEP (describing in reasonable detail the nature and reason for NOVASEP's recommended changes) and accepted by CUSTOMER (at CUSTOMER's sole election) shall be subject to a written agreement of both Parties which will constitute an amendment to the applicable Work Plan, such agreement including revised timelines, prices, specifications, quality and/or health and safety or environmental requirements. Any additional scope items must be promptly prospectively agreed by CUSTOMER prior to NOVASEP incurring any expenditure in respect of such additional scope items and if any change of scope will have a financial or other impact on the Work, NOVASEP will provide CUSTOMER with a written description of such impact in a proposed amendment to the relevant Work Plan. Should CUSTOMER ask for a change in the agreed packaging of the Product, or in the agreed batch size(s), or in the agreed size of vials, any costs or expenses resulting therefrom, including additional manufacturing, handling, sampling, packaging or storage costs or expenses will be borne by CUSTOMER subject to CUSTOMER's approval. Any charge increase which results from an agreed change of scope will be priced in advance by NOVASEP in a reasonable manner on a milestone or time and materials basis, for discussion and subsequent agreement between the Parties in advance of being incurred.

2.3 **Storage and destruction costs**. NOVASEP shall store (on CUSTOMER's behalf) at the Facility any Product or Materials for a maximum period of twelve (12) months from the date such Products or Materials are ready for delivery and shall store the Results at the Facility for a period of at least ten (10) years after such Results have been generated For the avoidance of doubt and without limitation, any Information regarding the Facility and/or which pertains to the manufacture, testing and quality of the Product (including Batch Records) (**"Production Records"**) shall be stored at the Facility for a period of at least ten (10) years after such information has been generated or for any such longer period as may be required by applicable laws and regulatory requirements of the European Union and the United States. Any storage of Products, Materials, Results or Production Records beyond the periods described above, shall be arranged by CUSTOMER who shall promptly collect the same from the Facility at CUSTOMER's expense NOVASEP shall notify CUSTOMER of the expiry of any relevant storage period at least six (6) months prior to such expiry date, in writing to provide CUSTOMER sufficient time in which to arrange collection and alternative storage of the Products, Materials and/or Results (as may be applicable). If at the end of the relevant storage period (or such longer time as may otherwise be agreed between the Parties), the Product, Materials, Results and Production Records have not been collected by CUSTOMER, NOVASEP shall notify CUSTOMER of the outstanding collection. NOVASEP shall be entitled to destroy such Product, Materials, Results and Production Records following the expiry of sixty (60) business days from the date of notification of outstanding collection to CUSTOMER Cost of destruction of any Product, Material, Results and Production Records are not included in the Price specified In the relevant Work Plan Such reasonable costs, if any, will therefore be charged by NOVASEP to CUSTOMER in addition to the Price.

2.4 **Equipment**. Should NOVASEP purchase Equipment (**"NOVASEP Equipment"**) such NOVASEP Equipment shall be owned by NOVASEP and be purchased at NOVASEP's cost save where the Parties have agreed in writing and prior to the acquisition of such NOVASEP Equipment that such NOVASEP Equipment will be used exclusively on behalf of CUSTOMER and in respect of a Work Plan(s) in which case such NOVASEP Equipment will be purchased at CUSTOMER's cost. If the Equipment is to be used in part on behalf of CUSTOMER and in part on behalf of third parties the Parties will determine in the relevant Work Plan their respective contributions thereto. Any acquisition, installation, validation or any other reasonable costs of any NOVASEP Equipment to be borne by CUSTOMER shall be expressly agreed in writing between the Parties in advance of such acquisition. Installation and validation being undertaken by or on behalf of NOVASEP (where such acquisition, installation and validation is not already Included in the Price).

Any Equipment provided by CUSTOMER to NOVASEP (**"CUSTOMER Equipment"**) shall be owned by CUSTOMER and used solely by NOVASEP for the performance of the Work (unless CUSTOMER, in its sole discretion, agrees to permit other uses of CUSTOMER Equipment by NOVASEP) CUSTOMER will reimburse NOVASEP for any costs authorized for the installation and validation of any CUSTOMER Equipment and for the acquisition, installation and validation of any Equipment purchased by NOVASEP (not already included in the Price) and agreed between the Parties. NOVASEP will be responsible for the appropriate operation and maintenance of all NOVASEP Equipment and CUSTOMER Equipment, NOVASEP will return CUSTOMER Equipment to CUSTOMER at CUSTOMER's reasonable cost EXW NOVASEP site (Incoterms 2010) when such CUSTOMER Equipment is no longer required in respect of any Work Plan as determined by the Project Team, or within twenty (20) business days following termination or expiry of this Agreement or the relevant Work Plan (whichever is the earlier). Running costs and maintenance of CUSTOMER Equipment are included in the Price. NOVASEP will not permit, allow, cause, enable or assist any third party to use any CUSTOMER Equipment or NOVASEP Equipment (where such exclusive use of NOVASEP Equipment is specifically agreed between the Parties in writing) purchased by NOVASEP in accordance with this section and identified as being for exclusive use without CUSTOMER's prior written consent.

2.5 **Use of Customer Background Data and Materials**. CUSTOMER hereby authorizes NOVASEP and its employees to use the Customer Background Data and the Materials to the extent necessary to perform the Work, NOVASEP acknowledges and recognizes that no other right of license to use in any way the Customer Background Data or the Materials is granted hereunder, by implication or otherwise.

2.6 **Supply of Materials by NOVASEP**. Unless agreed in a Work Plan, NOVASEP shall be responsible for the procurement of all commercially available Materials necessary for the manufacture of the Product including safety stock amounts where applicable and stipulated in a Work Plan (**"NOVASEP-sourced Materials"**). Unless specified to the contrary, the price of the Materials shall be included in the Price set out in the relevant Work Plan. Title to all NOVASEP-sourced Materials shall pass to CUSTOMER immediately upon NOVASEP's receipt of full cleared payment for such NOVASEP-sourced Materials from CUSTOMER. All NOVASEP-sourced Materials that are in NOVASEP's control and are to be used in the manufacture of the Product, as well as Product in NOVASEP's control, shall be stored in accordance with any storage guidelines agreed between the Parties and with due skill and care, it is the responsibility of NOVASEP to ensure that such NOVASEP-sourced Materials comply with any applicable specifications specified by CUSTOMER, that adequate quantities of such NOVASEP-sourced Materials are procured and received on time and with appropriate quality to the Facility. Should the late arrival of such NOVASEP-sourced Materials negatively impact the performance of the Work or the time

schedule in that Work Plan, NOVASEP shall, where such delay was due to the negligence or willful default of NOVASEP, be liable (subject to Sections 12.3 and 12.4 of this Agreement) for loss to CUSTOMER which could not otherwise have been avoided by CUSTOMER following such late delivery of such NOVASEP-sourced Materials (at no additional cost to CUSTOMER), other that where such late delivery of the NOVASEP-sourced Materials was exclusively due to the negligence or willful default of a third party and beyond the control of NOVASEP. In which case, NOVASEP shall use all Reasonable Endeavours to ensure that performance of the Work is as close to the time schedule in the Work Plan as possible.

2.7 **Supply of Information and Materials by CUSTOMER**. Where CUSTOMER supplies Materials or Customer Background Data to NOVASEP pursuant to a Work Plan or otherwise under this Agreement (**"CUSTOMER-sourced Materials"**), then it is the responsibility of CUSTOMER to ensure that adequate quantities of such CUSTOMER-sourced Materials are delivered on time and with appropriate quality to the Facility. Should the late arrival of such CUSTOMER-sourced Materials, or the quality of such CUSTOMER-sourced Materials, negatively impact the performance of the Work at the time schedule in an applicable Work Plan, then NOVASEP shall not be liable for the consequences of such late delivery and CUSTOMER shall compensate NOVASEP for any reasonably incurred additional costs of laboratory services and Facility downtime which could not otherwise have been avoided by NOVASEP and/or save to the extent such costs were attributable to the gross negligence or willful default of NOVASEP.

2.8 **Project, Manager and Project Team**. The Parties shall collaborate in good faith and in transparency for the proper performance of the Work via the Steering Group, the Project Manager and the Project Team. The Project Team will meet frequently either by telephone conference or it necessary, by face-to-face meetings, every two (2) weeks unless agreed otherwise, and for the duration of the relevant Work to ensure (amongst other things) that the Work is progressing in line with the time frames, to the Specification and any other requirements stipulated in the relevant Work Plan, to discuss and resolve any issues arising from the progression of the Work and to manage the Work on a day-to-day basis. In addition to the Project Team, each Party will assign a Project Manager (to be named in the relevant Work Plan) who will be the primary day-to-day point of contact for each Party.

2.9 **Steering Group**. Each Party will assign individuals to constitute the Steering Group on or before the Effective Date, whose roles will be as set out in this Agreement. The Steering Group will be co-chaired by the Parties and responsible for (amongst other things and without limitation) overseeing the relationship between the Parties in respect of all Work Plans and under this Agreement more generally and reviewing and approving any element of a Work Plan or this Agreement which requires the joint agreement of both Parties. The-Steering Group will meet quarterly (or at such other frequency to be agreed between the Parties) or at the reasonable request of either Party during the Term in order for the Steering Group to meet its objectives. CUSTOMER members of the Steering Group will be responsible for drafting the minutes of each meeting of the Steering Group (the **"Minutes"**) and will circulate a draft set of Minutes as soon as reasonably practicable following the relevant meeting for approval. NOVASEP will have five (5) business days in which to review and approve the Minutes (or revert to CUSTOMER with proposed amendments). Any Minutes not expressly approved by NOVASEP within this timeframe will be deemed approved by both Parties and not subject to further amendment.

2.10 **Replacements and Meetings**. In the event of removal or replacement of any member of the Steering Group or Project Team (the **"Departing Member"**), the Departing Member's Party will notify the other Party as far in advance as possible of the removal or replacement of the Departing Member and such Party will provide a replacement member for the Steering Group or Project Team (as applicable) with an appropriate level of experience, knowledge and technical skill. Each Party shall be responsible for its own costs in attending and conducting meetings between any or all of the Steering Group. Project Manager and/or Project Team. The Parties' intention is that all issues considered by the Steering Committee will be resolved unanimously but in the event that a unanimous agreement cannot be reached on any issue relating to a Work Plan, the provisions of Section 13.3 will apply.

2.11 **Product Specification**. Where the Work Plan requires the manufacture of the Product to meet a Specification, NOVASEP will use all Reasonable Endeavours to manufacture the Product to meet that Specification. The Parties will agree the Specifications as far as possible prior to signature by both Parties of the relevant Work Plan, and any Specifications agreed during the course of a Work Plan will be proposed by the Project Teams to (the Steering Group for approval. In the event that any amendments to the Specification are necessary, such amendments will be negotiated by the Project Team and approved by the Steering Group, in each case in good faith acting reasonably. Where agreement cannot be reached, the dispute resolution provisions of this Agreement will apply.

2.12 **Manufacturing Capacity and Reservations**. NOVASEP will, on agreement of, and in accordance with, a Work Plan, reserve slots in its cGMP manufacturing suite for those cGMP Batches to be manufactured under the relevant Work Plan according to the time frame in that Work Plan. Where the time frame is amended in accordance with section 2.13 of this Agreement (amongst other

sections) and such amendment affects the existing manufacturing schedule for Batches, NOVASEP will use reasonable endeavours to update its manufacturing schedule and reserve new slots for those affected Batches which will be reserved as near in time to the existing vacated slots as NOVASEP's then current schedule will permit. CUSTOMER may delay or cancel any slot reservation at any time upon prior written notice to NOVASEP subject to the payment of the delay and cancellation payments set out in Section 2.13 or Part 9 as applicable, and NOVASEP shall accordingly modify the time frame by delaying performance of those applicable Works associated with such delayed or cancelled slot.

2.13 **Rescheduling**. **The manufacture of cGMP Batches or activities requiring the use of a cGMP Facility**: CUSTOMER may delay or request the reschedule of any slot reservation for the manufacture of any cGMP Product or cGMP Batch, or any activities which require the use of a cGMP Facility (the **"Rescheduled Activity"** and the **"Reschedule Notice"**) at any time upon prior written notice to NOVASEP. Where a Reschedule Notice is provided to NOVASEP at least 3 calendar months prior to the agreed start date of the work which is to be the Rescheduled Activity, the delay or reschedule will be at no additional cost to CUSTOMER provided that CUSTOMER requests that the Rescheduled Activity is rescheduled within 12 calendar months from the date the relevant work was originally due to commence and that the Rescheduled Activity has not already been delayed or rescheduled pursuant to this Section 2.13. NOVASEP will use its Reasonable Endeavours to accommodate the change in schedule and to complete the Rescheduled Activity within the time frame requested by CUSTOMER. In the event that a Reschedule Notice is provided less than 3 months prior to the start date of the relevant work or has already been delayed or rescheduled pursuant to this Section 2.13, CUSTOMER will pay NOVASEP a rescheduling fee [**] in respect of the Rescheduled Activity (excluding the cost of Raw Materials as applicable) (the "**Rescheduling Fee**"), save that if NOVASEP, using its Reasonable Endeavours, is able to allocate the capacity which results from the Reschedule Notice for any other work (whether in respect of CUSTOMER or any third party), NOVASEP will immediately refund the Rescheduling Fee to CUSTOMER less NOVASEP'S reasonable out-of-pocket expenses.

2.14 **Replacement Product**: CUSTOMER may choose to reallocate a cGMP Batch reservation to an alternative Product, on not less than 6 months' written notice to NOVASEP prior to the start of that cGMP Batch manufacture. NOVASEP will use its best efforts to accommodate CUSTOMER'S request, at no extra cost to CUSTOMER save any reasonable transfer costs and product-specific fees to be mutually agreed in advance in writing (for example, but without limitation, Product-specific analytical methods).

2.15 **Reporting**. On a non-binding, indicative timeframe to be agreed between the Parties in a Work Plan (or otherwise on a reasonable frequency and unless specified as being binding and indicative in the relevant Work Plan), NOVASEP will keep CUSTOMER updated as to compliance with the time frame set out in a Work Plan via the Steering Committee and the Project Team, For each Work Plan, NOVASEP will prepare and provide to CUSTOMER a report detailing the Results of development work by NOVASEP based on a structure and covering certain content to be mutually agreed by the Parties prior to the initiation of any Work Plan and detailing progress with respect to any timeline, prior to delivery of any Product and the Results to CUSTOMER (the **"Developmental Report"**). CUSTOMER will review such Developmental Report in a reasonable timeframe prior to acceptance of the Product and/or the Results (and thus acceptance of the completion of the relevant Work Package). In the event that acceptance of a Developmental Report gives rise to a payment obligation on CUSTOMER, such payment will not be due or payable until such time as a final version of the Developmental Report has been accepted by CUSTOMER, such acceptance not to be unreasonably withheld or delayed. CUSTOMER shall provide NOVASEP with its comments on a draft version of a Developmental Report within fifteen (15) business days of receipt of such draft. NOVASEP shall provide CUSTOMER with a final version of a Developmental Report integrating, as the case may be, the reasonable comments of CUSTOMER within a further fifteen (15) business days. In the absence of comments from CUSTOMER within the fifteen (15) business day period the draft version of a Developmental Report shall be considered final and any associated payment obligation shall become due and payable. Separate from the Developmental Report, NOVASEP will, for the duration of a relevant Work Plan, make available to CUSTOMER, on request, all Results and any other data relating to such Work Plan as CUSTOMER may reasonably require to support CUSTOMER in making any decisions in respect of the said Work Plan and/or the Product which is the subject of such Work Plan and in respect of any of CUSTOMER's Product and regulatory activities and obligations.

2.16 **Performance standards**. For the avoidance of doubt NOVASEP shall use all Reasonable Endeavours in accordance with Good Industry Practice in the performance of the Work.

2.17 **cGMP and Quality**. NOVASEP will, where required under applicable regulatory obligations, comply with any applicable cGMP criteria for, and in its performance of, each aspect of the Work and with the requirements and recommendations stipulated in the International Conference on Harmonization guidelines on quality. NOVASEP will maintain, retain and store (i) materials generated from a run of the Product method of production (as used as a standard or reference for analytical testing purposes) of all cGMP Product for such period as required by applicable regulatory obligations; and (ii) all records required to be maintained by the terms of this

Agreement or any Work Plan and by applicable laws and/or regulatory obligations. After termination or expiry of this Agreement, NOVASEP will provide copies or samples (as the case may be) of all such materials and records to CUSTOMER upon CUSTOMER'S request and NOVASEP will not (subject to Section 2,3) dispose of the same without CUSTOMER's prior written consent.

2.18 **Qualification and Validation of NOVASEP's Facility, Utilities and Equlpment.** NOVASEP will maintain cGMP qualification and validation of the facility, as well as all utilities and equipment (including Equipment) used in the manufacture of the Product at the Facility, and shall make relevant reports applicable thereto available to CUSTOMER by way of copies or for review at the Facility, in either case at CUSTOMER's written request. The relevant Work Plan will specify certain testing, storage, release, cGMP, regulatory and other quality assurance requirements relating to manufacture and shipment of Product by NOVASEP under this Agreement.

2.19 **Regulatory Filings and Maintenance.** CUSTOMER will maintain and be the sole owner of and have full rights and freedoms to use all Regulatory Filings and all governmental approvals obtained from any regulatory authority with respect to the Product or the process of manufacture of the Product. NOVASEP will provide such documents and information to support and assist CUSTOMER in filing, prosecuting and securing Regulatory Filings and in maintaining regulatory authority approvals for the Product, as requested or as necessary in addition, NOVASEP will prepare and maintain and provide CUSTOMER with copies of manufacturing files, certificates, authorizations, data and other records that directly or indirectly pertain to the manufacture of the Product or other Product-related documentation as otherwise agreed in writing between the Parties.

2.20 **Safety and Efficacy Notification and Claims.** The NOVASEP Project Manager or Project Team members will be responsible for promptly notifying CUSTOMER of any information of notice of which it becomes aware concerning the safety or efficacy claims of the Product (or the manufacture process of the Product), including any threatened or pending action by any governmental or regulatory authority relating thereto. CUSTOMER shall be responsible for handling all such complaints and NOVASEP will cooperate in resolving any such complaints at CUSTOMER's request.

2.21 **Accident Reports.** To the extent permitted by law, each Party will report to the other, as soon as possible, all material accidents related to the manufacture, handling, use or storage of any Raw Materials or Product, including, without limitation, accidents resulting in; (i) personal injury requiring more than first aid treatment; (ii) chronic illness or loss of consciousness; (iii) material property damage; (iv) material environmental release; and (v) regulatory, safety, health or environmental audits.

2.22 **Audit**. Maximum once a year per Product, CUSTOMER may conduct (or have conducted on its behalf) on-site compliance quality audits of NOVASEP to inspect areas, equipment (including Equipment) and materials (including Materials and Products), the Facility, including procedures and data connected with a Work Plan and any packaging, testing or storage of any Product NOVASEP shall receive prior reasonable notice of such audit at least twenty (20) business days in advance, in order to make relevant staff available to attend the audit and comply with any reasonable requests of CUSTOMER. Such audit shall take place during normal business hours. CUSTOMER shall use its reasonable endeavors not to cause any disruption to NOVASEP's business and activity in carrying out such audit in the event that the audit under this Section extends beyond two (2) business days, NOVASEP will charge CUSTOMER a per diem of [**] which shall include reasonable access to NOVASEP's qualified and experienced employees. For the avoidance of doubt, such right of CUSTOMER does not include any right to inspect or audit NOVASEP's financial data or accounting records.

2.23 **For Cause Audit.** Without limitation and restriction in time, CUSTOMER may, immediately upon request, conduct compliance quality audits of NOVASEP to inspect areas, equipment and materials of the Facility where the Work is performed and records relating to the Work, where there has been any material breach of any obligation hereunder or of the Quality Agreements or there are circumstances giving rise to a reasonable concern of non-compliance with this Agreement, cGMP or any regulatory obligations.

2,24 **Regulatory Audit.** In addition to the annual audit, CUSTOMER shall be entitled to request, authorize or conduct (or have it done on its behalf) any necessary additional audit required pursuant to any notification from a governmental or regulatory authority to conduct an inspection of the Facility (or other facility) used in the development, manufacturing, storage or handling of the Product. Under such circumstances, NOVASEP will, without charge, permit governmental or regulatory authority bodies (together with CUSTOMER's designated representatives) to enter those areas of NOVASEP premises (including the Facility) used for the performance of the Works for the purpose of observing and inspecting the performance of the Works and those records of NOVASEP specific to the Works. During any such regulatory inspections, NOVASEP will provide reasonable assistance as requested by the relevant governmental or regulatory authority and shall promptly permit access to and copy and verify records and reports in NOVASEP's

possession, custody or control relating to the Works. In addition to the above, NOVASEP shall immediately notify CUSTOMER of any audit or inspection undertaken at the Facility by any authority or regulatory body that raises any issues, deviations, defects, actions or concerns with respect to the operation of the Facility. NOVASEP's personnel or record keeping, and shall provide full details of the same to CUSTOMER together with the remedial plan and updates as to NOVASEP's progress to resolving all issues, deviations, defects, actions or concerns.

2.25 **Other Services.** If NOVASEP, at CUSTOMER's written request, provides assistance or services to CUSTOMER for the Importation of any raw materials, intermediates or substances, or for the exportation of the Product or any deliverable, such services will be invoiced by NOVASEP to CUSTOMER at a rate of [**]

2.26 **Technology Transfer.** Upon (i) a material breach of this Agreement (including any Work Plan) by NOVASEP; and/or (ii) NOVASEP falling to comply with Good Industry Practice and/or use Reasonable Endeavours regarding the Delivery of a Product to CUSTOMER as required in a Work Plan, and/or (iii) mutual agreement between NOVASEP and CUSTOMER in writing that the Work or the applicable Work Plan lack technical feasibility; and/or (iv) three (3) failures by NOVASEP in any eighteen (18) month period to deliver Batches in accordance with the relevant Specification and failure to replace the same in accordance with Section 3.6 of this Agreement notwithstanding the application by NOVASEP of Reasonable Endeavours with respect thereto; and/or (v) NOVASEP advising CUSTOMER in writing that it does not have capacity to perform the Work in any Work Plan within a reasonable timeframe or to meet CUSTOMER's reasonable capacity requirements; and/or (vi) NOVASEP seeking to vary the terms of any Work Plan or any Price beyond what would reasonably be deemed to be reasonable commercial terms; and/or (vii) Upon any change of control of NOVASEP or any Affiliate controlling it (control having the meaning as defined in the definition of Affiliate) [**] and/or (viii) CUSTOMER's request at any time until twelve (12) months after the last of the Works has been completed, on a Work Plan by Work Plan basis but subject to payment, [**] to those costs budgeted by NOVASEP for the technology transfer activities, as pre-agreed by CUSTOMER, to a maximum fee of [**] have signed a commercial agreement providing funding for the construction or a NOVASEP commercial viral vector manufacturing facility (save that such fee shall not be payable if such transfer is to a NOVASEP facility) [**] reasonable, pre approved and properly incurred cost of the technology transfer [**] the event that no such agreement has been signed between [**]; CUSTOMER may by written notice to NOVASEP require NOVASEP to provide assistance for the technology transfer to CUSTOMER or any other person at CUSTOMER's direction of the manufacturing process and technology relating to the Product to enable the manufacture of the Product at a different facility and by a different person. Following NOVASEP's receipt of such notice, the Parties will establish, in good faith, a schedule and plan for such transfer (including the security and preservation of all NOVASEP Confidential Information) and NOVASEP will thereafter co-operate with and provide all assistance requested by CUSTOMER in Implementing and effecting such transfer, including by the provision of NOVASEP's personnel and NOVASEP will also make available, subject to any regulatory obligations, all CUSTOMER Materials, and at least one (1) copy of all documentation generated pursuant to the performance of the Work up to the date of termination or expiry, including (without limitation) Batch Records, development reports and production process documentation, in addition to any applicable fee provided pursuant to Section 2.26 (vii), the reasonable, pre-approved costs of such transfer will be borne by CUSTOMER save where the transfer is required or the agreement is terminated as a result of any material breach of this Agreement by NOVASEP.

2.27 **Variable Costs.** The costs of Raw Materials and other consumables, disposables and reagents requited for conducting the process to manufacture such Product in accordance with the standards and obligations of this Agreement (for example but without limitation, culture media, chromatographic resins, membranes and filters) (together the "Variable Costs") will be estimated by NOVASEP, as accurately as possible, in the applicable Work Plan. NOVASEP will use Reasonable Endeavours not to exceed the estimated Variable Costs per Work Plan. Where not included in the Price. NOVASEP will invoice CUSTOMER the actual and properly incurred Variable Costs incurred by NOVASEP in compliance with this Agreement with any overhead charges not to [**] of the Variable Cost paid by NOVASEP, and CUSTOMER will pay such invoice in accordance with the payment provisions in Section 9.1. in the event that actual and property incurred Variable Costs are likely to exceed the estimate set out in the relevant Work Plan, NOVASEP will notify CUSTOMER and obtain CUSTOMER's prior written approval in advance of incurring such increased Variable Costs (and provided they will be reasonably and necessarily incurred) and will use its best endeavours to reduce the increase in Variable Costs. Provided CUSTOMER has approved such increased Variable Costs in advance, NOVASEP shall invoice CUSTOMER for these additional costs with any overhead charges not [**] the Variable Cost paid by NOVASEP. Should the Variable Costs borne by NOVASEP at the expiration or termination of the relevant Work Package or Work Plan be less than the amount invoiced, then the difference shall be refunded to CUSTOMER.

3 CUSTOMER's obligations, Supplies and Delivery

3.1 **General obligation of CUSTOMER.** As a general obligation, CUSTOMER shall perform the tasks assigned to it as defined in this Agreement or as set out in a Work Plan. CUSTOMER shall also supply NOVASEP sufficiently in advance with such materials. Information and documents as NOVASEP may reasonably request for the proper performance of its obligations hereunder, as more specifically described in a Work Plan. CUSTOMER shall also take delivery of the Product manufactured by NOVASEP at NOVASEP's Facility and Results within seven (7) days following NOVASEP's notice of readiness to CUSTOMER.

3.2 **Packaging.** All Product and Results to be Delivered to CUSTOMER shall be packaged by NOVASEP in accordance with those agreed and applicable packaging standard operating procedures and the Specification.

3.3 **Delivery.** All Product and Results shaft be delivered to CUSTOMER FCA NOVASEP Facility In-Belgium (incoterms 2010 of the ICC) ("Delivered" or "Delivery" as applicable). Transportation and insurance costs in respect of the Delivery shall be borne by CUSTOMER For the avoidance of doubt should NOVASEP provide assistance to CUSTOMER (at CUSTOMER's express written request) for the organization of the shipment of the Product and/or the Results and/or choose the shipping agents and companies on behalf of CUSTOMER NOVASEP will not be responsible or liable for damages or loss that could occur to the Product and/or Results during Delivery as a consequence of that assistance. NOVASEP will provide CUSTOMER with advance notice of the anticipated date of Delivery and shall endeavor to provide the Results as early as possible prior to the date of Delivery of the Product. All Batch Records and Results shall be delivered by mail or electronic mail to CUSTOMER.

3.4 **Non-Certified Delivery.** Subject to any mandatory regulatory requirements relevant to the manufacture of cGMP Product for human use and other cGMP compliance, CUSTOMER may, by written notice, request following NOVASEP's quality department having reviewed the relevant Batch Records and any eventual deviations (to be carried out no later than ten (10) business days following receipt of such notice from CUSTOMER), that NOVASEP Delivers partially manufactured Product under quarantine status to CUSTOMER prior to NOVASEP issuing a Certificate of Analysis or prior to NOVASEP providing all documents in accordance with Section 3.4, to the extent required to perform an additional Product manufacturing step such as labelling or packaging ("Non-Certified Delivery") Notwithstanding such request and delivery, NOVASEP shall thereafter provide a Certificate of Analysis and all documents required pursuant to Section 3.3 of this Agreement.

3.5 **Examination of Products for Defects.** CUSTOMER shall examine and test Products delivered for (i) defect and non-conformity with any applicable specifications or cGMP standards which they are specified to meet and (ii) in the case of Product manufactured to Specification and released with a Certificate of Analysis, review the Batch Records to assess whether the Product fails to meet Specification (a "**Defect**") Where any Defect is identified CUSTOMER shall notify NOVASEP by written notice ("**Defect Notice**") in accordance with the following timetable, (i) within ten (10) days of collection following Delivery of any visual (to the naked eye) Defect, (ii) within thirty (30) days of receipt by CUSTOMER of documented Products (including, without limitation, Batch Records) of any errors in any such documented Products provided that NOVASEP provides timely answers to information requests and resolution of issues arising from CUSTOMER's review if such Products, and (iii) within ten (10) business days of discovery by CUSTOMER of any other defect including any defect which results from non conformity with NOVASEP's warranties or which existed when the Batch was delivered to CUSTOMER but was not discoverable by review of the Batch Records during the thirty (30) days after CUSTOMER's receipt of the Batch Records. Following service of a Defect Notice, NOVASEP will arrange with CUSTOMER to collect any Products which are the subject of the Defect Notice within ten (10) business days NOVASEP will promptly react to the Defect Notice and investigate the occurrence of and reasons for the Defect and shall report to the Project Team within twenty (20) business days of receipt, its findings and whether it accepts or disputes (in whole or part) responsibility for the Defect Should any Batch that is the subject of a Defect be subsequently re-certified by NOVASEP, NOVASEP shall ensure such Batch meets the Specification and conforms with the Certificate of Analysis.

3.6 **Consequences of Defective Product.** Where the Defect is, as between NOVASEP and CUSTOMER, substantially due to NOVASEP (or its Affiliates' or contractors') acts, omissions or breach of its obligations under this Agreement, (including where such acts and omissions or breaches could be, but are not limited, to operator mistakes equipment failure, power shortages and building environmental control failures) or where the Specification of a Batch is not met when the Parties have agreed that such Specification should be bidding with regards to a particular Batch, NOVASEP shall (i) use all Reasonable Endeavours to replace at its own cost and as soon as reasonably practicable (and in any event within one hundred and ninety (190) business days of the Defect notice) an equal quantity of Product free of defects as that which was Defective; and (ii) pay all expenses, fees and charges associated with the

manufacture and return of the defective Product, and (iii) reimburse CUSTOMER (subject to Sections 12.3 and 12.4 of this Agreement) for any reasonably Incurred or foreseeable costs incurred by CUSTOMER (and which could not be refunded to CUSTOMER), as a result of the Products being defective. The Parties agree and acknowledge that any samples held by NOVASEP from the manufacturing run pursuant to the terms of this Agreement including the Product that is Defective shall be made available for testing purposes in the event any Product is Defective. Any disputes regarding a Defect or calculating the appropriate refund of monies shall be referred to an Independent expert, reasonably acceptable to and appointed by both Parties and subject to confidentiality provisions comparable to those set out in this Agreement, The independent expert shall undertake the relevant analysts to assess whether the Product was defective and whether NOVASEP was responsible in any way. Both Parties agree to cooperate with the independent expert's reasonable requests for assistance in connection with its analysis hereunder. The independent expert shall act as an expert and not arbitrator. The decision of the independent expert shall be written and given in English and be considered final and binding on the Parties unless there has been a manifest error on the face or the decision whereupon the Parties shall revert to the dispute resolution procedure in this Agreement. The fees and expenses of such expert shall be borne in full by the Party against whom the Indendent expert decides.

4 NOVASEP's warranties

4.1 NOVASEP warrants and undertakes to CUSTOMER that;

(a) the Work will be conducted in a diligent and professional manner with professional skill and care and in accordance with cGMP. all applicable laws and otherwise in accordance with the terms of this Agreement;

(b) NOVASEP will not knowingly Infringe or misuse any third party intellectual Property Rights in its performance of the Work;

(c) NOVASEP has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material;

(d) the Facility shall be maintained in accordance with cGMP and all other applicable lows and regulations in such condition as will allow NOVASEP to manufacture the Product in compliance with cGMP, all other applicable laws and regulations, to meet the Specification and in conformance with the Master Production Record, and

(e) all Product (i) and Results shall be Delivered free of encumbrances of liens; (ii) shall be manufactured and analyzed in conformance with the Master Production Record; (iii) shall be manufactured in compliance with the requirements of cGMP and all other applicable laws and regulations; (iv) shall be packaged in accordance with the shipping guidelines; (v) shall conform, at the time of delivery, to the Specification, and (vi) where Product is released with a Certificate of Analysis, the Product will comply with the criteria specified in that Certificate of Analysis,

4.2 Except as expressly otherwise stated in this Agreement, NOVASEP expressly excludes and disclaims all other warranties (whether implied or express), including, without limitation; (i) any warranty of merchantability or (ii) any warranty of fitness of the Products and deliverables supplied under this Agreement for the particular purpose for which CUSTOMER intends to use them.

5. CUSTOMER's Warranties

5.1 CUSTOMER warrants and undertakes that to its knowledge any Customer Background Data, Materials, Equipment and Product which NOVASEP is required by CUSTOMER to use, access or modify is legally licensed to CUSTOMER or is CUSTOMER's own property, and that to its knowledge NOVASEP's use of Customer Background Data, Equipment, Product and Materials for those activities performed in accordance with the terms of this Agreement will not infringe the rights (including without limitation the intellectual Property Rights) of any third parties.

5.2 CUSTOMER warrants and represents to NOVASEP that the nature of the Materials and Product delivered by or on behalf of CUSTOMER to NOVASEP will conform to all relevant legal requirements.

5.3 CUSTOMER warrants and represents to NOVASEP that the nature of the Materials and Product delivered by or on behalf of CUSTOMER to NOVASEP will, so far as if is aware, be free of hazardous or toxic material unless clearly specified for known hazardous

materials such as cytostatic/cytotoxic materials, Material Safety Data Sheets and any specific safe material handling instructions applicable to the Materials and Product will be disclosed by CUSTOMER in advance to NOVASEP in writing and Included with shipments Before the beginning of the Work, CUSTOMER shall supply NOVASEP free of charge with copies of all safety information relating to the Materials and Product.

6 Intellectual Property Rights

6.1 **Pre-Existing Intellectual Property.** Any Intellectual Property Rights owned by a Party or licensed by a third party to a Party as of the Effective Date or before the commencement of the applicable Work Plan ("**Pre-Exiting IPR**") and as detailed in the schedules at Parts 6 and 7 for CUSTOMER Pre-Existing IPR and NOVASEP Pre-Existing IPR respectively, shall remain the sole and absolute property of the Party that owned or was licensed to use such Pre-Existing IPR. Nothing in this Agreement shall act as any assignment or transfer of the Pre-Existing IPR of either Party nor, save as expressly set out herein, any licence to any Party's Pre-Existing IPR.

6.2 **Intellectual Property Rights created in the course of performing the Work.** All Results and Work Plan IP that comprises (i) any improvement or enhancement to, or that is developed through the use of CUSTOMER's Pre-Existing IPR and/or (ii) any Upstream Results which incorporate, use, relate to, or arise from use of, any of the [**] and Irrespective of whether (i) or (ii) are generated alone by either Party or jointly between the Parties shall be owned solely by CUSTOMER ("CUSTOMER Foreground IPR") and title to CUSTOMER Foreground IPR will pass to CUSTOMER immediately on creation. All Results (including without limitation Downstream Results) and Work Plan IP that is not CUSTOMER Foreground IPR and specifically relates to NOVASEP's Pre-Existing IPR, whether generated alone by either Party or jointly between the Parties shall be owned solely by NOVASEP ("NOVASEP Foreground IPR") and title to NOVASEP Foreground IPR will pass to NOVASEP immediately on creation, NOVASEP will disclose to CUSTOMER, at the end of each Work Plan and via the Project Team, all Results comprised in NOVASEP Foreground IPR, any new NOVASEP Foreground IPR which was not previously used or disclosed in respect of the relevant Work Plan and CUSTOMER Foreground IPR generated in respect of the relevant Work Plan, For the avoidance of doubt, such disclosure will be subject to the confidentiality provisions set out in this Agreement. All Results and Work Plan IP which is not CUSTOMER Foreground IPR or NOVASEP Foreground IPR, whether generated alone by either Party or jointly between the Parties, shall be jointly owned in equal undivided shares by the Parties ("Jointly Owned Foreground IPR"), disclosed to CUSTOMER on creation (to the extent not already in CUSTOMER's possession) and held subject to the terms of this Agreement.

6.3 **Grant of Intellectual Property License for the performance of the Work.** Each Party hereby grants to the other for the Term a non-exclusive, royalty-free, sub-licensable limited licence in respect of their respective Pre-Existing IPR and Foreground IPR solely to the extent the same is required and necessary for the proper performance of the Work, on a Work Plan by Work Plan basis. This license (i) does not prevent the Party granting the licence from making any use of its own Pre-Existing IPR or Foreground IPR; and (ii) subject to Section 6.4 of this Agreement, terminates automatically upon the expiry of the applicable Work Plan or termination of this Agreement, whichever is the earlier. For the avoidance of doubt, the licence granted by this Section in respect of CUSTOMER's Pre-Existing IPR and Foreground IPR does not include any Inteliectual Property Rights licensed by a third party to CUSTOMER and which may be included in CUSTOMER's Pre-Existing IPR and/or CUSTOMER's Foreground IPR but in respect of which CUSTOMER has not been granted a license to sub-license or otherwise transfer such third party Intellectual Property Rights.

6.4 **License in respect of Intellectual Property Rights in Upstream Results.** In respect of Intellectual Property Rights in the Upstream Results that; pursuant to Section 6.2 of this Agreement, are part of CUSTOMER Foreground IPR, CUSTOMER hereby grants to NOVASEP, a perpetual, non-exclusive, royalty-free, worldwide license, sub-licensable (through one tier) to its Affiliates and to its other customers, commencing at the end of the first Work Plan, in respect of such Upstream Results, for any use outside the Field. For licences through subsequent tiers the Parties shall enter into good faith and timely efforts to agree the terms of any such licences on reasonable commercial terms. For the avoidance of doubt, NOVASEP will not be in breach of its confidentiality obligations under this Agreement by exercising its rights granted pursuant to this license provided that any disclosure made by NOVASEP is only under obligations of confidentiality consistent with those herein and disclosures are only to its sub-licensees and are necessary for NOVASEP to exercise the rights granted to it pursuant to this license.

For clarity, CUSTOMER hereby agrees and covenants that, provided that NOVASEP does not breach its confidentiality, non-use or any other obligations herein and otherwise complies with this Agreement, it shall not prevent NOVASEP (including without limitation any of NOVASEP's employees involved in the performance of the work) from performing work similar to the Work, for and/or with any third party, which includes the use [**] which is independently developed by NOVASEP or licensed or otherwise provided to NOVASEP by a third party. For the avoidance of doubt, NOVASEP shall not use any [**] provided of developed by or on behalf of CUSTOMER for any purpose in respect of any third party other than CUSTOMER other than as permitted under this Agreement.

6 5 **License to NOVASEP Intellectual Property Rights**. NOVASEP hereby grants to CUSTOMER a non-exclusive, perpetual, irrevocable, royalty free, fully paid, worldwide fully transferable license (with the right to grant and authorise the granting of sublicenses through multiple tiers) to use and (and in accordance with the provisions of Section 8.4 of this Agreement) disclose the NOVASEP intellectual Property Rights to the extent that the same is necessary to enable CUSTOMER and/or any of its licensees or subcontractors to (i) manufacture the Products; (ii) include such NOVASEP Intellectual Property Rights within any Regulatory Filings; and (iii) to use and disclose such NOVASEP intellectual Property Rights in conjunction with the labelling, marketing and sale of any Products. "NOVASEP Intellectual Property Rights" for the purposes of this Section 6.5 only means those intellectual Property Rights owned by or licensed to NOVASEP including NOVASEP Foreground IPR and any intellectual Property Rights in the Batch Records. This license shall survive the termination or expiry of this Agreement for any reason.

6.6 **Further Assurance and Right to file for protection**. NOVASEP shall promptly notify CUSTOMER of all CUSTOMER Foreground IPR developed hereunder and shall promptly do all acts and execute all documents and deeds reasonably necessary to vest in CUSTOMER the rights assigned or to be assigned to CUSTOMER pursuant to Section 6.2, of this Agreement. CUSTOMER may file potent protection on any intellectual Property Rights it owns in accordance with Section 6.2 of this Agreement and NOVASEP shall promptly upon request co-operate at CUSTOMER's reasonable expense, with any requests to assist or enable CUSTOMER's protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

CUSTOMER shall promptly notify NOVASEP of all NOVASEP Foreground IPR developed by CUSTOMER hereunder and shall promptly do all acts and execute all documents and deeds reasonably necessary to vest in NOVASEP the rights assigned or to be assigned to NOVASEP pursuant to Section 6.2 NOVASEP may file patent protection on any intellectual Property Rights it owns in accordance with Section 6.2 of this Agreement and CUSTOMER shall promptly upon request co-operate at NOVASEP's reasonable expense, with any requests to assist or enable NOVASEP's protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

6.7 **Jointly Owned Intellectual Property Rights.**

(a) Each Party shall promptly notify the other Party of all Jointly Owned Foreground IPR developed by that Party in accordance with Section 6.2 of this Agreement and the Parties will cooperate to promptly do all acts and execute all documents and deeds reasonably necessary to vest in both Parties the equal right to such Jointly Owned Foreground IPR, the costs of which shall be borne equally by both Parties.

(b) NOVASEP and CUSTOMER will be jointly responsible for agreeing and applying for protection for, and all filing, prosecution (including opposition), and maintenance with respect to, the intellectual Property Rights in the Jointly Owned Foreground IPR in all territories and countries agreed in writing between the Parties (the "**Joint IP Rights**"), Prosecution of such Joint IP Rights shall be [**] using patent counsel [**] NOVASEP and CUSTOMER shall cooperate in the preparation, filing, prosecution, and maintenance of all Joint IP Rights, Cooperation includes, without limitation, (i) consulting with the other Party as to the preparation, filing, prosecution, and maintenance of all Intellectual Property Rights reasonably prior to any deadline or action of any patent office, (ii) furnishing the other Party with all relevant documents reasonably in advance of filing, and including in such documents in good faith the comments thereon of the other Party, (iii) promptly executing all papers and instruments or requiring employees to execute papers and instruments as reasonable and appropriate: and (iv) informing the other Party of matters that may affect the preparation, filing, prosecution, or maintenance of any intellectual Property Rights Costs and expenses (beyond those of the Parries' own internal resources) relating to such filing, prosecution and maintenance of Joint IP Rights shall be [**]

(c) All decisions with respect to the enforcement of Joint IP Rights shall be made jointly by mutual agreement of the Parties. Each Party shall bear [**] for such enforcement as well as any adverse costs award made in connection with such enforcement.

(d) A Party may by written notice unilaterally surrender to the other Party all of its rights and obligations to all or any portion of the Joint IP Rights upon fifteen (15) days' written notice. in the event that a Party has given notice of its surrender of its rights and obligations to all or any portion of the Joint IP Rights (the **"Surrendering Party"**), from expiry of the notice the other Party shall become the sole owner of such Joint IP Rights (the **"Surrendered Joint IP Rights"**) and thereafter have the sole discretion with respect to the

filing, prosecution, maintenance and enforcement of the Surrendered Joint IP Rights Where the Surrendering Party gives notice to surrender its interest in any Joint IP Rights that are the subject of any enforcement action approved by the Parties pursuant to sub-section (c) above, the Surrendering Party shall [**] of such enforcement action unless or until the other Party releases it.

(e) The Surrendering Party hereby appoints the other Party to be its attorney to execute any such Instrument and/or do any such thing colefy for the limited and explicit purpose of recording the other Party as the sole proprietor of, and for perfecting all legal and equitable title in, the Surrendered Joint IP Rights (including any Joint IP Rights that are the subject of any enforcement action approved by the Parties in respect of which the Surrendering Party has given notice to the other Party to surrender its interest in accordance with sub-sections (c) and (d) above) and for no other purposes. The power of attorney granted by this clause expressly indudes, without limitation, the execution and/or recordal (where applicable) of an assignment. In respect of such Surrendered Joint IP Rights. The Surrendering Party acknowledges In favour of a third party that a certificate in writing signed by any director or the secretary of the other Party having the limited effect provided for by this power to record the other Party as the proprietor of the Surrendered Joint IP Rights falls within the authority conferred by this Agreement and shall be conclusive evidence that such is the case. This power of attorney is Irrevocable and shall survive termination of this Agreement or any Work Plan.

(f) **Mutual license in respect of Jointly Owned Foreground IPR**. Each Party hereby grants to the other Party a non-exclusive, perpetual, irrevocable, royalty free, fully paid, worldwide fully transferable license, sub-licensable through multiple tiers, to use and (subject to cacb Party's strict compliance with the provisions of Section 8 at all times) disclose the Jointly Owned Foreground IPR Notwithstanding the perpetual and Irrevocable nature of the foregoing licence, upon a Party becoming a Surrendering Party in respect of any Jointiy Owncd Foreground IPR in accordance with Sub-section (c) above or otherwise ceasing to have any ownership in respect or any Jointly Owned Foreground IPR, then this licence shall automatically terminate with respect to such Jointly Owned Foreground IPR. The provisions of this Section 6.7 survive the termination or expiry of this Agreement for any reason.

6.8 **Party's Names**. Except as otherwise provided for in this Agreement as agreed in writing between the Parties, 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 directors, officers or employees in any advertising, news release or other publication.

6.9 **Public Announcements**. Except as required by applicable law, rule or regulation or any stock exchange on which securities issued by a Party or its Affiliates are traded, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed, provided that each Party may mate any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 6.8 and which do not reveal non-public information about the other Party. For the avoidance of doubt, nothing in this clause (or otherwise in this Agreement) will prevent CUSTOMER from disclosing the fact that NOVASEP is the manufacturer of the Product, whether by disclosing such Information on Product packaging, labelling or documentation or to any of CUSTOMER's Affiliates, employees, licensees, customers, or to other bodies or individuals who may reasonably require such disclosure (including, for the avoidance of doubt, regulatory bodies) Such disclosure by CUSTOMER will not require NOVASEP's prior consent.

7 Future Cooperation

7.1 The Parties agree to explore, in good faith, the option for NOVASEP to plan and provide CUSTOMER with commercial scale manufacturing services of any Product specified in a Work Plan and the Parties respective investments and contributions to the necessary scale up such discussions to commence within three (3) calendar months from the Effective Date with respect to the Product which is the subject of the first Work Plan. For the avoidance of doubt, nothing in this Section 7 or otherwise in this Agreement shall bind CUSTOMER to engage NOVASEP in respect of commercial scale manufacturing services or as an equipment supplier, the engagement of which shall be at CUSTOMER's sole discretion.

7.2 Any refusal by CUSTOMER to engage NOVASEP in this regard will not adversely affect or otherwise prejudice CUSTOMER's receipt of services from NOVASEP and NOVASEP's performance of services and provision of Works as set out in any Work Plans.

8 Confidentiality

8.1 The Receiving Party shall keep strictly confidential all Confidential Information it receives from or on behalf of the Disclosing Party and shall not disclose the same to a third party without prior written consent of the Disclosing Party.

8.2 The foregoing obligations of confidentiality and the restrictions on use below shall not apply to any portion of the Disclosing Party's Confidential Information that the Receiving Party can demonstrate by documentary evidence:

(a) was fully and lawfully already in its possession free of any confidentiality obligation prior to receipt from the Disclosing Party, or

(b) was wholly in the public domain at the time of receipt from the Disclosing Party and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence; or

(c) became part of the public domain through no fault of the Receiving Party, its Affiliates or any of its licensees or sub-contractors (as may be agreed to during the Term by the Disclosing Party pursuant to the terms of this Agreement) and whether directly or indirectly; or

(d) was lawfully received by the Receiving Party from a third party having a right of further disclosure and who did not, directly or Indirectly, receive such Confidential information from the Disclosing Party; or

(e) is required by law, regulation, rule, act, or order of any governmental authority or agency to be disclosed by the Receiving Party, provided, however, that the Receiving Party gives the Disclosing Party sufficient advance written notice to permit the Disclosing Party to seek a protective order or other similar order with respect to such Confidential Information and thereafter discloses only the minimum Confidential Information required to be disclosed in order to comply.

8.3 Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Information is embraced by general disclosures in the public domain or in the possession of the Receiving Party. In addition, any combination of Confidential information shall not be considered in the public domain or in the possession of the Receiving Party merely because Individual elements there of are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

8.4 Confidential Information of the Disclosing Party shall not be used by the Receiving Party other than for the purpose of this Agreement, the performance of the Works or as otherwise permitted to be used under or in accordance with the terms of this Agreement including under any licenses granted hereunder and those third parties envisaged in Section 6.5 (i) and (ii). The Parties shall only disclose Confidential information to employees, sub-licensees, sub-contractors (who have been pre approved by the Disclosing Party in advance) and/or Affiliates who have a genuine need to access such information in order to fulfil the Parties' obligations under this Agreement and/or to exercise the Party's rights under this Agreement. Where any Confidential Information may be sub licensed by a Party such Confidential information may be disclosed to such sub licensee and any potential sublicenses or to any Permitted Sub-contractors (who have been pre-approved by the Disclosing Party in advance) subject to confidentiality obligations no less onerous than those herein.

8.5 The Receiving Party agrees that, at the other Party's request; or upon expiration or termination of this Agreement (whatever the reason), the Receiving Party shall forthwith return to the other Party any and all parts of the Disclosing Party's Confidential information provided in documentary form and will return, destroy or permanently delete (at the Disclosing Party's election) any copies or other tangible embodiments thereof made by the Receiving Party; except for one copy that may be retained in a secure file for compliance purposes only.

8.6 For the purposes of this Section 8, the CUSTOMER Foreground IPR shall be treated as Confidential Information of CUSTOMER and the NOVASEP Foreground IPR shall be treated as Confidential Information of NOVASEP.

8.7 Neither Party shall, without the prior written consent of the other Party, disclose to any third party the terms of this Agreement (including any Work Plan), which shall be treated as Confidential Information, save that the Receiving Party may under obligations of confidentiality disdose this Agreement and relevant contents to its employees, directors, shareholders, Investors, and any potential Investors, sublicenses or shareholders and/or any of their professional advisors on a 'need to know' basis.

8.8 The Receiving Party will ensure the proper and secure storage of all of the Disclosing Party's Confidential Information applying standards of care reasonably expected and no less stringent than standards applied to protection of the Recipient Party's own Confidential Information.

8.9 Other than the limited and restricted rights of use set out in this Section 8 or under any licences granted elsewhere in this Agreement, nothing in this Agreement intends to or has the effect of granting any right, title, licence or interest in or to the Receiving Party in respect of the Disclosing Party's Confidential Information.

8.10 These obligations of confidentiality and non-use are valid during the period of this Agreement and for a period of [**] years after its termination Each Party agrees to indemnify the other from any loss suffered as a result of the violation of the provisions in this Section 8.

9 Fees and expanses

9.1 CUSTOMER shall pay NOVASEP all sums specified in a Work Plan together with any agreed Variable Costs property incurred in accordance with Section 2.25 of this Agreement. Unless otherwise agreed, all Prices and Variable Costs (where applicable and agreed) are lump sum amounts and are inclusive of taxes, duties, levles, Value Added Tax, other fees of whatever nature imposed by or under the authority of any government or public authority and all other costs and expenses (including, without limitation, raw materials, duties or charges for transportation, insurance shipping, storage and custom clearance of the Product and the deliverables) that NOVASEP incurs to perform the Works which CUSTOMER agrees to pay in addition to the price for the Works as set out in the Work Plan, Such prices based on delivery being FCA NOVASEP's plant (Incoterms 2010 of the ICC). All down-payments made by CUSTOMER will be off-set against the applicable Price for the Works in case NOVASEP wishes to deliver to CUSTOMER any quantity of Product above foreseen or required quantities, as indicated in a Work Plan, CUSTOMER may accept Delivery of such greater quantity of Product but at no additional cost to CUSTOMER beyond the Price unless otherwise agreed between the Parties in writing.

9.2 CUSTOMER shall obtain at its own expense any export and import license or other official authorization and carry out all customs formalities necessary for the exportation and/or importation of the deliverables and NOVASEP shall assist CUSTOMER to the extent reasonable in applying for and obtaining such licenses, authorizations or formalities.

9.3 Subject to Section 2.13, NOVASEP shall issue invoices to CUSTOMER in Euros in respect of the Price in accordance with the terms of this Agreement and the amount and invoicing schedule set out in the relevant Work Plan and, in the absence of any such schedule or conflicting provision herein, within thirty (30) days following completion of the relevant Works for which any invoice is issued in accordance with Section 2.2 CUSTOMER will not be liable for the payment of any fees, charges and expenses not set out in a Work Plan or, agreed between the Parties in writing before being incurred.

9.4 All invoices issued in accordance with Section 9.3 that are not the subject of any bona fide dispute or query or subject to Section 9.5 shall be paid in full within thirty (30) days of the data the invoice is received by CUSTOMER. NOVASEP will be entitled, at its discretion to charge CUSTOMER a maximum interest at an annual rate of [**] above Bank of England base rate in respect of any late payment of outstanding sums duo in respect of work agreed by both Parties as being completed and satisfactory.

9.5 If CUSTOMER serves a Defect Notice or otherwise rejects any delivery of product, CUSTOMER shall not be required to pay any invoice with respect thereto until the later of (i) thirty (30) days after such Product is finally determined not to be Defective Product: or (ii) thirty (30) days after delivery by NOVASEP of replacement Product, as applicable.

9.6 The performance of the Work by NOVASEP may be subject to change in laws and regulations, in particular (but not only) as a result of the application of the European REACH regulation (1907/2006). For any proposed change in legislation which the Parties identify as likely to have a potential impact on costs for NOVASEP in respect of its manufacture of the Product (and not in respect of any other products or any other work NOVASEP may be undertaking in respect of any other party), the Project Team and/or Steering Group (as applicable) will discuss how the Parties can mitigate the risk of increased costs in advance of any such change to legistation coming into force Provided that the Parties comply with the terms of this Section 9 and that increased costs for NOVASEP arise exclusively as result of the Work (and not any work Undertaken for or on behalf of any third party), any such reasonable costs which have been pre-approved by COSTUMER will be borne by CUSTOMER.

9.7 All payments to NOVASEP pursuant to this Agreement shall, unless specified otherwise in a Work Plan or varied by written notice to CUSTOMER prior to CUSTOMER's receipt of an invoice under this Section 9, be made by bank transfer to the following bank account;

HENOGEN S.A
rue des Professeurs Jeener at Brachet 12
6041 Gosselles
Belgium
TVA [**]
Bank name [**]
IBAN [**]
BIC/SWIFT [**]

10 Term end Termination

10.1 This Agreement shall commence on the Effective Date, and shall continue (subject to earlier termination in accordance with this Agreement) in accordance with the time frame set forth in each Work Plan, and expire when the last of the Works is completed, unless otherwise agreed between the Parties (the "Term")

10.2 Either Party (the "**Non Defaulting Party**") may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to the other Party (the "**Defaulting Party**") if:

(a) the Defaulting Party is in material breach of this Agreement (including any of its obligations under a Work Plan) provided that such breach (where capable of remedy) has not been remedied within [**] of receipt of written notice from the terminating Party specifying the breach;

(b) the Defaulting Party is (a) generally unable to pay its debts as they become due; or (ii) has an administrator appointed or administration order made against it or an order for winding-up or dissolution made (otherwise than in the course of a bona fide reorganization previously approved in writing by the Non Defaulting Party) or liquidator appointed and such step is not withdrawn within 30 days; or

(c) any permit or regulatory license is permanently revoked preventing the performance of the services or completion of the Works by the Defaulting Party.

10.3 CUSTOMER may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to NOVASEP in the event of a change of control of NOVASEP or any Affiliate controlling it (control having the meaning set out in the definition of Affiliate) whereby NOVASEP or such controlling Affiliate becomes controlled by a Competitor of CUSTOMER.

10.4 In addition to this, CUSTOMER may terminate this Agreement or any element of the Works or a Work Plan for any reason with a prior written notice of at [**] detailing which (or all) of the Works, a Work Plan are to be terminated or this Agreement in its entirety subject to the provisions of Section 11.2 of this Agreement.

11 Effect of Termination

11.1 On the termination or expiration of this Agreement CUSTOMER shall in accordance with this Agreement pay NOVASEP for all unpaid fees and expenses accrued in accordance with the terms of this Agreement up to the date of termination or expiration Each Party shall promptly return all Confidential information of the other Party, save that:

(a) Both parties may retain one (1) copy for the purpose of monitoring its confidentiality undertaking as defined in this Agreement, and

(b) CUSTOMER may retain one (1) copy of [**] and

(c) NOVASEP may retain one (1) copy of [**]

Within [**] of the termination or expiration of this Agreement NOVASEP shall deliver to CUSTOMER all CUSTOMER Equipment under the conditions provided for in Section 2.4, any remaining quantity of Customer Materials and/or Product already manufactured by or on behalf of NOVASEP and paid for by CUSTOMER.

11.2 If the Agreement has been terminated by CUSTOMER for convenience in accordance with Section 10.4 above, CUSTOMER shall pay NOVASEP for [**]

11.3 The provisions of Sections [**] will survive expiry or termination of this Agreement.

12 Liability

12.1 Each Party shall indemnify the other and hold the other harmless from and against any and all liability for death, illness or injury to any third party or for loss or damage to any third party's property and against all claims, demands, proceedings and causes of action (collectively, the "Liabilities") resulting directly or indirectly therefrom and arising out of a third party claim (a "Claim") arising from each Party's activities in the performance of the Work and/or arising out of any negligent or wrongful act or default on the part of the Party or its employees in the performance of or in compliance with any of their obligations under this Agreement, except as and to the extent any such Liabilities arise out of or results of the other Party's activities. In the performance of the Work and/or arising out of any negligent or wrongful act or default on the part of the other Party or its employees in the performance of or in compliance with any of their obligations under this Agreement.

12.2 Additionally, CUSTOMER shall indemnify and hold NOVASEP, its Affiliates, and their respective directors, officers, employees and agents harmless from and against all Liabilities resulting directly or indirectly therefrom and arising out of a Claim arising out of, resulting from or related to activities performed by CUSTOMER in connection with the Drug Product and/or the Drug Substance, save to the extent any Liabilities and Claims arise from or are caused by any breach by NOVASEP of this Agreement or are the subject of NOVASEP's obligations to indemnify CUSTOMER pursuant to Section 12.1 above.

12.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOSSES OF PROFITS). WHETHER IN CONTRACT OR IN TORT, UNDER INDEMNITY, OR OTHERWISE ARISING OUT OF ANY TERMS OR CONDITIONS IN THIS AGREEMENT OR WITH RESPECT TO THE PERFORMANCE THERETO, EXCEPT IN CASE OF GROSS NEGLIGENCE OR WILFUL MISCONDUCT, OR MISUSE BY OR ON BEHALF OF A PARTY OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OTHER THAN WHEN NOVASEP IS ACTING IN ACCORDANCE WITH THE INSTRUCTIONS OF CUSTOMER BUT SUBJECT TO NOVASEP NOTIFYING CUSTOMER OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OF WHICH NOVASEP MAY OR SHOULD BE AWARE USING REASONABLE ENDEAVOURS AND/OR WHICH MAY IMPACT ON SUCH INSTRUCTIONS, OR USING CUSTOMER BACKGROUND DATA, CUSTOMER PRE-EXISTING IPR OR CUSTOMER FOREGROUND IPR.

12.4 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, THE LIABILITY OF NOVASEP ARISING OUT OF ANY TERMS OR CONDITIONS IN THIS AGREEMENT OR WITH RESPECT TO THE PERFORMANCE THERETO. BUT EXCLUDING ANY INFRINGEMENT OR MISUSE BY OR ON BEHALF OF NOVASEP OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS IN ITS PERFORMANCE OF THE WORK (OTHER THAN WHEN NOVASEP IS ACTING IN ACCORDANCE WITH THE INSTRUCTIONS OF CUSTOMER BUT SUBJECT TO NOVASEP NOTIFYING CUSTOMER OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OF WHICH NOVASEP MAY OR SHOULD BE AWARE USING REASONABLE ENDEAVOURS AND/OR WHICH MAY IMPACT ON SUCH INSTRUCTIONS, OR USING CUSTOMER BACKGROUND DATA, CUSTOMER PRE-EXISTING IPR OR CUSTOMER FOREGROUND IPR). SHALL BE LIMITED TO [**]

13 Applicable Law – Dispute Resolution

13.1 This Agreement shall be entirely and exclusively interpreted and enforced in accordance with the laws of England.

13.2 In case of disputes between the Parties arising from the enforcement and/or the interpretation of the Agreement, the Parties shall try to settle amicably rapidity such dispute by the Steering Group, and falling that by discussions between the CEO of each

Party. It is expressly agreed between the Parties that If no settlement can be found between them within a reasonable period of time, and in any case no later than two (2) months following the receipt by one Party of the written claim of the other Party, any disputes shall be brought in the Courts of England, which shall have exclusive Jurisdiction.

13.3 In case of disputes between the Parties arising from a Work Plan (or either Party's performance or non-performance of its obligations in respect of a Work Plan), the Parties shall try to settle amicably and rapidly such dispute by the Project Team. Disputes relating to a Work Plan that are not resolved by the Project Team within two (2) weeks of first notification will be escalated for resolution by the Steering Group and, where unsuccessfully resolved by the Steering Group within two (2) weeks of escalation from the Project Team, for discussion between the Chief Executive Officers of each Party Disputes under this Section 13 .3 not resolved amicably by the Chief Executive Officers in writing within one (1) week of the dispute being escalated from the Steering Group will finally be settled by the Courts of England.

13.4 In the event that either Party requires emergency relief in respect of a dispute, either Party shall be entitled to resort to litigation without observing the provisions regarding amicable dispute resolution in Sections 13.2 and 13.3.

14 Force Majeure

14.1 In this Agreement, Force Majeure means in relation to either Party, any circumstances beyond the reasonable control of that Party or rendering the performance by either Party impracticable due to the occurrence of a contingency the occurrence of which was not reasonably foreseeable at the time of contracting.

14.2 The following events arc notably (but not exclusively) considered as events of Force Majeure: war (whether or not declared), revolutions, riot or civil commotion, accident (beyond reasonable control), fire (beyond reasonable control), explosions (beyond reasonable control). Flood (beyond reasonable control), storm, and other exceptional and unexpected events beyond alt reasonable control of either party.

14.3 If any Force Majeure occurs in relation to either Party which affects or may affect the performance of any of its obligations under this Agreement, it shall notify the other Party forthwith as to the nature and extent of the circumstances in question.

14.4 Neither Party shall be deemed to be in breach of this Agreement, or shall be otherwise liable to the other Party, by reason only of any delay in performance, or the non performance of any of its obligations hereunder, to the extent that the delay or non performance is due to any Force Majeure of which it has duly notified the other Party, and the time for performance of that obligation shall be extended accordingly.

14.5 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by force Majeure for a continuous period in excess of ten (10) working days, the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

14.6 If the performance by either Party of any of its obligations under this Agreement is prevented of delayed by Force Majeure for ninety (90) days or more, consecutively or cumulatively, in any one (1) year, then the other Party shall in its discretion have the right to terminate this Agreement forthwith upon written notice.

15 General

15.1 This Agreement is binding upon and for the benefit of the undersigned Parties, their successors and assigns. The Parties are not entitled to assign or sub-contract any of their obligations under this Agreement without the other Party's prior written consent, except as expressly permitted herunder or otherwise in case of subcontracting, transfer or assignment to one of their Affiliates.

15.2 Each party is an independent contractor and neither is the agent of the other. Nothing in this Agreement is intended to or shall operate to create a partnership or joint venture or any kind between the Parties and no Party shall have authority to act in the name or on behalf of or otherwise to bind the other in any way.

15.3 If any provisions of this Agreement shall be held by a court of competent Jurisdiction to be Illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect. In such event, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision within the limits of applicable law or applicable court decisions.

15.4 It is understood and agreed between the Parties that no failure or delay by a Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

15.5 This Agreement, along with its appendices, if any constitute the entire agreement between the Parties with respect to the subject matter hereof, and it is expressly agreed that any and all prior understandings or agreements between the Parties relating to the subject matter of this Agreement, whether oral or written, are automatically cancelled by the execution of this Agreement in the event that any term in this Agreement conflicts with any term in a Work Plan or any Quality Agreement (except in respect of matters concerning cGMP responsibilities and processes, in which case, the terms of any Quality Agreement would prevail), the conflicting term of this Agreement will prevail.

15.6 The terms and conditions set forth in the Agreement and its appendices (including any amendment to a Work Plan) may only be modified in a subsequent writing signed by the Parties.

15.7 All notices to be given under the Agreement shall be in writing in English and left at or sent by first class registered or recorded delivery mail, or fax to the appropriate address shown in Section 15.8 or left at or sent to such other address as the Party concerned may from time to time designate by notice pursuant hereto.

15.8 The Parties' contact information is:

For NOVASEP: [**]
CEO HENOGEN SA
12 rue des Professors Jeener et Brachet
B-6041 Charleroi, Belgium
fax [**]

With copy (which shall not constitute notice) to:
NOVASEP HOLDING SAS
Attn [**]
39 rue Saint Jean de Dieu
69007 Lyon, France
Fax [**]

For CUSTOMER: [**]
Freeline Therapeutics,
UCL Royal Free Medical School,
Pond Street, London,
NW3 2QG,
United Kingdom
Email [**]
Fax [**]

15.9 This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which shall be an original but all of which together shall constitute one and the same instrument. This Agreement is not effective until each Party has executed at least one (1) counterpart.

Made in two original copies, one for each Party.

Signed by a duly authorized signatory for and on behalf of **HENOGEN SA**

Signature: [**]
Name: [**]
Position: Chief Executive Officer
Date: 11-Oct-2016

Signed by a duly authorized signatory for and on behalf of **FREELINE THERAPEUTICS LIMITED**

Signature: [**]
Name: [**]
Position: CEO
Date: 7-Oct-2016

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 3:
Work Plans

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 4:
Quality Agreement

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 5:
Steering Group

CUSTOMER Steering Group Members as at the Effective Date:

1. [**], Freeline Chief Development Officer (Chair)
2. [**], FIX Program Lead
3. [**], Freeline Chief Technology Officer

NOVASEP Steering Group Members as at the Effective Date:

1. [**], CEO of HENOGEN SA
2. [**], Strategic Project Director
3. [**], Strategy and Operations Director

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 6:
Customer Pre-existing IP

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 7:
Novasep Pre-existing IP

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 8:
Cancellation Fees

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Exhibit 10.11

CONFIDENTIAL

DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT

This **DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT** (this "Agreement"), effective as of this 6th day of October, 2017 (the "Effective Date"), between, **Freeline Therapeutics Limited** ("Customer"), having its principal place of business at 215 Euston Road, London NW1 2BE, UK, and **Brammer Bio MA, LLC,** a Delaware limited liability company with offices at 250 Binney Street, Cambridge, MA 02142 ("Brammer"). Customer and Brammer are referred to herein each as a "Party" and collectively as the "Parties".

WHEREAS, Brammer provides a full range of cell and gene therapy and viral vector process development and manufacturing services to the biopharmaceutical industry;

WHEREAS, Customer desires Brammer to perform certain services in accordance with the terms of and as more specifically set forth in this Agreement and its Work Statements (as defined below) related to the development, manufacture and supply of the Product (as defined below), and Brammer desires to perform such services;

WHEREAS, Customer and Brammer intend for this Agreement to cover certain development activities, including the transfer, facility fit and validation of Customer's Process (as defined below and attached hereto as Exhibit G), and the clinical supply and preparation for launch supply of the Product in accordance with the terms in Exhibit A;

WHEREAS, Customer and Brammer intend to enter into the first Work Statement ("Work Statement 1") on the same date as this Agreement, and, upon completion of the engineering run of the Product, to commence negotiations to finalize the second Work Statement, which will cover the clinical and preparation for launch supply of the Product: and

WHEREAS, Customer and Brammer further intend, subject to successful completion of Work Statement 1, to negotiate in good faith a Commercial Supply Agreement relating to the Product, substantially in the form set out in the non-binding Commercial Supply Term Sheet at Exhibit D.

NOW, THEREFORE, in consideration of the above statements and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

1. **Definitions.** Terms defined elsewhere in this Agreement will have the meanings set forth therein for all purposes of this Agreement unless otherwise specified to the contrary. The following terms will have the meaning set forth below in this Section 1:

1.1 "Affiliate(s)" means any person, firm, trust, partnership, corporation, company or other entity or combination thereof which directly or indirectly: (a) controls a Party; (b) is controlled by a Party; or (c) is under common control with a Party. As used in this definition, the terms "control" and "controlled" will mean ownership of fifty percent (50%) or more (including ownership by trusts with substantially the same beneficial interests) of the voting and equity rights of such person, firm, trust, partnership, corporation, company or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof.

1.2 "Actual Expenditure" has the meaning set forth in Section 8.4.

1 .3 "Applicable Laws" means all applicable ordinances, rules, regulations, laws, guidelines, guidances, requirements and court orders of any kind whatsoever of any Regulatory Authority applicable to a Party's activities hereunder, as amended from time to time, including cGMP (if applicable) of the USA FDA, the EMA, the European Commission, the International Conference on Harmonization (ICH) guidelines and regulations, and other regulatory jurisdictions as agreed to by both Parties.

1.4 "Approval Date" means the date of receipt by Customer of the first regulatory approval to market the Product as Manufactured by Brammer.

1.5 "Approved Vendor(s)" has the meaning set forth in Section 5.1

1.6 "Assays" means the AUC and infectious titer assays.

1.7 "Assumptions" has the meaning set forth in Section 9.1

1.8 "Batch" means a specific quantity, as set out in a Work Statement, of Drug Substance or Drug Product that is intended to have uniform character and quality within specified limits and is produced according to a single cycle of Manufacture, and shall include, without limitation, pilot batches, engineering batches, and GMP batches.

1.9 "Batch Documentation" has the meaning set forth in Section 7.1.

1.10 "Batch Record" (also referred to as "Manufacturing Batch Record (MBR)" or "Batch Production Record (BPR)'') means a manufacturing record for a Batch generated by Brammer concurrently with the production of a specific Batch such that successive steps in such processes are documented, and includes without limitation all documentation necessary to maintain compliance, batch records, specifications, compliance and quality assurance documentation, Certificates of Analysis, certificates of compliance, manufacturing batch records, deviation reports (including operator error or equipment failure), packaging records, documentation or records of environmental monitoring, and other materials generated by Brammer during or in connection with the Batch, whether recorded in writing or electronically.

1.11 "Brammer IPR" has the meaning set forth in Section 12.4.

1.12 "Brammer Failure" [**]

1.13 "Brammer Materials" means the materials identified in the applicable Work Statement as being provided by Brammer to be used in the Manufacture of the Product under the applicable Work Statement, including Process Consumables.

1.14 "Brammer Parties" has the meaning set forth in Section 17.1.

1.15 "Brammer Technology" [**]

1 .16 "Certificate of Analysis" means a written certificate listing the items tested, Manufacturer, specifications, testing methods and test results for a specific Batch.

1.17 "cGMP" or "GMP" means current good manufacturing practices, including the regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act, 21 C.F.R. Part 210 *et seq.*, as amended from time to time, applicable guidance documents issued by the FDA, EC Directive 2003/94/EC and European Medicines Agency guidance documents, applicable documents developed by the International Conference on Harmonization (ICH) to the extent that they are applicable to the Product and the Parties hereunder, and other Regulatory Authorities, as agreed to by the Parties, applicable to the manufacture and testing of pharmaceutical materials under Applicable Laws.

1.18 "Change of Control" means "any of the following events:

(i) any Third Party (or group of Third Parties acting in concert or otherwise) becomes the beneficial owner, directly or indirectly of, or otherwise obtains control, directly or indirectly of (A) a majority of the voting rights exercisable at shareholder meetings of a Party; or (B) the right to appoint or remove directors by holding a majority of the voting rights exercisable at meetings of the board of directors of the Party; or (C) the ability to direct or procure the direction of the management and policies of the Party, whether through ownership or shares, contract or otherwise; or

(ii) the Party consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into the Party, in either event pursuant to a transaction in which:

(1) the direct or indirect control of a majority of the voting rights exercisable at shareholder meetings of the surviving entity;

(2) the direct or indirect right to appoint or remove directors by holding a majority of the voting rights exercisable at meetings of the board of directors of the surviving entity; or

(3) the direct or indirect ability to direct or procure the direction of the management and policies of the surviving entity, whether through the ownership of shares; by contract or otherwise,

in each case is not held by the Persons holding such control, right or ability (as the case may be) preceding such consolidation or merger; or

(ii) the Party conveys, leases or transfers all or substantially all of its assets to any Third Party.

1.19 "Change Order" has the meaning set forth in Section 9.2.

1.20 "Claim" has the meaning set forth in Section 17.1.

1.21 "Commercially Reasonable Efforts" means, with respect to the activities of Brammer in the performance of the Services, carrying out such obligation using efforts consistent with contract development and manufacturing organizations in the biopharmaceutical industry, resources typically used by contract development and manufacturing organizations in the United States in the performance of such services to achieve a desired result, including human and technical resources, and the expenditure of funds which are necessary to complete such services and achieve such result. For clarity, acts of negligence or willful misconduct or failure to perform due to financial offers from third parties will not be deemed to be commercially reasonable.

1.22 "Confidential Information" means, all know-how (and all tangible and intangible embodiments thereof), and all other secret, confidential or proprietary information, data or materials, whether provided in written, oral, graphic, video, computer or other form, or by observation at the Party's facilities, which is owned or controlled by a Party and is disclosed or made available by such Party or an Affiliate of such Party to the other Party or an Affiliate of such other Party pursuant to this Agreement which: (a) if disclosed in written, graphic, electronic or other tangible form, is labeled as confidential or proprietary, (b) if disclosed orally or visually, is identified as confidential or proprietary at the time of disclosure and is confirmed to be confidential or proprietary by the Disclosing Party in writing to the Receiving Party within thirty (30) calendar days of such disclosure, or (c) by its nature, should reasonably be considered to be confidential or proprietary. Confidential Information of Customer includes business, technical and financial data, and know-how concerning the Customer Provided Materials, Customer Technology and the Product, the Specification and the Process of Exhibit G, provided, however that, to the extent Brammer Technology or New Brammer Technology is included in the Product, Specification, or Process, such Brammer Technology and New Brammer Technology do not lose their status as Confidential Information of Brammer by virtue of having been incorporated therein; and Confidential Information of Brammer includes proprietary technical data, know-how, and trade secrets concerning Brammer's production and purification methods, Brammer's equipment and techniques, Brammer's facilities and its design and operation, and Brammer Technology and New Brammer Technology, as well as business, financial and technical data.

1.23 "Customer Approval" has the meaning set forth in Section 7.1.

1.24 "Customer-Funded Equipment" means, if any, equipment which is funded and owned by the Customer, which may be used by Brammer solely in connection with the provision of the Services, and which will be installed, validated and maintained by Brammer during the term of this Agreement and will be specified in the applicable Work Statement.

1.25 "Customer Provided Materials" means the materials identified in the applicable Work Statement to be provided by Customer to Brammer hereunder, for use in the Manufacture of the Product under the applicable Work Statement. Customer Provided Materials will not include Brammer Materials.

1.26 "Customer Technology" [**] by or on behalf of Customer independent of this Agreement and without reliance upon the Confidential Information of Brammer.

1.27 "Customer Parties" has the meaning set forth in Section 17.2.

1.28 "Customer Representative" has the meaning set forth in Section 3.6.

1.29 "Defect" [**]

1.30 "Delinquency Period" has the meaning set forth in Section 8.5.

1.31 "Deliverable" means any work product to be provided by Brammer pursuant to this Agreement or a Work Statement, but excluding Product.

1.32 "Delivery Site" has the meaning set forth in Section 7.2.

1.33 "Disclosing Party" has the meaning set forth in Section 10.1.

1.34 "Disposition" means a documented decision on the acceptability for use of a specific Batch that is based on a process of reviewing data associated with the production and testing of the product.

1.35 "Drug Product" means the Product Manufactured by Brammer on behalf of Customer, into its final container closure, whether or not labeled.

1.36 "Drug Substance" means the non-sterile active pharmaceutical ingredient (as defined by ICH Q7) Manufactured by Brammer on behalf of Customer and identified in the applicable Work Statement.

1.37 "EMA" means the European Medicines Agency, and any successor agency entity thereof having or performing substantially the same function.

1.38 "Estimate" has the meaning set forth in Section 8.3.

1.39 "EU" means all of the European Union member states as of the applicable time during the term of this Agreement.

1.40 "Existing Confidentiality Agreement" means that certain Confidential Disclosure Agreement, dated 17th January 2017 by and between the Parties.

1.41 "Facility" means the Brammer manufacturing, laboratory and warehouse facility specified in the applicable Work Statement, or any other Brammer facility as agreed to in writing by the Parties.

1.42 "Force Majeure Event" has the meaning set forth in Section 21.

1.43 "FDA" means the United States Food and Drug Administration or any successor entity thereof having or performing substantially the same function.

1.44 "FTE" has the meaning set forth in Section 12.5(i).

1.45 "General Assumptions" has the meaning set forth in Section 9.1.

1.46 "ICH" means the International Conference on Harmonization.

1.47 "Improvement" means any modification, enhancement or improvement to a Technology, or any discovery related to such Technology, whether or not patented or patentable, and all associated Intellectual Property Rights therein or thereto.

1.48 "Indemnified Party" has the meaning set forth in Section 17.3.

1.49 "Indemnifying Party" has the meaning set forth in Section 17.3.

1.50 "Intellectual Property Rights" means any and all of the following: (a) Patents, (b) copyrights in both published and unpublished works, (c) rights in trade secrets and know-how, whether or not patentable or copyrightable, (d) trademark and service mark rights, (e) any and all other intellectual property rights, and (f) any and all registrations and applications for registration of any of the foregoing.

1.51 "Latent Defect" [**]

1.52 "Losses" has the meaning set forth in Section 17.1.

1.53 "Manufacture," "Manufactured," and "Manufacturing" means the steps, processes and activities used by Brammer to produce the Product, including, for example, the manufacturing, processing, packaging, labeling, testing, stability testing, Process Performance Qualification, and the release, shipping, storage or supply of Product as provided in the Work Statement, Batch Record and Master Batch Record.

1.54 "Master Batch Record" means the document containing the Specifications and instructions for the Manufacture and quality assurance of a Product, as such may be amended by the Parties in accordance with the terms hereof.

1.55 "Materials" means Customer Provided Materials and Brammer Materials.

1.56 "MHRA" means the Medicines and Healthcare products Regulatory Agency of the United Kingdom ("UK").

1.57 "New Brammer Technology" [**]

1.58 "New Customer Technology" [**]

1.59 "New Technology" means the New Brammer Technology or the New Customer Technology, as applicable.

1.60 "Pass-Through Costs" has the meaning set forth in Section 8.2.

1.61 "Patents" means patents and patent applications issued or pending therefrom anywhere in the world, together with any and all divisions, renewals, continuations and continuations-in-part thereof, and all patents granted thereon, and all reissues, re-examination certificates, certificates of invention and applications for certificates of invention, revalidations, substitutions, supplementary protection certificates, additions, utility models, and term restorations, extensions and foreign counterparts thereof.

1.62 "Permitted Recipients" has the meaning set forth in Section 8.2.

1.63 "Person" means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust or joint venture, or a governmental agency or political subdivision thereof.

1.64 "Process" means the processes and procedures used to Manufacture a Product in accordance with the Master Batch Record, including all protocols and standard operating procedure documents referenced therein, which are provided by Customer to Brammer or developed by Brammer and Customer hereunder.

1.65 "Process Consumables" means media, raw materials, chromatography columns, resins, filters, membranes, disposable analytical test kits, hoses, fitter housings, tubing, filling needles, disposable bags, disposable glass/plastic ware, cleaning supplies and other changeover parts used during the Manufacture of Product. Parties may list other Process Consumables to be added to the scope of this Agreement in subsequent Work Statements.

1.66 "Process Performance Qualification" or "PPQ" means the process agreed by the Parties for the collection and evaluation of data, from the process design stage through repeated production at final scale, which establishes scientific evidence that a Manufacturing Process is capable of consistently and reproducibly delivering Product meeting Specifications.

1.67 "Product" means Customer's product defined in the applicable Work Statement.

1.68 "Program" means all of the Services to be performed by Brammer for Customer as described in Work Statement(s) for such Program, including any properly mutually agreed and authorized amendments or Change Orders thereto.

1.69 "Program Assumptions" has the meaning set forth in Section 9.1.

1.70 "Program Manager" has the meaning set forth in Section 3.6.

1.71 "Quality Agreement" has the meaning set forth in Section 3.7.

1.72 "Receiving Party" has the meaning set forth in Section 10.1.

1.73 "Regulatory Authority" means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the manufacture, production, use or storage or transport, of any Product, including the FDA, the EMA, the MHRA and the European Commission.

1.74 "Reprocess" means introducing a Product back into, and repeating appropriate manipulation steps that are part of, the established Process.

1.75 "Result(s)" means all in-process analytical results, materials, data obtained, and reports developed and/or generated by Brammer in performing the Services related to the Product or Process. Any results, materials or data obtained, developed or generated outside of the conduct of the Services or that are not related to the Product or Process will not constitute Results. For the avoidance of doubt, documents that may be generated or used in the course of performing Services under the Program, but that are general to Brammer's business and do not relate to the Product or Process, such as a Facility and equipment SOPs, will not constitute Results.

1.76 "Retained Copies" has the meaning set forth in Section 20.5(ii).

1.77 "Retention Period" has the meaning set forth in Section 11.2.

1.78 "Service Fee" has the meaning set forth in Section 8.1.

1.79 "Services" means the services and activities to be performed by Brammer, any Brammer Affiliate, any of their respective employees, agents or consultants, or Approved Vendors hereunder as part of a Program, as more specifically set forth in the applicable Work Statement.

1.80 "SOP" means the written standard operating procedures and methods of Brammer, as the same may be amended, in Brammer's sole discretion, from time to time.

1.81 "Special Waste" means waste or effluent, which is required to be collected in a special container for external disposal.

1.82 "Specifications" means, with respect to a particular Product, the list of tests, references to any analytical methods and appropriate acceptance criteria which are numerical limits, ranges or other criteria for tests described, which establishes a set of criteria to which such Product should conform to be considered acceptable for its intended use, in each case, as in effect from time to time. The Parties will agree to the Specifications through the performance of the Services under the Work Statements.

1.83 "Stage" means a stage of the Program as set out in the applicable Work Statement.

1.84 "Technology" means all scientific, technical and other information, data, know-how, trade secrets, inventions (whether or not patentable), processes, compositions of matter, materials, methods, techniques, documentation, hardware, software and technology, whether or not protected or protectable under patent, trademark, copyright or similar law.

1.85 "Third Party" means any party other than Customer, Brammer and their respective Affiliates.

1.86 "Travel Expenses" means costs and expenses incurred by Brammer for travel and lodging required in order to carry out any Program.

1.87 "Wait Period" has the meaning set forth in Section 12.7.

1.88 "Work Statement" means a detailed work order, substantially in the form attached hereto as Exhibit A, that (a) includes, as appropriate, a description that specifies the Program, the scope of the Services under such Program, the estimated duration of the Program, and all other matters pertinent to completion of the Program, (b) references this Agreement, (c) is signed by authorized representatives of both Parties and (d) sets forth, at a minimum, the Services to be provided by Brammer and the fees to be paid by Customer for such Services, including the anticipated Travel Expenses, if any, and any modifications to such work statement that the Parties may agree in writing from time to time.

2. **Work Statements.**

2.1 This Agreement contains general terms and conditions under which Customer may engage Brammer to provide, and Brammer would provide, Services. Customer and Brammer will complete and execute an initial Work Statement as Exhibit A before any Services are provided. Each Work Statement will include, as appropriate, a description that specifies the Program, the scope of the Services under such Program, the estimated duration of the Program, and all other matters pertinent to completion of the Program, and, once executed by both Parties, such Work Statement will be deemed a part of this Agreement and incorporated herein by reference. To the extent any terms or provisions of a Work Statement conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement will control, except to the extent that the applicable Work Statement expressly states an intent to modify the terms of this Agreement on a specific matter. The Parties may amend a Work Statement by agreement in writing from time to time during the term of this Agreement.

2.2 The Parties envisage that they will enter into two Work Statement(s) in connection with this Agreement, with the second Work Statement covering Part 2 of the program of work, as set out in outline in Work Statement 1. In consideration of the Customer agreeing to commence good faith negotiations for the second Work Statement with Brammer no later than the date on which the engineering run Batch of the Product is accepted by the Customer, [**]

2.3 A Program will be complete when all Stages of the applicable Work Statement(s) have been completed or when the applicable Work Statement or this Agreement has been terminated pursuant to Section 20.

2.4 With respect to each Work Statement, Customer acknowledges that Brammer consulted with Customer in developing the Work Statement in a manner consistent with Brammer's then current reasonable understanding of, as applicable, United States (the "U.S."), EU and UK, and other regions as agreed to by the Parties, regulatory guidelines to the extent applicable to the Product and the Parties. Brammer does not, however, represent or warrant that the Program and/or the Results of the Services will satisfy the requirements of any Regulatory Authorities at the time of submission of such Results to such Regulatory Authorities. Customer will be responsible for obtaining all regulatory approvals relating to registration of the Product, but not for any existing licenses of Brammer, and will own the applicable regulatory filings and approvals. As between the Parties, Customer will be responsible for complying with all Applicable Laws relating to the shipping, distribution and marketing of Product.

3. **Program Performance**.

3.1 Brammer will use Commercially Reasonable Efforts to perform the Services for Customer in accordance with the applicable Work Statement and in accordance with all Applicable Laws.

3.2 [**]

3.3 Brammer will comply with cGMP applicable to the Services, provided that, should cGMP applicable to the Services be changed following the Effective Date, Brammer will use Commercially Reasonable Efforts to comply with such new cGMP requirements without interruption to cGMP status. In the event that compliance with such new cGMP requirements necessitates, in the reasonable determination of the Parties, a change in the Work Statement or the Services, Brammer will submit to Customer a proposed Change Order in accordance with Section 9.2.

3.4 Customer acknowledges that due to the unpredictable nature of biological processes, a Process Performance Qualification (as envisaged to be completed in the second Work Statement) needs to have taken place to establish the commercial process of Manufacturing the Product.

3.5 Brammer undertakes that it shall:

(i) use Commercially Reasonable Efforts to ensure that the Facility is ready to perform for the first relevant activity under each Work Statement in accordance with the timeline mutually agreed to by the Parties for such activity; Customer acknowledges that the timelines set forth in any Work Statement are good faith estimates using assumptions based on information available on the date on which the applicable Work Statement is executed. Customer understands that it needs to comply in a timely manner with all of its relevant obligations in order to enable Brammer to achieve such timelines;

(ii) give the Customer prompt written notice of any anticipated delay in the completion of the Facility; and

(iii) in the event of any delay in the Facility being ready in accordance with (i), use its best efforts (a) to complete the commissioning of the Facility as soon as possible and (b) to perform its obligations under each Work Statement using alternative resources and Facilities, including by giving the Customer priority in the use of available Brammer capacity.

3.6 Brammer will appoint a Brammer representative (the "Program Manager") to be responsible for overseeing the conduct of the Services and the completion of the Program by Brammer. The Program Manager will coordinate performance of the Services with a representative designated by Customer in writing (the "Customer Representative"), which representative will have responsibility over all matters relating to performance of the Services on behalf of Customer. Unless otherwise agreed in the Work Statement, or mutually agreed to by the Parties, all communications between Brammer and the Customer regarding the conduct of the Services pursuant to the Work Statement will be addressed to or

routed through the Program Manager and Customer Representative. The Program Manager and the Customer Representative are named in the Work Statement, and Brammer or Customer may, at its option, substitute, respectively, the Program Manager or the Customer Representative during the course of the Program by providing written notice to the other.

3.7 The Program Manager shall co-ordinate meetings of a joint project team to oversee and co-ordinate the performance of this Agreement on a day-to-day basis. The Program Manager and the Customer Representative shall determine, acting reasonably, which other individuals should be part of the joint project team or otherwise attend joint project team meetings from time to time. The joint project team shall meet in person or by phone every two (2) weeks, or more frequently as may be agreed. The Program Manager shall be responsible for taking minutes of each meeting of the joint project team and circulating such minutes to the Customer Representative for review.

3.8 The Parties shall each nominate two (2) individuals to sit on a joint steering committee to oversee the performance of this Agreement (the "JSC"). The JSC shall meet, whether in person or by telephone, once every 6 months, or ad hoc as may be agreed, to review the progress of all Work Statements and any other matters relating to the Agreement, based on written reports provided to them by the Program Manager and the Customer Representative. Where the JSC is unable, in good faith, to reach agreement on any matter referred to them, either Party may refer the matter for dispute resolution under Section 16. The matters referred to the JSC shall include, without limitation, the agreement of a Specification for a Work Statement; disputes over whether a Product contains a Defect; and such other matters as the Parties may determine from time to time.

3.9 Promptly following the execution of this Agreement, the Parties will enter into a detailed document specifying the quality and regulatory procedures and responsibilities of the Parties with respect to the Manufacture of Product (the "Quality Agreement", substantially in the form of the draft annexed as Exhibit E; provided, however, that, upon execution, the executed Quality Agreement will replace the draft in Exhibit E). In the event of any conflict between the terms and provisions of this Agreement and the terms and provisions of the Quality Agreement, the terms of this Agreement will control, except with respect to quality related matters.

3.10 The Parties confirm that, subject to successful completion of Work Statement 1, they intend to negotiate in good faith a Commercial Supply Agreement relating to the Product, substantially in the form set out in the non-binding Commercial Supply Term Sheet at Exhibit D.

4. **Program Materials.**

4.1 Customer Provided Materials.

(i) Customer will provide Brammer with sufficient amounts of the Customer Provided Materials with which to perform the Services as specified in the Work Statement. Unless the Work Statement includes the development of a manufacturing process by Brammer, Customer also will provide Brammer with all necessary Confidential information in Customer's possession and control to effect the reliable transfer of the Process from Customer to Brammer.

(ii) Customer Provided Materials will be delivered by Customer to the Facility at no cost to Brammer. Unless otherwise agreed by the Parties, Customer will deliver the Customer Provided Material in quantities sufficient to meet the expected requirements of Product Manufacturing.

(iii) Customer will provide Material Safety Data Sheets for all Customer Provided Materials and for each Product that are, in each case, accurate and complete to the best of

Customer's knowledge having taken all appropriate steps to inform itself of the same. Customer will notify Brammer of any unusual adverse health or environmental occurrence relating the Customer Provided Materials, and any Product, including but not limited to any claim or complaint by any Customer employee or Third Party.

(iv) Customer Provided Materials will remain the sole property of Customer at all times during the term of this Agreement, but will remain in the possession, control and care of Brammer following delivery of such Customer Provided Materials by Customer to the Facility. Brammer will use and store the Customer Provided Materials with due care and in compliance with Customer's instructions as set forth in the applicable Work Statement. Title and risk of loss or damage to such Materials will at all times remain with Customer, and Brammer will have no liability to Customer for such Materials except due to Brammer's negligence, breach of this Agreement or failure to comply with Applicable Laws.

(v) Import, Export, Customs. For all Customer Provided Materials being delivered to Brammer for Customer's account, and all Materials delivered by Brammer for Customer's account, Customer will be responsible at its sole cost and expense for satisfying all import, export and customs requirements, including United States Export Control Regulations, and Customer will be the importer and exporter of record (or utilize its own customs broker) for any Customer Provided Materials being imported and shipped to Brammer and for all Materials exported to another country, in each case, for Customer's account (but excluding, for the avoidance of doubt, any Materials exported by Brammer to an Affiliate or Third Party in connection with the performance of the Services, and any corresponding import). Brammer shall provide Customer with reasonable assistance in relation to the import and export of Materials pursuant to this Agreement, and Customer's obligations as the importer and exporter of record of all materials.

(vi) Upon completion of the Program, any remaining Customer Provided Materials will be, at Customer's sole expense and election (such election to be made by Customer to Brammer in writing no later than [**] either after Brammer's issuance of a Certificate of Analysis for the last applicable Product, or receipt of a notice of termination), returned to the Customer or destroyed/disposed of by Brammer. If Customer does not provide such election to Brammer within such [**] Brammer will, at Customer's expense, return to the Customer the applicable Customer Provided Materials. Notwithstanding anything to the contrary contained in this Agreement, (i) Brammer may retain Customer Provided Materials as required by Applicable Laws, and (ii) in no event will Brammer be required to store Customer Provided Materials for more than [**] after termination or expiration of an applicable Work Statement or this Agreement unless the Parties have entered into an appropriate storage agreement covering such items.

4.2 Brammer Materials and equipment; Customer-Funded Equipment.

(i) Brammer will use Commercially Reasonable Efforts to procure the Brammer Materials and all required equipment in a timely manner for use in the Program and each Manufacturing run as set forth in the Work Statement. Brammer will qualify vendors, perform audits according to agreed procedures and test and release Materials according to agreed procedures prior to the start of Manufacturing.

(ii) If necessary, Brammer will procure Customer-Funded Equipment to the extent required to perform the Service. Any required Customer-Funded Equipment and associated expenses will be set forth in the applicable Work Statement.

5. **Use of Vendors.**

5.1 Brammer reserves the right to employ vendors from time-to-time to undertake certain Services related to a Program (for example, for specialty testing, waste disposal, etc.) upon prior written notice to Customer describing the activities to be performed. All vendors must be pre-approved in writing by the Customer ("Approved Vendors"). A list of existing Approved Vendors as of its execution will be included in the Work Statement and updated from time to time, and any fees payable to an Approved Vendor must be approved in advance in writing by Customer. For mutually agreed upon non-routine Services provided by Approved Vendors (e.g., Services that are developmental in nature or specific to a Product and not, for example, standard specialty testing and waste disposal Services), each such Approved Vendor will be bound by written confidentiality, nonuse, and quality assurance obligations consistent with this Agreement, as well as an assignment to Brammer of all inventions or other intellectual property arising in the course of performing such Services, as necessary for Brammer to comply with its obligations to Customer under this Agreement.

5.2 Subject to the foregoing, Brammer will be responsible to Customer for managing the performance of Approved Vendors used for the Program. Brammer will work together with the Approved Vendor, and Customer if appropriate, to resolve any issues or failures by the Approved Vendor. Brammer shall only be responsible for the actions (or inactions) of an Approved Vendor resulting in a failure or Defect if such failure or Defect is the result of a Brammer Failure, in which case such failure or Defect shall be addressed in accordance with Section 7.9 and 7.10. Brammer will use Commercially Reasonable Efforts to enforce its legal and contractual rights (which, for non-routine Services and pursuant to Section 5.1, shall be in writing) against such Approved Vendor as necessary for Brammer to comply with its obligations under this Agreement or upon request from the Customer in the event of a material breach by such Approved Vendor.

6. **Facility Audits and Facility Visits.**

6.1 Facility Audits. Subject to Brammer's safety procedures, access control SOPs, and confidentiality limitations, Brammer will permit Customer's representatives, not more frequently than [**], during the term of this Agreement at mutually agreed upon times to audit the Facility as more specifically set forth in the Quality Agreement, provided, however, that Customer may conduct any additional for-cause audits at mutually agreed upon times with reasonable advance notification to Brammer. Customer will give Brammer reasonable advanced notice of any proposed routine audit but no fewer than [**] prior notice for a for-cause audit, and identify the individuals who will be in attendance; ***provided that*** a general quality audit will require a minimum of [**] prior notice. All routine audits will be during Brammer's normal business hours on weekdays and conducted in a manner that does not unreasonably interfere with Brammer's Services and does not otherwise unreasonably interfere with normal business activities. Brammer will [**] make its Facilities and all relevant records available for inspection by representatives of Regulatory Authorities in compliance with Applicable Laws, [**] All information, records, or business information concerning Brammer that is disclosed or made available by Brammer to Customer employees and representatives, and representatives of Regulatory Authorities, or otherwise obtained by such employees and representatives, in connection with any audit will be deemed to be Confidential Information of Brammer. [**]

6.2 Facility Visits. Subject to Brammer's safety procedures, access control SOPs, and confidentiality limitations, Brammer will permit Customer's representatives during the term of this Agreement, to visit the Facility at mutually agreed upon times, to support technology transfer and/or observe procedures and processes at mutually agreed upon times with reasonable advance notification to Brammer. Customer will give Brammer reasonable advanced notice of any proposed visit, but no fewer than [**] prior notice, and identify the individuals who will be in attendance, provided however that [**] notice will be required where Customer's representatives wish to visit the Facility in connection with a for-cause audit or an urgent Product safety related matter. All visits will be during Brammer's normal business hours on weekdays and conducted in a manner that does not unreasonably interfere with Brammer's Services and does not otherwise unreasonably interfere with normal business activities.

7. **Deliveryand Acceptance Procedures.**

7.1 Delivery and Acceptance of Batch Documentation. Brammer will manufacture each Batch of Product in accordance with the applicable Specifications and the relevant Work Statement, and store each such Batch in accordance with the applicable provisions of the Quality Agreement. As soon as Brammer has determined that such Batch complies with the Specifications and is ready for release to Customer, Brammer will send by fax and/or e-mail to Customer: (a) a packing list if applicable, (b) an invoice, (c) the Batch Record, and (d) the Certificate of Analysis (collectively, the "Batch Documentation"). Upon Customer's written acceptance of the Batch Documentation (or [**] following delivery to Customer of the Batch Documentation, if Customer makes no response) ("Customer Approval"), the Batch Documentation will be deemed approved and the relevant Batch of Product will be delivered as provided in Section 7.2.

7.2 Delivery of Batch. Following Customer Approval (pursuant to Section 7.1) of the Batch Documentation, Brammer will deliver each Batch of Product to Customer Ex Works (Incoterms 2010) to the Facility (the "Delivery Site") and Customer will take delivery of the same. Title to each Batch of Product will pass to Customer when Customer or Customer's designated carrier takes delivery of such Batch at the Delivery Site, and any undisputed invoices relating to the Batch are paid. All risks of loss or damage to any Batch of Product will pass to Customer on delivery at the Delivery Site. Brammer shall, without charge, provide Customer with reasonable support and advice in connection with the export of Product from the Delivery Site.

7.3 Acceptance of Batch Procedures. Upon receipt of each Batch of the Product, Customer will:

(i) inspect the Product and confirm that the quantity of Product received by Customer matches the quantity of Product set forth in the Batch Documentation, and make all the necessary reserves on the delivery receipt related to any shortage in the quantity of Product;

(ii) inform Brammer, by email of any shortage identified through the conduct of the inspection pursuant to Section 7.3(i) within [**] from the date of receipt by Customer of such Batch of Product; and

(iii) inform Brammer by email of any Defect within [**] from the date of delivery of such Batch of Product at the Delivery Site. Following receipt of such email Brammer and Customer will immediately initiate an investigation to determine the cause of the Defect.

7.4 Where any shortage in the quantity of Product received by the Customer is identified, the Customer may, in its sole discretion, either:

(i) accept the quantity of Product delivered and require Brammer not to deliver the shortfall amount; or

(ii) require Brammer to deliver the shortfall amount promptly and in any event within thirty (30) days.

Where the Customer chooses (i) above, the Customer is only obliged to pay for the volume of Product actually delivered.

7.5 During the period of [**] referred to in 7.3(iii) above, Customer shall be entitled to inspect and accept or reject such Batch for: (a) non-conformance with the Specifications; and (b) other non-conformance or shortage, based on an inspection of the visible appearance of such Batch. Customer will be under no obligation to accept a Batch with a Defect until the cause of the Defect has been determined, such cause to be investigated by Customer and Brammer in a timely manner.

7.6 In the event of any suspected Latent Defect notified to Brammer [**] the Parties shall work together to investigate the nature and cause of the Defect. The Customer shall either destroy or return to Brammer the defective Product and make no use of it. The Customer agrees that it shall not use any Product in any clinical trial (i) until the Customer has received notice from Brammer that Product has been released by Brammer QA; or (ii) if Brammer QA has at any time following such release of Product subsequently requested suspension of clinical use of the Product.

7.7 Acceptance of Deliverables. Where Brammer is required pursuant to a Work Statement to provide certain Deliverables, the Customer shall [**] to review them, including the ability to comment upon a draft version of any reports, and inform Brammer of any defect or issue in connection with such Deliverables, and to reject or accept such Deliverables. If no notice of rejection or acceptance is provided by Customer [**] Customer will be deemed to have accepted such Deliverables and the applicable invoice will be payable.

7.8 Disputes. In case of any disagreement between the Parties as to whether Product contains a Defect or a Latent Defect, whether a Deliverable is defective, or the existence of a Brammer Failure, the Customer Representative and the Program Manager will attempt in good faith to resolve any such disagreement and each Party will follow its standard operating procedures to determine whether such Product contains a Defect or Latent Defect and/or the cause of any such Defect or Latent Defect (or, as appropriate, whether the Deliverable is defective). If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed [**] from the date of the provision of notice regarding such Defect, Latent Defect or non-delivery or defective Deliverables) then discussion will be escalated to the JSC for resolution. In the event that the JSC is unable to resolve the matter within [**], the Parties shall refer the matter (of whether a Product contains a Defect or a Latent Defect, or whether a Deliverable is defective, or the existence of a Brammer Failure) for determination by an appropriately qualified independent laboratory, the identity of which will be agreed by the Parties in good faith, [**] The Parties agree that the determination of the independent laboratory shall be final and binding.

7.9 Drug Substance Non-Compliance and Remedies. Subject to Sections 7.11 and 7.13, if a Batch of Drug Substance contains a Defect caused by a Brammer Failure as determined upon investigation, Brammer will at Customer's election:

(i) [**]

[**]

7.10 Drug Product Non-Compliance and Remedies. Subject to Sections 7.11 and 7.13, if a Batch of Drug Product contains a Defect caused by a Brammer Failure as determined by an investigation, Brammer will at Customer's election:

(i) [**]

[**]

7.11 Other Defects. Notwithstanding anything to the contrary in this Agreement, Brammer will not have any liability for or responsibility to replace or Reprocess any Product which is defective or fails, or ceases to conform to the Specifications, or which is unusable for its intended purposes, in each case, unless such defect results from a Defect in Product which is not accepted under Section 7.3 and was caused by a Brammer Failure, or is a Latent Defect. Without limiting the generality of the foregoing, Brammer will not have any liability for or responsibility to replace or Reprocess any Product which is defective or fails or ceases to conform to the Specifications or which is unusable for its intended purposes, in each case, for any other reason.

7.12 Disposition of Non-Conforming Product. The ultimate disposition of non-conforming Product will, at Brammer's cost only for Brammer Failure, be the responsibility of Customer's quality assurance department.

7.13 Exclusive Remedy. The sole and exclusive remedies available to Customer for a Brammer Failure in connection with a Batch Defect or otherwise in connection with Product which fails or ceases to conform to the Specifications due to a Brammer Failure will be the remedies set forth in Section 7.9 or Section 7.10.

8. **Compensation**.

8.1 Customer will pay Brammer the fees and other payments and costs listed in the applicable Work Statement (the "Service Fees"), subject to Section 9. Brammer will issue invoices for Service Fees in accordance with the payment schedule set forth in the Work Statement, and Customer will pay the amounts set forth in each invoice within [**] of the date of such invoice, unless Customer notifies Brammer in writing of a disputed invoice amount. In the case of a disputed amount, the Parties will in good faith discuss the item and seek resolution and Customer will pay all undisputed amounts, if any, of such invoice.

8.2 The Service Fees do not include amounts payable by Customer for (a) Process Consumables; (b) Customer-Funded Equipment; (c) Services subcontracted to an Approved Vendor (including shipping charges for delivery of materials to and from an Approved Vendor); or (d) collection, storage, handling, transportation and disposal of Special Waste; ((a) through (d), collectively, "Pass-Through Costs"). Subject to Section 8.4 below, Brammer will invoice Customer for all Pass-Through Costs as incurred by Brammer. Amounts payable for Customer-Funded Equipment will include the direct cost to acquire the equipment, which will be procured and invoiced in accordance with Exhibit B. [**]

8.3 In the case of Process Consumables for the remainder of the Work Statement, at completion of Stage 1 of the Work Statement, and, in the case of Services subcontracted to an Approved Vendor, prior to the initiation of each Stage of the Program, Brammer will prepare and provide to Customer a good-faith itemized estimate (an "Estimate") of expected costs and expenses to be incurred by Brammer for Process Consumables and Services subcontracted to an Approved Vendor for such Stage. Within five (5) business days of receipt of each Estimate, Customer will either notify Brammer of Customer's acceptance and agreement of such Estimate, or notify Brammer with reasonable detail of any disputed items set forth in the Estimate. Failure to so notify Brammer within such five (5) business day period will be deemed to be Customer's agreement and acceptance of such Estimate. If Customer disputes any items set forth in the Estimate within such five (5) business day period, the Parties will discuss in good faith the disputed items and Brammer will re-issue an Estimate to Customer and the review and acceptance process set forth above will be applied to such re-issued Estimate. Following approval of each Estimate, Brammer will proceed, in accordance with the time schedule set forth in the Work Statement, with the purchase of Process Consumables.

8.4 Brammer will invoice Customer for such Process Consumables and Pass-Through Costs for the same amount included in the relevant approved Estimate. Upon completion of the applicable Stage or earlier termination of this Agreement, or the applicable Work Statement, Brammer will calculate the expenditure actually incurred for Process Consumables up to the date of completion or termination, plus the administrative fee as outlined in Section 8.2, and for the Customer-Funded Equipment procured for use during such Stage and associated costs (collectively, the "Actual Expenditure"). If the Actual Expenditure is greater than the corresponding Estimate, Brammer will issue a further invoice for a sum equivalent to the difference between the amount set forth in the Estimate and actually paid by Customer and the Actual Expenditure, subject always to any cap on Actual Expenditure which is included in the relevant Work Statement. If the Actual Expenditure is less than the corresponding Estimate, Brammer will issue a credit note against the earlier invoice for a sum equivalent to the difference, which credit may be applied to future amounts payable under this Agreement. Customer will pay the amounts set forth in each invoice within [**] of the date of such invoice, unless Customer notifies Brammer in writing of a disputed invoice amount. In the case of a dispute under this Section 8.4, the Parties will in good faith discuss the item and seek resolution and Customer will pay all undisputed amounts, if any, of the relevant invoice.

[**]

8.5 Late payments of undisputed amounts under this Agreement will incur an interest charge of [**] Brammer reserves the right to suspend the Services in the event of late payments of undisputed amounts after providing Customer written notice of such late payments and allowing Customer a period of [**] to pay the late amounts (any time after such period, the "Delinquency Period"), Brammer reserves the right to refuse receipt of new Customer Provided Material for Manufacture of additional Batches of Product and to otherwise suspend the Services.

8.6 All payments under this Agreement are exclusive of any taxes that may apply and will be paid gross, without deductions or set-offs, whether by way of withholding or other income taxes, and Customer will ensure that such sum is paid to Brammer as will, after deduction of such withholding or other income taxes, be equivalent to the consideration payable under this Agreement. Any duty, sales, use or excise taxes imposed by any governmental entity that apply to the provision of the Services will be borne by Customer (other than taxes based upon the income of Brammer).

8.7 All amounts payable to Brammer under this Agreement will be paid in U.S. Dollars, without deduction, and by authenticated and value dated Swift telegraphic transfer for any such payments made from outside the U.S., quoting invoice numbers of payment to the bank account identified in the applicable invoice or by such other means as Brammer will notify Customer in writing from time to time.

9. Work Statement and Specifications Changes.

9.1 The Service Fees are subject to a number of specific and general assumptions. The specific assumptions relate to the Work Statement and Program design and objectives, timing, capital expenditure requirements, if any, and other assumptions relating to the completion of the Program as set forth in the Work Statement (the "Program Assumptions'"). Brammer also assumes that the Customer will cooperate and perform its obligations under the Agreement in a timely manner, that no event outside the reasonable control of Brammer will occur, including the events described in Section 21 and that there are no changes to any Applicable Laws that materially adversely affect the Program (collectively, the "General Assumptions," and together with the Program Assumptions, collectively, the "Assumptions"). In the event that any of the Assumptions require modification or the objectives of the Program cannot be achieved based on the Assumptions then the Work Statement may be amended as provided in Section 9.2.

9.2 In the event Brammer is requested or required to perform services beyond that which are set forth in a Work Statement, any such additional services and compensation schedule must be mutually agreed upon by the Parties in writing prior to the provision of said services (a "Change Order"). A sample Change Order is attached hereto as Exhibit C. Each Change Order will detail the requested changes to the applicable task, responsibility, duty, budget, time line or other matter. A Change Order will become effective upon the execution of a Change Order by both Parties, and a Change Order will specify the period of time within which Brammer must implement the changes. Both parties agree to act in good faith and promptly when considering a Change Order requested by the other Party.

10. **Confidential Information/Legal Proceedings/Publicity.**

10.1 Term of Confidentiality Obligations. Except as otherwise provided in this Section 10, during the term of this Agreement and for a [**] of this Agreement, each Party (the "Receiving Party") agrees that it will keep the other Party's (the "Disclosing Party's") Confidential Information confidential and use it solely to conduct the activities contemplated, and to exercise rights, under this Agreement, and for no other purpose. The foregoing notwithstanding, with respect to Confidential Information that constitutes a trade secret, the Receiving Party's obligations under this Agreement to keep such information confidential will continue for as long as such information remains a trade secret.

10.2 Confidentiality and Non-Use Obligations. Each Party agrees that all Confidential Information disclosed to such Party or any of such Party's Affiliates by the other Party or an Affiliate of such other Party (a) will not be used by the Permitted Recipients except as authorized under this Agreement and in connection with the activities contemplated by this Agreement or in order to further the purposes of this Agreement and (b) will be maintained in confidence by the Receiving Party and such Party's Affiliates, with a degree of care that is not less than the Receiving Party typically exercises with respect to its own most valuable Confidential Information and in any case with not less than reasonable care. The Receiving Party will provide, upon the Disclosing Party's request, a certification that access and use is being controlled in accordance with this Agreement. The Disclosing Party will have the right to audit to verify compliance with this Agreement. Notwithstanding any other provision of this Agreement, disclosure of Confidential Information will not be prohibited to the extent required to comply with Applicable Laws or regulations, or with a valid court or administrative order, ***provided that*** the Receiving Party will (i) notify the Disclosing Party of any such disclosure requirement or request as soon as practicable (and to the extent that it is legally able to do so); (ii) cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which is responsive to such requirement or request. If Brammer becomes obliged to provide testimony or records regarding this Agreement in any legal or administrative proceeding relating to Customer, Customer will reimburse Brammer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Brammer's standard commercial rates.

10.3 Disclosures to Permitted Recipients. Each Party agrees that such Party and such Party's Affiliates will provide Confidential Information received from the Disclosing Party only on a need-to-know in connection with this Agreement basis and only to the Receiving Party's respective employees, directors, consultants, advisors, bona fide potential partners or investors, and to the employees, directors, consultants and advisors of the Receiving Party's Affiliates (collectively, "Permitted Recipients"), solely under conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement, and ***provided that*** each Party will remain responsible for any failure by its Permitted Recipients to treat such information and materials as required under Section 10.2. Neither Party shall allow access to the Confidential Information of the other Party to any Permitted Recipient who does not require such access in order to accomplish the purposes of this Agreement. Receiving Party and its Affiliates will use at least the same standard of care as it uses to protect its own most valuable confidential information and in any case with not less than reasonable care, to ensure that its Permitted Recipients do not disclose or make any unauthorized use or disclosure of the Confidential Information.

10.4 Exceptions to Confidential Information. Confidential Information will not include information that:

(a) was known or used by the Receiving Party or such Party's Affiliates prior to its date of disclosure to the Receiving Party as demonstrated by appropriate evidence; or

(b) either before or after the date of the disclosure to the Receiving Party or the Receiving Party's Affiliate is lawfully disclosed to the Receiving Party or any of such Party's Affiliates by sources other than the Disclosing Party rightfully in possession of such know-how and not bound by confidentiality obligations to the Disclosing Party; or

(c) either before or after the date of the disclosure to the Receiving Party or any of such Party's Affiliates is or becomes published or otherwise is or becomes part of the public knowledge, through no breach hereof on the part of the Receiving Party or such Party's Affiliates; or

(d) is independently developed by or for the Receiving Party or any of such Party's Affiliates without reference to or reliance upon the Confidential Information of the Disclosing Party as demonstrated by appropriate convincing evidence.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

10.5 Responsibility for Compliance with Confidentiality and Nonuse Obligations.

(i) The Receiving Party will be responsible for any intentional misuse or misappropriation by the Receiving Party or its Affiliates, or the Permitted Recipients or sublicensees of the Receiving Party or its Affiliates, of the Disclosing Party's Confidential Information.

(ii) Customer will promptly notify Brammer in writing of the Customer becoming aware of any actual or threatened disclosure, misappropriation or other violation of Brammer's Confidential Information by a Third Party, Customer, or Customer's Affiliate.

(iii) Cooperation. If at any time the Disclosing Party brings, or investigates the possibility of bringing, any claim against any Person for misappropriation of trade secrets and misuse of Confidential Information, then the Receiving Party, upon the request and at the expense of the Disclosing Party, will cooperate with and assist the Disclosing Party in the investigation or pursuit of such claim, and provide the Disclosing Party with any information in the possession of the Receiving Party that may be of use to the Disclosing Party in the investigation or pursuit of such claim.

10.6 Disclosure of Provisions of Agreement.

(i) Each Party agrees to hold as confidential the terms of this Agreement, except that (a) each Party shall have the right to disclose such terms to investors, bona fide potential investors, business partners, bona fide potential business partners, lenders, bona fide potential lenders, acquirers, bona fide potential acquirers, and investment bankers in connection with licensing, financing and acquisition activities, and due diligence processes related to such activities, ***provided that*** (a) any such Third Party has entered into a written obligation with the disclosing Party to treat such information and materials as confidential and requiring at least commercially reasonable obligations of confidentiality (and each Party will remain responsible for any failure by any of the foregoing Persons, to whom a Receiving Party may disclose Confidential Information) to treat such information as required under Section 10.2 hereof, and (b) each Party will have the right to disclose such terms as required by Applicable Law, regulation or legal

process, including by the rules or regulations of the SEC or similar regulatory agency in a country other than the United States, or of any stock exchange or other securities trading institution; ***provided that*** the Party subject to such disclosure requirement will, if reasonably practicable under the circumstances, provide the other Party with a reasonable opportunity to review and comment in advance on the disclosing Party's proposed disclosure and such disclosing Party will consider in good faith any comments thereon provided by the other Party. Such Party will exercise at least a reasonable standard of care and take commercially reasonable steps to protect Confidential Information of the Disclosing Party and disclose only such portion of Confidential Information of the Disclosing Party, if at all, as is reasonably required to be disclosed.

(ii) In the event that this Agreement will be included in any report, statement or other document filed by Customer or an Affiliate of Customer with the SEC or similar regulatory agency in a country other than the United States or any stock exchange or other securities trading institution, Customer will use, or will cause such Customer's Affiliate, as the case may be, to use, good faith efforts to obtain confidential treatment from the SEC, similar regulatory agency, stock exchange or other securities trading institution of any Brammer proprietary technical data, know-how, and trade secrets concerning Brammer's production and purification methods, Brammer's equipment and techniques, Brammer's facilities and its design and operation, and Brammer Technology and New Brammer Technology, as well as financial information or other information of a competitive or confidential nature, and will include in such confidentiality request such provisions of this Agreement as may be reasonably requested by Brammer.

10.7 Remedies. The Receiving Party acknowledges that a breach by it of any of the terms of this Agreement would cause irreparable harm to the Disclosing Party for which the Disclosing Party could not be adequately compensated by money damages. Accordingly, the Receiving Party agrees that, in addition to all other remedies available to the Disclosing Party in an action at law, in the event of any breach or threatened breach by the Receiving Party of the terms of this Agreement, the Disclosing Party will, without the necessity of proving actual damages or posting any bond or other security, be entitled to seek temporary and permanent injunctive relief, including, but not limited to, specific performance of the terms of this Agreement.

10.8 Non-Solicitation and Non-Hire. From the Effective Date [**] no Party will solicit an employee of another Party who is or has been involved in any activity to which this Agreement pertains. Notwithstanding the foregoing, nothing herein will restrict or preclude each Party's rights to make generalized searches for employees by way of a general solicitation for employment placed in a trade journal, newspaper or website, and which is not designed to target or specifically attract the employees of the other Parties.

10.9 No Disclosure of Unrelated Information. Neither Party will disclose confidential information to the other Party that is not reasonably necessary for performance of a Party's obligations under this Agreement, including but not limited to manufacturing processes for other products, marketing plans and clinical development plans. Notwithstanding the foregoing, nothing in this provision will limit the confidentiality and non-use obligations and rights herein.

10.10 Customer Provided Materials. Brammer will not transfer any Customer Provided Materials to any Third Party without Customer's written permission, unless such transfer is to an Approved Vendor, is consistent with the Program and is for use only for activities set out in the relevant Work Statement

10.11 No Licenses. Except as expressly provided in Section 12 hereof, no right or license, either express or implied, is granted under any Intellectual Property Right or by virtue of the disclosure of Confidential Information under this Agreement, or otherwise. The Parties agree that each Party has and will retain sole and exclusive rights of ownership in and to any Confidential Information of such Party.

10.12 Acknowledgment or Prior Confidentiality Obligations. The Parties acknowledge that Confidential Information has been provided by the Parties to each other prior to the Effective Date of this Agreement pursuant to the Existing Confidentiality Agreement. All Confidential Information (as defined in the Existing Confidentiality Agreement) exchanged between the Parties under the Existing Confidentiality Agreement will be deemed Confidential Information under this Agreement and will be subject to the terms of this Agreement.

11. **Work Product; Records**.

11.1 All work outputs, including reports of Results, will be prepared in accordance with Brammer's standard format unless otherwise specified in the Work Statement.

11.2 For each Batch of Product and any other Services provided, Brammer will keep and maintain records, including all Results produced in the conduct of the Services, for a period of [**] after completion of a Deliverable, or such longer period as required by the Applicable Laws (the "Retention Period"). For clarity, Brammer will be entitled to retain all original documents relating to the Program and will provide to Customer an electronic and paper copy of all Batch Records and other reports provided under this Agreement. At the end of the Retention Period, such records shall, at Customer's option and expense, either be (i) delivered to Customer or to its designee, or (ii) disposed of, but only after giving Customer [**] prior written notice of Brammer's intent to do so.

11.3 Brammer will take and retain, for such period and in such quantities as may be required by cGMP (if applicable) and the applicable Quality Agreement, samples of Product Manufactured under this Agreement, including samples required by Customer ("Customer-Owned Retains"). Further, upon Customer's written request and to the extent consistent with cGMP and Applicable Law, Brammer will provide to Customer reasonable access to such Customer-Owned Retains or agree that Brammer will perform testing on the Customer-Owned Retains. [**]

11.4 Right of Cross-Reference. [**] Brammer shall deliver to Customer for filing with the FDA or any foreign Regulatory Authority designated by Customer such authorization letters as Customer deems necessary for the foregoing purpose, which shall be in substantially the form attached hereto as Exhibit F, subject to such modifications as may be required by Applicable Law; *provided*, *however,* that if Customer proposes any material modifications to such form, Brammer shall be entitled to [**] for review and approval of the modified form; and *provided*, *further*, that Customer shall be responsible for all costs and expenses associated with its request for such cross-reference, and for obtaining any notarization, legalization or apostille that may be required for filing any authorization letter with any foreign Regulatory Authority. For the avoidance of doubt, Brammer shall not be required to provide directly to Customer any Brammer documents that are general to Brammer's business, such as a Facility and equipment SOPs unless such documents are expressly requested by a relevant Regulatory Authority or are required by Applicable Law.

12. **Intellectual Property**

12.1 Customer Technology. All right, title and interest in and to Customer Technology will remain vested solely in Customer. Customer hereby grants Brammer a non-exclusive, royalty-free license under all Intellectual Property Rights relating to Customer Technology for the sole purpose of performing the Services on behalf of Customer. Such license will expire upon the completion of such Services or the termination or expiration of this Agreement, whichever is the first to occur. Customer agrees that:

(i) Upon Brammer's prior written request, and in accordance with instructions provided by Brammer, Customer will, at Customer's expense and in its sole discretion, transfer such embodiments of Customer Technology as are reasonably required for the performance of the Services to Brammer for the sole purpose of enabling Brammer to perform the Services.

(ii) Without limiting the generality of the foregoing, Customer will provide to Brammer without charge, such written materials and assistance of Customer personnel as may be reasonably requested by Brammer to assist with the transfer and use of Customer Technology in performing the Services. All information provided to Brammer under this Section will be subject to the confidentiality provisions of this Agreement.

12.2 Brammer Technology. As between the Parties, all right, title and interest in and to Brammer Technology and all Intellectual Property Rights therein will remain solely in Brammer, except as provided in Section 12.4.

12.3 New Technology. In the event that, during performance of the Services, Brammer (or any personnel or entity acting on behalf of Brammer, including Approved Vendors retained to perform non-routine Services consistent with Section 5.1 and the Work Statement) solely or jointly with Customer creates, conceives, develops, or reduces to practice new Technology ("New Technology"), whether or not patentable, the following will apply:

(i) New Customer Technology. Customer will hold all right, title and interest in and to all New Customer Technology and all Intellectual Property Rights therein. Brammer hereby assigns, and to the extent not presently assignable shall assign, to Customer all right, title, and interest in and to all New Customer Technology. Brammer will take, and will procure that all Approved Vendors, retained to perform non-routine Services consistent with Section 5.1 and the Work Statement, shall take any actions, including but not limited to the execution of documents, reasonably requested by Customer, and at Customer's expense, to effect such assignment. Customer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any Patent that claims or covers the New Customer Technology.

(ii) New Brammer Technology. Brammer will hold all right, title and interest in and to all New Brammer Technology and all Intellectual Property Rights therein. Customer hereby assigns, and to the extent not presently assignable shall assign, to Brammer all right, title, and interest in and to all New Brammer Technology. Customer will take any actions, including but not limited to the execution of documents, reasonably requested by Brammer, and at Brammer's expense, to effect such assignment. Brammer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any Patent that claims or covers the New Brammer Technology.

12.4 License to Customer. [**]

12.5 Technology Transfer to Customer. [**]

12.6 Customer acknowledges that Brammer is in the business of providing services for a variety of organizations other than Customer. Accordingly, nothing in this Agreement or any Work Statement hereunder will preclude or limit Brammer from utilizing the general knowledge gained during the course of its performance hereunder to perform similar services for other customers.

12.7 The Parties acknowledge that successful completion of the Services may require a license under Third Party Intellectual Property Rights. [**] In the event either Party is put on notice by a Third Party of alleged infringement by Brammer of Third Party Intellectual Property Rights due to the Manufacture of Product, such Party will promptly inform the other Party of such notification. [**] Brammer will not be responsible for any adverse impact on the quality and stability of the process intermediates or final Product during the Wait Period or any subsequent impact on the process intermediates of final Product to the extent such impact is caused by the Wait Period, provided however that Brammer will keep Customer promptly informed of any such potential impact, and will discuss in good faith with Customer the extension of the Wait Period where such an extension is reasonably required to prevent damage to the Product or any intermediaries.

12.8 Brammer reserves the right to utilize data generated during the course of Services to support applications, assignments or other instruments necessary to apply for and obtain Patents with respect to Brammer Technology and New Brammer Technology, provided the data so utilized is de-identified and does not contain Customer Confidential Information. Brammer will notify Customer in advance of filing for any such Patent and Customer will have the right to require Brammer to reasonably delay any such Patent filing if such filing contains data that is Customer Confidential Information or which may be the subject of a Patent filing with respect to any New Customer Technology.

13. **Independent Contractor**. Brammer will perform the Services as an independent contractor of Customer and will have complete and exclusive control over the Facility, the equipment, and its employees and agents. Nothing in this Agreement will constitute Brammer, or anyone furnished or used by Brammer in the performance of the Services, as an employee, joint venturer, partner, or servant of Customer. Brammer also agrees that it will not have any rights to receive any employee benefits such as health insurance and accident insurance, sick leave or vacation as are in effect generally for employees of Customer. Neither Party will enter into any agreements or incur obligations on behalf of the other Party, nor commit the other party in any other manner without prior written consent from a duly authorized officer or representative of such other Party.

14. **Insurance**.

14.1 Customer will obtain and maintain with insurers having A.M. Best ratings of A-VII or higher at all time as of and after the Effective Date of this Agreement, at its own expense, [**]. Customer agrees to maintain at all times thereafter during the term of this Agreement such appropriate Clinical Trial Limits. Customer will provide Brammer with reasonable evidence of such coverage within thirty (30) days of execution of this Agreement. If any such policy is replaced, Customer agrees to purchase tail coverage or ensure that the new policy has a retroactive date that is consistent with the start of any work under a Work Statement and that Customer will continue to be covered on the replacement policy. Customer will provide Brammer with at least thirty (30) days' prior written notice of any change in or cancellation of the insurance coverage.

15. **Shipping**. Brammer will package for shipment Product, samples or other materials in accordance with the Work Statement and Customer's written instructions and at the Customer's expense. All shipments will be in accordance with Section 7.1 and Customer will bear all packaging, shipping and insurance charges. Brammer will pass through actual shipping and related charges as set forth in the Work Statement.

16. **Dispute Resolution**.

16.1 In the event any dispute arises between the Customer and Brammer with respect to any of the terms and conditions of this Agreement or the Program that cannot be resolved by the Customer

Representative and the Brammer Program Manager, then senior executives of the Customer and Brammer will meet as promptly as practicable after notice of such dispute to resolve in good faith such dispute. The senior executives of the Parties will attempt in good faith to resolve such dispute by negotiation and consultation for a thirty (30) day period following such referral.

16.2 If the Senior Executives of Customer and Brammer are unable to satisfactorily resolve the dispute within thirty (30) days, then such dispute will be finally settled by arbitration in accordance with this Section 16.2. The arbitration will be held in New York, NY, and except as noted below, will be conducted in accordance with the rules of the American Arbitration Association (or such successor organization) by one mutually agreeable arbitrator, who will be a lawyer having at least fifteen years of experience dealing with complex contracts, including those in biologics manufacturing. If the Parties cannot agree on an arbitrator within a reasonable period of time, an arbitrator will be appointed by the American Arbitration Association (or such successor organization). The arbitrator will have no authority to vary from or ignore the terms of this Agreement and will be bound by controlling law. The Parties may seek judicial intervention for emergency relief, such as restraining orders and injunctions where appropriate.

16.3 Any decision by the arbitrator will be binding upon the Parties and may be entered as final judgment in any court having jurisdiction. The cost of any arbitration proceeding will be borne by the Parties as the arbitrator will determine if the Parties have not otherwise agreed. The arbitrator will render his or her final decision in writing to the Parties.

16.4 The dispute resolution of Section 16 is without prejudice to the rights of the Parties to obtain injunctive relief under Section 10.7.

17. **Indemnification.**

17.1 Customer will indemnify and hold harmless Brammer and its Affiliates and each of its directors, officers, employees, and agents (the "Brammer Parties") against any and all Third Party charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands ("Claims") imposed upon a Brammer Party and associated damages awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations and expenses, including reasonable attorneys' fees) (collectively, "Losses") suffered or incurred in consequence of the following:

[**]

17.2 Brammer will indemnify and hold harmless Customer and its Affiliates and each of its directors, officers, employees, and agents (the "Customer Parties") against any and all Third Party Claims and associated Losses that the Customer Parties suffered or incurred in consequence of the following:

[**]

17.3 Upon receipt of notice of any Claim that may give rise to a right of indemnity from the other Party hereto, the Party seeking indemnification (the "Indemnified Party") will give prompt written notice thereof to the other Party, (the "Indemnifying Party") of the Claim for indemnity. Such Claim for indemnity will indicate the nature of the Claim and the basis therefor. Promptly after a claim is made for which the Indemnified Party seeks indemnity, the Indemnified Party will permit the Indemnifying Party, at its option and expense, to assume the complete defense of such Claim, provided, that, (a) the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense; (b) the Indemnifying Party will conduct the defense of any such Claim with due regard for the business interests and potential related liabilities of the Indemnified Party; and (c) the Indemnifying Party will, prior to making any settlement, consult with the Indemnified Party as to the terms of such settlement. The Indemnifying Party will not, in defense of any such Claim, settle or consent to an adverse judgment in any such claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnified Party or imposes additional material obligations (financial or otherwise) on such Indemnified Party, without the prior express written consent of such Indemnified Party (such consent not to be unreasonably withheld, conditioned or delayed). After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Claim, the Indemnifying Party will only be liable to the Indemnified Party for such reasonable legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnifying Party will be liable for all reasonable legal or other expenses incurred by the Indemnified Party in connection with the defense thereof and the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such

defense at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of any of the same without the consent of the Indemnifying Party (such consent not to be unreasonably withheld, conditioned or delayed.) If requested by the Indemnifying Party, the Indemnified Party agrees to cooperate with the Indemnifying Party and its counsel in contesting any Third Party Claim which the Indemnifying Party defends, or, if (i) appropriate and related to the Third Party Claim in question and (ii) reasonable in the judgment of the Indemnifying Party, in making any counterclaim against the Person asserting the Third Party Claim, or any cross complaint against any Person. If Brammer will be obliged to provide testimony or records regarding the subject matter of this Agreement in any legal or administrative proceeding not covered by the indemnity set forth above, Customer will reimburse Brammer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Brammer's standard commercial rates. If Customer will be obliged to provide testimony or records regarding the subject matter of this Agreement in any legal or administrative proceeding pursuant to any general inspection of Brammer's Facility or operations, Brammer will reimburse Customer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at cost.

18. **Limitations of Liability**.

18.1 BRAMMER'S LIABILITY UNDER THIS AGREEMENT HOWSOEVER ARISING WILL NOT EXCEED [**] BRAMMER ASSUMES NO LIABILITY FOR USE, STORAGE (AFTER TITLE PASSES TO CUSTOMER), DISPOSAL, MARKETING, OR SALE OF PRODUCT(S).

18.2 Consequential Damages Waiver. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, BUT NOT LIMITED TO, DAMAGES BASED UPON LOST PROFITS, BUSINESS INTERRUPTION, LOST BUSINESS, OR LOST SAVINGS (EXCEPT THAT IN CASE OF BREACH BY CUSTOMER, BRAMMER CAN RECOVER ITS LOST PROFITS UNDER THIS AGREEMENT THAT BRAMMER LOST AS A RESULT OF THE CONTRACT NOT BEING FULLY PERFORMED)) FOR ANY ACTS OR FAILURE TO ACT UNDER THIS AGREEMENT, EVEN IF IT HAS BEEN ADVISED OF THEIR POSSIBLE EXISTENCE.

18.3 The limitations of liability reflect the allocation of risk between the Parties. The limitations specified in this Section 18 will survive and apply even if any limited remedy specified in this Agreement is found to have failed of its essential purpose.

19. **Representations, Warranties and Covenants**.

19.1 Brammer Representations, Warranties and Covenants. Brammer represents, warrants and covenants to Customer that:

(i) it has the full power and right to enter into this Agreement and that, to its knowledge, there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by any Affiliate or any Third Party, private or public, that are inconsistent with the provisions of this Agreement;

(ii) the execution and delivery of this Agreement by Brammer has been authorized by all requisite corporate or company action and this Agreement is and will remain a valid and binding obligation of Brammer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

[**]

(iv) Brammer, its Affiliates and its Approved Vendors: (i) have not been debarred and are not subject to a pending debarment pursuant to Section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)); (iii) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. Brammer will notify Customer immediately if Brammer or any of its Affiliates or Approved Vendors is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Brammer's knowledge, is threatened; and

[**]

[**]

19.2 Customer Representations and Warranties. Customer represents, warrants and covenants to Brammer that:

(i) it has the full power and right to enter into this Agreement and that there are, to its knowledge, no outstanding agreements, assignments, licenses, encumbrances or rights held by any Affiliate or Third Party, private or public, that are inconsistent with the provisions of this Agreement;

(ii) the execution and delivery of this Agreement by Customer has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Customer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(iii) the Customer Provided Materials will be provided to Brammer free and clear of all liens and encumbrances and will be prepared by Customer in accordance with the agreed-upon specifications in the Work Statement;

(iv) [**]

(v) [**]

(vi) to the best of Customer's knowledge, the Customer Provided Materials are safe and non-hazardous for purposes of the Services to be performed hereunder.

19.3 EXCEPT AS SET FORTH HEREIN, BRAMMER EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED BY STATUTE, CUSTOM OF THE TRADE OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTIES OF TITLE OR NONINFRINGEMENT. ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ANY PERSON OR ENTITY ON BEHALF OF BRAMMER, INCLUDING EMPLOYEES OR REPRESENTATIVES OF BRAMMER, THAT ARE INCONSISTENT HEREWITH, WILL BE DISREGARDED AND WILL NOT BE BINDING ON BRAMMER. TO THE EXTENT PERMITTED BY APPLICABLE LAW, BRAMMER ASSUMES NO LIABILITY FOR USE, STORAGE (AFTER TITLE PASSES TO CUSTOMER), DISPOSAL, MARKETING, OR SALE OF PRODUCT(S).

20. **Term; Termination; Certain Effects of Termination**.

20.1 Unless earlier terminated in accordance with this Section 20, this Agreement will commence on the Effective Date and will continue until all Work Statements have been completed or terminated.

20.2 Mutual Agreement. [**]

20.3 Termination by Customer.

(i) **Termination of Clinical Trials**. [**] [**] [**]

(ii) **Termination for Convenience. [**]** [**] [**] Stage basis:

(iii) [**]

20.4 Termination by Either Party.

(i) **Termination for Material Breach. [**]**

[**]

(ii) **Termination by Insolvency.** [**]

(iii) [**]

(iv) In the event that Customer terminates this Agreement or any Work Statement pursuant to Section 20.4(i) (Termination for Brammer's Material Breach):

[**]

(v) In the event that Customer terminates this Agreement or any Work Statement pursuant to Section 20.4(ii) (Termination by insolvency):

[**]

20.5 In case of expiration or termination of this Agreement or any Work Statement for any reason, the following will apply:

(i) Brammer will, as soon as possible, supply Customer with documentation concerning the Results obtained through the effective date of expiration or termination upon satisfaction of amounts due.

(ii) Each Party will promptly return to the other all data and documents in any form comprising or containing any Confidential Information of the other Party, *except that* the Receiving Party may retain: (i) one copy of Confidential Information in secure legal archives for evidentiary purposes only and (ii) a copy of computer records or files containing such Confidential Information that have been created pursuant to automatic archiving or back-up procedures that cannot reasonably be deleted (collectively, "Retained Copies"), ***provided, however, that*** any such Retained Copies will be kept confidential by the Receiving Party in accordance with the terms and provisions of this Agreement for as long as the Receiving Party is in possession of the Retained Copies.

(iii) Brammer will deliver to Customer at the Delivery Site any and all quantities of Product Manufactured up to the effective date of expiration or termination upon satisfaction of amounts due and Customer will take delivery of the same, except that Brammer may [**].

(iv) Customer will pay Brammer [**].

(v) Brammer will return all Customer-Funded Equipment to Customer promptly on the termination or expiry of this Agreement or, where such Customer-Funded Equipment is not required for a subsequent Work Statement, any relevant Work Statement.

(vi) Brammer will return, ship, or destroy Customer Provided Materials and Brammer Materials procured according to the Work Statement at the Customer's direction and sole expense (other than in the case of termination for Brammer's Material Breach, in which case such costs shall be borne by Brammer), including expenses relating to shipping costs, return fees to vendors and any unreimbursed costs on any non-refundable or non-returnable items; ***provided that*** Brammer may dispose of Customer Provided Materials in its discretion, and Customer will have no right to the same, in the event Brammer does not receive direction in accordance with this Section 20.5 within [**] of termination or expiration of the relevant Work Statement.

20.6 With the termination of this Agreement, all Work Statements shall terminate, unless otherwise agreed to by the Parties. The termination of any individual Work Statement will have no effect on the continued existence and enforceability of this Agreement or any other Work Statement then pending. The expiry or termination of one Work Statement does not terminate another active Work Statement or this Agreement. Except the expiry of the Term of this Agreement, the Agreement is deemed to continue and apply to any outstanding Work Statement until the expiry or earlier termination of that Work Statement.

20.7 The termination of this Agreement for any reason will not affect any accrued rights or obligations of either Party as of the effective date of such termination, including obligations in respect of compensation for Services performed prior to the effective date of such expiration or termination of this Agreement. The following provisions will survive any expiration or termination of this Agreement: Sections 8, 10 through 12 (inclusive), 14, and 16 through 31 (inclusive), the provisions of the applicable Quality Agreement, and any other provision in this Agreement or its exhibits and attachments that by its nature and intent should remain valid after the expiration or termination of the Agreement.

21. **Force Majeure**. Either Party will be excused from performing its respective obligations under this Agreement, except for any obligation to make payment under a validly issued invoice, if its performance is delayed or prevented by any event beyond such Party's reasonable control (each, a "Force Majeure Event"), including acts of God, fire, explosion, weather, disease, war, terrorism, insurrection, civil strife, riots, labor dispute or strike, government action, or a shortage or failure of power outside such Party's reasonable control, ***provided that*** such performance will be excused only to the extent of and during such disability and ***provided that*** financial inability in and of itself will not be a Force Majeure Event. Any time specified for completion of performance in the Work Statement falling due during or subsequent to the occurrence of any or such events will be automatically extended for a period of time reasonably necessary to recover from such disability, provided however that the Parties shall, within [**] of the start of such delay, discuss the delay and how best to resolve the matter. Where Brammer is unable to complete performance within [**] of the start of any delay caused by a Force Majeure Event, Customer shall be entitled to terminate this Agreement and any Work Statement on [**]. Customer shall also have the right to terminate this Agreement and any Work Statement on [**] notice where Brammer's performance is delayed through Force Majeure Events by more than [**] in total in any calendar year. Brammer will promptly notify Customer if, by reason of any of the events referred to herein, Brammer is unable to meet any such time for performance specified in the Work Statement.

22. **Publicity**. Customer will not make a press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement, or any ancillary matter, without first obtaining the prior written consent of Brammer. Customer will provide a copy of the proposed text thereof to Brammer for its review and approval at least ten (10) days prior to the proposed release. Brammer may provide specific, reasonable comments on such release, announcement or publicity reasonably in advance of the date of the proposed release, but will not unreasonably withhold or delay its approval to such release, announcement or publicity. Brammer will not make a press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement without Customer's prior written consent.

23. **Assignment**. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement (a) in connection with the transfer or sale of all or substantially all of the assets of such Party to which this Agreement relates or, in the case of Customer, the Product; (b) in the event of the merger, reorganization or consolidation of a Party; or (c) to any Affiliate. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume all obligations of its assignor under this Agreement, provided however that if either Party assigns this Agreement to an Affiliate, such Party will continue to remain obligated under this Agreement; and, further provided, that, in connection with any assignment to a Third Party described in this Section 23, (i) the assigning Party will provide the other Party with prompt written notice of assignment, (ii) the permitted assignee will assume in writing all obligations of its assignor under this Agreement.

24. **No Implied Licenses**. No right or license under any Brammer Technology, New Brammer Technology, and Process of either Party is granted or will be granted by implication. All such rights or licenses are or will be granted only as expressly provided in this Agreement.

25. **Press Releases**. The Parties agree that any initial public announcement of the execution of this Agreement will be in the form of a mutual press release to be agreed upon by the Parties; provided, that the Parties will also agree on the timing of such public announcement. After such press release is published, each Party will be entitled to make or publish any public statement consistent with the contents thereof. Except as set forth in the preceding sentence, no press release, publicity or other form of public written disclosure related to this Agreement will be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing. This Section 25 will not apply to any disclosure that is deemed necessary, in the reasonable judgment of the responsible Party, to comply with national, federal or state laws or regulations.

26. **Use of Names**. Neither Party will make use of the name of the other Party in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party.

27. **Notices**. All notices to be given as required in the Agreement will be in writing and may be delivered by email or delivered personally or mailed either by a reputable overnight carrier with required receipt signature or certified mail, postage prepaid to the Parties at the addresses set forth below or at such other address as either Party may provide by written notice to the other party in accordance with the provisions of this Section 27. Such notice will be effective: (a) on the date sent, if delivered personally or by email (receipt of which is confirmed); (b) the date after delivery if sent by overnight carrier; or (c) on the date received if sent by certified mail.

If to Customer:

Freeline Therapeutics Limited
Attn: [**] Chief Development Officer
[**]
Email: [**]

If to Brammer:

Brammer Bio MA, LLC
Attn: [**] President & CEO
[**]
Email: [**]

28. **Choice of Law**. This Agreement, and all matters arising directly or indirectly hereunder, will be governed by, and construed in accordance with the laws of the State of New York, without giving effect to its choice of law provisions. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980.

29. **Waiver/ Severability**. No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances will be deemed to be or be construed as a further or continuing waiver of any such provision, or of any other provision or condition of this Agreement. The invalidity of any portion of this Agreement will not affect the validity, force or effect of the remaining portions of this Agreement. If it is ever held that any provision hereunder is too broad to permit enforcement of such provision to its fullest extent, such provision will be enforced to the maximum extent permitted by law.

30. **Entire Agreement; Modification/Counterparts**. This Agreement, together with the Work Statements and Appendices attached hereto, sets forth the entire agreement between the Parties hereto with respect to the performance of the Program by Brammer for Customer and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, and commitments with respect thereto and will take precedence over all terms, conditions and provisions of any purchase order form or form of order acknowledgment or other document purporting to address the same subject matter. This Agreement will not be waived, released, discharged, changed or modified in any manner except by an instrument signed by the duly authorized officers of each of the Parties hereto, which instrument will make specific reference to this Agreement and will express the plan or intention to modify same. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. For purposes of execution, facsimile signatures will be deemed originals.

31. **Construction**. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The headings and captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terın "including" as used herein will mean including, without limiting the generality of any description preceding such term. The language of this Agreement will be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Signature Page Follows]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

BRAMMER BIO MA, LLC

By: [**]
Name: [**]
Title: PRESIDENT & CEO

FREELINE THERAPEUTICS LIMITED

By: [**]
Name: [**]
Title: CEO

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT A

WORK STATEMENT No.: #1

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT B

CUSTOMER-FUNDED EQUIPMENT

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT C: CHANGE ORDER TEMPLATE

Attachment 1 to Change Order X
To Work Statement x to Development and Manufacturing Services Agreement Dated XX

Change Order X
To Purchase Order x to Development and Manufacturing Services Agreement Dated XX

This Change Order Number 1 to Work Statement No.:__ ("Change Order") is made effective as of October 5, 2017, (the "Effective Date") by and between **Freeline Therapeutics Limited** ("CUSTOMER") and **Brammer Bio MA, LLC** ("Brammer") and constitutes a 'Work Statement" under that certain Development and Manufacturing Services Agreement by and between the Parties, dated _____ (the "Agreement"), and in particular, Purchase Order No.:____ dated _____.

This Change Order 1 and the Services contemplated herein are subject to the terms and conditions of the Agreement. Capitalized terms not otherwise defined in this Change Order 1 shall have the meaning ascribed to such terms in the Agreement. To the extent any terms or provisions of this Change Order 1 conflict with the terms and provisions of the Agreement, the terms and provisions of the Agreement shall control.

The Parties hereby agree to make changes to the Services and terms only as follows:

Description of Change(s) and Assumption:

The Services are set forth in the Agreement of Purchase Order No.:___ of the Agreement are hereby amended to include the additional Services set forth in **Attachment 1** of this Change Order 1.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

BRAMMER BIO MA, LLC	FREELINE THERAPEUTICS LIMITED
By: _____	By: _____
Name:	Name:
Title:	Title:

[*Attachment 1 to Change Order X is attached to the Change order*]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT D

COMMERCIAL SUPPLY TERM SHEET

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT E

QUALITY AGREEMENT

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT F

FORM OF LETTER AUTHORIZING CROSS-REFERENCING

[Brammer Bio letterhead]

[Date]

[To be addressed to applicable Regulatory Authority holding Customer regulatory submission][1]

RE: Right of Reference to [identify Brammer regulatory submission]

Dear Sir/Madam:

Brammer Bio MA, LLC, the sponsor of *[Brammer regulatory submission]*, has granted Freeline Therapeutics Limited ("Freeline") and its successors and assigns, the right to reference and rely upon all information and data contained in *[Brammer regulatory submission]* in support ofFreeline *[identify Freeline regulatory submission]*.

By this letter, Brammer hereby authorizes the Food and Drug Administration [or Other Regulatory Authority] to cross-reference Brammer's *[Brammer regulatory submission]* in its review of Freeline *[identify Freeline regulatory submission]* for the purpose described above.

Please contact *[name and telephone number]* if you have you any questions regarding this right of reference.

Sincerely,

[Brammer signatory]
Title:

cc: [Name, Title]
Freeline Therapeutics Limited
215 Euston Road
London NW1 2BE, UK

1 If any such letter is to be delivered to a regulatory authority other than the FDA, the Parties acknowledge that appropriate modifications to this form will be necessary.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXHIBIT G

CUSTOMER'S PROCESS FOR TRANSFER TO BRAMMER

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

Exhibit 10.12

DEDICATED MANUFACTURING AND COMMERCIAL SUPPLY AGREEMENT

This **DEDICATED MANUFACTURING AND COMMERCIAL SUPPLY AGREEMENT** (this "Agreement"), effective as of this 30th day of June, 2020 (the "Effective Date"), between, **Freeline Therapeutics Limited**, having its principal place of business at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, UK ("Customer"), and **Brammer Bio MA, LLC**, a Delaware limited liability company with offices at 250 Binney Street, Cambridge, MA 02142 ("Brammer"). Customer and Brammer are referred to herein each as a "Party" and collectively as the "Parties."

WHEREAS, Brammer provides a full range of viral vector process and analytical development, clinical and commercial manufacturing and supply services to cell and gene therapy companies;

WHEREAS, the Parties have entered into that Development and Manufacturing Services Agreement, dated as of October 6, 2017, between Customer and Brammer (as amended from time to time, the "DMSA"), pursuant to which Brammer performs certain services (as defined therein) with respect to certain products for Customer, which products may be subject to the manufacture and supply by Brammer on behalf of Customer under this Agreement;

WHEREAS, Customer now desires that Brammer manufacture and supply the Product (as defined below) for clinical trial and commercialization purposes pursuant to this Agreement;

WHEREAS, Customer desires Brammer to reserve the Dedicated Capacity (as defined below) in one or more GMP Suite(s) (as defined below) in connection with such manufacture and supply, and Brammer wishes to provide such Dedicated Capacity; and

WHEREAS, in connection with such manufacture and supply, Customer and Brammer are entering into the Product Addendum (as defined below) for the Product, which shall describe the Services (as defined below) of manufacturing and supply activities that Brammer shall conduct for each such Product.

NOW, THEREFORE, in consideration of the above statements, the mutual covenants contained herein, and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

1. **Definitions**. Terms defined elsewhere in this Agreement will have the meanings set forth therein for all purposes of this Agreement unless otherwise specified to the contrary. The following terms will have the meaning set forth below in this Section 1:

1.1 "Acknowledgement" has the meaning set forth in Section 3.1.

1.2 "Action" means any charges, complaints, hearings, claim, demand, action, suit, countersuit, arbitration, inquiry, proceeding or investigation by or before any federal, state, local, foreign or international governmental authority or any arbitration or mediation tribunal.

1.3 "Additional Product" has the meaning set forth in Section 2.1(ii).

1.4 "Administrative Fee" has the meaning set forth in Section 4.4.

1.5 "Advanced Payment" has the meaning set forth in **Appendix C**.

1.6 "Affiliate(s)" means, with respect to any Person, any other Person which directly or indirectly: (a) controls such first Person; (b) is controlled by such first Person; or (c) is under common control with such first Person, whether now or in the future. As used in this definition, the terms "control" and "controlled" mean ownership of fifty percent (50%) or more (including ownership by trusts with substantially the same beneficial interests) of the voting and equity rights of a Person or the power to direct the management of such Person, including by way of contract.

1.7 "Agreement" has the meaning set forth in the preamble.

1.8 "Applicable Laws" means, with respect to any Person, any transnational, domestic or foreign federal, state or local law (statutory, common or otherwise), constitution, treaty, convention, ordinances, rules, regulations, laws, guidelines, guidances, requirements and court orders of any kind whatsoever of any governmental entity that is binding upon or applicable to such Person, as amended from time to time, including (a) cGMP (if applicable) of the FDA, (b) the EMA, (c) the European Commission, (d) the ICH guidelines and regulations, and (e) other regulatory jurisdictions as may be mutually agreed to in writing by both Parties.

1.9 "Approval Date" has the meaning set forth in Section 2.1(ii).

1.10 "Approved Vendor(s)" has the meaning set forth in Section 9.1.

1.11 "Artwork Change" has the meaning set forth in Section 2.10(a)(ii).

1.12 "Batch" means [**]

1.13 "Batch Documentation" has the meaning set forth in Section 5.1.

1.14 "Batch Pricing" has the meaning set forth in Section 4.1.

1.15 "Batch Record" (also referred to as "Manufacturing Batch Record (MBR)" or "Batch Production Record (BPR)") means, with respect to a Batch of Drug Substance or Drug Product, a manufacturing record for such Batch generated by Brammer concurrently with the production of such Batch such that successive steps in such processes are documented, and includes without limitation all documentation necessary to maintain compliance, batch records, specifications, compliance and quality assurance documentation, Certificates of Analysis, certificates of compliance, manufacturing batch records, deviation reports (including operator error or equipment failure), packaging records, documentation or records of environmental monitoring, and other materials generated by Brammer during or in connection with such Batch, whether recorded in writing or electronically.

1.16 "Binding Forecast" has the meaning set forth in Section 3.2.

1.17 "Brammer" has the meaning set forth in the first paragraph of the preamble section of this Agreement.

1.18 "Brammer Failure" [**]

1.19 "Brammer IPR" has the meaning set forth in Section 11.4.

1.20 "Brammer Marks" means the Marks set forth in **Appendix F**, as such appendix may be amended from time to time by the mutual written agreement of the Parties.

1.21 "Brammer Materials" means any and all materials to be consumed in the Manufacture and/or testing of the Product or incorporated into the Product or packaging of the Product, including Process Consumables, packaging materials, and components needed for the Manufacturing of the Product, in each case, other than the Customer Provided Materials.

1.22 "Brammer Parties" has the meaning set forth in Section 15.1.

1.23 "Brammer Technology" [**]

1.24 "Business Day" means a day other than a Saturday, Sunday or a bank or other public holiday in New York, New York or London, United Kingdom.

1.25 "Calendar Quarter" means a period of three (3) consecutive months during a Calendar Year beginning on and including January 1st, April 1st, July 1st or October 1st.

1.26 "Calendar Year" means a period of twelve (12) consecutive months beginning on and including January 1st.

1.27 "Capacity Access Fee" has the meaning set forth in Appendix **C.**

1.28 "Certificate of Analysis" means, with respect to a Batch of Drug Substance or Drug Product, a written certificate listing the items tested, Manufacturer, specifications, testing methods and test results for such Batch.

1.29 "Certificate of Compliance" means a document signed by an authorized representative of Brammer, certifying that a particular Lot of Drug Substance or Drug Product was Manufactured in accordance with cGMP (if applicable), all other Applicable Laws and the Specifications.

1.30 "cGMP" or "GMP" means the then-current good manufacturing practices, including the regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act, 21 C.F.R. Part 210 *et seq.*, as amended from time to time, applicable guidance documents issued by the FDA, European Commission Directive 2003/94/EC and EMA guidance documents, applicable documents developed by the ICH to the extent that they are applicable to the Drug Substance or Drug Product and the Parties hereunder, and other Regulatory Authorities applicable to the manufacture and testing of pharmaceutical materials under Applicable Laws.

1.31 "Change Order" means a written document setting forth Services to be provided by Brammer in addition to those set forth in the Product Addendum and Brammer's compensation therefor as mutually agreed upon by the Parties in writing prior to the provision of said Services. A sample Change Order is attached hereto as **Appendix D**.

1.32 "Clinical Failure" means any decision by the Customer, in its sole discretion, (a) [**]

1.33 "Commercially Reasonable Efforts" means, with respect to the activities of Brammer in the performance of the Services, performing such activities using efforts consistent with similarly situated contract development and manufacturing organizations in the biopharmaceutical industry, resources typically used by such contract development and manufacturing organizations in the United States in the performance of such activities to achieve a desired result, including human and technical resources, and the expenditure of funds which are necessary to complete such activities and achieve such result. For clarity, acts of negligence or willful misconduct or failure to comply with the terms herein or perform due to financial offers from third parties will not be deemed to be commercially reasonable.

1.34 "Confidential Information" means all know-how (and all tangible and intangible embodiments thereof) and all other secret, confidential or proprietary information, data or materials, whether in written, oral, graphic, video, computer or other form, which is disclosed or made available by a Party or an Affiliate of such Party to the other Party or an Affiliate of such other Party pursuant to this Agreement (including Confidential Information disclosed pursuant to the DMSA) or which is observed by a Party or an Affiliate of such Party at the other Party's facilities (including in connection with any audit or regulatory process conducted pursuant to this Agreement) or which arises as a result of this Agreement, and which: (a) if disclosed in written, graphic, electronic or other tangible form, is labeled as confidential or proprietary, (b) if disclosed orally or visually, is identified as confidential or proprietary at the time of disclosure and is confirmed to be confidential or proprietary by the disclosing Party in writing to the Receiving Party within [**] of such disclosure, or (c) by its nature, should reasonably be considered to be confidential or proprietary. Confidential Information of Customer includes business, technical and financial data, know-how and trade secrets concerning the Customer Provided Materials, the Drug Substance, the Drug Product, Customer Technology, and New Customer Technology. Confidential Information of Brammer includes proprietary technical data, and know-how concerning Brammer's production and purification methods, Brammer's equipment parameters and techniques, Brammer's facilities and their design and operation, and Brammer Technology and New Brammer Technology, as well as business, financial and technical data of Brammer.

1.35 "Control" means, with respect to any Technology or Intellectual Property Right, that a Party: (a) owns such Technology or Intellectual Property Right; or (b) has a license or right to use to such Technology or Intellectual Property Right, in each case of (a) and (b) with the legal right to grant to the other Party access, a right to use, or a license, or a sublicense (as applicable) to such Technology or Intellectual Property Right without violating the terms of any agreement or other arrangement with any Third Party or creating a payment obligation upon such Party, or knowingly misappropriating the proprietary or trade secret information of a Third Party.

1.36 "Customer" has the meaning set forth in the first paragraph of the preamble section of this Agreement.

1.37 "Customer Approval" has the meaning set forth in Section 5.1.

1.38 "Customer-Funded Equipment" means equipment, if any, which is funded and owned by the Customer, which may be used by Brammer solely in connection with the provision of the Services, and which will be installed, validated and maintained by Brammer during the Term and will be specified in the Product Addendum.

1.39 "Customer-Owned Retains" has the meaning set forth in Section 2.12.

1.40 "Customer Parties" has the meaning set forth in Section 15.2.

1.41 "Customer Process" means the process set forth on Exhibit 1 to the Product Addendum attached hereto, as may be amended from time to time by Customer upon Brammer's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

1.42 "Customer Provided Materials" means the materials identified in the Product Addendum to be provided by Customer to Brammer hereunder, for use in the Manufacture of the Product under the Product Addendum.

1.43 "Customer Representative" has the meaning set forth in Section 3.6.

1.44 "Customer Technology" [**]

1.45 "Dedicated Capacity" means the cGMP Manufacturing capacity exclusively dedicated to Customer for Brammer's delivery of Services under this Agreement and, as provided in Section 2.1(ii), Services (as defined in Section 1.38 of the DMSA) under the DMSA, in each case, through the GMP Suite and general processing areas, during the Term corresponding to the periods for which Customer pays the applicable Capacity Access Fee pursuant to Section 4.3 and as more specifically described in **Appendix C**, for Brammer's Manufacture of Product.

1.46 "Defect" [**]

1.47 "Deliverable" means any work product to be provided by Brammer pursuant to this Agreement, a Work Statement or the Product Addendum, but excluding the Product Manufactured by Brammer hereunder.

1.48 "Delivery Date" has the meaning set forth in Section 3.1.

1.49 "Delivery Site" has the meaning set forth in Section 5.2.

1.50 "Development Services" has the meaning set forth in Section 2.1(i).

1.51 "Disclosing Party" has the meaning set forth in Section 10.1.

1.52 "Disposition" means a documented decision on the acceptability for use of a specific Lot that is based on a process of reviewing data associated with the production and testing of the Product.

1.53 "DMSA" has the meaning set forth in the recitals.

1.54 "Drug Product" means the Product Manufactured by Brammer on behalf of Customer into its final container closure, whether or not labeled.

1.55 "Drug Substance" means the non-sterile active pharmaceutical ingredient Manufactured by Brammer on behalf of Customer and identified in the Product Addendum.

1.56 "Executives" has the meaning set forth in Section 3.7(c).

1.57 "Effective Date" has the meaning set forth in the first paragraph of the preamble section of this Agreement.

1.58 "EMA" means the European Medicines Agency, and any successor agency entity thereof having or performing substantially the same function.

1.59 "Facilities" or "Facility" means Brammer's manufacturing facilities located at [**] unless otherwise specifically agreed in writing by the Parties.

1.60 "FDA" means the United States Food and Drug Administration or any successor entity thereof having or performing substantially the same function.

1.61 "Forecast" has the meaning set forth in Section 3.2.

1.62 "Force Majeure Event" has the meaning set forth in Section 19.

1.63 "FTE" has the meaning set forth in Section 11.5.

1.64 "GMP Suite" has the meaning set forth in Section 2.3.

1.65 "ICH" means the International Conference on Harmonization.

1.66 "Initial Term" has the meaning set forth in Section 18.1.

1.67 "Indemnifying Party" has the meaning set forth in Section 15.3.

1.68 "Intellectual Property Rights" means any and all of the following: (a) Patents, (b) copyrights in both published and unpublished works, (c) trade secrets and know-how, whether or not patentable or copyrightable, (d) trademarks, service marks, trade names, trade dress and other indicators of source ("Marks"), (e) any and all other intellectual property rights, and (f) any and all registrations and applications for registration of, and all goodwill associated with, any of the foregoing.

1.69 "JSC" has the meaning set forth in Section 3.7.

1.70 "Latent Defect" [**]

1.71 "Launch" means the first commercial sale of the Product that has received Regulatory Approval together with all pricing and reimbursement approvals from the applicable Regulatory Authority, excluding, however, any sale or other distribution for compassionate use, named patient use or for use in a clinical trial, for test marketing or similar use in a country.

1.72 "License" has the meaning set forth in Section 11.4.

1.73 "Losses" has the meaning set forth in Section 15.1.

1.74 "Lot" means a Batch or a portion of a Batch, or multiple Batches of Product released under a single alpha-numeric identifier.

1.75 "Manufacture," "Manufactured," and "Manufacturing" means the steps, processes and activities used by Brammer to produce the Product, including, for example, the manufacturing, processing, packaging, labeling, testing, stability testing, Process Performance Qualification, and the release, shipping, storage or supply of the Product as provided in the Product Addendum, Batch Record, Master Batch Record and Quality Agreement.

1.76 "Manufacturer" means Brammer Bio MA, LLC.

1.77 "Marks" has the meaning set forth in Section 1.68.

1.78 "Master Batch Record" means the document containing the Specifications and instructions for the Manufacture and quality assurance of the Product, as such may be amended in writing by the mutual agreement of the Parties in accordance with the terms hereof.

1.79 "Maximum Drug Product Purchase Commitment" has the meaning set forth in Section 3.3.

1.80 "Maximum Purchase Commitment" has the meaning set forth in Section 3.3.

1.81 "Material Specification" means a document detailing the list of tests, formulations, references to any analytical methods and appropriate acceptance criteria that are numerical limits, ranges or other criteria for tests described, that establishes a set of criteria to which any Product Material should conform to be considered acceptable as per Brammer's quality requirements. For the avoidance of doubt, the Parties shall establish Material Specifications for all Product Materials relating to the Product.

1.82 "Minimum Purchase Commitment" has the meaning set forth in Section 3.3.

1.83 "MHRA" means the Medicines and Healthcare products Regulatory Agency of the United Kingdom.

1.84 "New Brammer Technology" [**]

1.85 "New Customer Technology" [**]

1.86 "New Technology" has the meaning set forth in Section 11.3.

1.87 "Non-Binding Forecast" has the meaning set forth in Section 3.4.

1.88 "Packaging Information" means the artwork, logo, marks, labels, patient information leaflets and other information attached to or otherwise included in the Product, in each case, as provided or approved by Customer.

1.89 "PAI" has the meaning set forth in Section 6.5.

1.90 "Party" or "Parties" has the meaning set forth in the first paragraph of the preamble section of this Agreement.

1.91 "Pass-Through Costs" has the meaning set forth in Section 4.4.

1.92 "Patents" means patents and patent applications issued or pending therefrom anywhere in the world, together with any and all divisions, renewals, continuations and continuations-in-part thereof, and all patents granted thereon, and all reissues, re-examination certificates, certificates of invention and applications for certificates of invention, revalidations, substitutions, supplementary protection certificates, additions, utility models, and term restorations, extensions and foreign counterparts thereof.

1.93 "Permitted Recipients" has the meaning set forth in Section 10.3.

1.94 "Person" means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust or joint venture, or a governmental entity or political subdivision thereof.

1.95 "PPI" has the meaning set forth in Section 4.2.

1.96 "Price" means, with respect to the Product, the price to be charged by Brammer for a Batch of Product Manufactured and supplied hereunder as delivered to Customer in accordance with Section 4.1 as set forth on **Appendix C**, as amended from time to time.

1.97 "Process" means the processes and procedures used to Manufacture the Product in accordance with the Master Batch Record, including all protocols and standard operating procedure documents referenced therein, which are provided by Customer to Brammer (including the Customer Process) or developed by Brammer pursuant to the DMSA.

1.98 "Process Consumables" means media, raw materials, chromatography columns, resins, filters, membranes, disposable analytical test kits, hoses, filter housings, tubing, filling needles, disposable bags, disposable glass/plastic ware, cleaning supplies and other changeover parts used during the Manufacture of the Product. The Parties may list other Process Consumables to be added to the scope of this Agreement in an amendment to the Product Addendum.

1.99 "Process Performance Qualification" or "PPQ" means the collection and evaluation of data, from the Process design stage through repeated production at final scale, which establishes scientific evidence that a manufacturing process is capable of consistently and reproducibly delivering the Product meeting Specifications, as described in the FDA's Guidance for Industry, Process Validation: General Principles and Practices, January 2011 (Rev. 1), as amended or updated from time to time.

1.100 "Product" means the Drug Substance or Drug Product, as applicable, as defined in the Product Addendum.

1.101 "Product Addendum" means the executed product addendum set forth in **Appendix A** as it may be updated from time to time by the mutual written agreement of the Parties, and any other product addendum executed by the Parties which may be issued under this Agreement from time to time.

1.102 "Product Materials" means the Customer Provided Materials and Brammer Materials.

1.103 "Program Manager" has the meaning set forth in Section 3.6.

1.104 "Purchase Order" means a written or electronic order form submitted by Customer in accordance with the terms of this Agreement to Brammer authorizing the Manufacture and supply of the Product.

1.105 "Quality Agreement" has the meaning set forth in Section 6.1.

1.106 "Quote" has the meaning set forth in Section 4.5.

1.107 "Recall" has the meaning set forth in Section 6.6.

1.108 "Receiving Party" has the meaning set forth in Section 10.1.

1.109 "Regulatory Approval" means in a particular country or regulatory jurisdiction, all approvals and authorizations, including any renewals and amendments thereof, of the applicable Regulatory Authority necessary for the manufacture, packaging, marketing, storage, import, export, transport, distribution, sale and use of a pharmaceutical or biologic product in such country or jurisdiction.

1.110 "Regulatory Authority" means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the Manufacture, production, use or storage or transport, of the Product, including the FDA, the EMA, the MHRA and the European Commission.

1.111 "Renewal Term" has the meaning set forth in Section 18.1.

1.112 "Reprocess" means introducing the Product back into, and repeating appropriate manipulation steps that are part of, the established Process.

1.113 "Required Changes" has the meaning set forth in Section 6.3.

1.114 "Reserved Products" means the products [**] set forth in **Appendix H**, which may be amended from time to time by Customer upon written notice to Brammer.

1.115 "Result(s)" means all in-process analytical results, materials, data obtained, and reports developed and/or generated by Brammer in performing the Services related to the Product or Process. Any results, materials or data obtained, developed or generated outside of the conduct of the Services or that are not related to the Product or Process will not constitute Results. For the avoidance of doubt, documents that may be generated or used in the course of performing Services, but that are general to Brammer's business and not specifically related to the Product or Process, such as Facility and equipment SOPs, will not constitute Results.

1.116 "Retained Copies" has the meaning set forth in Section 18.4(f)(iii).

1.117 "Retention Period" has the meaning set forth in Section 2.11.

1.118 "Serious Adverse Event" means an adverse drug experience or circumstance that results in any of the following outcomes: (a) death, (b) life-threatening condition, (c) inpatient hospitalization or a significant prolongation of existing hospitalization, (d) persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, (e) congenital anomaly/birth defect or (f) significant intervention required to prevent permanent impairment or damage.

1.119 "Services" means any and all Manufacture and supply of Product, and other services and activities to be performed by Brammer, any Brammer Affiliate, any of their respective employees, agents or consultants, or Approved Vendors hereunder, as more specifically set forth herein or in a Product Addendum or a Work Order.

1.120 "SOP" means the written standard operating procedures and methods of Brammer, as the same may be amended, in Brammer's sole discretion, from time to time.

1.121 "Special Waste" means waste or effluent, which is required pursuant to Applicable Laws to be collected in a special container for external disposal.

1.122 "Specifications" means the list of tests, references to any analytical methods and appropriate acceptance criteria that are numerical limits, ranges or other criteria for tests described, that establishes a set of criteria to which the Product should conform to be considered acceptable for its intended use (i) as approved by (or, prior to such approval, as submitted for approval to) a Regulatory Authority (or any subsequent amendment thereof) or (ii) if no such approval by, or submission to, a Regulatory Authority has yet occurred, as agreed to by the Parties in writing and set forth in Brammer's applicable quality system.

1.123 "Standards of Quality" means with respect to each Brammer Mark, the standards prescribed from time to time by Brammer, including standards relative to the quality, size, position, marking and appearance of the Brammer Mark, and the manner, disposition and use of the Brammer Mark and accompanying designations, on any document or other media, including any material used in the marketing or promotion of the Product.

1.124 "Storage Guidelines" means Brammer's procedures that describe the methods of preserving, monitoring and storing all Product Materials, under conditions as mutually agreed to in writing with Customer.

1.125 "Substituted Product" has the meaning set forth in Section 2.6.

1.126 "Substituted Product Addendum" has the meaning set forth in Section 2.6.

1.127 "Technology" means all scientific, technical and other information, data, know-how, trade secrets, inventions (whether or not patentable), processes, compositions of matter, materials, methods, techniques, documentation, hardware, software and technology, whether or not protected or protectable under Patent, trademark, copyright or similar law.

1.128 [**] has the meaning set forth in [**]

1.129 "Term" has the meaning set forth in Section 18.1.

1.130 "Third Party" means any Person other than Customer, Brammer and their respective Affiliates.

1.131 "U.S." means the United States of America and its territories and possessions.

1.132 "Vendor" means any Third Party (a) that supplies any Product Materials, Process Consumables or other products or Services to Brammer or its Affiliates or (b) to which Brammer has subcontracted the performance of any of its obligations under this Agreement.

1.133 "Work Statement" has the meaning set forth in Section 1.88 of the DMSA and is hereby incorporated by reference in its entirety.

2. **Overview of Agreement**.

2.1 Brammer Manufacturing and Supply Activities; Interpretation.

(i) Provision of Services Pursuant to DMSA. During the Term, Customer may request that Brammer provide certain services related to the Product that are outside the scope of Brammer's Manufacture and supply obligations under this Agreement, such as the conduct of Process Performance Qualification or services related to Process development in connection with the Product and the like ("Development Services"). Subject to this Section 2.1, the Parties agree that all Development Services will be set forth in a written Work Statement (as defined in Section 1.88 of the DMSA) to the DMSA, shall be considered Services (as defined in Section 1.38 of the DMSA) under the DMSA, shall be governed by all provisions of the DMSA, and shall not be governed by the terms of this Agreement. For clarity, other than the performance of Manufacturing activities to supply the Product ordered by Customer hereunder following a successful Process Performance Qualification campaign, all other activities or services of Brammer shall be considered "Development Services" for purposes of this Agreement and this Section 2.1(i).

(ii) Manufacture of Product under the DMSA. Notwithstanding anything to the contrary set forth in this Agreement or the DMSA (A) Brammer shall, at Customer's election, [**], any Batches of such Substituted Product or such Additional Product Manufactured pursuant to the [**], be Manufactured in the Dedicated Capacity and such Batches shall count towards the [**] Minimum Purchase Commitment, Maximum Purchase Commitment and Maximum Drug Product Purchase Commitment. All Batches of Product Manufactured by Brammer pursuant to the DMSA, which Customer requires Brammer to Manufacture in the Dedicated Capacity pursuant to Section 2.1(ii)(A), shall be subject to the forecasting requirements set forth in Section 3.

(iii) Agreement to Supply. During the Term, Brammer shall Manufacture and supply Product to Customer for clinical trial and commercial supply purposes in accordance with the provisions of this Agreement (including the Specification and Product Addendum), GMP, the Quality Agreement and Applicable Law.

(iv) Product Addendum; Interpretation. The Product Addendum shall be deemed to be incorporated into this Agreement. Any amendment to the terms of this Agreement shall be effective for the Product Addendum, unless such amendment or Product Addendum specifies otherwise. In the event of a conflict between the terms of this Agreement and the terms set forth in the Product Addendum (include any exhibit thereto), the terms of this Agreement shall control, except to the extent that the Product Addendum expressly and specifically states an intent to supersede this Agreement on a specific matter. Notwithstanding anything herein or in the DMSA to the contrary, unless expressly agreed to by the Parties in writing or as expressly set forth herein, in the event of a conflict between the terms of this Agreement and the DMSA, the terms of this Agreement shall govern with respect to post-Process Performance Qualification Services related to commercial supply of Product and subject to Section 2.6, the terms of the DMSA shall govern development and Process Performance Qualification Services under Work Statements conducted in the Dedicated Capacity.

2.2 Use of Facilities. Brammer shall perform all Manufacturing and supply and storage activities hereunder at the Facilities. Brammer shall not implement any changes to the Facilities reasonably likely to have any material or adverse effect on the conduct of the Manufacturing and supply activities set forth in this Agreement without Customer's prior written consent, which consent will not be unreasonably withheld, delayed or conditioned.

2.3 GMP Suite. Brammer shall maintain, within the Facilities, a GMP Manufacturing suite that is reserved to support the Dedicated Capacity in a state ready and available for Manufacture of Product in accordance with the Product Addendum, which suite is fully equipped, maintained and validated, and which includes a sufficient number of qualified and trained staff dedicated to such Manufacturing suite to conduct such activities (a "GMP Suite"), as provided in **Appendix C**. [**]

2.4 Regulatory Approvals. Brammer shall ensure that the Facilities will meet all statutory and regulatory requirements applicable to the Manufacture of Product. Brammer shall be responsible for properly maintaining the GMP Suite reserved for Dedicated Capacity within the Facilities, and for ensuring that all validated processes are carried out in accordance with the terms of such processes, all in accordance with Applicable Laws. Brammer shall obtain and maintain during the Term of this Agreement, at its own expense, any and all Facility-related Regulatory Approvals and any other permits necessary for the Manufacturing and supply activities conducted by Brammer under this Agreement, excluding Product-specific Regulatory Approvals. Subject to Sections 6.5 and 7.1, Customer shall be responsible for the costs of such Product-specific Regulatory Approvals as Pass-Through Costs contemplated by Section 4.4.

2.5 Scheduled Shutdowns. Brammer will provide Customer written notice of the dates and duration of any scheduled shutdowns or other events that will render the GMP Suite unavailable at least [**] prior to such scheduled shutdowns or unavailability (it being understood that no such shutdowns or other events will limit or otherwise modify Brammer's obligation to provide the Dedicated Capacity and supply of Product to Customer in accordance with the terms of this Agreement).

2.6 Flexible Use of Dedicated Capacity. [**] Customer's [**] or their respective partners' [**]

the foregoing requirements shall not require such products to be "late phase" or post-Process Performance Qualification Services). For clarity, the Dedicated Capacity under this Agreement is intended solely for GMP Manufacturing. [**] the Parties shall jointly develop under an applicable Work Statement, a Product Addendum for such Substituted Product ("Substituted Product Addendum"). The Parties acknowledge and agree that any services required to develop Manufacturing processes and analytical tests and/or transfer Substituted Products into the Dedicated Capacity will be the subject of additional Work Statements under the DMSA, [**] such Substituted Product shall constitute the "Product" hereunder, the applicable Substituted Product Addendum shall constitute the "Product Addendum" hereunder and Brammer shall Manufacture and supply such Product in accordance with the terms herein. [**] subject to Brammer's [**]

2.7 Right to Cross-Reference. Brammer hereby grants to Customer, its Affiliates and its sublicensees, with respect to the Product, a perpetual, irrevocable, sublicensable right to cross-reference Brammer's regulatory submissions and Facility approvals for the purpose of obtaining and maintaining Regulatory Approvals with respect to the Product anywhere in the world. Within [**] after Customer's written request, Brammer shall deliver to Customer for filing with the FDA or any foreign Regulatory Authority designated by Customer such authorization letters as Customer reasonably deems necessary for the foregoing purpose, which shall be substantially in the form attached hereto as **Appendix B**, subject to such modifications as may be required by Applicable Laws; *provided, however,* that if Customer proposes any material modifications to such form, Brammer shall be entitled to an additional [**] for review and approval of the modified form; and *provided, further,* that [**] associated with its request for such cross-reference, and for obtaining any notarization, legalization or apostille that may be required for filing any authorization letter with any foreign Regulatory Authority. For the avoidance of doubt, Brammer shall not be required to provide directly to Customer any Brammer documents that are general to Brammer's business, such as Facility and equipment SOPs unless such documents are necessary to obtain any Regulatory Approvals with respect to the Product.

2.8 Annual Capacity. Brammer shall supply quantities of Product consistent with the Forecasts and accepted Purchase Orders submitted by Customer in accordance with Section 3 below. Brammer shall have the GMP Suite reserved for Dedicated Capacity with the ability to produce the Maximum Purchase Commitment each Calendar Year and will otherwise devote the Dedicated Capacity to perform the Services in accordance with the provisions of this Agreement and, as provided in Section 2.1(ii), any Services (as such term is defined in the DMSA) under the DMSA. Brammer will use Commercially Reasonable Efforts to accommodate increases above Maximum Purchase Commitment and Maximum Drug Product Purchase Commitment either by increasing the number of Batches produced in the Dedicated Capacity or through providing additional capacity in the Facility, for example, through use of a non-dedicated suite for downstream processing.

2.9 Purchase of Product. Customer and Brammer agree that the Minimum and Maximum Purchase Commitments for the Drug Substance, for each Calendar Year of the Term or any Renewal Term will be as detailed in **Appendix C**, as may be amended by mutual written agreement of the Parties from time to time. Customer and its Affiliates shall purchase from Brammer, and Brammer will supply to Customer and

its Affiliates, Product in an amount equal to that detailed in the applicable Binding Forecast and accepted Purchase Orders submitted by Customer during the Term (it being understood that the aggregate quantity of Products ordered in Customer's Purchase Orders for any Calendar Year during the Term shall be no less than the Minimum Purchase Commitment, unless permitted pursuant to Section 3.3 or pursuant to the issuance by Brammer of an acceptance Acknowledgement in accordance with Section 3.1 of this Agreement, respectively).

2.10 Filling, Finishing and Packaging. Brammer shall be responsible for filling, finishing, vial labeling and primary packaging of any Product in accordance with this Agreement (including the Specifications and Product Addendum), Applicable Laws, the Quality Agreement, and the Packaging Information.

(a) Packaging.

(i) Legal Requirements for Packaging and Labeling. Customer shall inform Brammer of any requirements under any Applicable Laws relating to packaging or labeling of the Product to the extent Customer is aware of such Applicable Laws and shall notify Brammer promptly of any changes to such requirements of which Customer is aware, so that Brammer can modify or request its Approved Vendors to modify the packaging and labeling. Brammer shall not be responsible for any delay in the delivery of the Product to the extent any such delay is caused by failure of Customer to notify Brammer of any required modifications in sufficient time for Brammer or its Approved Vendor to make the modifications prior to the required delivery time. Brammer will promptly implement any changes to the packaging and labeling required by Customer, at Customer's expense, and promptly inform Customer of any delays in the delivery of Product caused thereby.

(ii) Use of the Name of Brammer. To the extent applicable, all Packaging Information, including changes to the Packaging Information in which or with which Customer chooses to have Brammer deliver a Product (any such change referred to as an "Artwork Change"), which contains the name of Brammer or its Affiliates (other than solely identifying Brammer or its Affiliates or their Approved Vendors as the manufacturer or supplier of the Product) shall be subject to the approval of Brammer, which shall not unreasonably withheld, conditioned or delayed.

2.11 Record-keeping. All work outputs, including reports of Results, will be prepared in accordance with Brammer's standard format unless otherwise specified in the Product Addendum. For each Lot of Product Manufactured under a Product Addendum, Brammer will keep and maintain records, including all Results produced in the conduct of its obligations hereunder, for a period of [**] after completion of the Manufacture of such Lot of Product and delivery of such Lot of Product to Customer, or such longer period as required by the Applicable Laws (the "Retention Period"). For clarity, subject to Article 10, Brammer will be entitled to retain all original documents relating to the Services and will provide to Customer an electronic and paper copy of all Batch Records, Results and other reports provided under this Agreement. At the end of the Retention Period, all such work outputs, records and reports shall, at Customer's option and expense, either be (i) delivered to Customer or to its designee, or (ii) disposed of by Brammer and certified in writing to Customer that such disposal has taken place if Customer has not requested in writing that such work outputs, records and reports be delivered to Customer within [**] of prior written notice of Brammer's intent to do so.

2.12 Samples of Product. Brammer will take and retain, for such period and in such quantities as may be required by cGMP (if applicable) and the Quality Agreement, samples of Product Manufactured under this Agreement, including samples required by Customer ("Customer-Owned Retains"). Further, upon Customer's written request and to the extent consistent with cGMP and Applicable Laws, Brammer will provide to Customer reasonable access to such Customer-Owned Retains or agree that Brammer will perform any and all testing requested by Customer on the Customer-Owned Retains. Customer acknowledges that Brammer may retain up to [**] of samples of filled Drug Product per Batch to the extent necessary to comply with Applicable Laws and this Agreement.

3. **Forecasting and Purchase Orders**.

3.1 Purchase Orders. On or before [**] and on or before [**] thereafter, Customer shall submit a Purchase Order for all the new quantities of Product, ordered by Customer for the immediately succeeding Calendar Quarter consistent with the Binding Forecast, pursuant to this Article 3 and such Purchase Order shall include a scheduled delivery date ("Delivery Date") upon which Brammer will deliver such quantities of Product. Within [**] following receipt of such Purchase Order, Brammer will issue a written acknowledgement specifying whether it accepts or rejects such Purchase Order ("Acknowledgement"); *provided however*, that Brammer shall accept such Purchase Order so long as the Purchase Order is consistent with the Maximum Purchase Commitment.

3.2 Binding Forecast. On or before [**], and on the [**] thereafter, Customer shall submit to Brammer a rolling [**] Batch forecast of Customer's anticipated demand for Product (each, a "Forecast"). The [**] of any Forecast shall be binding and non-cancellable by Customer once accepted by Brammer (the "Binding Forecast"), *provided* always that Brammer may only object to any Binding Forecast if it would result in Customer exceeding the Maximum Purchase Commitment in such Calendar Year. In the event that Brammer is unable to accept any changes by Customer to the prior [**] Forecast, Brammer will notify Customer within [**] of receiving the amended Binding Forecast and propose a reasonable alternative to meet Customer's needs.

3.3 Minimum and Maximum Purchase Commitment. Subject to Sections 4.3, 5.5, 5.8(d) and 5.9(c), following establishment of the Process for the Product pursuant to the Process Performance Qualification, during the Term, Customer shall be required to purchase at least the minimum number of Batches of Drug Substance annually, (the "Minimum Purchase Commitment") as specified in **Appendix C**. Subject to this Section 3.3 and Sections 4.3, 5.5, 5.8(d) and 5.9(c), if Customer fails to satisfy the Minimum Purchase Commitment in any Calendar Year, Brammer shall invoice Customer for the Batch Pricing for the number of Batches of Drug Substance needed for Customer to satisfy the Minimum Purchase Commitment for such Calendar Year and Customer shall, within [**] of receipt of invoice, pay to Brammer such Batch Pricing. Notwithstanding anything herein to the contrary, if Brammer fails to Manufacture and deliver the Minimum Purchase Commitment to Customer in any Calendar Year in accordance with the terms and conditions of this Agreement despite the provision of Purchase Orders from Customer to Brammer in such Calendar Year for a number of Batches of Drug Substance which, in the aggregate, equals or is greater than the Minimum Purchase Commitment, and if such failure to Manufacture and deliver the Minimum Purchase Commitment is not otherwise caused by Customer, Customer shall be relieved of its obligation to satisfy such Minimum Purchase Commitment in such Calendar Year to the extent of such failure by Brammer. By way of example only, if the Minimum Purchase Commitment in a Calendar Year is [**] of Drug Substance and despite Customer providing Brammer Purchase Orders for [**] or more Batches of Drug Substance in such Calendar Year, Brammer only Manufactures and delivers to Customer [**] Batches of Drug Substance in such Calendar Year as a result of a Force Majeure Event or a shutdown required by a Regulatory Authority, then the Minimum Purchase Commitment for such Calendar Year shall be reduced by [**] Batches of Drug Substance. Subject to 5.8(d) and 5.9(c), Customer and Brammer agree that a maximum number of Batches of Drug Substance per Calendar Year that can be ordered by Customer, based on level-loading the demand, and for which Brammer will reserve capacity in the Dedicated Capacity to meet a given demand for Drug Substance, is as defined in **Appendix C**, as may be amended by the mutual written agreement of the Parties from time to time (the "Maximum Purchase Commitment"). Brammer will also have the capacity at the Facility to produce at least the number of Batches of Drug Product equal to the number of Batches in the Maximum Purchase Commitment each Calendar Year ("Maximum Drug Product Purchase Commitment"). Subject to 5.8(d) and 5.9(c), if annual capacity exceeding the Maximum Purchase Commitment or Maximum

Drug Product Purchase Commitment is forecasted by Customer, Brammer will use Commercially Reasonable Efforts to increase capacity either through increasing the number of Batches produced in the Dedicated Capacity or through providing additional capacity in the Facilities such as, for example, through the use of another shared suite for downstream processing.

3.4 Non-Binding Forecast. The remaining portion of each Forecast not associated with the Binding Forecast (the "Non-Binding Forecast") shall be a good faith estimate on the part of Customer as to its expected needs but shall not be binding on either Party.

3.5 Brammer's Cancellation of Purchase Orders. If Customer refuses or fails to timely supply Customer Provided Materials in accordance with the Product Addendum, Brammer reserves the right to cancel that part of a Purchase Order for which Customer Provided Materials have not been provided, upon written notice to Customer, and Brammer shall have no further obligations or liability with respect to such part of such Purchase Order. Customer will be responsible for payment for such part of such Purchase Order that cannot be fulfilled due to its failure to provide Brammer with the necessary quantities of Customer Provided Materials. Any such cancellation of Purchase Orders to the extent caused by Customer's refusal or failure to timely supply Brammer with the Customer Provided Materials as required hereunder shall not constitute a breach of this Agreement by Brammer. Notwithstanding anything to the contrary herein, this Section 3.5 shall not apply in the event Brammer fails to comply with its obligations in Section 8.1.

3.6 Program Manager and Customer Representative. Brammer will appoint a Brammer representative (the "Program Manager") to be responsible for overseeing the Services provided by Brammer. The Program Manager will coordinate performance of the Services with a representative designated by Customer in writing (the "Customer Representative"), which representative will have responsibility over all matters relating to performance of the Services on behalf of Customer. Unless otherwise mutually agreed to by the Parties, all communications between Brammer and Customer regarding the provision of Services hereunder will be addressed to or copied to the Program Manager and Customer Representative. The Program Manager and the Customer Representative shall be named in each Purchase Order, and Brammer or Customer may, at its option, substitute, respectively, the Program Manager or the Customer Representative during the Term by providing written notice to the other Party.

3.7 Joint Steering Committee.

(a) Composition. The Parties shall maintain the Joint Steering Committee ("JSC"), having the respective responsibilities set forth below in this Section. The JSC shall be composed of an equal number of appropriate members of Customer's and Brammer's respective management teams having appropriate technical credentials, experience, knowledge, and decision-making authority within their respective organizations. In furtherance of the foregoing, the Parties acknowledge and agree that, at a minimum, the JSC shall include the following members or members of a substantially equivalent seniority and decision-making authority:

Brammer/Customer Co-Chairs
Brammer: VP & General Manager
Customer: SVP Product Supply

Quality Heads
Brammer: Site Quality Head or VP QA
Customer: Head of QA

Operational Heads
Brammer: Site Operational Head
Customer: VP CMC Project Delivery

Project Management
Brammer: Project Manager
Customer: External Supply Lead

The chair of the JSC will alternate each Calendar Year between Brammer's VP & General Manager and Customer's SVP Product Supply with the first Calendar Year in the Term being chaired by Brammer's VP & General Manager. The chairperson will be responsible for scheduling and leading meetings, establishing meeting agendas and other administrative matters relative to the meetings of the JSC but will have no express or implied authority beyond that held by the other members of the JSC (it being understood that the chair of the JSC shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote). Each Party may, with the written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned, invite non-member, non-voting representatives of such Party or any of such Party's Affiliates to attend meetings of the JSC.

(b) Responsibilities. The role of the JSC shall be the overall oversight, review and direction of the ongoing cooperation and communication between the Parties regarding the Services provided by Brammer hereunder (including any Services provided under each Work Statement and the Product Addendum) including:

(i) Meeting (A) on a Calendar Quarterly basis in person or by teleconference or videoconference and (B) on an ad hoc basis as agreed in writing between the Parties from time to time;

(ii) Monitoring the Services provided by Brammer to Customer hereunder, including in connection with the Product Addendum (*e.g.*, review of Forecasts, delivery of Products and Services, resolution of disputes, assessment of Process improvement opportunities, and review of regulatory needs, among others); and

(iii) The JSC shall not have the power to take any action under this Agreement to interpret, amend or modify this Agreement, or waive compliance therewith.

(c) Decisions. The JSC may make decisions with respect to any subject matter that is within the JSC's responsibilities set forth in Section 3.7(b). Subject to this Section 3.7(c), all decisions of the JSC shall be made by unanimous vote, with Customer and Brammer each having, collectively, among its respective members, one (1) vote in all such decisions. If the JSC cannot reach consensus with regard to any matter to be decided by the JSC within [**] after such matter has been brought to the JSC's attention, then such matter shall be referred to the VP & General Manager of Brammer and the SVP Product Supply of Customer (the "Executives") for resolution. Subject to Section 5.7, if the Executives cannot resolve the issue within [**] after the matter has been brought to their attention then, (i) [**] shall have the final decision-making authority on all matters to be decided by the JSC which exclusively relate to general Manufacturing practices or the Facilities generally, (ii) [**] shall have the final decision-making authority on all matters to be decided by the JSC which exclusively relate to the Product, including Regulatory Approvals for the Product and the Process, and (iii) with respect to any and all matters to be decided by the JSC which do not exclusively relate to general GMP Manufacturing practices, the Facilities generally, or the Product, such issue shall be subject to the dispute resolution procedures in Article 14.

3.8 Continuous Improvement. During the Term, Brammer and Customer shall use commercially reasonable efforts to agree, on an ongoing basis, on services provided by Brammer to develop, and implement improvements to the Services, Specifications, and Development Services to improve efficiency, reduce cost, resource utilization and ensure compliance (including obtaining any Regulatory Approval required

to implement such improvements) (collectively "Continuous Improvements"). Such services provided by Brammer in connection with Continuous Improvements shall be set out in a separate Work Statement agreed upon by the Parties in writing. In the event any such Continuous Improvement results in any reduction in such costs, the Parties shall share such reduction in costs equally and the Batch Pricing set forth in **Appendix C** shall be updated by Brammer as soon as reasonably practicable to incorporate such reduction in cost.

4. **Payments**.

4.1 Price Per Batch of Product. Customer shall purchase Drug Substance from Brammer at the applicable Price per Batch of Drug Substance set forth in **Appendix C**, as it may be amended by the mutual written agreement of the Parties from time to time ("Batch Pricing") in accordance with the terms of this Agreement. The Batch Pricing fees owed by Customer for Brammer's Manufacture of a Batch of Drug Substance shall be invoiced by Brammer as follows: [**] Customer shall pay Brammer for any undisputed Batch Pricing fees within [**] following receipt by Customer of Brammer's invoice for such Batch Pricing fees.

4.2 Annual Price Adjustments. Beginning on [**], the Batch Pricing as set forth in **Appendix C** shall be subject to [**], for the immediately prior [**] period.

4.3 Capacity Access Fee. Subject to terms and conditions herein, Customer shall pay the Capacity Access Fee as provided in **Appendix C** attached hereto. Notwithstanding anything herein to the contrary, if, at any time during any Calendar Year during the Term, Brammer does not provide the Dedicated Capacity or GMP Suite to Customer in accordance with the terms and conditions herein for any reason (excluding a Force Majeure Event of less than [**] in duration which does not interfere with Brammer's obligation to provide the Dedicated Capacity in accordance with Sections 2.3 and 2.8, but including, for the avoidance of doubt, any other Force Majeure Event or a shutdown required by a Regulatory Authority or a shutdown (whether scheduled or not scheduled) of greater than [**] in duration), then [**] (it being understood that the foregoing remedies shall in no way impact, reduce, limit or waive Customer's rights and remedies under this Agreement or Applicable Law for any breaches of this Agreement by Brammer).

4.4 Pass-Through Costs. The Batch Pricing does not include amounts payable by Customer for [**] costs ((i) through (v), collectively, "Pass-Through Costs"). Subject to the terms in **Appendix C** (including [**]), amounts payable for Customer-Funded Equipment will include the direct cost to acquire, install and qualify the equipment, which will be procured and invoiced in accordance with **Appendix C** and/or the applicable Product Addendum. [**] For

clarity and notwithstanding anything in this Agreement to the contrary, Brammer shall not incur any Pass-Through Costs which have not been approved by Customer. [**]

4.5 Billing for Pass-Through Costs. Prior to incurring any Pass-Through Costs in any Calendar Quarter, Brammer will prepare and provide to Customer a good-faith itemized bill of materials with quoted Pass-Through Costs (a "Quote") to be incurred by Brammer during such Calendar Quarter, including Pass-Through Costs for Process Consumables and services provided by or subcontracted to an Approved Vendor hereunder, as applicable, based on the Binding Forecast and the Batch Pricing for the Product. Within [**] of receipt of any Quote, Customer will either notify Brammer in writing of Customer's acceptance or rejection of such Quote or notify Brammer in writing with reasonable detail of any disputed items set forth in such Quote. Failure to so notify Brammer within such [**] period will be deemed to be Customer's acceptance of such Quote. If Customer disputes any items set forth in, or otherwise rejects, the Quote within such [**] period, the Parties will discuss in good faith the disputed items or the basis of such rejection and Brammer will re-issue a Quote to Customer and the review and acceptance process set forth above will be applied to such re-issued Quote. Following approval of each Quote, Brammer will proceed, in accordance with the time schedule set forth in the Product Addendum, with the purchase of Process Consumables for the Binding Forecast.

4.6 Other Invoicing. With respect to any fees charged to Customer in accordance with this Agreement, but for which the invoicing or payment of such fees are not otherwise specifically addressed in this Agreement, Brammer shall provide an invoice to Customer within [**] of each Calendar Quarter of all such fees incurred during such Calendar Quarter that shall include reasonable details regarding the basis for such fees. Customer shall pay Brammer any such undisputed fees upon [**] of receiving such invoice.

4.7 No Double Payments. Notwithstanding anything herein or in the DMSA to the contrary, Customer shall not be required to pay more than once for any specific lot of Product or Service provided by Brammer to Customer (it being understood that to the extent any specific lot of Product or Service is provided under the DMSA, Customer shall not be obligated to pay for the same lot of Product or Service under this Agreement and vice versa).

4.8 Taxes. All fees under this Agreement are exclusive of any withholding taxes that may apply and will be paid gross, without deductions or set-offs, and Customer will ensure that such sum is paid to Brammer as will, after deduction of such withholding taxes, be equivalent to the consideration payable under this Agreement; *provided* that Brammer shall cooperate with Customer to eliminate or reduce any such withholding taxes, including the provision of any certifications or forms which may eliminate or reduce any such withholding and which is Brammer is legally able to provide. Brammer represents to Customer that it is eligible for the benefits of the Royalties Article (Article 12) of the UK/USA tax treaty that is currently in force with respect to any payment made under this Agreement that qualifies as "royalties" within the meaning of that term in Article 12. Any duty, sales, use or excise taxes imposed by any governmental entity that apply to the provision of the Services will be borne by Customer (other than taxes based upon the income of Brammer) and Brammer shall provide, upon request, an invoice in respect of such taxes (if applicable).

4.9 Late payments. Late payments of undisputed amounts under this Agreement will incur an interest charge of [**] per month for the first [**] after such amounts are due and [**] per month beginning on the [**] month after such amounts are due and thereafter. Brammer reserves the right to suspend the Services in the event of late payments of undisputed amounts after providing Customer written notice of such late payments and allowing Customer a period of [**] to pay such late amounts, Brammer reserves the right to refuse receipt of new Customer Provided Material for Manufacture of additional Batches of Product.

4.10 Payment in U.S. Dollars. All amounts payable to Brammer under this Agreement will be quoted and paid in U.S. Dollars, without deduction, and by authenticated and value dated Swift telegraphic transfer for any such payments made from outside the U.S., quoting invoice numbers of payment to the bank account identified in the applicable invoice or by such other means as Brammer will notify Customer in writing from time to time.

4.11 Audits. Brammer will keep, and will cause its Approved Vendors to keep, complete, true and accurate records regarding any fees or costs invoiced to Customer hereunder for at least [**] following the Calendar Year to which they pertain. Subject to the terms and conditions herein, not more than [**] Customer, at its own cost, through an independent auditor reasonably acceptable to Brammer (and who has executed an appropriate confidentiality agreement reasonably acceptable to Brammer), may inspect and audit the relevant records of Brammer pertaining to the calculation of any fees or costs invoiced by Brammer under this Agreement. Brammer shall provide such auditor with access to the relevant records at Brammer's offices during reasonable business hours on a mutually agreed upon date and such auditor shall not disclose any Confidential Information of Brammer to Customer, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Brammer or the amount of fees or costs invoiced by Brammer to Customer under this Agreement. Customer shall provide Brammer with written notice of its election to inspect and audit such records not less than [**] prior to the proposed date of review of Brammer's records by Customer's auditor. Any such audit shall be limited to the relevant records from any Calendar Year ending not more than [**] prior to the date of the request. Should the auditor find that Brammer has undercharged Customer, Customer shall promptly pay Brammer the amount of such underpayment within [**] of such finding. If the auditor finds that Brammer has overcharged Customer, then Brammer shall (i) promptly refund Customer the relevant overpayment within [**] of such finding and (ii) reimburse Customer for the cost of the audit if such overpayment equals or exceeds [**] of the actual fees or costs due to Brammer for the applicable period.

5. **Delivery and Acceptance Procedures**.

5.1 Delivery and Acceptance of Batch Documentation. Brammer will Manufacture and store each Batch of Product in accordance with this Agreement, including the Specifications and Product Addendum, and Quality Agreement and deliver such Batch to Customer on the applicable Delivery Date for such Batch. As soon as Brammer has determined that such Batch complies with this Agreement and the Quality Agreement and is ready for release to Customer, Brammer will send by e-mail or other electronic means to Customer: (a) a packing list, if applicable, (b) an invoice, (c) the Batch Record, (d) the Certificate of Analysis and (e) Certificate of Compliance (collectively, the "Batch Documentation"). Upon Customer's written acceptance of the Batch Documentation or, if Customer provides no response, [**] following delivery to Customer of the Batch Documentation ("Customer Approval"), the Batch Documentation and the relevant Batch of Product will be delivered as provided in Section 5.2.

5.2 Delivery of Lot. Following Customer Approval pursuant to Section 5.1, Brammer will deliver each Lot of Product Ex Works (Incoterms 2010) on the Delivery Date and in a form reasonably sufficient to transfer such Lot to Customer at Brammer's Facility (the "Delivery Site"). Title to each Lot of Product will pass to Customer (except for title to Brammer IPR, if any, incorporated therein or forming part of the Product, which Brammer continues to own and which is subject to the License of Section 11.4) when Customer or Customer's designated carrier takes delivery of such Lot at the Delivery Site. All risk of loss or damage to any Lot of Product will pass to Customer when Customer or Customer's designated carrier takes delivery at the Delivery Site. Brammer shall, without charge, provide Customer with reasonable support and advice in connection with the export of Product from the Delivery Site.

5.3 Failure to Take Delivery. If Customer fails to take delivery of any Lot of Product on any scheduled Delivery Date and prior arrangements to store the Product have not been agreed to between the Parties, Brammer shall store such Product as Customer's agent, and Customer shall be invoiced on the first

day of each month following such scheduled delivery for reasonable administration and storage costs in accordance with the Product Addendum; *provided* that such invoice shall provide reasonably sufficient details on the basis for such costs. For each such stored Lot of Product, Customer agrees that: (a) Customer has made a fixed commitment to purchase such Lot of Product; (b) subject to the last sentence of this Section 5.3, title and risk of loss for such Lot of Product passes to Customer upon such scheduled Delivery Date even if Customer fails to take delivery of such Lot of Product on such scheduled Delivery Date, *provided* that such title and risk of loss shall not pass to Customer in the event Customer's failure to take delivery is caused by Brammer; (c) such Lot of Product shall be on a bill and hold basis; and (d) if no delivery date is determined at the time of billing, Brammer shall have the right to ship such Lot of Product to Customer [**] after billing, *provided that*, in the case of the foregoing clauses (a) – (d), such Lot of Product is included in the relevant Purchase Order for the Calendar Quarter in which it was intended to be delivered. Notwithstanding anything to contrary in this Section 5.3, (i) the foregoing shall not apply to any (A) Lot of Product for which Customer fails to take delivery due to any Defect caused by a Brammer Failure and (B) Lot of Product for which Customer has not provided Brammer a Purchase Order and (ii) in the event Customer fails to take delivery of any Lot of Product due to any Defect caused by a Brammer Failure, Brammer shall store such Product at no cost to Customer.

5.4 Acceptance of Product. Upon receipt of each Lot of Product by Customer (or its designee) at Customer's facilities, Customer (or its designee) may:

(a) inspect such Lot of Product and confirm that the quantity of Product received by Customer (or its designee) matches the quantity of Product set forth in the Batch Documentation and the quantity set forth in the applicable Purchase Order;

(b) inform Brammer, by email to the email address set forth in the Quality Agreement, of any shortage in the quantity of Product identified through the conduct of the inspection pursuant to Section 5.4(a) within [**] from such date of receipt by Customer of such Lot of Product; and

(c) inform Brammer by email of any Defect within [**] from the date Customer receives such Lot of Product at the Delivery Site.

5.5 Shortages. Where any shortage in the quantity or volume of Product received by the Customer is identified, the Customer may, in its sole discretion, either:

(a) accept the quantity of Product delivered and require Brammer not to deliver the shortfall amount (it being understood that in such case Customer shall only be obliged to pay for the volume of Product actually delivered); or

(b) require Brammer to deliver the shortfall amount promptly and in any event within [**].

Without limiting the foregoing, to the extent any such shortage in any Calendar Year causes Customer to fail to satisfy the Minimum Purchase Commitment, such Minimum Purchase Commitment in such Calendar Year shall be reduced by the amount of such shortage. The Parties acknowledge and agree that the foregoing remedies in no way impact, reduce, limit or waive Customer's rights and remedies under this Agreement or Applicable Law for any breaches of this Agreement by Brammer.

5.6 Lot Defects.

(a) Defects Discovered by Customer. During the period of [**] referred to in Section 5.4(c) above, Customer shall be entitled to inspect and accept or reject such Lot, in part or in whole, for: (i) any non-conformance with this Agreement (including the Specifications and Product

Addendum) and Quality Agreement; and (ii) any other non-conformance or shortage, based on an inspection of the visible appearance of such Batch. If Customer determines that such Lot contains any Defect, (x) Customer shall notify Brammer in writing of such determination in accordance with Section 5.4, (y) Customer will be under no obligation to accept such Lot until the cause of the Defect has been determined and (z) the Parties shall immediately initiate, and cooperate in good faith in, an investigation to determine the cause of such Defect in a timely manner. Upon Brammer's reasonable request, Customer shall provide Brammer with reasonably sufficient records to demonstrate that such Lot was maintained under proper storage conditions from the time Customer took delivery of such Lot of Product until the time Customer notified Brammer of such Defect. Brammer shall provide any additional information regarding such Defect as may reasonably be requested by Customer.

(b) Latent Defects. In the event of any suspected Latent Defect of any Product notified by Customer to Brammer (i) within [**] after delivery of such Product to Customer at the Delivery Site or (ii) at any time with respect to any defect resulting from the failure to Manufacture the Product in accordance with GMP that results in any recall of such Product, the Parties shall work in good faith together to investigate the nature and cause of such Latent Defect.

(c) Defect Actions. In the event that any Defect or Latent Defect of any Product is caused by any Brammer Failure, as promptly as reasonably practicable following the discovery of such Defect or Latent Defect, Customer, at its election, shall destroy or return to Brammer such defective Product, in each case, at Brammer's cost and make no further use of it; *provided* that, notwithstanding the foregoing, if Customer has received notice from Brammer that such Product has been released by Brammer QA, Customer may continue to use such Product unless and until Brammer QA has at any time following such release of such Product subsequently requested suspension of use of such Product, in which case, Customer shall cease such use as soon as reasonably practicable until any time that Brammer QA releases such Product again. In the event any Defect or Latent Defect of any Product is not caused by a Brammer Failure, Customer, shall have the right, but not the obligation, to destroy or return to Brammer such defective Product at Customer's cost.

(d) Defects Due to Customer Provided Materials. Customer shall be solely responsible for all costs and expenses incurred in connection with any Lot of Product containing a Defect to the extent any Customer Provided Material caused such Defect, and for all costs and expenses to re-Manufacture such Lot of Product, *provided* that Brammer shall be solely responsible for the foregoing to the extent the Customer Provided Material was not stored and handled by or on behalf of Brammer in compliance with this Agreement or Quality Agreement.

5.7 Disputes. In case of any disagreement between the Parties as to whether Product contains a Defect or a Latent Defect, whether a Deliverable (including the Batch Documentation) is defective, or the existence of a Brammer Failure, the Customer Representative and the Program Manager will attempt in good faith to resolve any such disagreement and each Party will follow its standard operating procedures to determine whether such Product contains a Defect or Latent Defect and/or the cause of any such Defect or Latent Defect (or, as appropriate, whether the Deliverable is defective). If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed [**} from the date of the provision of notice regarding such Defect, Latent Defect or non-delivery or defective Deliverables) then discussion will be escalated to the JSC for resolution. In the event that the JSC is unable to resolve such disagreement matter within [**] after such escalation and the subject matter of such disagreement is whether such Product complies with the Specification, the Parties shall refer such disagreement for determination by an appropriately qualified independent laboratory, the identity of which will be agreed by the Parties in good faith, and the costs of which shall be split equally between the Parties. The Parties agree that the determination of the independent laboratory shall be final and binding. For all other disagreements for which the JSC is unable to resolve within [**] after such escalation, such disagreements shall be subject to the dispute resolution procedures in Article 14.

5.8 Drug Substance Non-Compliance and Remedies. If a Lot of Drug Substance contains a Defect caused by a Brammer Failure as determined upon investigation, Brammer will at Customer's election:

[**]

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

[**]

5.9 Drug Product Non-Compliance and Remedies. If a Lot of Drug Product contains a Defect caused by a Brammer Failure as determined upon investigation, Brammer will at Customer's election:

[**]

5.10 Other Defects. Notwithstanding anything to the contrary in this Agreement, Brammer will not have any liability for any Product which is defective or fails, or ceases to conform to the Specifications, or which is unusable for its intended purposes, in each case, unless such defect results from a Defect in Product which was caused by a Brammer Failure or is a Latent Defect due to a Brammer Failure. Where any Product is defective or fails, or is unusable for its intended purposes, and such defect results from a Defect in the Product, Brammer undertakes to cooperate reasonably with Customer to review the relevant Process or Specification in order to arrive at a plan to remediate any repetition of such Defect, with any such remediation plan to be set out in a separate Work Statement under the DMSA.

5.11 Disposition of Non-Conforming Product. Except as otherwise expressly stated herein, the ultimate Disposition of non-conforming Product will be the responsibility of Customer's quality assurance department.

5.12 Non-Exclusive Remedy. The Parties acknowledge and agree that the remedies available to Customer for a Brammer Failure in connection with a Batch Defect or otherwise in connection with Product that fails or ceases to comply to this Agreement (including the Specifications and Product Addendum) and Quality Agreement due to a Brammer Failure set forth in Sections 5.8 and 5.9 of this Agreement shall in no way impact, reduce, limit or waive Customer's rights and remedies under this Agreement or Applicable Law for such Brammer Failure.

5.13 Survival. The provisions of Sections 5.6-5.13 shall survive termination or expiration of this Agreement, *provided that*, subsequent to the termination or expiration of this Agreement, [**] in each case, associated with the supply of such Lot of Product (it being understood that the foregoing shall in no way impact, reduce, limit or waive Customer's rights and remedies under this Agreement or Applicable Law for such Brammer Failure).

6. **Quality, Regulatory and Recalls**.

6.1 Quality Agreement. Within [**] following the execution of this Agreement or at such later time in advance of GMP Manufacturing as the Parties may mutually agree, the Parties will enter into a quality agreement substantially in the form attached hereto as **Appendix E** specifying the quality and regulatory procedures and responsibilities of the Parties with respect to the Manufacture of Product (the "Quality Agreement"). In the event of any conflict between the terms and provisions of this Agreement and the terms and provisions of the Quality Agreement, the terms of this Agreement will control, except with respect to matters of Product quality.

6.2 Quality Tests. Brammer or an Approved Vendor shall perform all tests required by the Specifications, the Quality Agreement, GMP, the Product Addendum and Applicable Law. Customer shall be responsible for all costs and expenses associated with such tests previously approved by Customer in writing, except for any tests required due to a Defect caused by a Brammer Failure.

6.3 Change Control. Brammer shall not unreasonably refuse any written request from Customer to make changes to the Process and re-validate as necessary, *provided* that any changes required by any applicable Regulatory Authority or Applicable Laws ("Required Changes") shall be implemented by Brammer as soon as reasonably practicable. Customer shall be responsible for any costs and expenses incurred to implement all Required Changes to the extent such Required Changes specifically relate to or specifically concern the Product (it being understood that Brammer shall be responsible for any costs and expenses incurred to implement all other Required Changes, including Required Changes that relate generally to Brammer's Facility or that specifically relate to or concern other products).

6.4 Regulatory Compliance. As between the Parties, (a) Customer shall be solely responsible for obtaining all Regulatory Approvals for the Product, including any applications and amendments in connection therewith and (b) Customer shall exclusively own all rights, interest and title in and to such Regulatory Approvals. Brammer shall obtain and maintain at all times during the Term all permits and licenses required by any Regulatory Authority with respect to providing the Services, including any permits and licenses relating to the general cGMP and other non-product specific regulatory site licenses. During the Term, Brammer will promptly (but in any event, with respect to information that is available to Brammer, within [**] after the date of Customer's request, or otherwise within [**] after the date of Customer's request) assist Customer with all regulatory matters relating to the Manufacturing of the Product, at Customer's request and at Customer's expense. Each Party intends and commits to cooperate to satisfy all Applicable Laws relating to the Manufacturing of the Product.

6.5 Regulatory Body Inspections. Brammer will support any pre-approval or GMP certification inspections (collectively, "PAI") of Brammer's Facilities by Regulatory Authorities by preparing for and hosting such Regulatory Authorities, as required (including as necessary for Customer to obtain Regulatory Approval of the Product), and by responding to findings in a timely manner, in consultation with Customer. Subject to Section 7.1, Customer shall compensate Brammer on a time and materials basis at Brammer's then-current rates for applicable employees' time necessary to prepare for and respond to such inspections to the extent such inspections exclusively relate to the Product. Brammer shall promptly notify Customer in writing of any inspection of Brammer's facility proposed or scheduled with the FDA or any other Regulatory Authority that relates to the Product or to general matters at the Facility that affect the Product. To the extent permitted by Applicable Laws, Customer will be allowed to have a reasonable number of representatives present and participate at any inspection by any Regulatory Authority that is specific to the Product, subject to Brammer's confidentiality requirements with regard to other customers of Brammer. If the FDA or any other Regulatory Authority conducts an inspection at Brammer's Facility, seizes any Product and/or Product Materials, requests a Recall or field alert be issued for any Product, or otherwise notifies Brammer of any violation or potential violation of any Applicable Laws or of any intended inspection of the Facility, Brammer shall promptly notify Customer in writing of such, and Brammer shall take such actions as may be required under the Quality Agreement. Brammer will provide Customer with a copy of any report or other written communication received from such Regulatory Authority as soon as reasonably practicable after receipt of such report or communication relating to the Facility (to the extent it relates to or affects the development or Manufacture of the Product), the Product, or the Process, within [**] after receipt, and will consult with Customer before responding to each such communication, and shall use commercially reasonable efforts to incorporate any Customer comments in such communications, *provided that* Brammer may reasonably redact any such reports to protect its Confidential Information (including information regarding products not sold to or systems not used to Manufacture Products for Customer). With respect to any of Brammer's final responses to any report or other written communication received from Regulatory Authority relating to (a) the Product or Process, (i) Brammer will provide Customer with a copy of its then-current draft response, redacted to the extent necessary to protect Brammer Confidential Information, at least [**] prior to submission of such response and shall consider in good faith any comments Customer provides to Brammer regarding such response for incorporation into such response, (ii) to the extent Brammer makes any material amendments to such response after providing Customer a copy of such response pursuant to the foregoing clause (i), Brammer shall use commercially reasonable efforts to

provide Customer a copy of such amendments prior to submission and shall consider in good faith any comments Customer provides to Brammer regarding such amendments for incorporation into such response and (iii) Brammer shall provide the final response as soon as reasonably practicable to Customer or (b) the Facility generally, Brammer will provide Customer with a copy of such response within [**] after submission of any such response. In the event that any such Regulatory Authority requests, but does not seize, a sample of the Product in connection with any such inspection, Brammer (i) shall promptly notify Customer in writing of such request, (ii) if permitted by Applicable Law, shall satisfy such request only after receiving Customer's written approval, such approval not to be unreasonably withheld or delayed, (iii) shall follow any reasonable procedures instructed by Customer in responding to such request and (iv) shall promptly send a sample of any Product requested by the Regulatory Authority to Customer. Brammer shall give and permit full access to all or any of its premises at any time to any authorized representative of any Regulatory Authority in connection with its obligations hereunder and shall co-operate fully with any such representative. All information, records, or business information concerning Brammer that is disclosed or made available by Brammer to representatives of Regulatory Authorities in connection with any audit or regulatory process will be deemed to be Confidential Information of Brammer.

6.6 Recalls. In the event Brammer believes a recall, field alert, Lot or Batch of Product withdrawal or field correction ("Recall") may be necessary with respect to any Lot or Batch of Product provided under this Agreement or Brammer is informed by a Regulatory Authority that such Recall is necessary, Brammer shall immediately notify Customer in writing. Brammer will not act to initiate a Recall without the express prior written approval of Customer, unless otherwise required by Applicable Laws (in which case, Brammer may only initiate such Recall to the extent required by Applicable Law). In the event Customer believes a Recall may be necessary with respect to any Lot or Batch of Product provided under this Agreement, Customer shall immediately notify Brammer in writing. In the event any such Recall is initiated, Brammer shall provide all reasonable cooperation and assistance to Customer with respect to such Recall. The cost and expenses of any Recall shall be borne [**] except if the Defect giving rise to the Recall resulted from a Brammer Failure, then Brammer shall reimburse Customer for [**]. For the avoidance of doubt, the remedies set forth in this Section 6.6 shall in no way impact, reduce, limit or waive Customer's rights and remedies under this Agreement or Applicable Law for any breaches of this Agreement by Brammer.

7. **Facility Audits and Facility Visits**.

7.1 Facility Audits. Subject to Brammer's safety procedures, access control SOPs, and confidentiality limitations, Brammer will permit Customer's representatives, not more frequently than once per [**] period, during the Term of this Agreement at mutually agreed upon times to audit the Facility as more specifically set forth in the Quality Agreement, *provided*, *however*, that Customer may conduct any additional for-cause audits or audits relating to an urgent Product safety issue. Customer will give Brammer (a) reasonable advanced notice of any for-cause audit or an audit relating to an urgent Product safety issue (as determined in Customer's reasonable discretion) but no fewer than [**] and (b) at least [**] prior notice of any general quality audit. Any such audit notice shall identify the individuals who will be in attendance. All routine audits will be during Brammer's normal business hours on weekdays and conducted in a manner that does not unreasonably interfere with Brammer's Manufacturing and development activities and does not otherwise unreasonably interfere with normal business activities. Brammer will, [**] make its Facilities and all relevant records available for inspection by representatives of Regulatory Authorities in compliance with Applicable Laws, and [**]. All information, records, or business information concerning Brammer that is disclosed or made available by Brammer to Customer's employees and representatives, and representatives of Regulatory Authorities, or otherwise obtained by such employees and representatives, in connection with any audit and which does not constitute Customer Confidential Information

will be deemed to be Confidential Information of Brammer. To the extent any audit by Regulatory Authorities of the Facility is necessary to obtain Regulatory Approval of the Product (and does not relate to any other products Brammer manufactures or supplies to any other Person), [**].

7.2 Facility Visits. Subject to Brammer's safety procedures, access control SOPs, and confidentiality limitations, Brammer will permit Customer's representatives during the Term of this Agreement, to visit the Facility, including the GMP Suite at mutually agreed upon times with reasonable advance notification to Brammer. Subject to Section 7.1, Customer will give Brammer reasonable advanced notice of any proposed visit, but no fewer than [**] prior notice and identify the individuals who will be in attendance. All visits will be during Brammer's normal business hours on weekdays and conducted consistent with Brammer's person-in-plant SOPs, and in a manner that does not unreasonably interfere with Brammer's performance of the Services and does not otherwise unreasonably interfere with normal business activities.

8. **Product Materials**.

8.1 Product Materials Report. Upon Customer's written request, Brammer shall promptly (and in any event within [**] of such request) provide Customer with a written report detailing the quantity of Product Materials that have been used or otherwise consumed during the period set forth in such request, the quantity of Product Materials that Brammer then-currently possesses for the purpose of Manufacturing the Product, and the expiration date of such Product Materials.

8.2 Procurement of Product Materials. Subject to Article 4, Brammer shall order sufficient quantities of all Product Materials (except Customer Provided Materials), including Process Consumables and agreed safety stocks, to accommodate up to [**] of a Forecast at Customer's sole cost and expense and as agreed between the Parties to reasonably avoid Manufacturing interruptions consistent with the agreed Binding Forecasts and accepted Purchase Orders. Subject to Article 4, Customer shall be responsible for excess or obsolete Product Materials (including Customer Provided Materials) purchased by Brammer to the extent (i) Customer previously approved the purchase of such Product Materials and (ii) such excess or obsolescence was caused by any of the following: a (A) change by Customer to a Binding Forecast, (B) without limiting this Section 8.2, change by Customer to the Specifications or the specifications of such Product Materials after such Product Materials have been purchased by Brammer based upon a Customer Purchase Order or a Binding Forecast, as applicable, or (C) without limiting Section 3, with respect to any Product, reduction by Customer in the quantity of such Product as specified in a Binding Forecast relative to the quantity of such Product that was specified in any previous Binding Forecast with respect to the same time period; *provided* that Brammer shall use Commercially Reasonable Efforts to minimize or otherwise mitigate the costs of such excess or obsolete Product Materials (including by using such Product Materials for other products or returning such Product Materials). To the extent required by the foregoing, Customer shall reimburse Brammer for such excess or obsolescence described in this Section 8.2 on a Calendar Quarterly basis within [**] following receipt of Brammer's invoice therefor.

8.3 Excess Inventory of Product Materials. Without limiting the foregoing, in the event Customer provides a notice to Brammer to substitute a Substituted Product under Section 2.6, Customer will purchase any non-cancellable excess inventory of Product Materials for the then-current Product that cannot be used to Manufacture the Substituted Product, including any Product Materials used to support production for Customer, and any long lead time items (as specified in the Product Addendum) previously procured by Brammer pursuant to a Binding Forecast, *provided* that Brammer shall use Commercially Reasonable Efforts to minimize or otherwise mitigate the costs of such excess Product Materials (including by using such Product Materials for other products or returning such Product Materials).

8.4 Responsibilities for Procurement of Product Materials; Approved Vendors. Brammer will use Commercially Reasonable Efforts to minimize any delays or disruptions to the Manufacturing schedule due to supply of Product Materials (except Customer Provided Materials) necessary for such Manufacturing consistent with the Product Addendum, *provided* that the foregoing shall not limit or otherwise modify Brammer's obligation to deliver Batches of Product by the applicable Delivery Date. The Parties agree that Brammer is responsible for, and shall administer, the procurement of such Product Materials (except Customer Provided Materials) in accordance with the terms herein, which responsibilities shall include: transporting, inspecting and storing the Product Materials; maintaining systems for material management; maintaining adequate supplies of Product Materials, to the extent required hereunder; and Approved Vendor and logistics management, in each case in accordance with the terms herein. To the extent that there are any issues with regard to the performance or ability to perform of an Approved Vendor, Brammer shall promptly notify Customer of such issue. The JSC shall determine a course of action with regard to improving the performance of such Approved Vendor or replacing such Approved Vendor, or if the JSC is unable to promptly agree to such course of action, Customer and Brammer shall mutually agree to a course of action with regard to such Approved Vendor.

8.5 Customer Provided Materials. Prior to each Calendar Quarter, Brammer shall inform Customer of the quantity of Customer Provided Materials and the timing for such Customer Provided Materials to be delivered to Brammer, in each case, necessary for Brammer to comply with its obligations to Manufacture the quantities of Product in the Purchase Order applicable for such Calendar Quarter by the Delivery Date set forth in such Purchase Order. Customer will ensure that all documents provided to Brammer, including those related to Customer's Process and Customer Provided Materials, are in English (it being understood that Customer will be responsible for translating any such document that is in any foreign-language to English).

(i) Delivery of Customer Provided Materials; Risk of Loss. Customer Provided Materials will be procured and delivered by Customer to the Facility at no cost to Brammer. Unless otherwise agreed by the Parties and subject to this Section 8.5, Customer will deliver the Customer Provided Material in quantities requested by Brammer. Customer Provided Materials will remain the sole property of Customer at all times during the Term of this Agreement, but will remain in the possession, control and care of Brammer following delivery of such Customer Provided Materials by Customer to the Facility. Brammer will use and store the Customer Provided Materials with due care and in compliance with Applicable Law, applicable Material Specifications, the Quality Agreement and the Storage Guidelines. Title and risk of loss to such Customer Provided Materials will at all times remain with Customer, and subject to the terms and conditions herein, Brammer will have no liability to Customer for such Customer Provided Materials except due to Brammer's negligence, breach of this Agreement or failure to comply with Applicable Laws.

(ii) Responsibility for Failure of Customer Provided Materials. Customer shall be solely responsible for all costs and expenses to the extent arising from (A) the failure of any Customer Provided Materials to conform to the applicable Material Specifications therefor at time of delivery to Brammer or (B) Customer's failure to use, handle or store Customer Provided Materials in accordance with the Material Specifications, all Applicable Laws, and the Quality Agreement.

(iii) Material Safety Data Sheets. Customer will provide Material Safety Data Sheets for all Customer Provided Materials and for the Product that are, in each case, accurate and complete to the best of Customer's knowledge having taken commercially reasonable steps to inform itself of the same. Customer will notify Brammer of any unusual adverse health or environmental occurrence relating the Customer Provided Materials, and any Product to the extent Customer becomes aware of any such occurrence, including but not limited to any claim or complaint by any Customer employee or Third Party of which Customer becomes aware.

(iv) Audits. In the event Customer requires Brammer to incorporate Customer's or any of Customer's Third-Party analytical subcontractor's results of release assays into Brammer's Certificate of Analysis, Brammer shall have the right at Customer's cost and upon reasonable notice (as mutually agreed to by the Parties, but no less than [**]) to audit any sites or laboratories used by Customer to conduct such release assays related to any Customer Provided Materials and Lot of Product, as set forth in the Quality Agreement, and as reasonably required by Applicable Law, Brammer procedures, or both, *provided* that (A) Brammer may only have two auditors conduct such audits, (B) Brammer may only audit each such site or laboratory [**] during the Term, and (C) the duration of any such audit may not exceed [**]. All such audits will be during Customer's normal business hours on weekdays and conducted in a manner that does not unreasonably interfere with Customer's or such Third Party's normal business activities. All information, records, or business information concerning Customer or such Third Party that is disclosed or made available by Customer or such Third Party in connection with such audit or otherwise obtained by or on behalf of Brammer in connection with any audit will be deemed to be Confidential Information of Customer.

8.6 Import, Export, Customs. For all Customer Provided Materials being delivered to Brammer for Customer's account, and all Product Materials delivered by Brammer for Customer's account, Customer will be responsible at its sole cost and expense for satisfying all import, export and customs requirements, including U.S. Export Control Regulations, and Customer will be the importer and exporter of record (or utilize its own customs broker) for any Customer Provided Materials being imported and shipped to Brammer and for all Product Materials or Product exported to another country, in each case, for Customer's account (but excluding, for the avoidance of doubt, any Product Materials exported by Brammer to an Affiliate or Third Party (including any Approved Vendor) in connection with the performance of the Services, and any corresponding import). Brammer shall provide Customer with reasonable assistance in relation to the import and export of Product Materials pursuant to this Agreement, and Customer's obligations as the importer and exporter of record of all materials.

8.7 Return of Customer Provided Materials. Upon the expiration or termination of this Agreement or upon Customer's notice to substitute a Substituted Product pursuant to Section 2.6, any remaining Customer Provided Materials will be, at Customer's sole expense and election (such election to be made by Customer to Brammer in writing no later than [**] either after such expiration or termination or after receipt of Customer's notice, as applicable), returned to the Customer or destroyed/disposed of by Brammer. If Customer does not provide such election to Brammer within such [**] period, Brammer will, at Customer's expense, return to the Customer the applicable Customer Provided Materials. Notwithstanding anything to the contrary contained in this Agreement, (a) Brammer may retain Customer Provided Materials as required by Applicable Laws, and (b) in no event will Brammer be required to store Customer Provided Materials for more than [**] after such expiration or termination or receipt of such notice unless the Parties have entered into an appropriate storage agreement covering such items.

9. **Use of Approved Vendors**.

9.1 Subject to the terms and conditions herein, Brammer reserves the right to employ vendors from time-to-time to undertake certain Services (for example, for specialty testing, waste disposal, etc.) upon prior written notice to Customer describing the activities to be performed. All vendors and Services for which Brammer desires to employ such vendors must be pre-approved by Customer in writing ("Approved Vendors"). A list of existing Approved Vendors as of its execution will be included in the Quality Agreement and updated from time to time by written agreement of the Parties, and any fees payable to an Approved Vendor must be approved in advance in writing by Customer. For mutually agreed upon non-routine Services (*e.g.*, Services that are developmental in nature or specific to a Product and not, for example, standard specialty testing and waste disposal services) provided by Approved Vendors or for any Approved Vendors that will reasonably have access to any of Customer's Confidential Information, each such Approved Vendor will be

bound by written confidentiality, nonuse, and quality assurance obligations consistent with this Agreement, as well as an assignment to Brammer of all inventions or other intellectual property arising in the course of performing such Services, as necessary for Brammer to comply with its obligations to Customer under this Agreement (including Brammer's obligations under Section 11.3(a)).

9.2 Subject to the foregoing, Brammer will be responsible to Customer for managing the performance of Approved Vendors. Brammer will work together with the Approved Vendor, and Customer, if appropriate, to resolve any issues or failures by the Approved Vendor. For the avoidance of doubt, (a) Brammer shall ensure that each Approved Vendor complies with the terms and conditions of this Agreement and the Quality Agreement (if applicable) and (b) use of an Approved Vendor shall not relieve or release Brammer from, or modify, any obligations of Brammer under this Agreement or the Quality Agreement.

10. **Confidential Information/Legal Proceedings/Publicity**.

10.1 Term of Confidentiality Obligations. Except as otherwise provided in this Article 10, during the Term of this Agreement and for a period of [**] of this Agreement, each Party (the "Receiving Party") agrees that it will keep the other Party's (the "Disclosing Party's") Confidential Information confidential and use it solely to conduct the activities contemplated, and to exercise rights, under this Agreement, and for no other purpose. Notwithstanding the foregoing, with respect to Confidential Information that constitutes a trade secret, the Receiving Party's obligations under this Agreement to keep such trade secret confidential will continue for as long as such information remains a trade secret.

10.2 Confidentiality and Non-Use Obligations. The Receiving Party agrees that all Confidential Information disclosed to the Receiving Party or any of its Affiliates by the Disclosing Party or any of its Affiliates (a) will not be used by the Permitted Recipients except as authorized under this Agreement and to the extent necessary to further the purposes of this Agreement and (b) will be maintained in confidence by the Receiving Party and such Party's Affiliates, with a degree of care that is not less than the Receiving Party typically exercises with respect to its own most valuable Confidential Information and in any case with not less than reasonable care. The Receiving Party will provide, upon the Disclosing Party's request, a certification that access to and use of the Disclosing Party's Confidential Information is being controlled in accordance with this Agreement. Notwithstanding any other provision of this Agreement, disclosure of Confidential Information will not be prohibited to the extent required to comply with Applicable Laws, or with a valid court or administrative order, *provided that* the Receiving Party will (i) notify the Disclosing Party of any such disclosure requirement or request as soon as practicable (and to the extent that it is legally able to do so); (ii) cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) in seeking, at the Disclosing Party's election, a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which is responsive to such requirement or request. If either Party becomes obliged to provide testimony or records regarding this Agreement in any legal or administrative proceeding relating to the other Party, such other Party will reimburse such Party for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at such Party's standard commercial rates.

10.3 Disclosures to Permitted Recipients. Each Party agrees that such Party and such Party's Affiliates will provide Confidential Information received from the Disclosing Party only on a need-to-know basis in connection with this Agreement and only to the Receiving Party's respective employees, directors, consultants, advisors, bona fide potential partners or investors, and to the employees, directors, consultants and advisors of the Receiving Party's Affiliates (collectively, "Permitted Recipients"), solely under conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement, and *provided that* each Party will remain responsible for any failure by its Permitted Recipients to treat such information and materials as required under Article 10. Neither Party shall allow access to the Confidential

Information of the other Party to any Permitted Recipient who does not require such access in order to accomplish the purposes of this Agreement. The Receiving Party will use at least the same standard of care as it uses to protect its own most valuable confidential information and in any case with not less than reasonable care and shall ensure that its Affiliates and Permitted Recipients do not disclose or make any unauthorized use or disclosure of the Confidential Information of the Disclosing Party except as expressly permitted herein.

10.4 Exceptions to Confidential Information. Confidential Information will not include information that:

(i) was known or used by the Receiving Party or such Party's Affiliates prior to its date of disclosure to the Receiving Party as demonstrated by appropriate evidence; or

(ii) either before or after the date of the disclosure to the Receiving Party or the Receiving Party's Affiliate, is lawfully disclosed to the Receiving Party or any of such Party's Affiliates by sources other than the Disclosing Party rightfully in possession of such information and not bound by confidentiality obligations to the Disclosing Party; or

(iii) either before or after the date of the disclosure to the Receiving Party or any of such Party's Affiliates, is or becomes published or otherwise is or becomes part of the public knowledge, through no breach hereof on the part of the Receiving Party or such Party's Affiliates; or

(iv) is independently developed by or for the Receiving Party or any of such Party's Affiliates without reference to or reliance upon the Confidential Information of the Disclosing Party as demonstrated by appropriate convincing evidence.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

10.5 Responsibility for Compliance with Confidentiality and Nonuse Obligations.

(a) The Receiving Party will be responsible for any unauthorized disclosure, misuse or misappropriation by the Receiving Party or its Affiliates, or the Permitted Recipients or sublicensees of the Receiving Party or its Affiliates, of the Disclosing Party's Confidential Information.

(b) Cooperation. If at any time the Disclosing Party brings, or investigates the possibility of bringing, any Action against any Person for misappropriation of trade secrets, or the misuse or unauthorized disclosure of Confidential Information, then the Receiving Party, upon the request and at the expense of the Disclosing Party, will cooperate with and assist the Disclosing Party in the investigation or pursuit of such Action, and provide the Disclosing Party with any information in the possession of the Receiving Party that may be of use to the Disclosing Party in the investigation or pursuit of such Action.

10.6 Disclosure of Provisions of Agreement.

(a) Each Party agrees to hold as confidential the terms of this Agreement, except that, notwithstanding anything herein to the contrary, (i) such Party shall have the right to disclose such terms to investors, bona fide potential investors, business partners, bona fide potential business partners, lenders, bona fide potential lenders, acquirers, bona fide potential acquirers, and investment bankers in connection with licensing, financing and acquisition activities, and due diligence processes related to such activities, *provided*

that any such Third Party has entered into a written obligation with such Party to treat such information and materials as confidential and requiring at least commercially reasonable obligations of confidentiality (and such Party will remain responsible for any failure by any of the foregoing Persons, to whom such Party may disclose Confidential Information) to treat such information as required under Section 10.2 hereof, and (ii) such Party will have the right to disclose such terms as required by Applicable Law, regulation or legal process, including by the rules or regulations of the SEC or similar regulatory agency in a country other than the United States, or of any stock exchange or other securities trading institution; *provided that* such Party subject to such disclosure requirement will, if reasonably practicable under the circumstances, provide the other Party with a reasonable opportunity to review and comment in advance on such Party's proposed disclosure and such Party will consider in good faith any comments thereon provided by such other Party.

(b) In the event that this Agreement will be included in any report, statement or other document filed by Customer or an Affiliate of Customer with the SEC or similar regulatory agency in a country other than the United States or any stock exchange or other securities trading institution, Customer will use, or will cause such Customer's Affiliate, as the case may be, to use, good faith efforts to obtain confidential treatment from the SEC, similar regulatory agency, stock exchange or other securities trading institution of any Brammer proprietary technical data, know-how, and trade secrets concerning Brammer's production and purification methods, Brammer's equipment and techniques, Brammer's facilities and its design and operation, and Brammer Technology and New Brammer Technology, as well as financial information or other information of a competitive or confidential nature, and will include in such confidentiality request such provisions of this Agreement as may be reasonably requested by Brammer, in each case, to the extent such confidential treatment would, in the reasonable judgment of Customer or such Affiliate, be permitted by Applicable Law and by the applicable rules and regulations of the SEC or any such similar regulatory agency, stock exchange or other securities trading institution.

10.7 Remedies. The Receiving Party acknowledges that a breach by it of any of the terms of this Article 10 would cause irreparable harm to the Disclosing Party for which the Disclosing Party could not be adequately compensated by money damages. Accordingly, the Receiving Party agrees that, in addition to all other remedies available to the Disclosing Party in an Action at law, in the event of any breach or threatened breach by the Receiving Party of the terms of this Agreement, the Disclosing Party will, without the necessity of proving actual damages or posting any bond or other security, be entitled to seek temporary and permanent injunctive relief, including, but not limited to, specific performance of the terms of this Agreement.

10.8 Non-Solicitation and Non-Hire. From the Effective Date and for a period of [**] no Party will solicit an employee of the other Party who is or has been involved in any activity to which this Agreement pertains. Notwithstanding the foregoing, nothing herein will restrict or preclude each Party's rights to make generalized searches for employees by way of a general solicitation for employment placed in a trade journal, newspaper or website, and which is not designed to target or specifically attract the employees of the other Parties.

10.9 Acknowledgment of Prior Confidentiality Obligations. The Parties acknowledge that Confidential Information has been provided by the Parties to each other prior to the Effective Date of this Agreement pursuant to the Existing Confidentiality Agreement. All Confidential Information (as defined in the Existing Confidentiality Agreement) exchanged between the Parties under the Existing Confidentiality Agreement will be deemed Confidential Information under this Agreement and will be subject to the terms of this Agreement.

10.10 Data Protection. With respect to its rights and obligations under this Agreement with regard to personal data, each Party shall at all times comply with all Applicable Laws relating to the processing of personal data and privacy and shall not perform any obligation under the Agreement in such a way as to cause either Party to breach any of its obligations under such Applicable Laws.

11. **Intellectual Property**.

11.1 Customer Technology. All right, title and interest in and to Customer Technology will remain vested solely in Customer. Subject to the terms and conditions herein, Customer hereby grants Brammer a non-exclusive, non-sublicensable, royalty-free license under all Intellectual Property Rights relating to Customer Technology for the sole purpose of performing and having performed the Services on behalf of Customer. Such license will expire upon the completion of such Services or the termination or expiration of this Agreement, whichever is the first to occur. Customer agrees that:

(a) Upon Brammer's prior written request, and in accordance with instructions provided by Brammer, Customer will, at Customer's expense and in its sole discretion, transfer such embodiments of Customer Technology as are reasonably required for the performance of the Services to Brammer for the sole purpose of enabling Brammer to perform the Services.

(b) Without limiting the generality of the foregoing, Customer will provide to Brammer without charge, such written materials and assistance of Customer personnel as may be reasonably requested by Brammer to assist with the transfer and use of Customer Technology in performing the Services. All information provided to Brammer under this Section 11.1 will be subject to the confidentiality provisions of this Agreement.

11.2 Brammer Technology. As between the Parties, all right, title and interest in and to Brammer Technology and all Intellectual Property Rights therein will remain vested solely in Brammer, except as expressly provided herein.

11.3 New Technology. In the event that, during performance of the Services, Brammer (or any Person acting on behalf of Brammer, including Approved Vendors) solely or jointly with Customer (or any personnel or Person acting on behalf of Customer) creates, conceives, develops, or reduces to practice new Technology ("New Technology"), whether or not patentable, the following will apply:

(a) New Customer Technology. Customer will exclusively own all right, title and interest in and to all New Customer Technology and all Intellectual Property Rights therein. Brammer hereby irrevocably assigns, and to the extent not presently assignable shall assign, to Customer all right, title, and interest in and to all New Customer Technology. Brammer will take and will procure that all Approved Vendors shall take any actions, including but not limited to the execution of documents, reasonably requested by Customer, and at Customer's expense, to effect such assignment. Customer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any Patent that claims or covers the New Customer Technology.

(b) New Brammer Technology. Brammer will exclusively own all right, title and interest in and to all New Brammer Technology and all Intellectual Property Rights therein. Customer hereby irrevocably assigns, and to the extent not presently assignable shall assign, to Brammer all right, title, and interest in and to all New Brammer Technology. Customer will take any actions, including but not limited to the execution of documents, reasonably requested by Brammer, and at Brammer's expense, to effect such assignment. Brammer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any Patent that claims or covers the New Brammer Technology.

11.4 Brammer IPR License. [**]

11.5 Technology Transfer to Customer. [**]

11.6 Third Party Intellectual Property Rights. The Parties acknowledge that the Manufacture and supply of the Product may require a license under Third Party Intellectual Property Rights. Brammer shall not incorporate any Third Party Intellectual Property Rights into the Product or the Process without the prior written consent of Customer. [**] In the event either Party is put on notice by a Third Party of alleged infringement by Brammer of Third Party Intellectual Property Rights due to the Manufacture of Product, such Party will promptly inform the other Party in writing of such notification. [**]

11.7 Data. Brammer reserves the right to utilize data generated during the course of performing its obligations under this Agreement to support applications, assignments or other instruments necessary to apply for and obtain Patents with respect to Brammer Technology and New Brammer Technology, *provided* the data so utilized is de-identified and does not contain any of Customer's Confidential Information, Customer Technology or New Customer Technology. Brammer will notify Customer in writing in advance of filing for any such Patent and Customer will have the right to require Brammer to reasonably delay any such Patent filing if such filing contains data that is Customer's Confidential Information or which may be the subject of a Patent filing with respect to any Customer Technology or New Customer Technology.

11.8 No Licenses. Except as expressly provided in Section 11 hereof, no right or license, either express or implied, is granted under any Intellectual Property Right or by virtue of the disclosure of Confidential Information under this Agreement, or otherwise. The Parties agree that each Party has and will retain sole and exclusive rights of ownership in and to any Confidential Information and Intellectual Property Rights of such Party.

11.9 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, a license of a right to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties acknowledge and agree that the Parties and their respective sublicensees, as sublicensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign counterpart thereto. The foregoing provisions are without prejudice to any rights the non-bankrupt Party may have arising under the Bankruptcy Code or other Laws.

12. **Independent Contractor**. Brammer will perform the Services as an independent contractor of Customer and will have complete and exclusive control over the Facility, the equipment, and its employees and agents. Nothing in this Agreement will constitute Brammer, or anyone furnished or used by Brammer in the performance of the Services, as an employee, joint ventures, partner, agent or servant of Customer. Brammer also agrees that it will not have any rights to receive any employee benefits such as health insurance and accident insurance, sick leave or vacation as are in effect generally for employees of Customer. Neither Party will enter into any agreements or incur obligations on behalf of the other Party, nor commit the other Party in any other manner without prior written consent from a duly authorized officer or representative of such other Party.

13. **Insurance**.

13.1 Customer Insurance. At all times during the Term of this Agreement and at its own expense, Customer will obtain and maintain certain insurance coverage, with insurers having A.M. Best ratings of A-VII or higher. [**] Customer will provide Brammer with reasonable evidence of such coverage within [**] of execution of this Agreement. If any such policy is replaced, Customer agrees to purchase tail coverage or ensure that the new policy has a retroactive date that is consistent with the start of any work under a Product Addendum and that Customer will continue to be covered on the replacement policy. Customer will provide Brammer with at least [**] prior written notice of any material change in or cancellation of the insurance coverage.

13.2 Brammer Insurance. At all times during the Term of this Agreement and at its own expense, Brammer shall obtain and maintain certain insurance coverage, with insurers having A.M. Best ratings of A-VII or higher. Brammer shall name Customer an additional insured with respect to: (i) [**] and (ii) [**].

Brammer will provide Customer with reasonable evidence of such coverage within [**] of execution of this Agreement. If any such policy is replaced, Brammer agrees to purchase tail coverage or ensure that the new policy has a retroactive date that is consistent with the start of any work under a Product Addendum and that Brammer will continue to be covered on the replacement policy. Brammer will provide Customer with at least [**] prior written notice of any change in or cancellation of the insurance coverage. Without limiting the foregoing, Brammer shall obtain and maintain insurance coverage which covers business interruption.

14. **Dispute Resolution**.

14.1 Disputes. In the event any dispute arises between the Customer and Brammer with respect to any of the terms and conditions of this Agreement or the Services that cannot be resolved by the Customer Representative and the Program Manager, then senior executives of the Customer and Brammer will meet as promptly as practicable after notice of such dispute to resolve in good faith such dispute. The senior executives of the Parties will attempt in good faith to resolve such dispute by negotiation and consultation for a [**] period following such referral.

14.2 Arbitration. If the Senior Executives of Customer and Brammer are unable to satisfactorily resolve the dispute within the [**] period set forth in Section 14.1, then such dispute will be finally settled by arbitration in accordance with this Section 14.2. The arbitration will be held in New York, NY, and except as noted below, will be conducted in accordance with the rules of the American Arbitration Association (or such successor organization) by one mutually agreeable arbitrator, who will be a lawyer having at least fifteen years of experience dealing with complex contracts, including those in biologics manufacturing. If the Parties cannot agree on an arbitrator within a reasonable period of time, an arbitrator will be appointed by the American Arbitration Association (or such successor organization). The arbitrator will have no authority to vary from or ignore the terms of this Agreement and will be bound by controlling law. The Parties may seek judicial intervention for emergency relief, such as restraining orders and injunctions where appropriate. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

14.3 Effect of Arbitrator's Decision. Any decision by the arbitrator will be final, binding upon the Parties, non-appealable, and may be entered as final judgment in any court of competent jurisdiction. The arbitrator will render his or her final decision in writing to the Parties. The arbitrator's final decision shall be subject to the limitations set forth in Article 16.

14.4 Other Limitations. Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither Party nor the applicable arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable Action based on the dispute, controversy or claim would be barred by the applicable statute of limitations in New York, NY.

14.5 Injunctive Relief. Notwithstanding anything in this Agreement to the contrary, nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the construction, scope, validity, enforceability, inventorship or infringement, misappropriation or other violation of any Intellectual Property Rights; and no such claim shall be subject to arbitration pursuant to Sections 14.2-14.4. Any action brought by either Party pursuant to this Section 14.5 shall be venued exclusively in the state or federal courts of the State of New York and each Party expressly and irrevocably consents and submits to the jurisdiction of such courts having appropriate jurisdiction in connection with any such legal proceeding.

15. **Indemnification**.

15.1 Customer will indemnify, defend, and hold harmless Brammer and its Affiliates and each of its directors, officers, employees, and agents (the "Brammer Parties") against any and all Third Party Actions asserted against, or imposed upon, a Brammer Party and associated damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations and expenses, including reasonable attorneys' fees (collectively, "Losses") that the Brammer Parties suffer or incur to the extent caused by any of the following:

[**]

15.2 Brammer will indemnify, defend, and hold harmless Customer and its Affiliates and each of its directors, officers, employees, and agents (the "Customer Parties") against any and all Third Party Actions asserted against, or imposed upon, a Customer Party and associated Losses that any Customer Parties suffer or incur to the extent caused by any of the following:

[**]

15.3 Upon receipt of notice of any Action that may give rise to a right of indemnity from the other Party, the Party seeking indemnification (the "Indemnified Party") will give prompt written notice thereof to the other Party (the "Indemnifying Party") of the Action for indemnity. Such claim for indemnity will indicate the nature of the Action and the basis therefor. Promptly after an Action is made for which the Indemnified Party seeks indemnity, the Indemnified Party will permit the Indemnifying Party, at its option and expense, to assume the complete defense of such Action, *provided that*, (a) the Indemnified Party will have the right to participate in the defense of any such Action at its own cost and expense; (b) the Indemnifying Party will conduct the defense of any such Action with due regard for the business interests and potential related liabilities of the Indemnified Party; and (c) the Indemnifying Party will, prior to making any settlement, consult with the Indemnified Party as to the terms of such settlement. The Indemnifying Party will not, in defense of any such Action, settle or consent to an adverse judgment in any such Action that adversely affects the rights or interests of any Indemnified Party, involves the admission of any fault or violation of Applicable Law on behalf of the Indemnified Party or imposes additional obligations (financial or otherwise) on such Indemnified Party, without the prior express written consent of such Indemnified Party (such consent not to be unreasonably withheld, conditioned or delayed). After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Action, the Indemnifying Party will only be liable to the Indemnified Party for such reasonable legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof, at the request of the Indemnifying Party, *provided* that the foregoing shall not limit, impact, reduce, or waive any of the Indemnified Party's rights and remedies under this Agreement or Applicable Law for any breaches of this Agreement by the Indemnified Party. As to those

Actions with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnifying Party will be liable for all reasonable legal or other expenses incurred by the Indemnified Party in connection with the defense thereof (it being understood that, in the case of Brammer as the Indemnifying Party, the foregoing shall not limit, impact, reduce, or waive Customer's rights and remedies under this Agreement or Applicable Law for any breaches of this Agreement by Brammer) and the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense at the Indemnifying Party's own cost and expense and will not settle or otherwise dispose of any of the same without the consent of the Indemnifying Party (such consent not to be unreasonably withheld, conditioned or delayed). If requested by the Indemnifying Party, the Indemnified Party agrees to cooperate with the Indemnifying Party and its counsel in contesting any Third Party Action which the Indemnifying Party defends, or, if (i) appropriate and related to the Third Party Action in question and (ii) reasonable in the judgment of the Indemnifying Party, in making any counterclaim against the Person asserting the Third Party Action, or any cross complaint against any Person. If Brammer will be obliged to provide testimony or records regarding the subject matter of this Agreement in any legal or administrative proceeding against or filed by Customer not covered by the indemnity set forth above (other than any proceeding between the Parties with respect to any disputes under this Agreement), Customer will reimburse Brammer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Brammer's standard commercial rates. If Customer will be obliged to provide testimony or records regarding the subject matter of this Agreement in any legal or administrative proceeding against or filed by Brammer not covered by the indemnity set forth above (other than any proceeding between the Parties with respect to any disputes under this Agreement), Brammer will reimburse Customer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at cost.

16. **Limitations of Liability**.

16.1 EXCEPT FOR (A) [**] LIABILITY UNDER THE INDEMNITIES SET OUT IN [**] – [**] – [**] (B) [**] LIABILITY RESULTING FROM ITS BREACH OF ITS [**] AND (C) [**] GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, [**] LIABILITY UNDER THIS AGREEMENT IN ANY GIVEN CALENDAR YEAR WILL NOT EXCEED (i) [**] AND (ii) [**]

16.2 Consequential Damages Waiver. EXCEPT FOR EACH PARTY'S LIABILITY RESULTING FROM ITS (i) INDEMNIFICATION OBLIGATIONS SET FORTH IN [**] – [**] – [**] (ii) GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, AND (iii) BREACH OF ITS [**], IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, BUT NOT LIMITED TO, DAMAGES BASED UPON LOST PROFITS, BUSINESS INTERRUPTION, LOST BUSINESS, OR LOST SAVINGS FOR ANY ACTS OR FAILURE TO ACT UNDER THIS AGREEMENT, EVEN IF IT HAS BEEN ADVISED OF THEIR POSSIBLE EXISTENCE.

16.3 The limitations of liability reflect the allocation of risk between the Parties. The limitations specified in this Article 16 will survive and apply even if any limited remedy specified in this Agreement is found to have failed of its essential purpose.

17. **Representations, Warranties and Covenants**.

17.1 Brammer Representations, Warranties and Covenants. Brammer represents, warrants and covenants to Customer that:

(a) it has the full power and right to enter into this Agreement and that, to its knowledge, there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by Brammer or any Affiliate or any Third Party, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by Brammer has been authorized by all requisite corporate or company action and this Agreement is and will remain a valid and binding obligation of Brammer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) Brammer shall hold during the Term of this Agreement all licenses, permits and similar authorizations required by any Regulatory Authority for Brammer to perform its obligations under this Agreement;

(d) the Lots of Product furnished by Brammer to Customer under this Agreement:

[**]

(ii) shall be Manufactured with Product Materials (other than Customer Provided Materials as furnished to Brammer hereunder) that conform to the applicable specifications for such Product Materials;

(iii) shall not contain any Product Material or Customer Provided Materials that has not been used, handled or stored by or on behalf of Brammer in accordance with this Agreement (including the Specifications and Product Addendum), Material Specifications, the Storage Guidelines, all Applicable Laws, and the Quality Agreement, *provided*, however, that the foregoing only applies to the use, handling, and storage of Customer Provided Materials after such time as they have been delivered to Brammer hereunder; and

(iv) shall not be adulterated or misbranded within the meaning of Sections 501 and 502, respectively, of the FD&C Act and any other Applicable Laws and shall comply with the 1913 Virus-Serum-Toxin Act, 21 U.S.C. 151-159 and 21 C.F.R. Parts 101 to 118, as amended by the 1985 Food Security Act (as applicable with respect to veterinary biologics), in each case except to the extent resulting from (A) any Customer Provided Materials as provided to Brammer hereunder; or (B) Customer's specifications for the text (including any logos or other graphics) for any packaging material used in connection with Product;

(e) the Brammer Materials shall be provided hereunder free and clear of all liens and encumbrances and will be prepared by Brammer in accordance with the terms of this Agreement and the Quality Agreement;

(f) the Facility and all equipment utilized in the Manufacture and supply of Product hereunder by Brammer (including the GMP Suite and Dedicated Capacity) shall, during the Term of this Agreement, be maintained in good operating condition and shall be maintained and operated in accordance with all Applicable Laws, including cGMPs;

(g) Brammer, its Affiliates and its Approved Vendors: (i) have not been debarred and are not subject to a pending debarment pursuant to Section 306 of the United States Food, Drug and Cosmetic Act, 21

U.S.C. § 335a; (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)); (iii) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending Action. Brammer will notify Customer immediately if Brammer or any of its Affiliates or Approved Vendors is subject to the foregoing, or if any Action relating to the foregoing is pending, or to the best of Brammer's knowledge, is threatened;

[**]

17.2 Customer Representations and Warranties. Customer represents, warrants and covenants to Brammer that:

(a) it has the full power and right to enter into this Agreement and that there are, to its knowledge, no outstanding agreements, assignments, licenses, encumbrances or rights held by Customer or any Affiliate of Customer or Third Party, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by Customer has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Customer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) Customer shall comply with all Applicable Laws in the use, marketing, distribution and sale of each Product and hold during the Term of this Agreement all applicable licenses, permits and similar authorizations required by any Regulatory Authority for Customer to perform its obligations under this Agreement and to use, have used, market, distribute and sell each Product;

(d) the Customer Provided Materials will be provided to Brammer free and clear of all liens and encumbrances and will be prepared by Customer in accordance with the agreed-upon specifications in the Work Statement;

(e) the Customer Provided Materials, as furnished to Brammer under this Agreement, shall have been used, handled and stored by Customer in conformance with the Material Specifications, Storage Guidelines as set forth in the Product Addendum, all Applicable Laws, and the Quality Agreement prior to delivery to Brammer;

(f) Customer's specifications for the text (including any trademarks, logos or other graphics) for all packaging material used in connection with Product, and any such packaging material for the Product provided by Customer or its designee, shall be true and accurate in all material respects and comply with all Applicable Laws;

[**]

(h) None of the Customer Provided Materials as furnished by Customer to Brammer under this Agreement, or Customer's specifications for the packaging material used in connection with Product shall result in any Product being adulterated or misbranded within the meaning of Sections 501 and 502, respectively, of the FD&C Act and any other Applicable Laws;

(i) to the best of Customer's knowledge, the Customer Provided Materials provided by Customer to Brammer hereunder comply with the applicable Material Safety Data Sheets;

(j) to Customer's knowledge, the Customer Provided Materials and Customer-Funded Equipment (if provided by Customer to Brammer) will be provided to Brammer by Customer free of contamination by noxious or toxic agents, infectious agents (including any microbiological or viral agents of infection (*e.g.*, bacteria, fungae, mycoplasmas, prions, and viruses)) and/or corrosive agents; and

(k) The execution, delivery and performance of this Agreement by Customer will not violate any agreement or instrument to which Customer is a party.

17.3 EXCEPT AS SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED BY STATUTE, CUSTOM OF THE TRADE OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTIES OF TITLE OR NONINFRINGEMENT. ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ANY PERSON OR ENTITY ON BEHALF OF A PARTY, INCLUDING EMPLOYEES OR REPRESENTATIVES OF SUCH PARTY, THAT ARE INCONSISTENT HEREWITH, WILL BE DISREGARDED AND WILL NOT BE BINDING ON SUCH PARTY.

18. **Term; Termination; Certain Effects of Termination; Amendment to DMSA Term**.

18.1 Term. Unless earlier terminated in accordance with Sections 18.2 and 18.3, the term of this Agreement shall commence on the Effective Date and shall continue until [**] (the "Initial Term"). The Term shall automatically renew for successive three (3) year terms (each a "Renewal Term" and together with the Initial Term, the "Term") unless Customer notifies Brammer of its intention not to renew no less than [**] prior to the expiration of the Initial Term or any Renewal Term.

18.2 Termination by Customer.

(a) Termination for Convenience. [**]

(b) Clinical Failure. [**]

(c) Failure to Provide the Dedicated Capacity. [**]

18.3 Termination by Either Party.

(a) Termination by Brammer for Material Breach of Customer. [**]

(b) Termination by Customer for Material Breach of Brammer. [**]

(c) Termination by Insolvency. [**]

18.4 Effect of Termination.

(a) In the event Customer terminates this Agreement pursuant to Section 18.2(a), [**]

(b) In the event Customer terminates this Agreement pursuant to Section 18.2(b), [**]

(c) In the event Customer terminates this Agreement pursuant to Section 18.2(c), [**]

(d) In the event Brammer terminates the Agreement pursuant to Section 18.3(a) or Section 18.3(c), [**]

(e) In the event Customer terminates this Agreement pursuant to Section 18.2(c), Section 18.3(b) or Section 18.3(c), [**]

(f) In addition to the foregoing clauses (a)-(e), in the case of any expiration or termination of this Agreement for any reason, the following will apply:

(i) All licenses or other rights granted to Brammer by the Customer herein will automatically terminate.

(ii) Brammer will, as soon as possible, supply Customer with any and all documentation concerning the Results obtained through the effective date of such expiration or termination.

(iii) The Receiving Party will promptly return to the other all data and documents in any form comprising or containing any Confidential Information of the Disclosing Party, *provided that* the Receiving Party may retain: (a) one copy of the Disclosing Party's Confidential Information in secure legal archives for evidentiary purposes only and (b) a copy of computer records or files containing such Confidential Information that have been created pursuant to automatic archiving or back-up procedures that cannot reasonably be deleted (collectively, "Retained Copies"), *provided, however,* that any such Retained Copies will be kept confidential by the Receiving Party in accordance with the terms and provisions of this Agreement for as long as the Receiving Party is in possession of the Retained Copies.

(iv) Brammer will deliver to Customer at the Delivery Site any and all quantities of Product Manufactured up to the effective date of such expiration or termination, except that Brammer may [**].

(v) [**].

(vi) Brammer will return, ship, or destroy Customer Provided Materials and Product Materials procured according to the Purchase Order at Customer's direction and sole expense prior to the effective date of such expiration or termination, including expenses relating to shipping costs, return fees to Vendors and any unreimbursed costs on any non-refundable or non-returnable items; *provided that* Brammer may dispose of Customer Provided Materials in its discretion, and Customer will have no right to the same, in the event Brammer does not receive direction in accordance with this Section 18.4(vi) within [**] of termination or expiration of this Agreement.

(vii) Brammer will return all Customer-Funded Equipment to Customer in a manner reasonably requested by Customer promptly after such termination or expiry of this Agreement.

18.5 Survival. The termination or expiration of this Agreement for any reason will not affect any accrued rights or obligations of either Party as of the effective date of such termination or expiration. The following provisions will survive any expiration or termination of this Agreement: Articles 1, 10, 12, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 and 28, and Sections 2.1(iv), 4.10, 5.4-5.13, 8.7, 11.1 (solely with respect to the first sentence), 11.2, 11.3, 11.4, 11.8, and 17.3, the provisions of the applicable Quality Agreement, and any other provision in this Agreement or its Appendices and attachments that by its nature and intent should remain valid after the expiration or termination of the Agreement.

19. **Force Majeure**. Subject to Section 4.3, either Party will be excused from performing its respective obligations under this Agreement, except for any obligation to make an undisputed payment under an issued invoice in accordance with the terms herein, if its performance is delayed or prevented by any event beyond such Party's reasonable control (each, a "Force Majeure Event"), including acts of God, fire, explosion, weather, disease, war, terrorism, insurrection, civil strife, riots, labor dispute or strike, government action, or

a shortage or failure of power outside such Party's reasonable control, *provided that* (a) such performance will be excused only to the extent of and during such disability, (b) such performance shall be resumed as soon as practicable after such Force Majeure Event is removed, and (c) financial inability in and of itself will not be a Force Majeure Event. Brammer shall give notice to Customer as soon as practicable after the occurrence of a Force Majeure Event affecting Brammer stating, insofar as then known, the probable extent to which Brammer will be unable to perform and to the extent to which Brammer's performance will be delayed. Any time specified for completion of performance in the Product Addendum falling due during or subsequent to the occurrence of any or such events will be automatically extended for a period of time reasonably necessary to recover from such disability, *provided however* that Brammer use Commercially Reasonable Efforts to recover from such disability. The Parties shall, within [**] of the start of such delay, discuss the delay and how best to resolve the matter.

20. **Assignment**. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement (a) in connection with the transfer or sale of all or substantially all of the assets of such Party to which this Agreement relates or, in the case of Customer, the Product; (b) in the event of the merger, reorganization or consolidation of a Party; or (c) to any Affiliate. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume all obligations of its assignor under this Agreement, *provided however* that if either Party assigns this Agreement to an Affiliate, such Party will continue to remain obligated under this Agreement; and, *further provided*, *that*, in connection with any assignment to a Third Party described in this Section 20, (i) the assigning Party will provide the other Party with prompt written notice of assignment and (ii) the permitted assignee will assume in writing all obligations of its assignor under this Agreement.

21. **Publicity**. Except as permitted under Article 10, neither Party will make a press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement, or any ancillary matter, without first obtaining the prior written consent of the other Party, *provided that* the foregoing shall not limit or restrict Customer's ability to make any such press release, announcement or other publicity regarding the Product. To the extent either Party desires to make such a press release, announcement or other formal publicity, such Party will provide a copy of the proposed text thereof to the other Party for its review and approval at least [**] prior to the proposed release. Such other Party may provide specific, reasonable comments on such release, announcement or publicity reasonably in advance of the date of the proposed release, but will not unreasonably withhold or delay its approval to such release, announcement or publicity.

22. **Press Releases**. The Parties agree that any initial public announcement of the execution of this Agreement will be in the form of a mutual press release to be agreed upon by the Parties; *provided*, *that* the Parties will also agree on the timing of such public announcement. After such press release is published, each Party will be entitled to make or publish any public statement consistent with the contents thereof. Except as set forth in the preceding sentence or as permitted under Article 10, no press release, publicity or other form of public written disclosure related to this Agreement will be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing. This Section 22 will not apply to any disclosure that is deemed necessary, in the reasonable judgment of the responsible Party, to comply with national, federal or state laws or regulations.

23. **Use of Names**. Except as expressly provided herein, neither Party will make use of the name of the other Party in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party.

24. **Notices**. All notices to be given as required in the Agreement will be in writing and may be delivered by email or delivered personally or mailed either by a reputable overnight carrier with required receipt signature or certified mail, postage prepaid to the Parties at the addresses set forth below or at such

other address as either Party may provide by written notice to the other Party in accordance with the provisions of this Section 24. Such notice will be effective: (i) on the date sent, if delivered personally or by email (receipt of which is confirmed); (ii) the date after delivery if sent by overnight carrier; or (iii) on the date received if sent by certified mail.

If to Customer:

Freeline Therapeutics Limited
Attn: [**]

If to Brammer:

Brammer Bio
Attn: [**]

With a copy to (which shall not constitute notice): [**]

25. **Choice of Law; Jurisdiction and Venue**. This Agreement, and all matters arising directly or indirectly hereunder, will be governed by, and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws principles. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980.

26. **Waiver/Severability**. No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances will be deemed to be or be construed as a further or continuing waiver of any such provision, or of any other provision or condition of this Agreement. The invalidity of any portion of this Agreement will not affect the validity, force or effect of the remaining portions of this Agreement. If it is ever held that any provision hereunder is too broad to permit enforcement of such provision to its fullest extent, such provision will be enforced to the maximum extent permitted by law.

27. **Entire Agreement; Modification/Counterparts**. This Agreement, together with the Product Addendum and Appendices attached hereto, the DMSA and the Quality Agreement sets forth the entire agreement between the Parties with respect to the subject matter hereof and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, and commitments with respect thereto and will take precedence over all terms, conditions and provisions of any purchase order form or form of order acknowledgment or other document purporting to address the same subject matter. This Agreement will not be waived, released, discharged, changed or modified in any manner except by an instrument signed by the duly authorized officers of each of the Parties, which instrument will make specific reference to this Agreement and will express the plan or intention to modify same. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. For purposes of execution, signatures by facsimile, PDF format or other electronic transmission will be deemed to bind each Party as if they were original signatures.

28. **Construction**. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders and the word

"or" is used in the inclusive sense (and/or). The headings and captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "Agreement", "hereof", "herein" and "hereunder" as used herein will mean this Agreement, the Product Addendum, and Appendices attached hereto as a whole and not to any particular provision of this Agreement. All Appendices annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in any Appendix but not otherwise defined therein, shall have the meaning as defined in this Agreement. The term "including" as used herein will mean including, without limiting the generality of any description preceding such term. The term "day" shall mean a calendar day. The language of this Agreement will be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto. The terms "Work Order" and "Work Statement" are used interchangeably herein. "Writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively. References to "law", "laws" or to a particular statute or law shall be deemed also to include any and all Applicable Law.

[*Signature Page Follows*]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

BRAMMER BIO MA, LLC

By: [**]
Name: [**]
Title: [**]

FREELINE THERAPEUTICS LIMITED

By: [**]
Name: [**]
Title: [**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX A

Product Addendum

This Product Addendum is entered into on June 30, 2020, by and between Freeline Therapeutics Limited ("Customer") and Brammer Bio MA, LLC ("Brammer") pursuant to that Dedicated Manufacturing and Commercial Supply Agreement dated June 26, 2020.

WHEREAS, Customer and Brammer are Parties to that certain Dedicated Manufacturing and Commercial Supply Agreement effective as of June 30, 2020 (the "Agreement"), pursuant to which Brammer manufactures and supplies Product to Customer for clinical trial and commercialization purposes;

WHEREAS, the Parties agreed that in connection with such manufacture and supply, Customer and Brammer would enter into a Product Addendum that would detail the specific manufacturing and supply activities to be conducted for each Product;

WHEREAS, the Parties desire to enter into this Product Addendum specifically as to the Product identified herein; and

WHEREAS, unless otherwise specified below, this Product Addendum is governed by the terms and conditions of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, the Parties agree as follows:

1. Definitions

Capitalized terms which are not defined herein shall have the meaning ascribed to such terms in the Agreement.

2. Incorporation of Terms; Conflict with Agreement

This Product Addendum is entered into between Customer and Brammer pursuant to, and in accordance with, the terms of the Agreement, which is hereby incorporated by reference into this Product Addendum, amended only to the extent specified below. To the extent there are any inconsistencies or conflicts between this Product Addendum and the Agreement, the Agreement shall control unless otherwise expressly agreed to in writing by the Parties or otherwise expressly set forth below.

3. Term

This Product Addendum will be effective during the Term of the Agreement, unless earlier terminated in accordance with the Agreement.

4. Scope

Subject to the terms and conditions of the Agreement, Brammer shall Manufacture the Product identified below under the additional terms and conditions identified below:

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

IN WITNESS WHEREOF, the Parties have caused this Product Addendum to be executed by their respective duly authorized representatives as of the date first above written.

[**]

BRAMMER BIO MA, LLC

By: [**]
Name: [**]
Title: [**]

FREELINE THERAPEUTICS LIMITED

By: [**]
Name:: [**]
Title: [**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

Exhibit 1 to Product Addendum
Manufacturing Steps

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

Exhibit 2 to Product Addendum
Pricing and Payment Terms

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

SCHEDULE I TO EXHIBIT 2 OF PRODUCT ADDENDUM: ANALYTICAL METHODS AND TESTING

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

SCHEDULE II TO EXHIBIT 2 OF PRODUCT ADDENDUM: STABILITY STUDIES

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

Exhibit 3 to Product Addendum

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX B

FORM OF LETTER AUTHORIZING CROSS-REFERENCING

[*Brammer Bio letterhead*]

[*Date*]

[*To be addressed to applicable Regulatory Authority holding Customer regulatory submission*][1]

RE: Right of Reference to [identify Brammer regulatory submission]

Dear Sir/Madam:

Brammer Bio MA, LLC, the sponsor of [*Brammer regulatory submission*], has granted CUSTOMER and its successors and assigns, the right to reference and rely upon all information and data contained in [*Brammer regulatory submission*] in support of CUSTOMER [*identify CUSTOMER regulatory submission*].

By this letter, Brammer hereby authorizes the Food and Drug Administration [or Other Regulatory Authority] to cross-reference Brammer's [*Brammer regulatory submission*] in its review of CUSTOMER [*identify Customer regulatory submission*] for the purpose described above.

Please contact [*name and telephone number*] if you have you any questions regarding this right of reference.

Sincerely,

[*Brammer signatory***]**
Title:

cc: [Name, Title]

CUSTOMER ADDRESS

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1 If any such letter is to be delivered to a regulatory authority other than the FDA, the Parties acknowledge that appropriate modifications to this form will be necessary.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX C

DEDICATED CAPACITY AND PURCHASE OF PRODUCT

Capacity Access Fee

In connection with performing the Services, Brammer shall utilize an [**] bioreactor and associated drug substance processing equipment in one, single cGMP Suite reserved for Dedicated Capacity at the Facilities. Subject to the terms and conditions in this Agreement, during the Term, the Dedicated Capacity shall be, beginning on [**] subject to an annual Capacity Access Fee of [**].

The Capacity Access Fee will be [**].

Payment Terms

In consideration for the reservation of the Dedicated Capacity and the resources being applied to establish such Dedicated Capacity, Customer has made an advanced, non-refundable payment of [**] ("Advanced Payment") as follows: [**] The total Advanced Payment amount of [**] will be credited against each quarterly Capacity Access Fee beginning [**] at the rate of [**] .

Equipment for Dedicated Capacity

As of the Effective Date, Brammer has procured, funded and qualified all necessary equipment for Dedicated Capacity, including all equipment necessary to Manufacture the Drug Substance and Drug Product. [**]. Additional equipment can be procured, qualified and maintained by Brammer, at Customer's sole election, as Customer-Funded Equipment and, subject to the foregoing [**] credit, invoiced to Customer as a Pass-Through Cost under the Product Addendum. Any equipment funded by Customer shall be returned to Customer upon expiration or termination of this Agreement.

Minimum and Maximum Number of Batch Starts per annum

All references in the Agreement to the Minimum and Maximum Purchase Commitments shall be read to mean the annual minimum and maximum number of Drug Substance Batches produced in the Dedicated Capacity as set forth below and assumes level-loading of demand. (It being understood that the Dedicated Capacity shall be capable of Manufacturing the Maximum Purchase Commitments each Calendar Year).

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

Minimum Batches of Drug Substance Annually	Maximum Batches of Drug Substance Annually
[**]	[**]

*The amount will be prorated if there is a partial final Calendar Year at termination of the Agreement.
**This number assumes that [**] cell culture and AAV purification would be accommodated in the same GMP Suite. Should Customer require more than [**] Batches of Drug Substance annually, assuming level-loading of demand, Brammer will use Commercially Reasonable Efforts to accommodate the increase (at additional costs to be jointly agreed upon by the Parties).

Batch Pricing

All references in the Agreement to the Batch Pricing shall be read to mean the amount set forth below.

Drug Substance Batch Price
[**]

The Batch Pricing covers only the value of the Services and does not include Pass-Through Costs.

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX D

CHANGE ORDER TEMPLATE

Attachment 1 to Change Order X
to Product Addendum x
to Development and Manufacturing Services Agreement Dated XX

Change Order X
to Purchase Order x to Development and Dedicated Manufacturing and Commercial Supply Agreement Dated XX

This Change Order Number 1 to Product Addendum No.: ____ ("Change Order 1") is made effective as of _____, (the "Effective Date") by and between **Freeline Therapeutics Limited** ("CUSTOMER") and **Brammer Bio MA, LLC** ("Brammer") and constitutes a "Work Statement" under that certain Dedicated Manufacturing and Commercial Supply Agreement by and between the Parties, dated _____ (the "Agreement"), and in particular, Purchase Order No.: _____ dated _____.

This Change Order 1 and the Services contemplated herein are subject to the terms and conditions of the Agreement. Capitalized terms not otherwise defined in this Change Order 1 shall have the meaning ascribed to such terms in the Agreement. To the extent any terms or provisions of this Change Order 1 conflict with the terms and provisions of the Agreement, the terms and provisions of the Agreement shall control.

The Parties hereby agree to make changes to the Services and terms only as follows:

Description of Change(s) and Assumptions:

The Services as set forth in the Agreement of Purchase Order No.: ___ of the Agreement are hereby amended to include the additional Services set forth in **Attachment 1** of this Change Order 1.

IN WITNESS WHEREOF, the Parties hereto have caused this Change Order No. 1 to be executed as of the Effective Date by their duly authorized representatives.

BRAMMER BIO MA, LLC		**FREELINE THERAPEUTICS LIMITED**	
By:	_____	By:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____

[Attachment 1 to Changer Order X is attached to the Changer order]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX E

FORM OF QUALITY AGREEMENT

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX F

BRAMMER MARKS

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX G

[Intentionally Omitted]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if disclosed.

APPENDIX H

RESERVED PRODUCTS

[**]