As filed with the Securities and Exchange Commission on March 14, 2022

Registration No. 333-262643

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 2 TO FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

HELIX ACQUISITION CORP.*
(Exact name of registrant as specified in its charter)

Cayman Islands	**6770**	**N/A**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

c/o Cormorant Asset Management, LLP
200 Clarendon Street, FL 52
Boston, MA 02116
(857) 702-0370
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Maples Fiduciary Services (Delaware) Inc.
4001 Kennett Pike, Suite 302
Wilmington, Delaware 19807
+1 (302)-338-9130
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Joel L. Rubinstein **Elliott Smith** **White & Case LLP** **1221 Avenue of the Americas** **New York, NY 10020** **(212) 819-8200**	**Copies to:** **Matthew Gardner** **Michael Johns** **Maples and Calder** **P.O. Box 309, Ugland House,** **Grand Cayman** **Cayman Islands, KY1-1104** **+1 (345) 949-8066**	**Ryan A. Murr** **Branden C. Berns** **Gibson, Dunn & Crutcher LLP** **555 Mission Street, Suite 3000** **San Francisco, CA 94105** **(415) 393-8200**

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

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 a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, 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. ☐

*** All ordinary shares being registered for resale hereunder will be issued by Helix in connection with the business combination with MoonLake Immunotherapeutics AG. Upon the closing of the business combination, Helix will change its name to MoonLake Immunotherapeutics.**

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This registration statement registers the resale of up to 11,500,000 Class A Ordinary Shares (the "***PIPE Shares***"), par value $0.0001 per share, of Helix Acquisition Corp., a Cayman Islands exempted company ("***Helix***"), by the selling shareholders named in this prospectus (or their permitted transferees) (the "***Selling Shareholders***"). The Selling Shareholders are expected to be issued the PIPE Shares in private placements immediately prior to or substantially concurrently with the consummation of the proposed business combination (the "***Business Combination***") by and among Helix, MoonLake Immunotherapeutics AG, a Swiss stock corporation ("***MoonLake***"), the existing securityholders of MoonLake (collectively, the "***ML Parties***"), Helix Holdings LLC, a Cayman Islands limited liability company and the sponsor of Helix, and the representative of the ML Parties.

The PIPE Shares will not be issued and outstanding at the time of the extraordinary general meeting of Helix's shareholders relating to the Business Combination and, accordingly, will not be entitled to vote at the extraordinary general meeting and will not have redemption rights in connection therewith. Further, the holders of the PIPE Shares will not receive any proceeds from the trust account established in connection with Helix's initial public offering in the event Helix does not consummate an initial business combination by the October 22, 2022 deadline set forth in its amended and restated memorandum and articles of association. In the event the Business Combination is not approved by Helix shareholders or the other conditions precedent to the consummation of the Business Combination are not met or waived, the PIPE Shares will not be issued and Helix will seek to withdraw this registration statement prior to its effectiveness.

Helix is filing this Amendment No. 2 to the registration statement as an exhibits-only filing to file the exhibits attached hereto. Accordingly, this amendment consists only of the facing page, this explanatory note, Part II of the registration statement, the signature pages to the registration statement, and the filed exhibits.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated expenses to be borne by the registrant in connection with the issuance and distribution of the Class A Ordinary Shares being registered hereby.

Expense	Estimated Amount
Securities and Exchange Commission registration fee	$ 10,532.57
Accounting fees and expenses	$ 15,000.00
Legal fees and expenses	$ 75,000.00
Financial printing and miscellaneous expenses	$ 20,000.00
Total	$ 120,532.57

We will bear all costs, expenses and fees in connection with the registration of the Class A Ordinary Shares being registered hereby, including with regard to compliance with state securities or "blue sky" laws. The Selling Shareholders, however, will bear all underwriting commissions and discounts, if any, attributable to their sale of the Class A Ordinary Shares. All amounts are estimates except the SEC registration fee.

Item 14. Indemnification of Directors and Officers.

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against willful default, willful neglect, civil fraud or the consequences of committing a crime. The Proposed MAA provide for indemnification of our officers and directors to the maximum extent permitted by law, including for any liability incurred in their capacities as such, except through their own actual fraud, willful default or willful neglect. We purchased a policy of directors' and officers' liability insurance that insures our officers and directors against the cost of defense, settlement or payment of a judgment in some circumstances and insures us against our obligations to indemnify our officers and directors.

We have entered into indemnification agreements with each of our directors and officers in which we have agreed to indemnify, defend and hold harmless, and also advance expenses as incurred, to the fullest extent permitted under applicable law, from damage arising from the fact that such person is or was an officer or director of our company or our subsidiaries.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, our amended and restated certificate of incorporation, our amended and restated bylaws, any agreement, any vote of stockholders or disinterested directors or otherwise.

Our indemnification obligations may discourage shareholders from bringing a lawsuit against our officers or directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our officers and directors, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against our officers and directors pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities.

In connection with Helix's formation on August 13, 2020, the Sponsor paid $25,000, or approximately $0.007 per share, to cover certain of our offering costs in exchange 3,593,750 founder shares. Such securities were issued in connection with our organization pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act. On September 30, 2020, the Sponsor surrendered, for no consideration, 718,750 Class B Ordinary Shares, resulting in our Sponsor holding 2,875,000 founder shares with a value of approximately $0.009 per share.

Simultaneously with the closing of Helix's IPO on October 22, 2020, the Sponsor purchased an aggregate of 430,000 private placement shares, at a price of $10.00 per share, for an aggregate of $4,300,000, in a private placement exempt from registration pursuant to Section 4(a)(2) of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

The following exhibits are filed as part of this registration statement:

Exhibit	Description
2.1†	Business Combination Agreement, dated as of October 4, 2021, by and among Helix Acquisition Corp., MoonLake Immunotherapeutics AG, the existing shareholders and option rights holders of MoonLake Immunotherapeutics AG, Helix Holdings LLC, and Matthias Bodenstedt (incorporated by reference to Exhibit 2.1 of Helix's Form 8-K, filed with the SEC on October 4, 2021).
3.1	Amended and Restated Memorandum and Articles of Association of Helix Acquisition Corp. (incorporated by reference to Exhibit 3.1 to Helix's Form 8-K, filed with the SEC on October 22, 2020).
3.2	Proposed Memorandum and Articles of Association of MoonLake Immunotherapeutics (incorporated by reference to Annex B of Helix's Definitive Proxy Statement, filed with the SEC on February 14, 2022).
4.1	Specimen Ordinary Share Certificate (incorporated by reference to Exhibit 4.1 of Helix's Form S-1/A (File No. 333-249197), filed with the SEC on October 14, 2021).
5.1*	Opinion of Maples and Calder.
10.1	Investment Agreement, dated as of October 4, 2021, by and among Helix Acquisition Corp., MoonLake Immunotherapeutics AG and the existing shareholders and option rights holders of MoonLake Immunotherapeutics AG (incorporated by reference to Exhibit 10.1 of Helix's Form 8-K, filed with the SEC on October 4, 2021).
10.2	Form of Amended and Restated Shareholders' Agreement (incorporated by reference to Exhibit 10.2 of Helix's Form 8-K, filed with the SEC on October 4, 2021).
10.3	Letter Agreement, dated October 19, 2020, among Helix Acquisition Corp., Helix Holdings LLC and each of the officers and directors of Helix (incorporated by reference to Exhibit 10.1 of Helix's Form 8-K, filed with the SEC on October 22, 2020).
10.4	Amended Sponsor Agreement, dated as of October 4, 2021, by and among Helix Acquisition Corp., Helix Holdings LLC, and the officers and directors of Helix Acquisition Corp (incorporated by reference to Exhibit 10.4 of Helix's Form 8-K, filed with the SEC on October 4, 2021).
10.5	Registration Rights Agreement, dated October 19, 2020, among the Company, Helix Holdings LLC and the Holders signatory thereto (incorporated by reference to Exhibit 10.3 of Helix's Form 8-K, filed with the SEC on October 22, 2020).
10.6	Form of Amended and Restated Registration Rights Agreement (incorporated by reference to Annex E of Helix's Definitive Proxy Statement, filed with the SEC on February 14, 2022).
10.7	Form of Subscription Agreement (incorporated by reference to Exhibit 10.3 of Helix's Form 8-K, filed with the SEC on October 4, 2021).
10.8+	Form of MoonLake Immunotherapeutics 2022 Equity Incentive Plan (incorporated by reference to Annex C of Helix's Definitive Proxy Statement, filed with the SEC on February 14, 2022).
10.9**†#	License Agreement, dated April 29, 2021, by and between MoonLake Immunotherapeutics AG and MERCK Healthcare KGaA.

10.10**	Side Letter to License Agreement, dated April 29, 2021, by and between MoonLake Immunotherapeutics AG and MERCK Healthcare KGaA.
10.11**†#	Contract Manufacturing Agreement, dated October 15, 2018, by and between MoonLake Immunotherapeutics AG, as assignee of MERCK Healthcare KGaA, and Richter-Helm Biologics GmbH & Co.
10.12**#	Amendment No. 2 to Contract Manufacturing Agreement, by and between MoonLake Immunotherapeutics AG, as assignee of MERCK Healthcare KGaA, and Richter-Helm Biologics GmbH & Co.
10.13**	Assignment of Contract Manufacturing Agreement, dated July 1, 2021, by and among MoonLake Immunotherapeutics AG, MERCK Healthcare KGaA, and Richter-Helm Biologics GmbH & Co.
10.14*+	Employment Agreement, dated April 30, 2021, by and between MoonLake Immunotherapeutics AG and Dr. Jorge Santos da Silva.
10.15*+	Amendment to Employment Agreement, dated September 9, 2021, by and between MoonLake Immunotherapeutics AG and Dr. Jorge Santos da Silva.
10.16*+	Employment Agreement, dated April 30, 2021, by and between MoonLake Immunotherapeutics AG and Prof. Dr. Kristian Reich.
10.17*+	Amendment to Employment Agreement, dated November 8, 2021, by and between MoonLake Immunotherapeutics AG and Prof. Dr. Kristian Reich.
10.18*+	Employment Agreement, dated May 10, 2021, by and between MoonLake Immunotherapeutics AG and Matthias Bodenstedt.
10.19*+	Amendment to Employment Agreement, dated June 22, 2021, by and between MoonLake Immunotherapeutics AG and Matthias Bodenstedt.
10.20*+	Employment Agreement, dated April 30, 2021, by and between MoonLake Immunotherapeutics AG and Jonkheer Arnout Michiel Ploos van Amstel.
10.21*+	Amendment to Employment Agreement, dated September 9, 2021, by and between MoonLake Immunotherapeutics AG and Jonkheer Arnout Michiel Ploos van Amstel.
10.22*†+	Termination Agreement, dated December 13, 2021, by and between MoonLake Immunotherapeutics AG and Jonkheer Arnout Michiel Ploos van Amstel.
10.23*†+	Board Member Agreement, dated September 25, 2021, by and between MoonLake Immunotherapeutics AG and Simon Sturge.
10.24*+	Employee Share Participation Plan of MoonLake Immunotherapeutics AG, dated July 23, 2021.
10.25*+	Employee Stock Option Plan of MoonLake Immunotherapeutics AG, dated July 23, 2021.
10.26*+	Employee Share Participation Plan of MoonLake Immunotherapeutics AG, dated December 14, 2021.
10.27*+	Employee Stock Option Plan of MoonLake Immunotherapeutics AG, dated December 14, 2021.
10.28*	Loan Agreement, dated October 15, 2021, by and among MoonLake Immunotherapeutics AG and the Lenders named therein.
10.29*	Amendment to the Loan Amendment, dated January 18, 2022, by and among MoonLake Immunotherapeutics AG and the Lenders named therein.
10.30*	Second Amendment to the Loan Agreement, dated February 15, 2022, by and among MoonLake Immunotherapeutics AG and the Lenders named therein.
10.31	Convertible Loan Agreement, dated as of February 20, 2022, by and among Cormorant Private Healthcare Fund IV, L.P., MoonLake Immunotherapeutics AG, Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P. and Helix Acquisition Corp. (incorporated by reference to Exhibit 10.1 of Helix's Form 8-K, filed with the SEC on February 25, 2022).
10.32*+	Form of Indemnification Agreement for directors and executive officers.
23.1*	Consent of WithumSmith+Brown, PC.
23.2*	Consent of Baker Tilly US, LLP.
23.3*	Consent of Maples and Calder (included in Exhibit 5.1 hereto).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).
107*	Filing Fee Table.

* Previously filed.
** Filed herewith.
† The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5).
+ Indicates a management contract of compensatory plan.
# Portions of the Exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however, that* no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) Insofar as indemnification for liabilities arising under the Securities Act 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 SEC such indemnification is against public policy as expressed in the Securities 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 whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on the 14th day of March, 2022.

HELIX ACQUISITION CORP.

By: /s/ Bihua Chen
Name: Bihua Chen
Title: Chief Executive Officer and Chairwoman

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

Name	Title	Date
* Bihua Chen	Chief Executive Officer and Chairwoman (Principal Executive Officer)	March 14, 2022
/s/ Dr. Andrew J. Phillips Dr. Andrew J. Phillips	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2022
* Dr. Nancy Chang	Director	March 14, 2022
* Will Lewis	Director	March 14, 2022
* John Schmid	Director	March 14, 2022

*By: /s/ Dr. Andrew J. Phillips
Dr. Andrew J. Phillips
Attorney-in-fact

Exhibit 10.9

Execution Copy

Certain confidential information contained in this document, marked by brackets as [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. In addition, certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

LICENSE AGREEMENT

dated April 29, 2021

by and between

Merck Healthcare KGaA, Darmstadt, Germany

and

MoonLake Immunotherapeutics AG

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "**Agreement**") is dated as of April 29, 2021 (the "**Effective Date**") by and between **MERCK Healthcare KGaA**, a corporation with general partners organized under German law, having a place of business at Frankfurter Strasse 250, 64293 Darmstadt, Germany ("**Licensor**") and MoonLake Immunotherapeutics AG, a corporation organized under the laws of Switzerland, having a place of business at Untermüli 7 / Postfach 7444, 6302 Zug, Switzerland ("**Licensee**"). Licensor and Licensee may be referred to herein as a "**Party**" or, collectively, as "**Parties**".

RECITALS

WHEREAS, Licensor is engaged, among other activities, in the development, manufacture and commercialization of pharmaceutical products;

WHEREAS, Licensee is a newly established legal entity whose specific purposes are to develop, manufacture and subsequently commercialize the proprietary compound that is the subject of this Agreement;

WHEREAS, pursuant to the Initial License Agreement (as hereinafter defined), Licensor has developed a proprietary compound known as M1095 (an anti-IL17A/F nanobody) in a collaboration with the Initial Licensor (as hereinafter defined) and has obtained rights under certain platform intellectual property owned or controlled by the Initial Licensor;

WHEREAS, Initial Licensor has opted out of the Initial Project (as hereinafter defined) in accordance with the Initial License Agreement and thereafter has assigned to Licensor a patent family seeking to protect M1095, and Licensor has all necessary rights to further develop and commercialize M1095 and products containing M1095, including the right to grant a sublicense of such development and commercialization rights (subject to the Initial License Agreement and Underlying GMP License), all to the extent set out in greater detail in this Agreement; and

WHEREAS, Licensor wishes to license and sublicense to Licensee, on an exclusive or non-exclusive basis, as applicable and further defined hereinafter, the right to Develop (as hereinafter defined) and Commercialize (as hereinafter defined) M1095 and products containing M1095.

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein, the Parties agree as follows.

ARTICLE 1 - DEFINITIONS

In this Agreement the following terms, when capitalized, shall have the following meanings, and such meanings shall apply equally to both the singular and plural forms of the terms defined:

1.1. "**Accounting Standards**" means either IFRS or U.S. GAAP.

1.2. "**Affiliate**" means a Person that now or in the future, directly or indirectly, controls, is controlled by or is under common control with another Person, but only for so long as such control exists. For the purposes of this Section 1.1, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct, or cause the direction of, the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise, entitled to vote in the election of its directors.

1.3. "**Applicable Laws**" means any supranational, federal, state, local or foreign law, statute, ordinance or principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency guidelines or other requirement, license or permit of any Governmental Body, which may be in effect from time to time, to the extent applicable under or in connection with this Agreement or any activities related to this Agreement.

1.4. "**Business Day**" means a day other than Saturday or Sunday, and other than national holidays in the United States, Switzerland or Germany, on which banking institutions in New York, New York, United States, as well as Zug, Switzerland, and Frankfurt, Germany, are open for business.

1.5. "**Calendar Quarter**" means each three (3) month period commencing January 1, April 1, July 1 or October 1; *provided*, *however*, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end on the date of termination or expiration of this Agreement.

1.6. "**Calendar Year**" means the period beginning on January 1 and ending on December 31 of the same year; *provided*, *however*, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.7. "**Change of Control**" means, with respect to a Person or one or more of its Affiliates, whether in one transaction or a series of related transactions: (a) the acquisition by any third party of beneficial ownership of fifty percent (50%) or more of the then-outstanding shares or voting power of such Party; (b) the consummation of a business combination involving such Party with any third party, unless, following such business combination, the stockholders of such Party immediately prior to such business combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares or voting power of the entity resulting from such business combination; or (c) the sale of all or substantially all of such Party's assets or business relating to the subject matter of the Agreement to any third party (whether by asset sale, stock sale, merger, exclusive license or otherwise).

1.8. "**Clinical Trial**" means a clinical trial in which a pharmaceutical product is administered in human subjects that has been approved by a Regulatory Authority and Institutional Review Board or Ethics Committee, and is designed to measure the safety or therapeutic efficacy of the pharmaceutical product in such subjects. Clinical Trials shall include Phase I Trials, Phase II Trials and Phase III Trials.

1.9. "**Combination Product**" means a Licensed Product that (a) includes one or more active ingredients in addition to the Compounds or (b) is combined with one or more products, devices, pieces of equipment or components.

1.10. "**Commercialization**" or "**Commercialize**" means, with respect to a product, any and all activities undertaken before or after Regulatory Approval of an NDA for such product and directed to the commercial exploitation of such product, including the marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of such product, and interacting with Regulatory Authorities regarding the foregoing.

1.11. "**Commercially Reasonable Efforts**" means, (a) with respect to the efforts to be expended by any Party with respect to any objective under this Agreement (other than as provided under clause (b)), such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances, and (b) with respect to any objective relating to Development or Commercialization of a Licensed Product by Licensee, the level of efforts and resources (measured as of the time that such efforts and resources are required to be used under this Agreement) that are commonly devoted by similarly situated biotechnology companies or pharmaceutical companies (measured in terms of size and resources), as the case may be, to Develop or Commercialize, as the case may be, a comparable product for the same Indications, at a similar stage in its development (including taking into consideration factors such as, safety, efficacy, regulatory status and applicable regulatory requirements) or product life. If a Party assigns its rights or obligations under this Agreement to an Affiliate or marketing partner, if and to the extent permitted under this Agreement, then, with respect to such Affiliate or marketing partner, Commercially Reasonable Efforts shall mean at least (i) the efforts and resources as required from the assigning Party pursuant to the first part of this Section 1.11 or (ii) such reasonable, good-faith efforts and resources as such Affiliate or marketing partner would normally devote to the accomplishment of a similar objective under similar circumstances, whatever is more beneficial for the non-assigning Party, again taking into account all relevant factors. For clarity, it is understood that Commercially Reasonable Efforts shall be evaluated on a country-by-country basis based on factors relevant to the particular country (including, size of market, availability and enforcement of market exclusivity (whether by Patent Right, regulatory exclusivity or otherwise), anticipated or approved labeling, pricing strategies, likelihood of gray-market goods, Applicable Laws, and likelihood of Regulatory Approval) and it is expected that the level of efforts required may be different for different countries and may change over time for particular countries.

1.12. "**Competing Product**" means, with respect to a Licensed Product that is being sold in a country or jurisdiction in the Territory, any product that: (a) is sold in such country or jurisdiction by a Third Party that (i) has not obtained the rights to market or sell such product as a Sublicensee or distributor of Licensee and (ii) did not purchase such product in a chain of distribution that included Licensee or any of its Affiliates or Sublicensees; and (b) the Commercialization of which would be Covered by a Pending Claim of a Licensor Patent (for purposes of determining whether a Pending Claim of a Licensor Patent would be infringed, such Pending Claim shall be treated as if issued in the form then being prosecuted).

1.13. "**Competing Biologic Product**" means any product that contains any of the following: an inhibitor of IL-17 or an inhibitor of any receptor of IL-17.

1.14. "**Competitor**" means a Third Party that owns or controls a Competing Biologic Product that (i) has completed a Phase I Trial and is entering or is then in, or has completed, a Phase II Trial or Phase III Trial or (ii) is then being commercialized in one or more countries in the Territory (any such Competing Biologic Product an "**Acquired Competing Biologic Product**").

1.15. "**Compound**" means the compound described as Anti-IL17A/F Nanobody (also known to the Parties as "M1095" or "sonelokimab") having the sequence set forth on Schedule 1.15 and, all modifications, derivatives, fragments or variants thereof.

1.16. "**Confidential Information**" of a Party means information relating to the business, operations or products of such Party or any of its Affiliates, including any Know-How, marketing plans, strategies, customer lists, or other information that such Party discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party or Affiliate in oral, written, graphic, or electronic form. For purposes of this Agreement, confidential information of the Initial Licensor shall be Confidential Information of Licensor. For clarity, such confidential information of the Initial Licensor may be subject to additional restrictions based on the Initial License Agreement; *provided* that Licensor identifies in writing such confidential information of the Initial Licensor to Licensee. For the avoidance of doubt, the Development Plan and any updates thereto shall be considered the Confidential Information of Licensee.

1.17. "**Controlled**" means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that the Person or one of its Affiliates owns or has a license or sublicense to such right, item, or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such right, item or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party, in particular such Third Party that has assigned or licensed such Patent Rights, Know-How or material to such Party (or any Affiliate of such Party). For the avoidance of doubt, Licensor shall not be deemed to "Control" any Patent Rights, Know-How or material owned by a Third Party (including, for greater clarity, the Initial Licensor) for which Licensor or any of its Licensor Affiliates have no rights to license or sublicense any rights under such Patent Rights, Know-How or material to Licensee in accordance with the terms herein.

1.18. "**Cover**" means, with respect to any claim of any Patent Right and product in any jurisdiction, that such claim would be infringed, absent a license granted under such Patent Right, by the Development, Manufacture, distribution, offering for sale, sale, importation, exportation or other Commercialization of such product (or any element thereof) in such jurisdiction; *provided* that in determining whether a claim of a pending Patent application would be infringed, it shall be treated as if issued in the form then being prosecuted. "**Covered**" and "**Covering**" have correlative meanings.

1.19. "**Data Protection Law**" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data, and repealing Directive 95/46/EC (the "**GDPR**") as well as, to the extent applicable, any other data protection laws of the country in which Licensee is established and any other data protection laws applicable to Licensee in connection with this Agreement.

1.20. "**Development**" means, with respect to a compound or product, the performance of all pre-clinical and clinical development, including toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis, Clinical Trials (excluding Clinical Trials conducted after Regulatory Approval for such compound or product), manufacturing and regulatory activities that are required to obtain Regulatory Approval for such compound or product in the Territory under this Agreement, and interacting with Regulatory Authorities regarding the foregoing. For the avoidance of doubt, Development shall include all research activities. When used as a verb, "**Develop**", "**Developed**", or "**Developing**" means to engage in Development.

1.21. "**Drug Product**" means the final formulation containing Drug Substance filled in naked syringes for use in Clinical Trials.

1.22. "**Drug Substance**" means the drug substance required for the manufacturing of the drug product form of the Licensed Products, which is on stock at Licensor on the Effective Date.

1.23. "**EMA**" means the European Medicines Agency, or any successor agency thereto.

1.24. "**Equity Documentation**" means the investment agreement between certain investors, the Licensor, the founders of the Licensee and the Licensee, dated on or around the date hereof and the share purchase agreement between the Licensee and the Licensor dated on or around the date hereof.

1.25. "**EU**" or "**European Union**" means the European Union, as its membership may be altered from time to time, and any successor thereto.

1.26. "**European Commission**" means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

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

1.28. "**Field**" means the diagnosis, treatment, palliation, or prevention of any disease or condition in humans or animals.

1.29. "**First Commercial Sale**" means, with respect to any Licensed Product in a country in the Territory, the first sale or commercial transfer or disposition for value of the Licensed Product to a Third Party by Licensee or its Affiliates in such country after Regulatory Approval of such Licensed Product has been granted in such country, or such sale is otherwise permitted, by the applicable Regulatory Authority of such country; *provided* that any sale, transfer or disposition of the type described in the last paragraph of Section 1.61 shall not constitute a First Commercial Sale.

1.30. "**FTE**" means one thousand six hundred (1600) hours of work per annum devoted to the specified activities that are carried out by one or more qualified professional employees of Licensor or its Affiliates, such as scientists, research and manufacturing staff, quality control and assurance personnel, technicians or the like, but excluding non-technical, non-professional personnel such as secretarial or administrative staff.

1.31. "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or the equivalent laws in any country or jurisdiction within the Territory, each as may be amended and applicable from time to time.

1.32. "**GMP**" means all applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time.

1.33. "**Governmental Body**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.34. "**ICC**" means the International Chamber of Commerce.

1.35. "**IFRS**" or "**International Financial Reporting Standards**" means the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board ("**IASB**") and the International Financial Reporting Interpretations Committee ("**IFRIC**"), as such accounting standards may be amended from time to time.

1.36. "**IND**" means an investigational new drug application filed with the FDA for approval to commence Clinical Trials or the equivalent application or filing filed with any equivalent agency or Governmental Body outside the United States (including any supra-national entity such as in the European Union) for approval to commence Clinical Trials in such jurisdiction, and including all regulations at 21 U.S. C.F.R. § 312 et seq. and equivalent foreign regulations.

1.37. "**Indication**" means a separate and distinct disease or medical condition, a significant manifestation of a disease or medical condition, or symptoms associated with a disease or medical condition, or a risk for a disease or medical condition; *provided* that an Indication is only distinct from another Indication if the diseases associated with such Indications are (a) listed in two different blocks of the ICD-10 or any successor publication (by way of example, any neoplasm under C15 is in a different block from any neoplasm under block C16, whereas C15.0 and C15.1 belong to the same block) and (b) studied by Licensee or any of its Affiliates or Sublicensees under separate Clinical Trials; *provided further*, that, notwithstanding the foregoing, psoriatic arthritis, ankylosing spondylitis and hidradenitis suppurativa shall be separate Indications.

1.38. "**Initial License Agreement**" means the Agreement for Joint Discovery and Development by and between Initial Licensor and Licensor, dated September 3, 2008.

1.39. "**Initial Licensor**" means Ablynx N.V., Belgium.

1.40. "**Initial Project**" means the Anti-IL17A/F Nanobody project pursued by Initial Licensor and Licensor together which led to the development of M1095.

1.41. "**Initiation**" or **"Initiate"** means, when used with respect to any Clinical Trial, the first dosing of the first patient in such Clinical Trial.

1.42. "**Inlicensed Know-How**" means any and all Know-How owned or Controlled by the Initial Licensor and licensed or sublicensed to Licensor or any Licensor Affiliate as of the Effective Date or at any time during the Term that is necessary or useful for the Development, Manufacture, use, or Commercialization of any Compound or Licensed Product.

1.43. "**Inlicensed Patents**" means any and all Patent Rights that are owned or Controlled by the Initial Licensor and licensed or sublicensed to Licensor or any Licensor Affiliate as of the Effective Date or at any time during the Term, that contain one or more Pending Claims and/or Valid Claims that, but for the license granted under such Patent Rights, would be infringed by the Development or Commercialization of any Compound or Licensed Product.

1.44. "**Inlicensed Technology**" means the Inlicensed Know-How and Inlicensed Patents.

1.45. "**Intellectual Property**" means any and all intellectual property and similar proprietary rights in any jurisdiction throughout the world, including any and all of the following: (a) Patent Rights, (b) trademarks, trade names, trade dress, certification marks, domain names, logos, and service marks, including all registrations and applications for registration of, and all goodwill associated with, any of the foregoing, (c) copyrights and registrations and applications for registration thereof and (d) Know-How.

1.46. "**Know-How**" means any and all: (a) scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specification and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of Development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application; and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material, including drug substance samples, intermediates of drug substance samples, drug product samples and intermediates of drug product samples. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, or a development relating to the item, is (and remains) not known to the public. "Know-How" includes any rights including copyright, database or design rights protecting such Know-How. "Know-How" excludes Patent Rights.

1.47. "**Knowledge**" means, with respect to a matter that is the subject of a given representation or warranty of Licensor, the actual knowledge, information or belief of the officers and directors of Licensor listed on Schedule 1.47 based on such individuals' good faith understanding of the facts and information in their possession or control following reasonable inquiry as to such facts and information. "**Knowingly**" means with Knowledge.

1.48. "**Licensed Product**" means any pharmaceutical or biological product, including any form, presentation, dosage form or formulation thereof, that contains or comprises, in whole or in part, any Compound as an active ingredient (either as the sole active ingredient or in combination with one or more other active ingredients). For clarity, different forms, presentations, formulations or dosage strengths of a given Licensed Product shall be considered the same Licensed Product for purposes of this Agreement.

1.49. "**Licensor Affiliate**" means any Affiliate of Licensor that is part of Merck KGaA's healthcare sector. In no event shall Licensor Affiliate be construed to include Merck KGaA's life sciences sector (operating in the United States as EMD Millipore and MilliporeSigma) or Merck KGaA's electronics sector (formerly referred to as Performance Materials).

1.50. "**Licensor Exclusive Know-How**" means any and all Know-How that is owned or Controlled by Licensor or any Licensor Affiliate as of the Effective Date and at any time during the Term that is necessary or useful in the Development, Manufacture, use, or Commercialization of any Compound or Licensed Product and specifically related to any Compound and not applicable to other compounds or drugs. The Know-How to be set forth in the Transfer Plan will, to Licensor's Knowledge, constitute all of such Know-How owned or Controlled by Licensor or any Licensor Affiliate as of the Effective Date.

1.51. "**Licensor Know-How**" means Licensor Exclusive Know-How and Licensor Non-Exclusive Know-How.

1.52. "**Licensor Materials**" means any and all chemical, biological or physical materials that are owned or Controlled by Licensor or any Licensor Affiliate as of the Effective Date and that are necessary or useful for the Development, Manufacture, use or Commercialization of any Compound or Licensed Product.

1.53. "**Licensor Non-Exclusive Know-How**" means any and all Know-How that is owned or Controlled by Licensor or any Licensor Affiliate at any time during the Term and that is necessary or useful in the Development, Manufacture, use, or Commercialization of any Compound or Licensed Product, excluding Licensor Exclusive Know-How.

1.54. "**Licensor Non-Exclusive Patents**" means any and all Patent Rights that are owned or Controlled by Licensor or any Licensor Affiliate during the Term and that Cover any Licensed Product or Compound or that are necessary for the Development, Manufacture, use, or Commercialization of any Compound or Licensed Product, excluding Licensor Patents.

1.55. "**Licensor Patents**" means any and all Patent Rights that are owned or Controlled by Licensor or any Licensor Affiliate (a) as of the Effective Date and that Cover any Licensed Product or Compound or that are necessary for the Development, Manufacture, use, or Commercialization of any Compound or Licensed Product, including the Patent Rights set forth on Schedule 1.55, or (b) during the Term to the extent that such Patent Rights specifically Cover the composition of matter, formulation, methods of manufacturing or methods of using any Licensed Product or Compound and do not Cover the composition of matter, formulation, methods of manufacturing or methods of using any other product or compound.

1.56. "**Licensor Technology**" means the Licensor Know-How, the Licensor Patents and the Licensor Materials, collectively.

1.57. "**Major Market**" means each of Japan, Germany, France, Italy, the United Kingdom, Spain and the United States of America.

1.58. "**Manufacture**" means all activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, and storage of a product, or any components thereof, manufacture of preclinical, clinical and commercial supply, product characterization, quality assurance and quality control development, testing and release, and interacting with Regulatory Authorities regarding the foregoing.

1.59. "**Manufacturing Quality Agreement**" means the quality assurance agreement mutually agreed upon in writing by the Parties, which shall outline the Parties' respective responsibilities on quality matters, being entered into by the Parties in conjunction herewith prior to the delivery of Drug Product by Licensor or any of its Affiliates to Licensee, covering all quality assurance agreements being entered into by the Parties in conjunction with manufacturing of the Drug Product by Licensor.

1.60. "**NDA**" means a New Drug Application filed pursuant to the requirements of the FDA, as more fully defined in 21 U.S. C.F.R. § 314.3 et seq., a Biologics License Application filed pursuant to the requirements of the FDA, as more fully defined in 21 U.S. C.F.R. § 601, and any equivalent application submitted in any country in the Territory, including all additions, deletions or supplements thereto, and as any and all such requirements may be amended, or supplanted, at any time.

1.61. "**Net Sales**" means the gross amounts invoiced by Licensee, its Affiliates and/or its Sublicensees for sales in an arm's length transaction of a Licensed Product to independent or unaffiliated Third-Party purchasers (other than a Sublicensee for such Licensed Product) of such Licensed Product, less the following deductions with respect to such sales to the extent that such amounts are either included in the billing as a line item as part of the gross amount invoiced, or otherwise permitted by Accounting Standards to be specifically attributable to actual sales of a Licensed Product and where such deductions have actually been taken, have been paid for, or have accrued in respect of the amount invoiced: [***].

In the event that a Licensed Product under this Agreement is sold as a Combination Product ("**Combination Sale**"), then Net Sales for such Combination Product shall be calculated separately for each Calendar Quarter and shall be the portion of such Combination Sale allocable to the Licensed Product included in such Combination Product determined as follows:

Except as provided below, the Net Sales amount for a Combination Sale shall equal the gross amount invoiced for the Combination Sale, reduced by the deductions permitted under (a) to (g) above) (the "**Net Combination Sale Amount**"), multiplied by the fraction A/(A+B), where:

A is the invoice price in that Calendar Quarter, in the country where such Combination Sale occurs, of the Licensed Product contained in the Combination Product, if sold as a separate Licensed Product in such country by Licensee or its Affiliates and **B** is the aggregate of the invoice price or prices, in that Calendar Quarter and in such country, of such other active ingredients/components, as the case may be, included in the Combination Product if sold separately in such country by Licensee or its Affiliates, as applicable.

Where the calculation of Net Sales resulting from a Combination Sale (including the determination of the invoice price) in a country cannot be determined by the foregoing method, the calculation of Net Sales for such Combination Sale shall be that portion of the Net Combination Sale Amount reasonably determined on a country-by-country basis by mutual written agreement of the Parties in good faith taking into account the relevant value of the Licensed Product and the other ingredient or component included in the Combination Product, as reflected in their respective market prices. In case no such agreement can be found, an independent expert agreed upon in writing by both Parties, or failing such agreement, the ICC by way of ad hoc expert proceedings, shall determine such relative value contributions and such determination shall be final and binding upon the Parties (it being understood that the expert appointed in such ICC ad hoc expert proceedings shall be appointed by the ICC International Centre for ADR in accordance with the Rules for the Appointment of Experts and Neutrals of the ICC).

In the event a Licensed Product is "bundled" for sale together with one or more other products in a country (a "**Product Bundle**"), then Net Sales for such Licensed Product shall be the portion of the gross amount invoiced for the sale of the Product Bundle by Licensee or its Affiliates or its Sublicensees (less the deductions permitted under (a) to (g) above) allocable to the Licensed Product, which portion shall be determined based on the list price of the Licensed Product when sold as a separate Licensed Product in such country relative to the list price of the other product(s) in the Product Bundle or group of products when those other product(s) are sold as separate product(s) in such country. Where such portion cannot be calculated in a country by the foregoing method because one of the products in the bundle or group of products is not sold separately in such country or the list price for the Licensed Product and/or other product(s) cannot be reasonably determined, then the calculation of Net Sales for the Licensed Product in such Product Bundle shall be that portion of the gross amount invoiced for the sale of the Product Bundle or group of products (less the deductions permitted under (a) to (g) above) reasonably determined in good faith by mutual written agreement of the Parties, and where no such agreement can be found, an independent expert agreed upon in writing by both Parties, or failing such agreement, the ICC by way of ad hoc expert proceedings, shall determine the value of the Licensed Product included in the Product Bundle or group of products, and such determination shall be final and binding upon the Parties (it being understood that the expert appointed in such ICC ad hoc expert proceedings shall be appointed by the ICC International Centre for ADR in accordance with the Rules for the Appointment of Experts and Neutrals of the ICC).

For clarification, sale of a Licensed Product by Licensee, its Affiliates and/or its Sublicensees to another of these entities for resale by such entity to a Third Party (other than a Sublicensee for such Licensed Product) shall not be deemed a sale for purposes of this definition of "Net Sales" hereunder and such sales shall not constitute a "First Commercial Sale". Further, transfers or dispositions of a Licensed Product (i) in connection with patient assistance programs, (ii) for charitable or promotional purposes, (iii) for preclinical, clinical, regulatory or governmental purposes or under so-called "named patient" or other limited access programs, or (iv) for use in any tests or studies reasonably necessary to comply with any Applicable Laws, regulation or request by a Regulatory Authority, shall not, in each case of clauses (i)-(iv), be deemed sales of such Licensed Product for purposes of this definition of "Net Sales" and such sales shall not constitute a First Commercial Sale.

1.62. "**Out-of-Pocket Costs**" means, with respect to Licensor, reasonable, documented costs and expenses paid by Licensor to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards), other than employees of Licensor or its Affiliates. For clarity, all reasonable, documented fees due by Licensor to any contract service provider shall be understood as included in the definition of Out-of-Pocket Costs.

1.63. "**Patent Right(s)**" means any and all (a) national, regional and international patents and patent applications, including provisional patent applications, (b) patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)) and (e) rights to claim priority to any of the foregoing.

1.64. "**Pending Claim**" means a patent claim of a pending patent application which claim (i) has not been cancelled, withdrawn, abandoned or refused by a court or other Governmental Body of competent jurisdiction in a final decision from which no appeal can be or has been taken and (ii) has not been pending for more than [***] from the filing date of the first priority application that has been invoked for such patent application that contains such claim (or if no such priority has been invoked, from the filing date of such patent application). It is understood that any claim that has been pending for more than the period of [***] referred to in the previous sentence shall not be considered a Pending Claim for the purposes of this Agreement. Notwithstanding anything to the contrary in this Agreement, it is agreed between the Parties that a claim of a pending patent application shall not be deemed a Pending Claim for the purposes of this Agreement if it is directed to obviously unpatentable subject matter (for example, either because of statutory unpatentability or unpatentability over relevant prior art). Should a dispute arise on the patentability of any subject matter of a claim according to the preceding sentence, this dispute shall be finally settled by binding expert determination, the expert being a renowned independent patent attorney nominated by Licensor and acceptable to Licensee, which patent attorney must not be a former employee of either Party and must not have been involved in any services for either Party before said arbitration. If the Parties fail to agree on an expert, such a dispute shall be finally settled by the ICC by way of ad hoc expert proceedings, and such resolution shall be final and binding upon the Parties (it being understood that the expert appointed in such ICC ad hoc expert proceedings shall be appointed by the ICC International Centre for ADR in accordance with the Rules for the Appointment of Experts and Neutrals of the ICC). Irrespective of the outcome of such expert determination, the cost of such independent patent attorney shall be shared between the Parties on [***] basis.

1.65. "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.66. "**Personal Data**" means any information relating to an identified or identifiable natural person as defined in the GDPR.

1.67. "**Phase I Trial**" means a Clinical Trial in which the Licensed Product is administered to human subjects at multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamic properties of the Licensed Product, and which is consistent with 21 U.S. CFR § 312.21(a).

1.68. "**Phase II Trial**" means a Clinical Trial of the Licensed Product in human patients, the principal purposes of which are to make a preliminary determination that the Licensed Product is safe for its intended use, to determine its optimal dose, and to obtain sufficient information about the Licensed Product's efficacy to permit the design of Phase III Trials, and which is consistent with 21 U.S. CFR § 312.21(b).

1.69. "**Phase III Trial**" means a pivotal Clinical Trial of any Licensed Product, with a defined dose or a set of defined doses, which trial is designed to ascertain efficacy and safety of such compound or product for the purpose of enabling the preparation and submission of an NDA with the FDA or other applicable Regulatory Authority, and which is consistent with 21 U.S. C.F.R. § 312.21(c).

1.70. "**PMDA**" means the Japanese Pharmaceutical and Medical Device Agency or its successor.

1.71. "**Product Specifications**" means the product quality specifications applicable to the Drug Substance and Drug Product, which are substantially similar to those used by Licensor for Drug Substance and Drug Product prior to the Effective Date. As between the Parties, such specifications will be set forth in the Manufacturing Quality Agreement. Any change to such specifications must be mutually agreed in writing between the Parties in accordance with the rules set forth in such Manufacturing Quality Agreement.

1.72. "**RCT**" means Research Corporation Technologies, Inc. (Delaware).

1.73. "**RCT Know-How**" means any and all Know-How owned or Controlled by RCT and licensed or sublicensed to Licensor or any Licensor Affiliate as of the Effective Date or at any time during the Term that is necessary or useful for the Development, Manufacture, use, or Commercialization of any Compound or Licensed Product.

1.74. "**RCT Patents**" means any and all Patent Rights that are owned or Controlled by RCT and licensed or sublicensed to Licensor or any Licensor Affiliate as of the Effective Date or at any time during the Term, that Cover any Licensed Product or Compound or are otherwise necessary for the Development, Manufacture, use or Commercialization of any Compound or Licensed Product.

1.75. "**Regulatory Approval**" means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority necessary for the Development, Manufacture or Commercialization of a Licensed Product in a particular country or jurisdiction.

1.76. "**Regulatory Authority**" means (a) in the United States, the FDA, (b) in the European Union, the EMA or the European Commission, (c) in Japan, the PMDA or (d) any Governmental Body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.

1.77. "**Regulatory Filing**" means, with respect to any Licensed Product, the submission of any NDA for such Licensed Product to an applicable Regulatory Authority in any country by Licensee.

1.78. "**Regulatory Filing Acceptance**" means, with respect to any NDA and any country, the receipt by Licensee or any of its Affiliates or Sublicensees of written notice from the relevant Regulatory Authority in such country that such NDA has met all the criteria for filing acceptance under Applicable Law.

1.79. "**Sublicensee**" means a Person other than an Affiliate of Licensee to which Licensee (or its Affiliate) has, pursuant to Section 2.1(c), granted sublicense rights under any of the license rights granted under Sections 2.1(a) or 2.1(b), but excluding any compulsory sublicensees or compulsory licensees. "**Sublicense**" shall be construed accordingly.

1.80. "**Successful Completion**" means, with respect to any Clinical Trial of any Licensed Product, the completion of such Clinical Trial where such Licensed Product achieved the intended primary endpoint established at the beginning of such Clinical Trial with a favourable medical benefit/risk balance (including considering any serious adverse medical events), allowing further Development or Commercialization, as applicable, of such Licensed Product.

1.81. "**Supply Costs**" means the actual fully-loaded cost to Licensor or its Affiliates for the Manufacture of Compounds or Licensed Products (in particular turning Drug Substance to Drug Product), calculated using a methodology consistently applied by Licensor and consistent with Accounting Standards, plus a mark-up of [***].

1.82. "**Tax**" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

1.83. "**Territory**" means all the countries in the world.

1.84. "**Third Party**" means any Person that is not a Party or an Affiliate of a Party.

1.85. "**Third-Party License Agreement**" means any agreement entered into by a Party or its Affiliate with a Third Party, or any amendment or supplement thereto, in each case following the Effective Date, whereby royalties, fees or other payments are to be made by a Party or its Affiliate to such Third Party in connection with the grant of rights under Intellectual Property rights owned or controlled by such Third Party, which rights are reasonably necessary or useful to Develop, Manufacture, have made, import, export, use or Commercialize any Compounds or Licensed Product.

1.86. "**UK MHRA**" means the United Kingdom Medicines and Healthcare products Regulatory Agency.

1.87. **"Underlying GMP License**" means that certain license agreement between Licensor and RCT relating to a GMP manufacturing process for using a strain of *Pichia pastoris*.

1.88. "**United Kingdom**" means the United Kingdom of Great Britain and Northern Ireland.

1.89. "**United States**" or "**U.S.**" means the United States of America and its territories and possessions, including Puerto Rico.

1.90. "**U.S. GAAP**" means generally accepted accounting principles in the United States.

1.91. "**Valid Claim**" means a claim in an unexpired and issued Patent Right, which claim has not been disclaimed, revoked or held invalid or unenforceable by a final nonappealable decision of a court or other Governmental Body of competent jurisdiction.

1.92. **Other Terms**. The definition of each of the following terms is set forth in the section or part of this Agreement indicated below:

"**Achieved Commercial Milestone**" has the meaning set forth in Section 4.4(c)(iii).

"**Acquired Competing Biologic Product"** has the meaning set forth in Section 1.14.

"**Action**" has the meaning set forth in Section 5.4(b).

"**Agreement**" has the meaning set forth in the first and opening paragraph of this Agreement.

"**Alliance Manager**" has the meaning set forth in Section 11.3.

"**Allowed Deductions**" has the meaning set forth in Section 4.5(c).

"**Auditor**" has the meaning set forth in Section 4.7.

"**Combination Sale**" has the meaning set forth in Section 1.61.

"**Commercial Milestone Event**" has the meaning set forth in Section 4.4(a).

"**Controlling Party**" has the meaning set forth in Section 5.5(c).

"**Development Plan**" has the meaning set forth in Section 3.1(b).

"**Diligence Obligations**" has the meaning set forth in Section 3.5.

"**Dispute**" has the meaning set forth in Section 11.11(a).

"**Effective Date**" has the meaning set forth in the first and opening paragraph of this Agreement.

"**Excluded Claim**" has the meaning set forth in Section 11.11(e).

"**Extension Payment**" has the meaning set forth in Section 3.5.

"**GDPR**" has the meaning set forth in Section 1.19.

"**Licensor's Equity Consideration**" has the meaning set forth in Section 4.2.

"**ICC Rules**" has the meaning set forth in Section 11.11(a).

"**Improper Conduct**" has the meaning set forth in Section 3.8.

"**Indemnified Party**" has the meaning set forth in Section 8.3.

"**Indemnifying Party**" has the meaning set forth in Section 8.3.

"**Initial Response**" has the meaning set forth in Section 3.1(d).

"**Initial Response Period**" has the meaning set forth in Section 3.1(d).

"**Licensee**" has the meaning set forth in the first and opening paragraph of this Agreement.

"**Licensee Indemnitees**" has the meaning set forth in Section 8.1.

"**Licensee Patents**" has the meaning set forth in Section 5.2.

"**Licensor**" has the meaning set forth in the first and opening paragraph of this Agreement.

"**Licensor Indemnitees**" has the meaning set forth in Section 8.2.

"**Losses**" has the meaning set forth in Section 8.1.

"**Manufacturing Technology Transfer Plan**" has the meaning set forth in Section 2.2(d).

"**Milestone Event**" has the meaning set forth in Section 4.3.

"**Milestone Event #1**" has the meaning set forth in Section 4.3.

"**Milestone Event #2**" has the meaning set forth in Section 4.3.

"**Milestone Event #6**" has the meaning set forth in Section 4.3.

"**Milestone Event #7**" has the meaning set forth in Section 4.3.

"**Milestone Event #8**" has the meaning set forth in Section 4.3.

"**Milestone Payment**" has the meaning set forth in Section 4.3.

"**Partnering Notice**" has the meaning set forth in Section 3.1(d).

"**Parties**" has the meaning set forth in the first and opening paragraph of this Agreement.

"**Party**" has the meaning set forth in the first and opening paragraph of this Agreement.

"**Patent Challenge**" has the meaning set forth in Section 9.6.

"**Product Bundle**" has the meaning set forth in Section 1.61.

"**ROFN Period**" has the meaning set forth in Section 3.1(d).

"**ROFN Rights**" has the meaning set forth in Section 3.1(d).

"**Royalty Term**" has the meaning set forth in Section 4.5(h).

"**Senior Executives**" are defined in Section 10.2.

"**Tax Credit**" has the meaning set forth in Section 4.8.

"**Term**" has the meaning set forth in Section 9.1.

"**Third-Party Action**" has the meaning set forth in Section 5.5(a).

"**Transfer Plan**" has the meaning set forth in Section 2.2(c).

"**Transition Committee**" has the meaning set forth in Section 2.2(b).

"**Upfront Payment**" has the meaning set forth in Section 4.1.

"**Withholding Tax**" has the meaning set forth in Section 4.8.

ARTICLE 2 - GRANT OF LICENSE

2.1. **Grant of License**.

(a) **Exclusive License**. Subject to the terms and conditions of this Agreement (and expressly conditional upon receipt by Licensor of the (partial) consideration set forth in Section 4.1), Licensor hereby grants to Licensee a royalty- and milestone-bearing exclusive (even as to Licensor), sublicensable (to the extent set forth in Section 2.1(c)), right and license under the Licensor Patents, Licensor Materials and the Licensor Exclusive Know-How to Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, export and import and otherwise Commercialize the Compounds and Licensed Products in the Field in the Territory.

(b) **Non-Exclusive License**. Subject to the terms and conditions of this Agreement (and expressly conditional upon receipt by Licensor of the (partial) consideration set forth in Section 4.1), Licensor hereby grants to Licensee a royalty- and milestone-bearing non-exclusive, sublicensable (to the extent set forth in Section 2.1(c)), right and license under the Inlicensed Patents, Licensor Non-Exclusive Patents, Inlicensed Know-How, the RCT Patents, the RCT Know-How and the Licensor Non-Exclusive Know-How to Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, export and import and otherwise Commercialize the Compounds and Licensed Products in the Field in the Territory.

(c) **Sublicenses**. Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant to Third Parties, through one (1) or more tiers, sublicenses under the licenses and sublicenses granted by Licensor to Licensee under Sections 2.1(a) and 2.1(b); *provided*, that: (i) each Sublicense agreement shall be consistent with the terms and conditions of this Agreement; (ii) Licensee shall remain responsible for the performance of all of its Sublicensees under such Sublicense agreements to the same extent as if such activities were conducted by Licensee, and shall remain responsible for any payments due hereunder with respect to activities of any Sublicensees; and (iii) Licensee shall ensure that its Sublicensees comply with the terms and conditions of this Agreement; *provided further* that Licensor shall not terminate this Agreement for any act or omission of any such Sublicensees that constitutes a breach of this Agreement if Licensee terminates such Sublicensee's applicable sublicense agreement within [***] of becoming aware of such act or omission or if such breach is cured in accordance with Section 9.4. Licensee shall provide notice to Licensor of any Sublicense entered into, and, upon request, Licensee shall provide Licensor with a copy of each such executed Sublicense agreement; *provided*, that Licensee may redact from each such Sublicense agreement all (x) financial terms and (y) other provisions that are not relevant to Licensee's performance hereunder.

(d) **Obligations**. The rights and sublicenses granted to Licensee under Section 2.1(b) with respect to Inlicensed Patents, and Inlicensed Know-How are subject to the scope, obligations and limitations of the Initial License Agreement that are binding on Licensor. Inlicensed Technology is subject to specific restrictions under the Initial License Agreement and those restrictions shall apply accordingly to this Agreement, *mutatis mutandis*. For the avoidance of doubt, it is agreed between the Parties that, notwithstanding anything to the contrary in Section 2.1(b) of this Agreement, the rights and sublicenses granted under Section 2.1(b) are subject to Licensee's compliance with Sections 23.2, 13.3, 13.4, 14.2, 15.2, 15.3, 15.4, 18.2 to 18.4, 29.10, 29.11, 29.12, 33.1, and 37.22(f) and (h)-(l), and Article 31 as set forth under Section 26.2 under the Initial License Agreement. Licensor is required under Section 26.2 of the Initial License Agreement to include the right of Initial Licensor to invoke the following Sections of the Initial License Agreement directly against Licensee: Sections 11.5, 13.3, 13.4, 14.2, 15.2 to 15.4, 18.2 to 18.4, 21.3, 37.22(f), (h)-(l), and the last sentence of 37.25. Further, Licensor is required to inform Initial Licensor about the identity of Licensee and allow independent counsel review of this Agreement for Initial Licensor as further set forth below in Section 6.1.

2.2. **Technology Transfer**.

(a) **Overview.** Subject to the terms of this Agreement, Licensor shall make available to Licensee the Licensor Know-How, Inlicensed Know-How and Licensor Materials as of the Effective Date, whereby such transfer shall be in accordance with a Transfer Plan in an orderly fashion and in a manner mutually agreed in writing by the Parties, which shall take into account the value, usefulness and confidentiality of the transferred Licensor Technology and Inlicensed Know-How. In conjunction with the transfer of Personal Data, as applicable, Licensee and Licensor will enter into a data transfer agreement to the extent required to comply with Data Protection Law.

(b) **Transition Committee.** Within [***] following the Effective Date, the Parties will establish a committee to manage the transition of the Compounds and Licensed Products to Licensee (the "**Transition Committee**"), that meets on a regularly scheduled basis to: (i) lead the generation of a Transfer Plan and Manufacturing Technology Transfer Plan and (ii) oversee and coordinate activities related to the transfer set forth in the Transfer Plan and the Manufacturing Technology Transfer Plan. Each Party will nominate [***] to the Transition Committee, who possess a general understanding of research, development, regulatory and manufacturing matters to act as its representatives and provide written notice thereof to the other Party. The Transition Committee shall remain in existence until the completion of the technology transfer set forth in the Transfer Plan. Any disputes among the Transition Committee shall be resolved in accordance with ARTICLE 10.

(c) **Transfer Plan**. Within [***] following the Effective Date, the Parties shall mutually agree, under the lead of the Transition Committee, on a documented transfer plan (the "**Transfer Plan**") to transfer to Licensee the Licensor Know-How, Inlicensed Know-How and Licensor Materials in the possession and under Control of Licensor, any Licensor Affiliates, or Third Party contractors. An outline of key building blocks, to be reflected in the Transfer Plan, is attached to this Agreement as Schedule 2.2. With respect to any Licensor Know-How, Inlicensed Know-How or Licensor Materials which are not in the possession of Licensor but are in the possession of Third Party contractors, if requested by Licensee, Licensor shall as promptly as reasonably practicable execute one or more letters of authorization to permit such Third Party contractors to disclose and transfer such Licensor Know-How, Inlicensed Know-How and Licensor Materials to Licensee as part of the Transfer Plan. The Transfer Plan shall include (i) a detailed listing of the Licensor Know-How, Inlicensed Know-How and Licensor Materials to be transferred to Licensee, (ii) mutual understanding on a detailed description of the required infrastructure to facilitate the transfer contemplated in such Transfer Plan, including the transfer of the Licensor Know-How, Inlicensed Know-How and Licensor Materials (such as information technology platforms, storage facilities, and means of transfer or transport), (iii) a reasonably detailed timeframe for the transfer of the Licensor Know-How, Inlicensed Know-How and Licensor Material to Licensee, and (iv) estimated budget for the contemplated technology transfer. For clarity, such activities to be undertaken by Licensor and to be set forth in the Transfer Plan comprise, but are not limited to: transferring (A) the Licensor Know-How and Inlicensed Know-How and providing support therefor, (B) all correspondence, submissions, filings or other documentation of communication with any Regulatory Authority and support therefor, (C) all Licensor Materials, (D) digital copies of the materials in the virtual data room set up by or on behalf of Licensor relating to the subject matter hereunder, and (E) all clinical and pre-clinical data owned or Controlled by Licensor or any of its Affiliates for the Compounds or Licensed Products. It is the understanding of both Parties that (1) the transfer shall be completed within a timeframe of [***] following the approval of the Transfer Plan by the Transition Committee, or such longer timeframe as may be mutually agreed in writing by the Parties, and (2) if, following the completion of the transfer, Licensee reasonably requests additional materials comprised in the Licensor Materials (but not yet transferred) that are necessary for Licensee's performance of the Development Plan, Licensor shall provide such additional materials as promptly as reasonably practicable.

(d) **Manufacturing Technology Transfer.** Further, within [***] following the Effective Date, a plan describing the transfer of the Manufacturing technology, including analytical methods, Drug Product Manufacturing processes will be agreed in writing by the Parties (the "**Manufacturing Technology Transfer Plan**"). An outline of key building blocks, to be reflected in the Manufacturing Technology Transfer Plan, is attached to this Agreement as Schedule 2.2. The transfer process for the Manufacturing technology, including timelines, activities and the extent of support needed, shall be detailed within the Manufacturing Technology Transfer Plan.

2.3. **Technology Transfer Cost Reimbursement**.

(a) Licensor will provide reasonable support and assistance to Licensee during the technology transfer set forth in the Transfer Plan and Manufacturing Technology Transfer Plan (such amount of support to be specified in the Transfer Plan and Manufacturing Technology Transfer Plan). Such support to be provided by Licensor will include access to appropriate specified Licensor employees for a maximum of [***] after the Effective Date or such longer timeframe as may be mutually agreed in writing by the Parties. Licensee will reimburse Licensor for any reasonable Out-of-Pocket Costs and internal FTE hours based on a rate of [***] per hour for each FTE hour; *provided* that the first [***] hours of such support shall be provided at no cost to Licensee. Contemporaneously with the completion of drafting the Transfer Plan and the Manufacturing Technology Transfer Plan, Licensor shall provide Licensee with a reasonably detailed, good faith estimate of the time and costs expected to be incurred by Licensor for activities outlined under the Transfer Plan and the Manufacturing Technology Transfer Plan, and Licensor will periodically, prior to the start of each Calendar Quarter during which the Parties are conducting activities under the Transfer Plan and the Manufacturing Technology Transfer Plan (as applicable), provide Licensee with updates to such estimate. If Licensor anticipates that the costs to be incurred by Licensor during any Calendar Quarter will exceed the aggregate estimated cost of such activities in such good faith estimate by more than [***] of the relevant aggregate Calendar Quarter cost estimate, Licensor will promptly notify Licensee, provide an updated estimate and discuss the relevant factors leading to such anticipated excess costs in the Transition Committee.

(b) Licensor will invoice Licensee within thirty (30) days after the end of each Calendar Quarter for all FTE costs, Supply Costs, and Out-of-Pocket Costs incurred by Licensor or its Affiliates in such Calendar Quarter for activities outlined under the Transfer Plan. Licensor shall use Commercially Reasonable Efforts to execute Licensor's activities under the Transfer Plan in a cost-efficient manner, and any costs incurred by Licensor in excess of the budgets outlined in the Transfer Plan will require unanimous written consent by the Transition Committee. Subject to Section 2.3(a), Licensee will pay such invoices within thirty (30) days after receipt thereof.

ARTICLE 3 - DEVELOPMENT AND COMMERCIALIZATION

3.1. **Development of Licensed Product by Licensee**.

(a) In accordance with the terms of this Agreement, as between the Parties, Licensee shall have the exclusive right and responsibility to Develop Licensed Products and to conduct (either itself or through its Affiliates, agents, subcontractors or Sublicensees) all Clinical Trials and non-clinical studies Licensee believes appropriate to obtain Regulatory Approval for the Licensed Products in any Indication in the Territory.

(b) Subject to the terms and conditions of this Agreement (including Section 3.5), the Development of each Licensed Product shall be in accordance with the development plan attached hereto as Schedule 3.1(b) (the "**Development Plan**"). The Development Plan will describe the proposed overall program of Development, the Development assumptions, Development steps and personnel allocation of Licensee for Licensed Products in the initial target indications of Psoriatic Arthritis, Ankylosing Spondylitis and Hidradenitis Suppurativa, and shall in particular include a clinical development plan that outlines any contemplated Clinical Trial (including estimated timelines and milestones, treatment arms, primary and secondary endpoints and estimated number of patients per study) to be undertaken by Licensee to obtain Regulatory Approval in the Major Markets.

(c) Licensee shall provide Licensor with bi-annual updates to the Development Plan, in the first quarter of each Calendar Year, and such updates shall take into account the progress and status of Development in any Indication, in particular the completion or cessation of Development activities or commencement of new Development activities.

(d) The first time that Licensee determines that it intends to grant license rights to a Third Party partner for the Development or Commercialization of a Licensed Product for the treatment of Multiple Sclerosis (such rights to Develop or Commercialize, the "**ROFN Rights**"), Licensee shall notify Licensor in writing as promptly as reasonably practicable (the "**Partnering Notice**"). Within [***] after receiving the Partnering Notice (the "**Initial Response Period**"), Licensor shall notify Licensee in writing as to whether or not Licensor desires to obtain such ROFN Rights (such notice, the "**Initial Response**"). If Licensor provides an Initial Response to Licensee within the Initial Response Period that indicates that Licensor desires to obtain such ROFN Rights, then Licensor shall have a one-time right of first negotiation to obtain from Licensee such ROFN Rights for a period of up to [***] after receipt of the Partnering Notice by Licensor (the "**ROFN Period**"). During the ROFN Period, the Parties shall negotiate in good faith on the terms and conditions under which Licensor may obtain such ROFN Rights; *provided* that neither Party shall be obligated to enter into any agreement with regard to such ROFN Rights. During the ROFN Period, Licensee may not enter into an agreement with a Third Party in relation to such ROFN Rights or solicit new interest from any Third Party regarding such ROFN Rights; *provided*, *however*, that Licensee will not be restricted from negotiation with a Third Party that has expressed or subsequently expresses interest in obtaining such ROFN Rights without solicitation from Licensee. In the event that (i) Licensor does not provide any Initial Response to Licensee within the Initial Response Period, (ii) Licensor indicates in the Initial Response that it is not interested in obtaining such ROFN Rights or (iii) the Parties do not execute an agreement within the ROFN Period (or any mutually agreed upon extension), then Licensee shall be free to enter into an agreement with any Third Party regarding such ROFN Rights on such terms as Licensee may determine in its sole discretion, and Licensee shall no longer be subject to the obligations set forth in this Section 3.1(d). For the avoidance of doubt, (A) the rights granted to Licensor under this Section 3.1(d) may only be triggered one time during the Term and (B) notwithstanding anything to the contrary in this Agreement, in no event shall a Change of Control of Licensee or any of its Affiliates trigger the rights granted to Licensor under this Section 3.1(d).

3.2. **Commercialization**.

(a) Subject to the terms and conditions of this Agreement (including Section 3.5), as between the Parties, Licensee shall have the exclusive right and responsibility to Commercialize Licensed Products in the Territory (either itself or through its Affiliates, agents, subcontractors, Sublicensees or other Third Parties selected by Licensee).

(b) The Commercialization of each Licensed Product shall be governed by a commercialization plan that describes the proposed overall program of Commercialization, summarizing at a high level of detail the specified Commercialization activities planned for the upcoming year for each Major Market in the Territory, including (i) information on marketing strategy and sales targets, (ii) an overview on economic and regulatory conditions, (iii) timelines and key activities (including obtaining and maintaining pricing and reimbursement approval) prior to and after the First Commercial Sale of a Licensed Product in a given country in the Territory and (iv) personnel resources required to fulfill such activities in due time (the "**Commercialization Plan**"). The Commercialization Plan shall be prepared by Licensee [***] prior to the expected date of Commercialization of the Licensed Product. Such Commercialization Plan shall thereafter be updated by Licensee and sent to Licensor at least annually during the Term.

(c) Licensee shall discuss with Licensor any contemplated material change to the Commercialization Plan and consider in good faith any substantive comment Licensor may have regarding such change; *provided* that Licensee shall have the final decision making authority with respect to any such changes (it being understood that, for the avoidance of doubt, such final decision making authority shall not limit Licensee's Diligence Obligations).

3.3. **Manufacturing and Supply**.

(a) Subject to (i) the terms and conditions of this Agreement and the Underlying GMP License and (ii) Licensor's retained right to Manufacture Drug Product itself or through one or more Third Parties selected by Licensor on behalf of Licensee pursuant to this Section 3.3, Licensee shall have the exclusive right to Manufacture the Compounds and the Licensed Products itself or through one or more Third Parties selected by Licensee.

(b) Subject to the Parties having entered a Manufacturing Quality Agreement, upon Licensee's request ("**Supply Request**"), Licensor agrees to Manufacture and supply Drug Product, Drug Product assembled in [***] and/or placebo, as applicable, to Licensee for Clinical Trial supply in accordance with this Section 3.3(b). Licensor shall supply such Drug Product and placebo to [***] at Licensor's Supply Costs, within [***] from the initiation of production, and Drug Product assembled in [***] and such placebo will be delivered within [***] of the initiation of production of the Drug Product or at such other date mutually agreed upon in writing by the Parties. Licensor shall initiate production of Drug Product, Drug Product assembled in [***] and/or placebo, as applicable, within [***] from Licensor's receipt of a Supply Request; *provided* that the first production period shall begin no later than [***]. Licensor shall provide an invoice to Licensee upon Licensor's delivery of the Drug Product, Drug Product in [***] and/or placebo, as applicable.

(c) Licensor shall manufacture the Drug Product, Drug Product in [***] and/or placebo, as applicable, in accordance with this Section 3.3(c). The Parties acknowledge and agree that (i) the maximum quantity of Drug Substance from which Licensor is obligated to manufacture Drug Product hereunder is [***] of Drug Substance, which is expected to produce between [***] to [***] syringes of Drug Product, depending on strength(s) targeted (as determined by Licensee) and (ii) a maximum of two manufacturing campaigns is foreseen (it being understood that any manufacturing campaign that results in Drug Product that does not comply with the Manufacturing Quality Agreement shall not count towards the foregoing maximum of [***] manufacturing campaigns). A first slot, comprising up to [***] presentations (e.g., [***], [***] and [***]) but excluding assembly of [***] auto-injector devices, has been provisionally reserved for [***]. Licensor shall store the Drug Substance in a manner compliant with Applicable Laws and the Manufacturing Quality Agreement, and using at least the same standard of care consistent with Licensor's past practices and shall not destroy, alter or otherwise dispose of any Drug Substance without the prior written consent of Licensee. The Parties agree that the volumes set forth in this Section 3.3(c) with respect to Drug Product are estimates and are not binding. Licensor shall not be obliged to Manufacture Drug Product in excess of the amount of Drug Substance on stock with Licensor as of the Effective Date taking into account the respective yield and batch size. In the event that Drug Product Manufactured by Licensor is rejected pursuant to the Manufacturing Quality Agreement, Licensor shall replace such non-conforming Drug Product out of the Drug Substance inventory existing as of the Effective Date. Licensee shall have no claim for any loss of Drug Substance, nor shall Licensor be obligated to manufacture additional quantities of Drug Substance, and Licensee's sole remedy in case of rejection of Drug Product shall be the repayment of any amounts paid by Licensee to Licensor for the manufacturing services provided hereunder. Upon the earlier to occur of (x) Licensee's request or (y) the completion of the second manufacturing campaign hereunder, Licensor shall promptly transfer to Licensee at Licensee's expense any and all remaining Drug Substance remaining in Licensor's possession at such time.

(d) Other than as provided in Section 3.3(b) and Section 3.3(c), Licensor shall have no further obligation to manufacture or supply Drug Product hereunder. Notwithstanding the foregoing, Licensor may consider in good faith to Manufacture further volumes of Drug Product upon timely request by Licensee and upon the supply of Drug Substance by Licensee, which final decision shall be under Licensor's discretion.

(e) As soon as reasonably practicable following the Effective Date (and, in any event, within [***] thereafter), the Parties shall agree upon and execute a Manufacturing Quality Agreement, which shall, at a minimum, contain the Product Specifications. The supply of Drug Product under this Section 3.3 by Licensor shall also be governed by the terms and conditions of the Manufacturing Quality Agreement. To the extent that there is any conflict between the terms and conditions of this Agreement and the Manufacturing Quality Agreement, the terms and conditions of this Agreement shall govern and control, except with respect to conflicts or contradictions for matters of quality or technical nature, in which case the Manufacturing Quality Agreement shall prevail.

3.4. **Regulatory Filings and Pharmacovigilance**.

(a) **Regulatory Filings**. As between the Parties, Licensee shall be exclusively responsible for and shall have the exclusive right to own and maintain all regulatory filings and Regulatory Approvals for the Licensed Products, including all INDs and NDAs, and shall be exclusively responsible for and exclusively control all communications with Regulatory Authorities with respect to such Licensed Products. Licensor hereby agrees to transfer the IND held by Licensor in connection with the Licensed Products to Licensee as soon as possible, but at the latest prior to the start of any Clinical Trial for any Licensed Product sponsored by Licensee, unless agreed by the Transfer Committee that such IND transfer can be accomplished earlier (it being understood that until such IND can be transferred to Licensee, Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee an exclusive (even as to Licensor and its Affiliates) fully sublicensable, worldwide license and right of reference under such IND to Develop, Manufacture, have Manufactured, use and otherwise Commercialize the Compounds and Licensed Products in the Territory in the Field). To the extent Licensor receives any written or oral communication from any Regulatory Authority relating to a Licensed Product, or is notified of any such communication to the Initial Licensor, Licensor shall refer such Regulatory Authority to Licensee and provide Licensee with a copy of any written communication received by Licensor or Initial Licensor or, if applicable, complete and accurate minutes of such oral communication. Upon Licensee's request, Licensor shall use Commercially Reasonable Efforts to designate a qualified representative who shall facilitate any assistance by Initial Licensor required by Licensee and, together with the representatives of Licensee (or where a Sublicensee is the primary point of contact, of the relevant Sublicensee, to the extent provided for in the relevant Sublicense), participate in and contribute to meetings with the Regulatory Authorities with respect to regulatory matters relating solely to the Licensed Products. All reasonable and documented costs incurred by Licensor related to the regulatory assistance provided hereunder shall be reimbursed by Licensee in accordance with Section 2.3.

(b) **Pharmacovigilance**. The safety teams of the Parties shall, as soon as reasonably practicable following the Effective Date, set up a meeting and agree on the transfer of the safety data of the global safety database from Licensor to Licensee. The transfer of such global safety database shall be completed prior to the initial dosing of the first patient in a Clinical Trial conducted by or on behalf of Licensee or any of its Affiliates in connection with any Compound or Licensed Product. After completion of the transfer of such global safety database, Licensee will be solely responsible for all safety aspects of the Licensed Products and for ensuring compliance with all Applicable Law pertaining to safety reporting of the Licensed Products and related activities. If Licensor has or receives any information regarding any adverse event which may be related to the use of any Licensed Product, then Licensor shall provide Licensee with all such information within such reasonable timelines which enable Licensee to comply with all Applicable Laws and relevant regulations and requirements to the extent such information is not otherwise in the possession of Licensee. The adverse event information shall be sent to the following Licensee e-mail address: info@moonlaketx.com or such other e-mail address as provided in advance by Licensee to Licensor in writing.

(c) **Product Recalls**. Licensee shall have the final decision-making authority in its sole discretion to determine whether and how to implement a recall or other market withdrawal of any Licensed Product.

3.5. **Diligence by Licensee**. Licensee shall use Commercially Reasonable Efforts to (a) Develop one (1) Licensed Product in at least two (2) Indications, in accordance with the applicable Development Plan as updated or amended from time to time, (b) launch and Commercialize one (1) Licensed Product in each of the Major Markets within [***] after having received the required Regulatory Approval (including pricing approval, if required for Commercialization) in the respective Major Market, (c) secure within [***] after the Effective Date a binding contract research organization agreement with a qualified vendor for the Development of [***] Licensed Product in at least [***] Indications under the Development Plan, (d) Initiate the first two Phase II Trials for the Licensed Product within [***] after the Effective Date, taking into account any regulatory requirements or feedback from the FDA and/or EMA and (e) in the event that Licensee (x) undergoes a Change of Control, which results in Licensee being controlled by a Competitor or (y) otherwise acquires an Acquired Competing Biologic Product (other than any Licensed Product), (1) following a Successful Completion of a [***] for a Licensed Product conducted by Licensee or any of its Affiliates, Initiate in at least [***] [***] a [***] for such Licensed Product and (2) following the Successful Completion of a [***] for a Licensed Product conducted by Licensee or any of its Affiliates, prepare for and submit at least [***] [***] in a [***] for such Licensed Product, in each case, taking into account any regulatory requirements or feedback from the FDA and/or EMA (collectively, the "**Diligence Obligations**"). Notwithstanding the foregoing or anything else in this Agreement to the contrary, Licensor acknowledges and agrees that (i) in no event shall Licensee be deemed to be in breach of this Section 3.5 if any failure of Licensee to comply with its Diligence Obligations results from (A) Licensor's breach of any terms of this Agreement (including Licensor's failure to timely provide Drug Products in compliance with Section 3.3 and the Manufacturing Quality Agreement), (B) any rejection of Drug Supply by Licensee under Section 3.3 or (C) any delay on the part of any Regulatory Authority, and (ii) at Licensee's election, Licensee may extend the time frame set forth in clause (d) of the Diligence Obligations by providing Licensor written notice of such election and payment of [***] per each month of such extension (such payment, an "**Extension Payment**") (it being understood that Licensee shall not be deemed to have breached this Section 3.5 during any period of time for which Licensee has paid Licensor an Extension Payment).

3.6. **Reporting Obligations and Information Rights**.

(a) Licensee shall by [***] of each Calendar Year provide Licensor with a written report or presentation summarizing in reasonable detail its Development and, as applicable, Commercialization activities conducted during the preceding Calendar Year, along with a copy of the then current Development Plan. Further, Licensee shall provide an oral update via phone or in person to Licensor each Calendar Year during normal business hours at a time mutually agreed upon by the Parties by [***] of each Calendar Year. Further, Licensee shall notify Licensor of the Initiation of any Phase III Trial for a Licensed Product promptly, but no later than [***] after such Initiation of such Phase III Trial.

(b) **Data Protection Law Reporting**. To the extent required by Data Protection Law, Licensee shall, at no cost to Licensor, make available on request in a timely manner such information as is reasonably required by Licensor to determine whether or not Personal Data obtained, processed or stored in connection with the Development, Manufacture or Commercialization of a Compound or a Licensed Product under this Agreement is or has been processed by Licensee or its Affiliates in compliance with Data Protection Law and Licensee's covenants in Section 7.4. To the extent required by Data Protection Law, (i) Licensee shall inform Licensor of any rectification or erasure of Personal Data or restriction of processing under Data Protection Law; *provided* such Personal Data was disclosed to Licensor in the course of the performance of this Agreement and (ii) Licensee shall promptly notify Licensor in writing after becoming aware of any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data provided hereunder to Licensee by Licensor. In such case, Licensor may request further reasonable information about the incident, including a reasonably detailed description of the incident and the categories of Personal Data affected by the incident. The Parties acknowledge and agree that any information provided by Licensee to Licensor under this Section 3.6(b) shall be considered Confidential Information of Licensee.

3.7. **Trademarks**. As between the Parties, Licensee shall have the sole authority to select trademarks for the Licensed Products and shall exclusively own all such trademarks.

3.8. **Compliance Obligations**. Licensor intends to conduct its business in accordance with environmental, labor and social standards and to abide by the standards set forth in the Licensor Code of Conduct and the Licensor Human Rights Charter (available at http://www.merckgroup.com). Licensee shall comply, and shall ensure that its Affiliates or subcontractors comply, with all Applicable Laws relating to environmental, labor and social standards. Licensee further acknowledges and ensures that Licensee and its Affiliates (and Licensee shall use Commercially Reasonable Efforts to ensure that its subcontractors) are familiar with the provisions of the United States Foreign Corrupt Practices Act, the UK Bribery Act and applicable local bribery and corruption laws, and shall not take or permit any action that will either constitute a violation under, or cause Licensor to be in violation of, the provisions of the United States Foreign Corrupt Practices Act, the UK Bribery Act or applicable local bribery and corruption law, environmental, labor and social standards and the Licensor Code of Conduct and Licensor Human Rights Charter (collectively, "**Improper Conduct**"). In addition to any other rights Licensor may have under this Agreement, if Licensee notifies Licensor of, or if Licensor otherwise has a reasonable suspicion of, the occurrence of Improper Conduct, Licensor may, upon reasonable prior written notice to Licensee, have an independent auditor who is selected by Licensor and approved by Licensee (and whose fee is not contingent upon the outcome of the audit and who has executed a confidentiality agreement reasonably acceptable to Licensee) inspect the premises, books and records of Licensee relevant to Improper Conduct during normal business hours for the purpose of ensuring compliance by Licensee of its obligations under this Section 3.8. The auditor shall promptly notify Licensor in writing of its conclusions and, provide any evidence of non-compliance by Licensee (it being understood that (a) the information shared with Licensor shall be limited to information relating thereto and (b) any analysis or reports prepared by the auditor in connection with such audit shall be considered Confidential Information of Licensee).

ARTICLE 4 - FINANCIAL TERMS

4.1. **Upfront Payment**. In partial consideration for the grant of the rights hereunder, Licensee shall pay to Licensor a one-time, non-refundable, non-creditable sum of twenty-five million U.S. Dollars ($25,000,000.00) (the "**Upfront Payment**") within thirty (30) days after the Effective Date.

4.2. **Equity Consideration**. As further partial consideration for the grant of the rights and licenses hereunder, no later than the Effective Date, Licensee shall transfer to Licensor, against the payment of one U.S. Dollar ($1.00), such number of Licensee's Series A Preferred Stock representing 9.9% of Licensee's equity on an undiluted basis, as referenced, among others, in the Equity Documentation ("**Licensor's Equity Consideration**"). In this context, the Parties shall, together with other investors, sign the Equity Documentation on or prior to the Effective Date. Licensor's Equity Consideration shall be transferred to Licensor by Licensee in accordance with the terms of the Equity Documentation.

4.3. **Milestone Payments**. With respect to each milestone event set forth in the table below (a "**Milestone Event**"), Licensee shall notify Licensor within [***] after the first achievement by Licensee or any of its Affiliates or Sublicensees of such Milestone Event with a Licensed Product. Following such notice, Licensor shall issue an invoice to Licensee for the milestone payment applicable to such Milestone Event. Subject to the terms and conditions herein, as further consideration for the grant of the rights hereunder, Licensee shall, within [***] after Licensee's receipt of such invoice, pay to Licensor the one-time milestone payment applicable to such Milestone Event set forth below (each such payment, a "**Milestone Payment**").

Milestone Payment (in Euro)	**Milestone Event**
[***]	[***] (such Milestone Event, "**Milestone Event #1**")
[***]	[***] (other than the Indication of Milestone Event #1) (such Milestone Event, "**Milestone Event #2**")
[***]	[***]
[***]	[***]
[***]	[***]
[***]([***])	[***](such Milestone Event, "**Milestone Event #6**")
[***] ([***])	[***]("**Milestone Event #7**")
[***] ([***])	[***]("**Milestone Event #8**")
[***]	[***]
[***]	[***]
[***]	[***]

Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that, for purposes of this Section 4.3**.** the following shall apply:

(a) If, prior to the achievement of Milestone Event #1 or Milestone Event #2 by Licensee or any of its Affiliates or Sublicensees, Licensor is obligated to pay to Initial Licensor under the Initial License Agreement (i) the [***] milestone payment for the "[***]" milestone event and (ii) the [***] milestone payment for the "[***]" milestone event, Licensee shall pay such [***] and [***], as applicable, to Licensor within [***] after Licensee's receipt of an applicable invoice; *provided* that (x) Licensor shall provide Licensee written notice of such milestone payments becoming due as soon as reasonably practicable, (y) upon payment of such [***] to Licensor, Licensee shall no longer be obligated to pay Licensor any milestone payment in connection with the achievement of Milestone Event #1 by Licensee or any of its Affiliates or Sublicensees and (z) upon payment of such [***] to Licensor, Licensee shall no longer be obligated to pay Licensor any milestone payment in connection with the achievement of Milestone Event #2 by Licensee or any of its Affiliates or Sublicensees.

(b) A Milestone Event that occurs in or with respect to the "EU" shall mean any such event in or with respect to (i) in the case of a Milestone Event relating to the [***], any country of the European Union or the United Kingdom, or (ii) in the case of a Milestone Event related to [***], the UK MHRA, EMA or the European Commission.

(c) Licensee's obligation to pay the Milestone Payments pursuant to this Section 4.3 shall apply accordingly, if one or more of the Milestone Events set forth above is achieved with respect to a Licensed Product containing or comprising, in whole or in part, a Compound as an active ingredient in combination with one or more other active ingredients.

(d) Except with respect to Milestone Event #6, Milestone Event #7, and Milestone Event #8, each of which may be achieved and paid no more than [***] times, in no event shall any Milestone Payment set forth in this Section 4.3 be paid more than once, even if the same Milestone Event is achieved by more than one Licensed Product or achieved multiple times by the same Licensed Product.

(e) The maximum aggregate amount payable by Licensee (i) under this Section 4.3 is [***], (ii) under Milestone Event #6 is [***], (iii) under Milestone Event #7 is [***] and (iv) under Milestone Event #8 is [***].

4.4. **Commercial Event Milestones**.

(a) Subject to the terms and conditions of this Agreement, as further partial consideration for Licensor's grant of rights and licenses to Licensee hereunder, Licensee shall pay Licensor the following one-time amounts upon the achievement of the following commercial event milestones (each, a "**Commercial Milestone Event**") by Licensee or any of its Affiliates or Sublicensees on a Licensed Product-by-Licensed Product basis:

(i) [***] for the first Calendar Year in which the aggregate annual Net Sales in all Indications of such Licensed Product in the Territory equals or exceeds [***];

(ii) [***] for the first Calendar Year in which the aggregate annual Net Sales in all Indications of such Licensed Product in the Territory equals or exceeds [***];

(iii) [***] for the first Calendar Year in which the aggregate annual Net Sales in all Indications of such Licensed Product in the Territory equals or exceeds [***];

(iv) [***] for the first Calendar Year in which the aggregate annual Net Sales in all Indications of such Licensed Product in the Territory equals or exceeds [***]; and

(v) [***] for the first Calendar Year in which the aggregate annual Net Sales in all Indications of such Licensed Product in the Territory equals or exceeds [***].

(b) Licensee shall deliver written notice to Licensor of the achievement of a Commercial Milestone Event by Licensee or any of its Affiliates or Sublicensees with respect to a Licensed Product within [***] following the end of the Calendar Year in which such Commercial Milestone Event is achieved. Licensee shall deliver the corresponding Commercial Milestone Event payment for such Commercial Milestone Event to Licensor within [***] of Licensee's receipt of a corresponding invoice from Licensor for such Commercial Milestone Event payment set forth in the aforementioned written notice.

(c) Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that, for purposes of this Section 4.4 the following shall apply:

(i) Each payment corresponding to a Commercial Milestone Event shall be payable by Licensee to Licensor upon the first achievement of each Commercial Milestone Event by Licensee or any of its Affiliates or Sublicensees with respect to the first Licensed Product to achieve such Commercial Milestone Event.

(ii) In no event shall any payment set forth in this Section 4.4 be paid more than once, regardless of the number of Calendar Years in which such Licensed Product achieves such Commercial Milestone Event and regardless of the number of Licensed Products to achieve such Commercial Milestone Event. By way of example only, if for a Calendar Year, aggregate annual Net Sales for all Indications of a Licensed Product in the Territory are [***], the total Commercial Milestone Event payments earned shall be [***], and such commercial event payment shall no longer be payable in any subsequent Calendar Year. The maximum aggregate amount payable by Licensee under this Section 4.4 with respect to a Licensed Product is [***].

(iii) If any Commercial Milestone Event ("**Achieved Commercial Milestone**") is achieved by a Licensed Product in any Calendar Year and any preceding Milestone Event with respect to such Licensed Product has not achieved in such Calendar Year or any preceding Calendar Year by any Licensed Product, such preceding Commercial Milestone Event shall be deemed to have been achieved upon the achievement of such Achieved Commercial Milestone. By way of example only, if in the first Calendar Year following the First Commercial Sale of a Licensed Product, annual Net Sales for all Indications of such Licensed Product in the Territory are [***], and the Commercial Milestone Event in Section 4.4(a)(i) above has not previously been achieved by any Licensed Product in any Calendar Year, the Commercial Milestone Events in Section 4.4(a)(i) and Section 4.4(a)(ii) shall both be deemed to have been achieved.

4.5. **Royalty**.

(a) **Royalty Rate**. Subject to the terms and conditions of this Agreement, as further consideration for Licensor's grant of the rights and licenses to Licensee hereunder, Licensee shall pay to Licensor on a Licensed Product-by-Licensed Product and country-by-country basis, a royalty on aggregate Net Sales of such Licensed Product in such country during the Royalty Term for such Licensed Product at the rate of [***]. Except as expressly set forth in this Agreement, such royalty shall not be subject to offset or reduction for any reason, including any royalties, milestone payments or other consideration that Licensee pays under any Third-Party licenses.

(b) **Underlying GMP License**. Licensee shall reimburse Licensor for all payments due under the Underlying GMP License solely to the extent such payments relate to the Compounds and Licensed Products and are accrued on or following the Effective Date. In addition to the Royalty Rate under Section 4.5(a), Licensee shall pay to Licensor the royalties due to RCT to the extent such royalties relate to the Compounds and Licensed Products at the same time when the royalty payments under this Section 4.5 become due. For the remaining payments due under the Underlying GMP License, Licensor will send an invoice to Licensee, and Licensee will repay those amounts within thirty (30) days of receipt of such invoice. Further, Licensee shall use Commercially Reasonable Efforts to support Licensor in providing reports and data required under the Underlying GMP License. Notwithstanding anything in this Agreement to the contrary, at such time as Licensee enters into a direct license agreement with RCT pursuant to Section 7.4(e), Licensee shall have no further obligation to reimburse Licensor for any payments due under the Underlying GMP License with respect to any Compounds or Licensed Products.

(c) **Allowed Deductions.** The obligation of Licensee to pay royalties to Licensor under Section 4.5(a) shall be reduced upon the occurrence of the following events (such reductions, "**Allowed Deductions**"):

(i) In the event that (A) no Valid Claim or Pending Claim of any Licensor Patent or Inlicensed Patents Covering a Licensed Product exists in a country or (B) no Valid Claim of any Licensor Patent or Inlicensed Patents Covering a Licensed Product exists in a country, but a Pending Claim of a Licensor Patent or an Inlicensed Patent Covering a Licensed Product exists in such country and a Competing Product enters the market in such country, then in each case of clauses (A) and (B), Licensee's obligation to pay royalties on Net Sales of such Licensed Product in such country shall be reduced by [***]; *provided* that, in the case of (B), such reduction shall only apply until either (1) a Valid Claim of a Licensor Patent or Inlicensed Patent in said country is granted or (2) in the case of clause (B), the applicable Competing Product is withdrawn from the market in such country.

(ii) In the event that it is reasonably necessary for Licensee to enter into a Third-Party License Agreement in order to Develop, Manufacture or Commercialize any Licensed Product and Licensee subsequently pays such Third Party royalties, milestone payments or any other payments under such Third-Party License Agreement, Licensee may offset [***] of any such royalty, milestone or other payments made under such Third-Party License Agreements against Licensee's obligation to pay Licensor royalties under Section 4.5(a). For clarity, no deductions can be taken for payments with respect to the Underlying GMP License or such direct license agreement between Licensee and RCT pursuant to Section 7.4(e), if applicable.

(iii) In the event that the total Euro amount of the royalty reductions permitted pursuant to paragraphs (i) and (ii) of this Section 4.5(c) for a particular Calendar Quarter equals an amount greater than [***] of the Euro amount of royalties with respect to the Licensed Products that would otherwise be due from Licensee to Licensor for such Calendar Quarter, the total Euro amount of the royalty reductions for such Calendar Quarter shall be limited to the amount equal to [***] of the Euro amount of royalties that would otherwise be due.

(iv) Subject to the terms and conditions of this Agreement, during the term of the Initial License Agreement, in no event shall the Euro amount of royalties after aforementioned royalty reductions (if applicable) payable from Licensee to Licensor be [***] than the royalties due from Licensor to [***] in any given Calendar Quarter.

(v) Should Licensor determine after receipt of the royalty report described in Section 4.6(b), that its royalty obligations under the [***] [***] the royalty obligations due by Licensee under Section 4.5(a) after taking into account the Allowed Deductions under Section 4.5(c)(i)-(iii), Licensor shall promptly notify Licensee in writing thereof with a detailed explanation of the basis for such determination, including an accounting of its calculations of royalty obligations owed under the [***], and send an invoice to Licensee for the differential amount. Licensee shall repay any such undisputed amounts within thirty (30) days of Licensee's receipt of such invoice.

(d) **Attribution to Multiple Products**. If the rights to any Intellectual Property that is the subject of any Third-Party License Agreement are also attributable to products other than the Compounds or Licensed Products, then only an equitable portion of any amounts payable under it shall be allocated to such Compounds and Licensed Products, as determined from time to time by the Parties in good faith.

(e) **Royalty Deduction Carry Forward**. In the event that Licensee is not able to make the full amount of its Allowed Deductions against royalties, Licensee shall be entitled to deduct any undeducted amounts against any royalties due to Licensor in any subsequent Calendar Quarters until fully deducted; *provided* that Section 4.5(c)(iii) and (iv) shall continue to apply to such subsequent Calendar Quarters.

(f) **Compulsory License**. In the event that Licensor or Licensee receives a request for a compulsory license for any Licensed Product anywhere in the world, it shall promptly notify the other Party in writing. If any Third Party obtains a compulsory license in the Territory, then Licensor or Licensee (whoever has first notice) shall promptly notify the other Party. If either Party receives any payments from a Third Party pursuant to such a compulsory license, [***] of such payments shall be distributed to Initial Licensor and the remainder of such payments shall be considered Net Sales under this Agreement and shall be subject to the royalty obligations set forth in Section 4.5 (it being understood that, notwithstanding anything in this Agreement to the contrary, any sales of any Licensed Product by a compulsory licensee shall not be deemed a Net Sale of such Licensed Product for purposes of Section 4.4 or Section 4.5).

(g) **Royalties Generally**. Nothing herein contained shall obligate Licensee to pay or cause to be paid to Licensor more than one royalty on any unit of a Licensed Product.

(h) **Royalty Term**. Licensee's obligation to pay royalties under Section 4.5 shall be on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of a Licensed Product in a country until the later of (i) ten (10) years from such First Commercial Sale of such Licensed Product in such country or (ii) the expiration or invalidation of the last remaining Valid Claim of a Licensor Patent or Inlicensed Patent Covering such Licensed Product in such country ("**Royalty Term**").

(i) **Payment of Royalties**. Simultaneous with the delivery of the report described in Section 4.6(b) hereof, Licensee shall pay, or cause to be paid, to Licensor at such place as Licensor may from time to time designate in writing, all royalties earned pursuant to this Section 4.5 in the preceding Calendar Quarter, taking into account all Allowed Deductions. All such payments shall be made in Euros.

4.6. **Royalty Reports; Currency Conversion; Disputes Regarding Reports**.

(a) Net Sales shall be calculated and reported in Euros. With respect to Net Sales denominated in a currency other than Euros, Licensee shall convert each applicable monthly net sales into Euros by using the then-current and reasonable standard exchange rates applied to and derived from its external reporting.

(b) Commencing with the Calendar Quarter in which the First Commercial Sale of a Licensed Product is made by Licensee or its Affiliate or Sublicensee, Licensee shall submit to Licensor with each royalty payment a detailed, written report detailing its computation of royalties due on Net Sales on a Licensed Product-by-Licensed Product and a country-by-country basis during each Calendar Quarter within [***] after the end of each Calendar Quarter, and the report shall indicate: (i) the amount of Net Sales of each Licensed Product sold by Licensee or its Affiliates or Sublicensees during the reporting period; (ii) the royalties due thereon; (iii) the exchange rates used in determining the amount of Euros; (iv) the number of units and average selling price for each Licensed Product included in Net Sales for such Calendar Quarter, (v) the computation of the Allowed Deductions (if any) under Section 4.5(c), and (vi) any other information reasonably requested by Licensor and necessary to assess the calculation of the royalty payments.

(c) All payments to Licensor hereunder shall be made by deposit of Euros in the requisite amount to such bank account as Licensor may from time to time designate by written notice to Licensee. Royalties shall be calculated and reported in Euros based upon the Net Sales in Euros. For accounting and documentation purposes, Licensor shall provide to Licensee an invoice for the Upfront Payment, milestone payments and royalty payments that are payable hereunder. The Parties may vary the method of payment set forth herein at any time upon mutual agreement, and any change shall be consistent with the Applicable Laws at the place of payment or remittance.

4.7. **Record Retention, Inspection**. Licensee shall keep or cause its Affiliates to keep complete and accurate records in accordance with Licensee's then-normal accounting principles of Net Sales of Licensed Products and royalties payable under Section 4.5 for a period of [***] after the end of each Calendar Year in which such Net Sales occur. At the request of Licensor an independent chartered or certified public accountant ("**Auditor**") chosen by Licensor but approved in writing by Licensee (which approval shall not be unreasonably withheld or delayed) shall be allowed access during ordinary business hours to such records pertaining to the preceding [***] solely to verify the accuracy of any royalty payments made to Licensor under Section 4.5; *provided* that (x) such Auditor shall in no event be entitled to any contingency fee (or otherwise have any portion of its compensation be directly or indirectly determined based on the outcome of such inspection), (y) such Auditor shall execute a confidentiality agreement that is reasonably acceptable to Licensee and such records or information examined by such Auditor shall be the Confidential Information of Licensee and be subject to ARTICLE 6 and (z) Licensor shall not be permitted to exercise such inspection right more often than [***] each Calendar Year and no such records may be audited more than [***]. The accountant shall not disclose to Licensor any information other than that which should properly be contained in a report of matters relevant to Net Sales and royalty calculation and payment arising under Section 4.5 above. Any inspection conducted under this Section 4.7 shall be at the expense of Licensor, unless such inspection reveals any underpayment of the payments due hereunder for the audited period by at least [***], in which case the full costs of such inspection for such period shall be borne by Licensee. Any underpayment shall be paid by Licensee to Licensor within thirty (30) days of written notice of the results of such inspection with interest on the underpayment at the rate specified in Section 4.10 from the date such payment was originally due. Any overpayment shall be credited against future amounts due by Licensee to Licensor; *provided* that to the extent no future amounts are due by Licensee to Licensor hereunder, Licensor shall pay to Licensee such overpayment within thirty (30) days of written notice of the results of such inspection.

4.8. **Withholding Tax**. Licensor shall be responsible for the payment of any and all Taxes levied on account of the royalties and other payments paid to Licensor by Licensee or its Affiliates and received by Licensor under this Agreement. If Applicable Laws require that Taxes shall be deducted and withheld from royalties or other payments paid under this Agreement (the "**Withholding Tax**"), Licensee shall, and shall procure that its Affiliates proceed accordingly, (a) increase the amount of the payment due from Licensee to Licensor to an amount which (after making any Withholding Tax deduction) leaves an amount equal to the payment which would have been due if no Withholding Tax deduction had been required ([***]), (b) deduct those Withholding Taxes assessed thereon from the payment owed hereunder; (c) pay the Withholding Taxes to the proper Governmental Body; (d) send evidence of the obligation together with proof of Withholding Tax payment to Licensor within [***] following such payment; and (e) remit the net amount including the Tax gross-up, after Withholding Tax. Licensor shall take all necessary steps and the Parties shall cooperate in any way reasonably requested by a Party to obtain available reductions of, credits against, relief or remissions for, rebate or repayment of or refunds of such Withholding Taxes (the "**Tax Credit**") to the ultimate benefit of the Licensee. Assuming that Licensor is the beneficial owner of Licensor Technology, the cooperation referred to in the foregoing sentence shall include Licensor providing Licensee with a written confirmation from the competent Tax authority on the Tax application form that Licensor has its residence for Tax purposes in Germany. If the Licensor determines that it has obtained or utilized a Tax Credit either on a standalone or an affiliated basis, Licensor shall pay an amount to the Licensee which the Licensor determines and not in excess of the Tax Credit actually obtained or utilized, providing such evidence to the Licensee in respect of such amounts as the Licensee may reasonably request in writing, will leave it (after that payment) in the same after-Tax position as it would have been in had the Withholding Tax deduction not been made by the Licensee.

4.9. **Indirect Tax**. All royalties and other payments to be paid by Licensee to Licensor shall be understood as net amounts for indirect Tax (VAT, GST, Sales Tax and similar) purposes. It is the common understanding of the Parties that the transactions under this Agreement are not subject to indirect Tax in the country of the Licensor.

4.10. **Late Payments**. All payments under this Agreement shall earn interest from the date due until paid at a per annum rate equal to the lesser of (a) the maximum rate permissible under Applicable Laws and (b) [***] above the monthly Reuters (01 EURIBOR), measured at 2 p.m. Frankfurt/Germany time on the date payment is due. Interest will be calculated on an actual/360 basis. An example of the interest rate calculation follows, assuming that the Reuters interest rate is 0.25% and a payment of 10,000,000 EUR is thirty (30) days overdue:

Step 1: applicable annual interest rate on a 365/360 basis = [***]% + 0.25% = [***]%

Step 2: applicable interest rate for the period of delay = 30/360 x [***]% = [***]%

Step 3: total interest due = 10,000,000 EUR x [***]% = [***] EUR

4.11. **No Obligation to Achieve Milestone Events or Commercial Milestone Events**. Licensor hereby acknowledges and agrees that (a) there is no assurance that the Licensor will receive any Milestone Payments or Commercial Milestone Event payments and it is possible that no Milestone Events or Commercial Milestone Events will be achieved without any breach of this Agreement by Licensee or its Affiliates, (b) Licensee has not promised or projected any amounts to be received by Licensor in respect of any Milestone Payments or Commercial Milestone Event payments, and Licensor has not relied on any statements or information provided by or on behalf of Licensee with respect to the likelihood of development or potential sales of any Licensed Product and (c) Licensee shall have no obligation to use Commercially Reasonable Efforts other than as set forth in Section 3.5.

ARTICLE 5 - IP OWNERSHIP, INVENTIONS AND PATENT PROSECUTION AND MAINTENANCE

5.1. **Intellectual Property Ownership**.

(a) Subject to the licenses and rights granted in this Agreement, as between the Parties, Licensor shall own or Control and retain all right, title and interest in the Licensor Technology and in any and all other Patent Rights, Know-How and other Intellectual Property rights that are (i) in existence and Controlled by Licensor as of the Effective Date or (ii) developed by, for or on behalf of Licensor after the Effective Date other than in the course of performance of this Agreement.

(b) Subject to the licenses and rights granted in this Agreement, as between the Parties, Licensee shall own or Control and retain all right, title and interest in any and all other Patent Rights, Know-How and other Intellectual Property rights that are (i) in existence and Controlled by Licensee as of the Effective Date or (ii) developed by, for or on behalf of Licensee after the Effective Date other than in the course of performance of this Agreement.

(c) All right, title and interest in any and all other Patent Rights, Know-How and Intellectual Property rights that are developed in the course of performance of this Agreement shall be owned, as between the Parties, (i) solely by Licensor, if developed solely by employees, agents or independent contractors of Licensor, or (ii) solely by Licensee, if developed solely by employees, agents or independent contractors of Licensee and its Affiliates and (iii) jointly and equally by both Parties, if developed jointly by employees, agents or independent contractors of both Parties; *provided* that any such Patent rights jointly owned by the Parties shall be included in the Licensor Patents and subject to the terms and conditions herein. Determination of ‘joint’ or ’sole’ inventorship will be made in accordance with U.S. patent laws.

5.2. **Patent Prosecution, Maintenance and Enforcement of Licensee Patents**. For the avoidance of doubt, as between the Parties, Licensee shall have the sole right, but not the obligation, to file, prosecute, maintain and enforce the Patent Rights owned by Licensee pursuant to Section 5.1 (such Patent Rights, the “**Licensee Patents**”). Licensee shall bear all costs and expenses of filing, prosecuting and maintaining Licensee Patents in the Territory.

5.3. **Patent Prosecution and Maintenance of Licensor Patents**.

(a) **US Drug Product Listing**. As between the Parties, Licensee shall have the sole right to determine which of the Licensor Patents, if any, shall be (i) listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations pursuant to 21 U.S. C.F.R. § 355, or (ii) provided to any biosimilar applicant pursuant to 42 U.S.C. § 262(l), in each case of clauses (i) or (ii), or any successor Law in the United States, together with any comparable laws in any other country in the Territory. Licensor shall provide, consistent with its obligations under Applicable Law, reasonable cooperation to Licensee in filing and maintaining such registrar (and foreign equivalent) listings.

(b) **Responsibility and Costs**. As between the Parties, Licensee shall have the first right, but not the obligation, to file, prosecute and maintain Licensor Patents, including any related proceedings (e.g., interferences, oppositions, reexaminations, reissues, revocations, nullifications, post-grant review, *inter partes* review, etc.). Licensee shall bear all costs and expenses of filing, prosecuting and maintaining Licensor Patents. Licensee shall keep Licensor informed of the status of the filing and prosecution of Licensor Patents or related proceedings (e.g., interferences, oppositions, reexaminations, reissues, revocations, nullifications, post-grant review, *inter partes* review, etc.) in a timely manner, and will take into consideration the advice and recommendations of Licensor. At Licensee's request, Licensor will provide Licensee with reasonable free-of-charge assistance in prosecuting and defending Licensor Patents to the extent possible, including providing such data in Licensor's possession and control that is, in Licensee's reasonable judgment, needed to support the prosecution of a Licensor Patent.

(c) **Election Not to File and Prosecute Licensor Patents**. If Licensee elects not to file or to continue to prosecute or maintain a Licensor Patent in Licensor's name, then it shall notify Licensor in writing at least [***] before any deadline applicable to the filing, prosecution or maintenance of such Licensor Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Licensor Patent in such country of possession. In such case, Licensor shall have the right to pursue the filing or support the continued prosecution or maintenance of such Licensor Patent. If Licensor fails to continue prosecution or maintenance of any of the Licensor Patents then such abandoned Licensor Patents shall not extend the Royalty Term (i.e., no royalty payments shall be due under this Agreement on account of such abandoned Licensor Patents).

(d) **Patent Term Extension**. As between the Parties, Licensee shall have the first right and decision-making authority regarding obtaining patent term extensions for Licensor Patents. Licensor shall provide Licensee with all relevant information, documentation and assistance in this respect as may reasonably be requested by Licensee. Any such assistance, supply of information and consultation shall be provided promptly and in a manner that will ensure that all patent term extensions for Licensor Patents are obtained wherever legally permissible, and to the maximum extent available. In the event that any election with respect to obtaining patent term extensions is to be made, Licensee shall have the first right to make such elections, and Licensor shall abide by all such elections. If Licensee elects not to file for a patent term extension for any Licensor Patent Covering a Licensed Product which has received Regulatory Approval where legally permissible, Licensor shall have the right to file for any patent term extensions or restorations or supplemental protection certificates or their equivalents with respect to such Licensor Patent in any country or jurisdiction in the Territory.

5.4. **Enforcement of Patent Rights**.

(a) **Notice**. If either Party believes that an infringement, unauthorized use, misappropriation or ownership claim or threatened infringement or other such activity by a Third Party exists with respect to any Licensor Technology or Inlicensed Technology, or if a Third Party claims that any Licensor Patent or Inlicensed Patent is invalid or unenforceable (collectively, "**Third Party Infringement**"), the Party possessing such knowledge or belief shall notify the other Party and provide it with details of such infringement or claim that are known by such Party.

(b) **Right to Bring an Action**. As between the Parties, Licensee shall have the first right, but not the obligation, to attempt to resolve any Third-Party Infringement, including by filing an infringement suit, defending against such claim or taking other similar action, with respect to a Licensor Patent (each, an "**Action**") and to compromise or settle any such Third-Party Infringement or claim. At Licensee's request, Licensor shall immediately provide Licensee with all relevant documentation (as may be requested by Licensee) evidencing that Licensee is validly empowered by Licensor to take such an Action. Licensor shall be obligated to join Licensee in any such Action if Licensee determines that Licensor is a necessary and/or indispensable party to such Action, and Licensor hereby consents to being joined in, such Action. Licensor further covenants to facilitate the joinder of the Initial Licensor in any such Action if Licensee determines that Initial Licensor is a necessary and/or indispensable party to such Action. If Licensee does not intend to prosecute or defend an Action, Licensee shall promptly inform Licensor, and Licensor shall then have the right, but not the obligation, to attempt to resolve any Third-Party Infringement or claim, including by filing an Action with respect to a Licensor Patent and to compromise or settle any such infringement or claim. Licensor shall cooperate and assist Licensee in all reasonable respects in connection with an Action brought under this Section 5.4(b) and shall facilitate any necessary cooperation and assistance from the Initial Licensor.

(c) **Costs of an Action**. Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 8, the respective Party taking such Action shall pay all costs associated with such Action.

(d) **Settlement**. Neither Party shall settle or otherwise compromise any Action without the prior written consent of the other Party that would (i) give rise to liability (economic or otherwise) to the other Party or any of their respective Affiliates (or, in the case of Licensee, Sublicensees) or (ii) in any manner alter, diminish or be in derogation of the other Party's rights under this Agreement.

(e) **Reasonable Assistance**. The Party not enforcing or defending Licensor Patents shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement of any Out-of-Pocket Costs incurred by the non-enforcing or non-defending Party in providing such assistance.

(f) **Distribution of Amounts Recovered**. Any amounts recovered by the Party taking an Action pursuant to this Section 5.4, whether by settlement or judgment, shall be allocated in the following order: (i) to reimburse the Party taking such Action for any costs incurred, (ii) to reimburse the Party not taking such Action for its costs incurred in such Action, if it joins such Action; and (iii) the remaining amount of such recovery shall be paid to or kept by Licensee; *provided* that such remaining amount be deemed to be Net Sales and Licensee shall pay to Licensor a royalty on such remaining amount based on the royalty rates set forth in Section 4.5.

5.5. **Third-Party Actions Claiming Infringement**.

(a) **Notice**. If a Party becomes aware of any claim or action by a Third Party against either Party that claims that a Licensed Product, or its use, Development, Manufacture or Commercialization infringes, misappropriates or otherwise violates such Third Party's Intellectual Property rights (each, a "**Third-Party Action**"), such Party shall promptly notify the other Party in writing of all details regarding such Third-Party Action that is reasonably available to such Party.

(b) **Right to Defend.** As between the Parties, Licensee shall have the first right, at its sole expense, but not the obligation, to defend a Third-Party Action through counsel of its choosing. If Licensee declines or fails to assert its intention to defend such Third-Party Action to Licensor within [***] of Licensee's receipt or sending, applicable, of written notice under Section 5.5(a), then Licensor shall have the right to defend such Third-Party Action. The Party defending such Third-Party Action shall have the sole and exclusive right to select counsel for such Third-Party Action.

(c) **Consultation**. The Party defending a Third-Party Action pursuant to Section 5.5(b) shall be the "**Controlling Party**". The Controlling Party shall consult in good faith with the non-Controlling Party on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy; *provided* that, subject to ARTICLE 6 and Section 5.5(f), the Controlling Party shall have all final decision making authority with respect to such Third-Party Action. The Parties shall reasonably cooperate with each other in all such Third-Party Actions. The non-Controlling Party will be entitled to be represented by independent counsel of its own choice at its own expense.

(d) **Appeal**. In the event that a judgment in a Third-Party Action is entered against the Controlling Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it will promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) prior to the date on which such right to appeal will lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal at such non-Controlling Party's own cost and expense. If Applicable Laws requires the other Party's involvement in an appeal, the other Party shall be a nominal party of the appeal and shall provide reasonable cooperation to such Party at such Party's expense.

(e) **Costs of an Action**. Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 8 and the last sentence of Section 5.5(c) and this Section 5.5(e), the Controlling Party shall pay all costs associated with such Third-Party Action other than the expenses of the other Party if the other Party elects to join such Third-Party Action. Each Party shall have the right to join a Third-Party Action defended by the other Party, at its own expense.

(f) **No Settlement Without Consent**. Neither Party shall settle or otherwise compromise any Third-Party Action without the prior written consent of the other Party that would (i) give rise to liability (economic or otherwise) to the other Party or any of their respective Affiliates (or, in the case of Licensee, Sublicensees) or (ii) in any manner alter, diminish or be in derogation of the other Party's rights under this Agreement.

5.6. **Certification Under Drug Price Competition and Patent Restoration Act**. Licensor shall immediately give written notice to Licensee of any certification of which it becomes aware filed pursuant to 21 U.S. C.F.R. § 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any Licensor Patents or Inlicensed Patents Covering a Compound or a Licensed Product, or the Manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the Manufacture, use or sale of a product by a Third Party or any other any allegations of alleged patent invalidity, unenforceability or non-infringement of any Licensor Patents or Inlicensed Patents pursuant to a bioequivalent or biosimilar application.

ARTICLE 6 - CONFIDENTIALITY

6.1. **Confidentiality Obligations**. Each Party agrees that, for the Term and for [***] thereafter, such Party shall, and shall ensure that its officers, directors, employees and agents shall, keep completely confidential and not publish or otherwise disclose and not use for any purpose except as expressly permitted hereunder any Confidential Information disclosed to it by the other Party pursuant to this Agreement. For clarity, Section 31.15 of the Initial Licensor Agreement shall apply to such Confidential Information that is attributable to the Initial Licensor and for the confidentiality term of the Initial License Agreement such confidential information shall be subject to confidentiality obligations as set forth therein. The foregoing obligations shall not apply to any Confidential Information disclosed by a Party hereunder to the extent that the receiving Party can demonstrate that such Confidential Information:

(a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure to the receiving Party and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was subsequently lawfully disclosed to the receiving Party or its Affiliates by a Third Party without an obligation of confidentiality other than in contravention of a confidentiality obligation of such Third Party to the disclosing Party; or

(e) was developed or discovered by employees or agents of the receiving Party or its Affiliates without use of or reference to the Confidential Information of the disclosing Party.

Notwithstanding the above obligations of confidentiality and non-use, a receiving Party may disclose Confidential Information of the disclosing Party to the extent that such disclosure is reasonably necessary in connection with:

(i) in the case of Licensee as the receiving Party, (A) the filing or prosecuting patent applications included in the Licensee Patents or Licensor Patents, subject to the terms of Section 5.2 or Section 5.3, (B) prosecuting or defending litigations regarding the Licensor Patents or any Licensed Products, (C) conducting pre-clinical studies or Clinical Trials for any Licensed Product or Compound and (D) seeking Regulatory Approval of any Licensed Product;

(ii) complying with Applicable Laws (including securities law and the rules of any securities exchange or market on which a Party's securities are or may in the future be listed or traded) or court order, if in the reasonable opinion of such receiving Party's counsel, such disclosure is necessary for such compliance; *provided, however*, that except where impracticable, such receiving Party shall give the disclosing Party reasonable advance written notice of such disclosure requirement (which shall include a copy of any applicable subpoena or order) and shall afford such disclosing Party a reasonable opportunity to oppose, limit or secure confidential treatment for such required disclosure, and in the event of any such required disclosure, (A) such receiving Party shall disclose only that portion of the Confidential Information of such disclosing Party that such receiving Party is legally required to disclose, (B) such Confidential Information may only be used for the purposes for which the order was issued or such disclosure was required by Applicable Law, and (C) such receiving Party shall endeavour to obtain confidential treatment of economic, trade secret information and such other information as may be requested by the disclosing Party, and shall provide the disclosing Party with the proposed confidential treatment request with reasonable time for such disclosing Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the disclosing Party;

(iii) disclosure, in connection with the performance of this Agreement and solely on a "need to know basis", to Affiliates, existing or potential collaborators (including existing or potential co-marketing and co-promotion contractors), research collaborators, employees, consultants, or agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this ARTICLE 6 ; *provided, however*, that such receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this ARTICLE 6 to treat such Confidential Information as required under this ARTICLE 6; and

(iv) disclosure made by such receiving Party to existing or potential acquirers, merger candidates, Sublicensees, investment bankers, public and private sources of funding, existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing or in connection with an acquisition, merger, Sublicense or similar transaction, *provided* that such receiving Party has secured an agreement from any such Third Party to be bound by obligations of confidentiality and restrictions on use of Confidential Information that are no less restrictive than the obligations set forth in this ARTICLE 6.

For clarity, Licensor is entitled to share this Agreement with independent legal counsel selected by Initial Licensor to have such counsel review compliance of this Agreement with the Initial License Agreement.

6.2. **Publications.** Licensor shall not publish any information relating to any Compound or Licensed Product without the prior written consent of Licensee (which consent may not be unreasonably withheld), unless such information has already been publicly disclosed either prior to the Effective Date or after the Effective Date through no fault of Licensor or otherwise not in violation of this Agreement. Licensee shall have the right to make such publications as it chooses, in its sole discretion, without the approval of Licensor, unless Licensor's company name shall be used. Licensor shall submit to Licensee for Licensee's written approval any publication or presentation (including in any seminars, symposia or otherwise) of information related directly or indirectly to the Licensed Product for review and approval at least [***] prior to submission for the proposed date of publication or presentation.

6.3. **Press Releases and Disclosure**.

(a) The proposed public announcement by Licensor of the execution of this Agreement is set forth in Schedule 6.3 hereto.

(b) Licensor may not make any subsequent press release or public announcements regarding this Agreement without the prior written consent of Licensee unless the Licensor believes it is required to issue a press release or make another public announcement to comply with Applicable Laws as a publicly traded company (in which case, such press release or public announcements shall comply with the terms of Section 6.1(e)(ii). Licensor will provide the text of such planned disclosure to Licensee no less than [***] prior to disclosure and make reasonable efforts to incorporate all reasonable comments of Licensee regarding such disclosure.

(c) Licensee shall have the right to make such press releases as it chooses, in its sole discretion, without the approval of Licensor, unless Licensor's company name shall be used. In such case, Licensee will inform Licensor no less than [***] prior to the planned publication of such press release and request approval.

ARTICLE 7 - REPRESENTATIONS AND WARRANTIES

7.1. **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that, as of the Effective Date:

(a) it is duly organized, validly existing and in good standing under the Applicable Laws of the jurisdiction of its incorporation and has full power, authority and right to enter into this Agreement and to perform its obligations hereunder in accordance with the terms and conditions hereof;

(b) all requisite corporate action has been taken to authorize its execution, delivery and performance of this Agreement;

(c) this Agreement has been duly executed and delivered on behalf of such Party, and is legally binding and enforceable on each Party in accordance with its terms;

(d) the execution, delivery and performance of this Agreement by such Party does not breach, violate, contravene or constitute a default under any contract, arrangement or commitment to which such Party is a party or by which it is bound, or violate any statute, law or regulation or any court or Governmental Body having jurisdiction over such Party; and

(e) no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Body, domestic or foreign, under any Applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements.

7.2. **Licensor Representations and Warranties**. Licensor represents and warrants to Licensee that:

(a) As of the Effective Date, subject to the limitations contained in the Initial License Agreement and the Underlying GMP License, (i) Licensor has all right, title and interest in and to the Licensor Technology and (ii) the Licensor Technology is free and clear of any liens, charges, encumbrances or rights of others to possession or use.

(b) As of the Effective Date, Initial Licensor has opted out in full from the Initial Project pursuant to Section 9.5 of the Initial License Agreement.

(c) As of the Effective Date, neither Licensor nor any of its Affiliates are Developing, Manufacturing or Commercializing, or have plans to Develop, Manufacture or Commercialize, either directly or indirectly, any inhibitor of IL-17 or inhibitor of any receptor of IL-17, other than in performance of Licensor's obligations under this Agreement.

(d) As of the Effective Date, the Patent Rights set forth on Schedule 1.55 constitute all Licensor Patents owned or Controlled by Licensor as of the Effective Date. As of the time the Transfer Plan is agreed upon in writing by the Parties, the Know-How and Licensor Materials to be set forth in such Transfer Plan constitute all Licensor Know-How, Inlicensed Know-How and Licensor Materials owned or Controlled by Licensor as of the Effective Date.

(e) As of the Effective Date, to Licensor's Knowledge, no Affiliate of Licensor owns or Controls any Patent Rights that are necessary for the Development, Manufacture or Commercialization of any Compound or Licensed Product.

(f) As of the Effective Date, Licensor does not have the right to grant a license or sublicense under any Patent Rights or Know-How Controlled by any of Licensor's Affiliates other than Licensor Affiliates.

(g) As of the Effective Date, no claims have been asserted, or, to Licensor's Knowledge, threatened by any Person, nor are there any valid grounds for any claim of any such kind (i) challenging the validity, enforceability, effectiveness, or ownership of any Licensor Patents or Inlicensed Patents (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court), or (ii) to the effect that the Development, Manufacture, Commercialization or use of any Compound or Licensed Product infringes, misappropriates or otherwise violates or will infringe, misappropriate or otherwise violate any Intellectual Property right of any Person.

(h) As of the Effective Date, Licensor is not aware of any facts or circumstances that are reasonably likely to provide a basis for a finding of invalidity or unenforceability of any of the Licensor Patents.

(i) As of the Effective Date, Licensor has the right to grant to Licensee all of the rights and licenses granted by Licensor to Licensee under this Agreement (including pursuant to Section 2.1 hereof).

(j) As of the Effective Date, to Licensor's Knowledge, the Licensor Materials were manufactured, tested, stored and handled in accordance with all Applicable Laws and specifications (including, to the extent applicable, any release specifications as provided by Licensor to Licensee in writing prior to the Effective Date) and the Licensor Materials are not adulterated or misbranded within the meaning of any Applicable Law.

(k) As of the Effective Date, to Licensor's Knowledge, no Third Party is infringing, misappropriating or otherwise violating any of the Licensor Patents or Inlicensed Patents.

(l) As of the Effective Date, the Initial License Agreement is a valid and binding agreement between Licensor and the Initial Licensor and neither Licensor nor, to Licensor's Knowledge, the Initial Licensor is or has been in default or breach in any material respect under the terms of the Initial License Agreement and, to Licensor's Knowledge, no event or circumstance has occurred that, with notice or lapse of time or both, would constitute any event of default or breach in any material respect thereunder.

(m) As of the Effective Date, a copy of the Initial License Agreement and Underlying GMP License have been delivered to Licensee which, except for appropriate redactions, are true and complete.

(n) As of the Effective Date, to Licensor's Knowledge, neither Licensor, nor any of its employees, officers, subcontractors, or consultants who have rendered services relating to the Compounds or Licensed Products: (i) has ever been debarred or is subject to debarment or convicted of a crime for which a Person could be debarred by the FDA under 21 U.S.C. Section 335a or (ii) has ever been under indictment for a crime for which a Person could be so debarred.

(o) With respect to Drug Product and placebo Manufactured and supplied to Licensee pursuant to Section 3.3, such Drug Product and placebo shall have been Manufactured in accordance with GMP (if applicable), Applicable Laws and the Manufacturing Quality Agreement.

7.3. **Licensor Covenant**. Licensor (a) shall comply with the terms and conditions of, and perform all relevant obligations under, the Initial License Agreement and the Underlying GMP License, (b) shall not modify, amend or terminate the Initial License Agreement or the Underlying GMP License or agree to do any of the foregoing such that Licensee's rights under this Agreement would be impacted without Licensee's prior written consent and (c) shall enforce all of its rights and Initial Licensor's obligations under the Initial License Agreement (including Section 4 of the Initial License Agreement) and its rights and RCT's obligations under the Underlying GMP License, in each case upon the request of Licensee.

7.4. **Licensee Representations, Warranties and Covenants**. Licensee represents, warrants and covenants to Licensor as follows:

(a) As of the Effective Date, all written declarations made, directly or indirectly, by Licensee to Licensor related to Licensee's qualifications, ability and competence to Develop and Commercialize the Licensed Products in the Territory are true and correct.

(b) As of the Effective Date and at any time during the Term, Licensee (i) shall have and maintain facilities, personnel, experience and expertise sufficient in quality and quantity to perform its obligations hereunder (including through subcontractors or Sublicensees), (ii) shall perform its obligations hereunder with reasonable due care and in conformity with current generally accepted industry standards and procedures and (iii) shall procure that its management establishes and maintains appropriate quality assurance, quality controls and review procedures to secure good standard performance of its obligations hereunder.

(c) As of the Effective Date and at any time during the Term, Licensee will procure that all data related to human samples and other Personal Data obtained in course of the Development, Manufacturing or Commercialization of a Compound or a Licensed Product will be obtained, processed and stored in compliance with Applicable Laws, including applicable Data Protection Law, in all material respects. In particular, to the extent applicable to the activities contemplated to be conducted by this Agreement and required by Applicable Law, the signature of the informed consent from the donor will be obtained, the confidentiality and anonymization of the human samples will be procured and the personnel involved in such activities will be authorized and will have the capacity to perform such activities, in each case, in all material respects.

(d) As of the Effective Date and at any time during the Term, Licensee will comply with all Applicable Laws for the care, welfare and ethical treatment of animals in the country where the Development is being performed. In order to ensure proper treatment and use of animals, Licensee will adhere at a minimum to (i) Licensor's policy on the use, care and welfare of laboratory animals, (ii) Licensor Standard on "Housing and Husbandry Practices for Common Laboratory Animals", (iii) the principle of "3Rs" – reduction, refinement and replacement of animal studies; (iv) the principle to offer state of the art housing and husbandry conditions in the care and use of animals which means access to species appropriate food and water; access to species specific housing, including species appropriate temperature and humidity levels; access to humane care and a program of veterinary care; animal housing that minimizes the development of abnormal behaviors; review of study design and purpose by institutional ethical review panel; commitment to minimizing pain and distress during the studies conducted under the research plan and work is performed by demonstrable trained staff; *provided* that in each case of clauses (i)–(iv) such policies, standards and principles have been provided to Licensee in writing prior to the Effective Date.

(e) Prior to First Commercial Sale of a Licensed Product, Licensee shall use Commercially Reasonable Efforts to request a direct license agreement from RCT such that Licensee no longer requires a sublicense under the Underlying GMP License and shall use Commercially Reasonable Efforts to negotiate in good faith with RCT the terms and conditions of such license agreement. Notwithstanding the foregoing, Licensor acknowledges and agrees that in no event shall Licensee be deemed to be in breach of this Section 7.4(e) if Licensee is unable to enter into any such direct license agreement with RCT.

7.5. **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS OF A COMPOUND OR LICENSED PRODUCT FOR A PARTICULAR PURPOSE.

7.6. **Limitation of Liability**. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, LOSS OF USE, DAMAGE TO GOODWILL, OR LOSS OF BUSINESS); *PROVIDED, HOWEVER*, THAT THE FOREGOING SHALL NOT APPLY TO (a) ANY BREACH BY A PARTY OF ARTICLE 6 HEREOF, (b) THE WILLFUL MISCONDUCT, OR GROSS NEGLIGENCE BY A PARTY, OR (c) FOR AMOUNTS THAT ARE SUBJECT TO THE PARTIES' RESPECTIVE INDEMNITY OBLIGATIONS UNDER ARTICLE 8.

ARTICLE 8 - INDEMNIFICATION AND INSURANCE

8.1. **Indemnification by Licensor**. Licensor shall defend, indemnify and hold harmless Licensee and its Affiliates, and their respective officers, directors, employees and agents (the "**Licensee Indemnitees**") from and against any and all liability, damage, loss, cost and expense (including reasonable attorney's fees and expenses of litigation) ("**Losses**") arising or resulting from any claims made or suits brought by Third Parties to the extent such Losses arise or result from (a) a breach of any of Licensor's representations, warranties or covenants set forth in Section 7.1 or Section 7.2, (b) the failure of any Licensor Indemnitee to comply with Applicable Law in connection with Licensor's performance of its obligations or exercise of its rights under this Agreement; (c) the gross negligence, willful misconduct or fraud of any Licensor Indemnitee; (d) any Development or Manufacture of any Compound or Licensed Products performed by or for Licensor or any of its Affiliates on or prior to the Effective Date, including any product liability claims in the Territory or any personal injury or property damage in the Territory arising therefrom; and/or (e) any personal injury that is caused by any Drug Product Manufactured pursuant to Section 3.3 which fails to conform to the Manufacturing Quality Agreement; *except* in the case of clauses (a)-(e) for Losses to the extent arising out of any matter for which Licensee has an indemnification obligation to Licensor pursuant to Section 8.2.

8.2. **Indemnification by Licensee**. Licensee shall defend, indemnify and hold harmless Licensor, its Affiliates, and their respective officers, directors, employees and agents (the "**Licensor Indemnitees**") from and against any and all Losses arising or resulting from any claims made or suits brought by Third Parties to the extent such Losses arise or result from (a) the negligence or willful misconduct of Licensee or its Affiliates and its or their respective directors, officers, employees and agents, in connection with the performance of Licensee's obligations or exercise of Licensee's rights under this Agreement; (b) a breach of any of Licensee representations, warranties or covenants set forth in Section 7.4; (c) the activities that are actually conducted by or on behalf of Licensee or its Affiliates under this Agreement on or after the Effective Date, including the Development, Manufacture and Commercialization of the Compounds and/or Licensed Products, in particular the handling and storage by or on behalf of Licensee or its Affiliates of any chemical agents or other compounds for the purpose of conducting Development by or on behalf of Licensee or its Affiliates, including any product liability, personal injury, property damage or other damage caused thereby; or (d) any infringement of Patent Rights of any Third Party, on or after the Effective Date, by Licensee or its Affiliates with respect to any Development or Commercialization on any Licensed Product anywhere in the world or with respect to any other activity performed under this Agreement; *except* in the case of clauses (a)-(d) for Losses to the extent arising out of any matter for which Licensor has an indemnification obligation to Licensee pursuant to Section 8.1.

8.3. **Procedure**. A Party seeking indemnification under this ARTICLE 8 ("**Indemnified Party**") shall give prompt written notification to the other Party ("**Indemnifying Party**") of the claim for which indemnification may be sought (it being understood and agreed, however, that the failure by a Party to give notice of such claim as provided in this Section 8.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice). Within ninety (90) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the other Party, assume control of the defense of such claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs and expenses, including reasonable attorneys' fees and disbursements, incurred by the Indemnified Party in defending itself within sixty (60) days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; *provided* that, if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on written advice from outside counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such claim sufficiently adverse to make unadvisable the representation by the same counsel of both Parties under Applicable Laws, ethical rules or equitable principles, the Indemnifying Party shall be responsible for the reasonable fees and expenses of a single counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnifying Party shall not agree to any settlement of such claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party, that would have an adverse effect on the Indemnified Party's interests (including any rights under this Agreement or the scope or enforceability of the Licensor Technology or Inlicensed Technology) or that acknowledges fault by the Indemnified Party, without the prior written consent of the Indemnified Party.

8.4. **Insurance**. Each Party shall maintain, at its cost, insurance against liability and other risks associated with its activities and obligations under this Agreement, in such amounts and on such terms as are customary for a company such as the respective Party for the activities to be conducted by it under this Agreement. Each Party shall furnish to the other Party evidence of such insurance upon request. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this ARTICLE 8.

ARTICLE 9 - TERM AND TERMINATION

9.1. **Term of Agreement**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE 9, shall continue in full force and effect, on a Licensed Product-by-Licensed Product and country-by-country basis, until the date on which the Royalty Term in such country with respect to such Licensed Product expires. Upon expiration of the Term with respect to any Licensed Product in any country, the licenses granted under this Agreement (including the licenses granted under Section 2.1) with respect to such Licensed Product in such country shall become fully paid up, royalty free, perpetual and irrevocable.

9.2. **Termination of this Agreement by Licensee for Convenience / for Safety Reasons**.

(a) Following receipt by Licensor of the Upfront Payment set forth in Section 4.1 above, Licensee may, at its convenience, terminate this Agreement in its entirety upon ninety (90) days' prior written notice to Licensor.

(b) At any time during the Term, Licensee may terminate this Agreement in its entirety upon ninety (90) days' prior written notice to Licensor, if, based upon an analysis of the existing information at any time, Licensee has the reasonable belief that the medical risk/benefit of any Licensed Product is unfavorable in light of the welfare of patients and not suitable for further Development or Commercialization.

9.3. **Termination for Non-Payment**. If Licensee has not paid a milestone payment by the required respective payment dates set forth in Sections 4.3 and 4.4 and/or Licensee fails to grant Licensor's Equity Consideration as agreed in Section 4.2 and the Equity Documentation, Licensor shall have the right to terminate this Agreement if such breach is not cured within [***] after written notice thereof is given to Licensee by Licensor; *provided* that in the case of a bona fide dispute over whether or to what extent a payment by Licensee to Licensor is due, Licensor's right to terminate this Agreement under this Section 9.3 shall be tolled during the pendency of such dispute.

9.4. **Termination for Breach and Other Causes**.

(a) Subject to Sections 9.4(b) and 9.4(c), if either Party materially breaches this Agreement or the Initial License Agreement, the non-breaching Party may deliver written notice of such breach to the other Party. The breaching Party shall have [***] from the date of such Party's receipt of such written notice to cure such breach; *provided*, that if such breach is capable of being cured but cannot be cured within the applicable cure period, the breaching Party may cure such breach during an additional period as is reasonable in the circumstances by initiating actions to cure such breach during such applicable cure period and using reasonable efforts to pursue such cure. If the allegedly breaching Party fails to cure such breach within the applicable cure period set forth above, then subject to Sections 9.4(b) and 9.4(c), the Party originally delivering the written notice of breach may terminate this Agreement immediately by providing written notice of termination to the other Party.

(b) Notwithstanding anything in this Agreement to the contrary, in the event that Licensor believes that Licensee has materially breached its Diligence Obligations with regard to Development or Commercialization under Section 3.5, Licensor shall notify Licensee thereof in writing, specifying the basis for its belief, and the Parties shall discuss in good faith such concerns. If, after the expiry of [***] following the commencement of such good faith discussions and in the reasonable opinion of Licensor, Licensor reasonably believes that Licensee remains in breach of its Diligence Obligations or has not undertaken reasonable efforts to cure such breach, the matter shall be referred to the dispute resolution procedures set forth in ARTICLE 10 and Section 9.4(c) shall apply.

(c) Any right to terminate this Agreement under Section 9.4(a) or Section 9.4(b), shall be stayed and the applicable cure period tolled if, during such cure period, the Party alleged to have been in breach has initiated dispute resolution in accordance with ARTICLE 10 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with ARTICLE 10. If a Party is determined to be in material breach of this Agreement or of the Initial License Agreement by the dispute resolution procedures set forth in ARTICLE 10, the non-breaching Party may terminate this Agreement if the breaching Party fails to cure such breach within [***] after the conclusion of the dispute resolution procedure (and such termination shall then be effective upon written notification from the notifying Party to the breaching Party); *provided* that if Licensee is determined to have breached its Diligence Obligations with respect to any Licensed Product in any country by the dispute resolution procedures set forth in ARTICLE 10 and does not cure such breach within [***] after the conclusion of the dispute resolution procedure, Licensor may only terminate this Agreement with respect to such Licensed Product and country.

(d) If Initial Licensor alleges a breach by Licensor of the Initial License Agreement based on the material breach by Licensee of its obligations under this Agreement, Licensor shall inform Licensee of such allegation in writing as soon as is reasonably possible. The Parties shall work together to cure such material breach in accordance with the Initial License Agreement. If following such efforts the Parties are unable to cure a material breach of the Initial License Agreement due to the Licensee's uncured material breach of this Agreement, and the Initial Licensor terminates the Initial License Agreement as a result, then, Licensee will be considered to be in breach of this Agreement with no further cure possible and Licensor shall be entitled to terminate this Agreement with immediate effect; *provided* that if Licensee disputes in good faith such alleged breach of the Initial License Agreement, Licensor shall assist and cooperate with Licensee to submit such dispute to the respective dispute resolution mechanisms of the Initial License Agreement and for so long as there is no final determination as to whether Licensor, as a result of Licensee acts or omissions hereunder, has breached the Initial License Agreement (and the Initial License Agreement is not in fact terminated), Licensor shall have no right to terminate this Agreement pursuant to this Section 9.4(d).

(e) If Initial Licensor alleges a breach by Licensor of the Initial License Agreement, where termination of such Initial License Agreement or any diminishment of the scope or exclusivity of the Sublicenses granted to Licensee under the Inlicensed Technology is being or could reasonably be sought by the Initial Licensor, then Licensor will promptly, but in no event more than [***] thereafter, provide written notice thereof to Licensee and grant Licensee the right (but not the obligation) to cure such alleged breach. However, if Licensor disputes the material breach of the Initial License Agreement, the respective dispute resolution mechanisms of the Initial License Agreement shall have priority and for as long as there is no final determination as to whether the Licensor has breached the Initial License Agreement (and the Initial License Agreement is not in fact terminated), the Licensee shall have no right to make any claims with respect to such alleged breach of the Initial License Agreement towards the Licensor. In the event that a breach is undisputed or finally determined to have occurred, and such breach is not timely cured or not capable of being timely cured by Licensor, then in accordance with Section 37.25 of the Initial License Agreement, Licensee shall have the right to enter into a direct license with Initial Licensor, including without limitation by way of Licensor assigning this Agreement to the Initial Licensor. Licensee may offset the costs of curing the alleged breach of the Licensor against any amounts due to Licensor under this Agreement, to the extent that the breach of the Initial License Agreement did not arise from Licensee's breach of this Agreement.

9.5. **No Termination on Bankruptcy**. To the extent permitted by Applicable Laws, all rights and licenses granted pursuant to this Agreement by a Party to the other Party shall not be terminated on the insolvency or bankruptcy of such Party or its Affiliates, and each Party hereby claims the benefit of any Applicable Laws which may enable it to prevent such termination. All rights and licenses granted under or pursuant to this Agreement by Licensor are, and shall otherwise be deemed to be, licenses of rights to "intellectual property" as defined under any Applicable Law governing bankruptcy. The Parties agree that Licensee, as the recipient of such rights under this Agreement, shall retain and may exercise all of its rights and elections to the fullest extent permitted under any Applicable Law governing bankruptcy.

9.6. **No Challenge**. In the event that Licensee or any of its Affiliates or Sublicensees, anywhere in the world, institutes, prosecutes or otherwise participates in (or in any way aids any Third Party in instituting, prosecuting or participating in), at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy, or for an enjoinment, injunction or any other equitable remedy, including any interference, re-examination, opposition or any similar proceeding, alleging that any claim in a Licensor Patent is invalid, unenforceable or otherwise not patentable, except in the case where asserted as a defense or counterclaim to an action brought by Licensor against Licensee or any of its Affiliates or Sublicensees ("**Patent Challenge**"), Licensor shall have the right to terminate with immediate effect (i) this Agreement or, in its sole discretion, (ii) the license granted to Licensee or Sublicensee under such challenged Licensor Patent, on a patent-by-patent basis, upon written notice to Licensee, and, as necessary, its Affiliates or Sublicensees; *provided*, *however*, that Licensor shall have no right to terminate this Agreement if such Patent Challenge is brought by a Sublicensee of Licensee and Licensee as soon as reasonably practicable terminates the applicable Sublicense or such Sublicensee terminates or otherwise withdraws such Patent Challenge within [***] following notice of Licensee's intent to terminate such applicable Sublicense.

9.7. **Effects of Termination or Expiration**.

(a) **Accrued Rights and Obligations**. Termination or expiration of this Agreement shall not release either Party from its obligations accrued prior to the effective date of such termination or expiration nor deprive either Party from any rights that this Agreement has conferred on such Party prior to such effective date. Such obligations and rights shall survive termination or expiration of this Agreement. Termination of this Agreement by either Party shall be in addition to and not in lieu of any other remedies available to such Party, at law and in equity.

(b) **Surviving Terms**. Notwithstanding anything in this Agreement to the contrary, the following provisions shall expressly survive any expiration or termination of this Agreement in accordance with their terms: ARTICLES 1 (Definitions), 6 (Confidentiality), 10 (Dispute Resolution), 11 (Miscellaneous) and Sections 4.4 (Sales Milestone Payments (to the extent sales milestone payment obligations are not fully fulfilled upon expiration of the Royalty Term)), 4.8 (Withholding Tax (to the extent sales milestone payment obligations are not fully fulfilled upon expiration of the Royalty Term)), 5.1 (Intellectual Property Ownership), 5.4 (Enforcement of Patent Rights (but only in respect of Third Party Infringements and Actions arising during the Term and pending at the time of such expiration or termination), 7.5 (Disclaimer), 7.6 (Limitation of Liability), 8.1 (Indemnification by Licensor), 8.2 (Indemnification by Licensee), 8.3 (Procedure)9.5 (No Termination on Bankruptcy) and 9.7 (Effects of Termination or Expiration).

(c) **Consequences of Termination by Licensee pursuant to Section 9.2 or by Licensor pursuant to Sections 9.3 or 9.4**. Upon any termination of this Agreement pursuant to Section 9.2 or by Licensor pursuant to Section 9.3 or Section 9.4 in whole:

(i) all licenses granted by Licensor to Licensee under Section 2.1 shall terminate;

(ii) Licensee shall if Licensor at its sole discretion decides to take over and then-pending Clinical Trials being conducted by Licensee or any of its Affiliates for any Licensed Products, upon written request by Licensor and subject to Licensor assuming legal responsibility for such Clinical Trials, transfer to Licensor, at Licensor's cost and expense, except in the case of termination of this Agreement for material breach by Licensee in which case Licensee shall bear the cost and expense, all regulatory documentation, regulatory dossiers and Regulatory Approvals prepared or obtained by or on behalf of Licensee prior to the date of such termination, to the extent transferable. If Licensor does not want to continue Clinical Trials, Licensee shall wind such Clinical Trials down in line with Applicable Laws and at Licensee's sole cost and expense;

(iii) each receiving Party shall return to the disclosing Party (or at the disclosing Party's request, destroy) all Confidential Information of the disclosing Party then-in the possession and control of the receiving Party; *provided* that the receiving Party may retain a copy of computer records or files containing such Confidential Information of the Disclosing Party that have been created pursuant to automatic archiving or back-up procedures that cannot reasonably be deleted; *provided*, *however*, that such copy 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 such copy;

(iv) to the extent permitted under Applicable Law, Licensee shall, at Licensor's option, transfer to Licensor, at cost except in the case of termination of this Agreement for material breach by Licensee in which case Licensee shall transfer to Licensor free of charge, any and all chemical, biological or physical materials exclusively relating to or comprising Licensed Products, including clinical supplies of Licensed Products, that are then-owned or Controlled by Licensee;

(v) Licensee or its Affiliates shall cease all Commercialization of Licensed Products in the Territory in a prompt manner and in accordance with Applicable Laws; *provided*, however, that Licensee or its Affiliates shall be entitled, during the [***]' period following the effective date of such termination, to sell any commercial inventory of Licensed Products which remains on hand as of the effective date of the termination, so long as Licensee pays to Licensor the royalties and, if applicable, sales milestones applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement. Any commercial inventory remaining following such [***]' period shall be offered for sale to Licensor, at a price equal to fully loaded cost of goods plus [***]% surcharge; and

(vi) Licensee shall reasonably cooperate with Licensor and its designees to facilitate an orderly and prompt transition of the Development and Commercialization activities with respect to the Licensed Products and shall provide all transition services reasonably requested by Licensor to the extent necessary for this purpose.

(d) **Consequences of Termination by Licensee pursuant to Sections 9.4**. Upon any termination of this Agreement by Licensee pursuant to Sections 9.4, Licensee or its Affiliates shall be entitled to sell any commercial inventory of Licensed Products which remains on hand as of the date of the termination, so long as Licensee pays to Licensor the royalties and, if applicable, sales milestones applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement.

(e) **Consequences of Termination in Part**. Upon any termination of this Agreement by Licensor pursuant to Section 9.4 not in whole, but in part with view to one or more Licensed Products or one or more countries of the Territory, Section 9.7(c) shall apply accordingly, but solely with view to the terminated Licensed Product or, as the case may be, the terminated country.

ARTICLE 10 - DISPUTE RESOLUTION

10.1. **Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish under this ARTICLE 10 procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. Any disputes shall be brought to the attention of the Alliance Managers for resolution. The Alliance Managers will endeavor to propose and define mutually acceptable solutions and facilitate communications in an attempt to bring the dispute to a mutually agreeable resolution. In the event that the Parties are unable to resolve such dispute through diligent review and deliberation by the Alliance Managers within [***] from the day that one Party had designated the issue as a dispute in written notice to the other Party, then either Party shall have the right to escalate such matter to the Senior Executives (as defined below) as set forth in Section 10.2.

10.2. **Escalation to Senior Executives**. Either Party may, by written notice to the other Party, request that a dispute that remains unresolved by the Alliance Managers for the [***] period set forth in Section 10.1 be resolved by the Senior Executives, within [***] after referral of such dispute to them. The Senior Executive for Licensor shall be Licensor's Senior Vice President of Global Business Development and for Licensee shall be Licensee's Chief Executive Officer (collectively, the "**Senior Executives**"). If the Senior Executives cannot resolve such dispute within [***] after referral of such dispute to them, then, at any time after such [***] period, either Party may proceed to enforce any and all of its rights with respect to such dispute in accordance with Section 11.11.

10.3. **Injunctive Relief**. No provision herein shall be construed as precluding a Party from bringing an action for (preliminary or permanent) injunctive relief prior to the initiation or completion of the above procedure.

ARTICLE 11 - MISCELLANEOUS

11.1. **Relationship of the Parties**. Each Party is an independent contractor under this Agreement. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

11.2. **Performance by Affiliates**. Each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates; *provided*, *however*, that such other Party shall remain responsible for the performance by its Affiliates as if such obligations were performed by such other Party.

11.3. **Alliance Managers**. Each Party will appoint a representative of such Party to act as its Alliance Manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers will serve as the primary contact point between the Parties. Each Party may replace its Alliance Manager at any time upon notice to the other Party. The initial Alliance Managers will be: [***], for Licensor and [***] for Licensee.

11.4. **Assignment**.

(a) Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Licensee without the prior written consent of Licensor (not to be unreasonably withheld or delayed). Notwithstanding the foregoing, Licensee may assign this Agreement in whole without the consent of Licensor to (i) any Affiliate or (ii) a successor to substantially all of the business of Licensee to which this Agreement relates, in connection with any merger, sale of stock, sale of assets or other similar transaction.

(b) Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Licensor without the prior written consent of Licensee (not to be unreasonably withheld or delayed). Notwithstanding the foregoing, Licensor may assign this Agreement in whole without the consent of Licensee to (i) any Affiliate or (ii) a successor to all of the Licensor Technology and Licensor's entire right, title and interest under the Initial License Agreement. Licensor shall not, directly or indirectly, assign or otherwise transfer to any Third Party any of its right, title or interest in or to, or obligations under, the Initial License Agreement or any Licensor Technology separate and apart from its rights, title and interests in or to, and obligations under, this Agreement.

(c) No assignment under this Section 11.4 shall relieve the assigning Party of any of its responsibilities or obligations hereunder and *provided*, *further*, that as a condition of such assignment, the assignee shall agree to be bound by all obligations of the assigning Party hereunder. Any assignment in contravention of this Section 11.4 shall be null and void.

(d) This Agreement shall be binding upon the successors and permitted assigns of the Parties. In the event that Licensor assigns, delegates or otherwise transfers this Agreement, in whole or in part, to an Affiliate of Licensor, Licensor hereby agrees to be jointly and severally liable with any such Affiliates for the actions of such Affiliates and for any and all amounts that become due and payable hereunder to Licensee. In the event that Licensee assigns or otherwise transfers or assigns this Agreement to an Affiliate of Licensee, Licensee hereby agrees to be jointly and severally liable with any such Affiliates for the actions of such Affiliates and for any and all amounts that become due and payable hereunder to Licensor.

(e) Any assignment not in accordance with this Section 11.4 shall be void.

11.5. **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

11.6. **Accounting Procedures**. Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with Accounting Standards.

11.7. **Force Majeure**. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labour disputes, fire, flood, pandemic or disease outbreaks (including with respect to COVID-19), failure or delay of transportation, default by suppliers or unavailability of raw materials, governmental acts or restrictions or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as promptly as reasonably practicable (including its best estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as reasonably practicable.

11.8. **No Implied License; No Trademark Rights**. Except as expressly provided herein, no right or license is granted to Licensee hereunder by implication, estoppel, or otherwise to any Know-How, Patent Right or other Intellectual Property right owned or Controlled by Licensor or its Affiliates. No right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.

11.9. **Entire Agreement; Amendments**. This Agreement constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

11.10. **Governing Law**. This Agreement shall be governed by and interpreted in accordance with the laws of Switzerland, excluding the United Nations Convention on Contracts for the International Sale of Goods (CISG) and the application of any conflict of laws principles that would require application of the laws of a jurisdiction outside of Switzerland.

11.11. **Arbitration**.

(a) Except as expressly permitted in Section 11.11(f), if a dispute arises between the Parties in connection with or relating to this Agreement (each, a "**Dispute**") that the Parties are unable to resolve in accordance with ARTICLE 10 and that is not an Excluded Claim, and a Party wishes to pursue the Dispute, such Dispute shall be finally resolved by binding arbitration administered in accordance with the Rules of Arbitration of the ICC then in effect (the "**ICC Rules**").

(b) The arbitration shall be conducted by a panel of three (3) neutral arbitrators, each of whom shall have significant legal or business experience in the pharmaceutical industry, and none of whom shall be a current or former employee or director, or a current significant shareholder, of either Party or any of their respective Affiliates or Sublicensees. Each Party shall select in the request for arbitration and in the answer to the request, respectively, one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator, who will act as president of the arbitral tribunal, within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, the third (3rd) arbitrator shall be appointed by the ICC. The place of arbitration shall be Zurich, Switzerland, and all proceedings and communications shall be in English. The award rendered by the arbitral tribunal shall be final, binding and judgment may be entered upon it in any court of competent jurisdiction.

(c) Either Party may apply to the arbitral tribunal for preliminary injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. 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.

(d) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party or both Parties, respectively.

(e) As used in this Section 11.11, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns (i) the construction, scope, validity, enforceability, inventorship or infringement, misappropriation or other violation of any Intellectual Property; or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

(f) Nothing contained in this Agreement shall deny either Party the right to seek preliminary injunctive 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 any Excluded Claim and no such Excluded Claim shall be subject to arbitration.

11.12. **Notices and Deliveries**. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party.

If to Licensor, addressed to:

Merck Healthcare KGaA
[***]
Attention: Head of Alliance Management

With a copy, which shall not constitute notice, to:

Merck Healthcare KGaA
Frankfurter Straße 250
64293 Darmstadt
Germany
Attention: Healthcare Legal Department / LE-H
Facsimile: [***]

If to Licensee, addressed to:

Untermüli 7
Postfach 7444
6302 Zug
Schweiz/Switzerland
Attention: Chief Operating Officer

Any such notice shall be deemed delivered on the date received.

11.13. **Language**. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

11.14. **Waiver**. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

11.15. **Severability**. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

11.16. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages with signatures (in form of handwritten, non-certified electronic or certified electronic signatures), will be deemed an original.

11.17. **Remedies**. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek any relief available under Applicable Law, including (preliminary or permanent) injunctive relief and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

11.18. **Headings; Construction; Interpretation**. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with the definitions for such terms provided herein or, if no such definitions are provided, with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Applicable Laws to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement. All Schedules and Exhibits to this Agreement shall form an integral part of this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Laws refers to such Applicable Laws as from time to time enacted, repealed or amended, (c) the words “herein”, “hereof” and “hereunder”, and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (d) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (e) the word “or” is used in the inclusive sense (and/or), unless otherwise indicated by the term “either/or” and (f) the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. Any reference in this Agreement to “royalty” or “royalties” (whether used in capitalized letters or not) shall include royalties and other recurring or deferred payments payable by a Party to the other Party for compensation or consideration of rights granted hereunder.

[Signature Pages follow]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed and delivered in duplicate by their duly authorized representatives with legal and binding effect as of the date first above written.

MoonLake Immunotherapeutics AG		**Merck Healthcare KGaA**	
By:	/s/ Arnout Ploos van Amstel	By:	[***]
Name:	Arnout Ploos van Amstel MSc. Econ	Name:	[***]
Title:	Chief Operating Officer	Title:	[***]
By:	/s/ Kristian Reich	By:	[***]
Name:	Kristian Reich MD, PhD	Name:	[***]
Title:	Chief Scientific Officer	Title:	[***]

Exhibit 10.10

Certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

April 29, 2021

Merck Healthcare KGaA Frankfurter Straße 250
64293 Darmstadt
Germany
Attention: Head of Alliance Management

Merck Healthcare KGaA Frankfurter Straße 250
64293 Darmstadt Germany
Attention: Healthcare Legal Department / LE-H

Re: Effect of Assignment of the License Agreement upon a Termination of Initial License Agreement

Dear Madams and Sirs:

Reference is made to that certain License Agreement by and between **MERCK Healthcare KGaA**, a corporation with general partners organized under German law, having a place of business at Frankfurter Strasse 250, 64293 Darmstadt, Germany("**Licensor**"), and **MoonLake Immunotherapeutics AG**, a corporation organized under the laws of Switzerland, having a place of business at Untermüli 7 / Postfach 7444, 6302 Zug, Switzerland ("**Licensee**") effective as of April 29, 2021 (the "**License Agreement**"), a copy of which is attached hereto as Exhibit A.

Pursuant to the License Agreement, Licensor sublicenses to Licensee certain intellectual property licensed to Licensor by Ablynx N.V., Belgium ("**Initial Licensor**") pursuant to that certain Agreement for Joint Discovery and Development by and between Initial Licensor and Licensor, dated September 3, 2008 (such agreement, the "**Initial License Agreement**"). Pursuant to Section 37.25 of the Initial License Agreement, in the event of termination of the Initial License Agreement for any reason, the License Agreement is automatically assigned to Initial Licensor. In the event of any such termination of the Initial License Agreement and assignment of the License Agreement to the Initial Licensor, the Parties desire for Licensor to continue to be bound by the terms of the License Agreement with respect to certain patents, materials and know-how owned or controlled by Licensor and Licensor Affiliates.

In consideration of the covenants and conditions set forth herein, the Parties hereby agree as follows:

1. **Definitions** .. Capitalized terms used but not otherwise defined herein shall have the meanings set forth in the License Agreement.

2. **Effect of Assignment of the License Agreement upon a Termination of Initial License Agreement**. The Parties hereby agree that in the event the License Agreement is assigned or otherwise transferred by Licensor (or any of its successors-in- interest under the License Agreement) to the Initial Licensor pursuant to Section 37.25 of the Initial License Agreement, whether in whole or in part, and notwithstanding any such assignment or transfer, Licensor hereby agrees that the license granted by Licensor to Licensee under the License Agreement shall continue in full force and effect and Licensor shall be bound by any and all of Licensor's obligations and liabilities under the License Agreement; *provided* that, with respect to obligations and liabilities relating to Intellectual Property rights, such obligations and liabilities shall be limited to those Patent Rights, materials and Know-How that remain owned or Controlled by Licensor or any Licensor Affiliate following the termination of the Initial License Agreement.

3. **No Changes** . The Parties acknowledge and agree that the terms and conditions of the License Agreement shall remain in full force and effect to the full extent provided therein and shall not be limited, modified, altered, expanded or superseded by this letter agreement except as set forth herein.

4. **Assignment**.

(a) This letter agreement shall not be assignable by either Party without the prior written consent of the other Party (not to be unreasonably withheld or delayed). Following any such permissible assignment, this letter agreement shall be binding upon the successors and permitted assigns of the Parties. Notwithstanding the foregoing, (i) Licensee may assign this letter agreement in whole without the consent of Licensor to (A) any Affiliate or (B) a successor to substantially all of the business of Licensee to which this letter agreement relates, in connection with any merger, sale of stock, sale of assets or other similar transaction or (ii) Licensor may assign this letter agreement in whole without the consent of Licensee to (A) any Affiliate or (B) a successor to all (but not less than all) of the Licensor Technology. In the event that either Party assigns or otherwise transfers the License Agreement in accordance with Section 11.4 of the License Agreement, such assigning Party shall assign all of its rights and obligations under this letter agreement to such assignee and such assignee shall agree to be bound by all obligations of the assigning Party hereunder.

(b) The Parties acknowledge and agree that this letter agreement runs with the Licensor Technology. In the event that Licensor or any of its Affiliates sells, conveys, assigns or otherwise transfers to any other Person any Licensor Technology, Licensor shall cause the acquiring Person to agree in writing to be bound by the terms and conditions of this letter agreement. Any sale, conveyance, assignment or transfer in contravention of the foregoing shall be null and void *ab initio*.

5. **Miscellaneous**.

(a) **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this letter agreement.

(b) **Entire Agreement; Amendment**. This letter agreement and the License Agreement constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this letter agreement shall be valid or effective unless made in a writing referencing this letter agreement and signed by a duly authorized officer of each Party.

(c) **Governing Law; Jurisdiction**. This letter agreement shall be governed by and interpreted in accordance with the laws of Switzerland, excluding the United Nations Convention on Contracts for the International Sale of Goods (CISG) and the application of any conflict of laws principles that would require application of the laws of a jurisdiction outside of Switzerland. This letter agreement will be subject to the exclusive jurisdiction of the courts of competent jurisdiction located in the City of Zug, Switzerland.

(d) **General Provisions.** The Parties hereby acknowledge and agree that Sections 7.5 (*Disclaimer*), 7.6 (*Limitation of Liability*), 11.1 (*Relationship of the Parties*), 11.11 (*Notices and Deliveries*), 11.12 (*Language*), 11.13 (*Waiver*), 11.14 (*Severability*), 11.15 (*Counterparts*), 11.16 (*Equitable Relief*) and 11.17 (*Headings; Construction; Interpretation*) and Articles 6 (*Confidentiality*) and 10 (*Dispute Resolution*) of the License Agreement are incorporated herein by reference and shall apply in full force and effect to this letter agreement *mutatis mutandis* as if contained in the body of this letter agreement.

By signing where indicated below and returning it to the undersigned, you acknowledge and agree to be bound by the terms and conditions of this letter agreement.

[Signature Pages Follow]

Very truly yours,

MoonLake Immunotherapeutics AG

By: /s/ Arnout Ploos van Amstel
Name: Arnout Ploos van Amstel MSc. Econ
Title: Chief Operating Officer

By: /s/ Kristian Reich
Name: Kristian Reich MD, PhD
Title: Chief Scientific Officer

Acknowledged and agreed:

Merck Healthcare KGaA

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

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

Exhibit 10.11

Certain confidential information contained in this document, marked by brackets as [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. In addition, certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

CLINICAL AND COMMERCIAL MANUFACTURING AGREEMENT

dated October 15th, 2018

by and between

Richter-Helm BioLogics GmbH & Co. KG

and

Merck KGaA

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CLINICAL AND COMMERCIAL MANUFACTURING AGREEMENT

This CLINICAL AND COMMERCIAL MANUFACTURING AGREEMENT (the "Agreement") is made as of October 15th, 2018 (the "**Effective Date**") by and between Richter Helm Biologics GmbH & Co. KG, a corporation organized under the laws of Germany having a place of business at [***] ("Manufacturer"), and Merck KGaA, a corporation organized under the laws of Germany having a place of business at Frankfurter Straße 250, 64293 Darmstadt, Germany ("**Merck**"). Manufacturer and Merck may be referred to herein as a "**Party**" or, collectively, as "**Parties**."

RECITALS

WHEREAS, Merck, its Affiliates or a Merck's designated third party are engaged in the discovery, development, manufacture and sale of pharmaceuticals products and intend to conduct clinical trials of the Products (as defined below);

WHEREAS, in order to ensure a continuous manufacturing and a reliable supply of the Product for the development of Merck's Anti IL-17 A/F Nanobody®, an investigational therapy for the potential treatment of inflammatory deseases, in a phase III study in plaque psoriasis, and to secure enough manufacturing capacity after the potential launch of the Product Merck is interested in entering in an agreement with Manufacturer for clinical and commercial manufacturing services;

WHEREAS, Manufacturer has the requisite infrastructure, licenses, permits and capabilities, including trained and experienced personnel and technical skills, to manufacture and supply the Product (as defined below) to Merck for the aforesaid purposes and in accordance with this Agreement;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms. Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Adverse Event**" means any of: an "adverse drug experience," a "life-threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience," as those terms are defined at either 21 C.F.R. § 312.32 or 21 C.F.R. § 314.80 or other applicable or other regulations and laws".

1.2 "**Affiliate**" means a person or entity that Controls, is Controlled by or is under common Control with a Party, but only for so long as such control exists. "**Control**" means the ownership of more than fifty (50%) percent of the voting stock of any organization or the legal power to direct or cause the direction of the general management of the organization as appropriate, and "**Controlled**" shall be construed accordingly.

1.3 "**Agreed Hourly Rate**" means the hourly rate which has been agreed between both Parties as per **Schedule 1**.

1.4 "**Applicable Laws**" means the applicable provisions of constitutions, statutes, laws, rules, treaties, regulations, orders and decrees of all applicable Regulatory Authorities.

1.5 "**Batch**" means a batch of the Product manufactured by Manufacturer on a [***] litre scale under cGMP, in accordance with the Services Related Requirements of the Specifications and Quality Agreement and using the Manufacturing Process.

1.6 "**Batch Documentation**" means all documentation relating to a Batch, including the executed Batch record and additional documents relating to the Batch such as the analytical testing records, the release for the Materials, deviations, and all documents relating to a Batch that Manufacturer is required to maintain according to cGMP, the Services Related Requirements of the Specifications, the Quality Agreement, the relevant Purchase Order or Work Order, and all Applicable Laws.

1.7 "**Change of Control**" means with respect to Manufacturer, the consummation of any transaction (or series of related transactions) of the following events: (a) any Third Party (or group of Third Parties acting in concert) becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the total voting power of the stock or other ownership interests (as applicable) then outstanding of Manufacturer normally entitled to vote in elections of directors or equivalent governing body, (b) Manufacturer consolidates with or merges into another entity, or any entity consolidates with or merges into Manufacturer, in either event pursuant to a transaction in which more than fifty percent (50%) of the total voting power of the stock or other ownership interests (as applicable) outstanding of the surviving entity normally entitled to vote in elections of directors or equivalent governing body is not held by the parties holding at least fifty percent (50%) of the outstanding stock or other ownership interests (as applicable) of Manufacturer immediately preceding such consolidation or merger, (c) any other arrangement whereby a Third Party controls or has the right to control the board of directors or equivalent governing body that has the ability to cause the direction of the management or policies of Manufacturer or (d) Manufacturer shall dissolve, transfer, sell, assign, mortgage, encumber, pledge, or otherwise dispose of (i) all or substantially all of its assets, or (ii) any controlling interest in its business (whether in the form of stock or otherwise) or the Manufacturing Site.

1.8 "**Commercial Manufacturing Services**" means the tasks and activities to be performed by Manufacturer hereunder, except for the Development Services, as further set out in the Agreement and in the Purchase Orders, in case all conditions under Section 2.2 are met and satisfied, which shall include, (i) the manufacture of (Batches of) the Product using the Manufacturing Process, (ii) all activities and services (be it under cGMP, research laboratory or non-cGMP conditions) related thereto, such as, without limitation, performance of assays and other analytical work, quality control of the Product, storage of the Product, and (iii), storage activities, and (iv) all further services and activities (be it under cGMP, research laboratory or non-cGMP conditions) as may be mutually agreed in writing between the Parties from time to time; all as performed by the Manufacturer 011 behalf of Merck pursuant to the terms and conditions of this Agreement. For the avoidance of doubt, Manufacturing Services do not include tasks and activities to be performed by Merck (such as sample analysis) and Manufacturer shall not be liable hereunder for any failure of Merck in performing such tasks and activities.

1.9 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by either Party with respect to any objective, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances as expeditiously as possible, which in no event shall be less than the standard of care generally adhered to in the industry of such Party for the providing of such efforts. "**Confidential Information**" means any and all information (in whatever form, tangible or intangible) relating to either Party's, their Affiliates' and/or their business partners' business and/or technologies and/or any business, employee or customer information or data which is disclosed, or otherwise comes into possession of the other Party, directly or indirectly as a result of this Agreement and which is of a confidential nature (including, without limitation, any information relating to business affairs, operations, products, processes, methodologies, formulae, plans, intentions, projections, know-how, Intellectual Property, trade secrets, market opportunities, suppliers, customers, marketing activities, sales, software, computer and telecommunications systems, costs and prices, wage rates, records, finances and personnel).

1.10 "**Confidentiality Agreement (CDA)**" means the confidentiality agreement entered into between the Parties effective as of [***].

1.11 "**Current Good Manufacturing Practice**" or "**cGMP**" means the Current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Product(s) in the Territory, as required:

(A) if the Manufacturing Site is within the European Union or if the Product(s) is/are to be supplied to a country within the European Union, by the standards, rules, principles and guidelines set out in the provisions of Chapter II of EC Commission Directive 2003/94/EC, together with Volume 4 of the Rules Governing Medicinal Products in the European Union entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use";

(B) if the Manufacturing Site is within the United States of America, or if the Product(s) is/are to be supplied to the Unites States of America, by the provisions of 21 C.F.R., parts 210 and 211 and all applicable rules, regulations, orders and guidance published by the FDA (as defined below);

(C) if the Manufacturing Site is in, or if the Product(s) is/are to be supplied to, any other part of the Territory, such standards as the Parties may agree in writing to reflect the requirements of Regulatory Authorities in the country of manufacture or supply; and

(D) such other requirements as agreed between the Parties and set out in the Quality Agreement, in each case, as amended and updated from time to time.

1.12 "**Defect**" means, in respect of a Product, a failure to comply with the applicable Specification and/or to have been manufactured in accordance with cGMP, and "**Defective**" shall be construed accordingly.

1.13 "**Defective Product**" means a Product with a Defect.

1.14 "**Delivery Date**" means the date agreed by Merck and Manufacturer for the delivery of Products in a Work Order or in a Purchase Order according to ARTICLE 4.

1.15 "**Delivery Terms**" means EXW [***] Incoterms 2010 or such other terms as may be agreed in writing between the Parties and terms such as "delivery" and "delivered" shall be construed accordingly. Accordingly, Merck shall be responsible for the transport of the Product and shall engage a carrier. However, Manufacturer shall coordinate in advance with Merck's carrier each shipment of the Products.

1.16 "**Development Services**" means all the tasks and activities to be performed by Manufacturer pursuant to **Schedule 5** for the supply of the Product in the context of the phase III clinical trial described in the recitals above including but not limited to the Technical Transfer, the manufacture and supply of Engineering Batche(s), the GMP Batches (Phase III) and the PPQ Batches, as described in **Schedule 5**. In the event Merck reasonably requires further tasks and activities for the manufacture of the Product to be used by Merck for development purposes in a phase III clinical trial and Manufacturer is able to provide such further tasks and actives, Manufacturer shall upon request of Merck provide them against Merck's payment of a reasonable additional price.

1.17 "**Engineering Batch**" means a Batch that is produced to test production equipment, to finalize process control strategy and/or to train operations staff and is not released by Manufacturer for human use. Engineering Batches to test the production equipment will be produced at the Manufacturing Site. Engineering Batch will be at the cause scale as [***].

1.18 "**Executive Officers**" means, together, a member of the senior management of the pharmaceutical division of Merck /executive management board of the pharmaceutical division reporting to the executive board of Merck and the Chief Executive Officer of Manufacturer.

1.19 "**Finished Medicinal Product**" means any pharmaceutical product(s) comprising the Product.

1.20 "**Force Majeure Event**" means in relation to either Party, any circumstances beyond the reasonable control (including the taking of reasonable precautions) of that Party (including without limitation any acts or restraints of governments or public authorities, war, terrorism, revolution, riot or civil commotion disruption at suppliers, fire, explosion, accident, flood, sabotage, lack of adequate fuel, power, Materials, transportation, labour dispute and/or general strike of a national or industry-wide nature).

1.21 "**Governmental Authority**" means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, (ii) a federal, state, province, county, city or other political subdivision thereof or (iii) any supranational body, including any Regulatory Authority.

1.22 "**Hazardous Materials**" means any material or substance that, whether by its nature or use, is now or hereafter defined or regulated as a hazardous waste, hazardous substance, pollutant, or contaminant under any Applicable Law relating to or addressing public and employee health and safety and protection of the environment, or which is toxic, explosive, corrosive, flammable, radioactive, carcinogenic, mutagenic or otherwise hazardous or which is or contains petroleum, gasoline, diesel, fuel, another petroleum hydrocarbon product, or polychlorinated biphenyls. Hazardous Materials specifically include asbestos-containing materials (ACM), mold and lead-based paints.

1.23 "**Independent Expert**" means a laboratory or expert mutually agreed upon by the Parties who shall act as an expert in accordance with the ICC Rules for Expertise, and if no agreement can be reached then the Parties will accept a laboratory or expert appointed by the International Chamber of Commerce of Switzerland according to the ICC Rules for Expertise.

1.24 "**Intellectual Property**" means patents, trademarks, service marks, design rights (whether registerable or otherwise), including applications for any of the foregoing, copyright, all rights in know-how, trade or business secrets and/or trade or business names and other rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the Territory whether registerable or not.

1.25 "**Latent Defect**" means a Defect existing at the time of delivery of the Product in question to Merck, but which could not reasonably be discovered by a visual inspection of its outer packaging or any accompanying documentation.

1.26 "**Losses**" means all losses, claims, liabilities, costs, awards, fines, penalties, expenses (including reasonable attorney's fees, court fees and other reasonable professional expenses) and damages of any nature whatsoever reasonably foreseeable and unavoidable, however, always excluding any loss of profit or anticipated profit, loss of production, losses caused by business interruptions, loss of revenue and loss of goodwill or reputation.

1.27 "**Manufacturing License**" means any consent, permit, authorization or approval required for or in connection with the Manufacture of the Product at the Manufacturing Site(s)and the export/import of the Product to Merck in accordance with the Delivery Terms, including any license required pursuant to Article 13.1 of the Directive 2001/20/EC, Article 61 of Regulation 536/2004, Article 40 of Directive 2001/83/EC and, as applicable, a current drug establishment registration with the FDA (as defined below) as set forth in 21 C.F.R. §207.

1.28 "**Manufacturing Process**" means the anti IL-17 A/F Nanobody manufacturing process proprietary to Merck and transferred to Manufacturer as set out in the master batch records of the Product.

1.29 "**Manufacturing Run**" means a manufacturing run for the Product on a [***] scale under cGMP, in accordance with the Services Related Requirements of the Specifications and Quality Agreement and using the Manufacturing Process.

1.30 "**Manufacturing Site**" means the manufacturing facility located at [***] or such other manufacturing facility of Manufacturer as agreed to by the Parties pursuant to the change control procedures set out in the Quality Agreement.

1.31 "**Materials**" means the active ingredients, raw materials, excipients, packaging materials and components used in the manufacture of the Products.

1.32 "**Price**" means for Development Services the amounts set out in **Schedule 1** and for Commercial Manufacturing Services, the price set out in Section 6.2.

1.33 "**Product License**" means the product license, marketing authorization or any other authorization(s) (as the case may be) required for the marketing, sale and/or distribution or clinical investigation of Finished Medicinal Products by Merck in the jurisdictions in which the foregoing activities take place, or extension or renewal of any of the foregoing.

1.34 "**Product(s)**" means each of the products set out in the Specifications as included in the Quality Agreement.

1.35 "**Qualified Person**" means the person named in the Quality Agreement (or any replacement notified in writing by Manufacturer, from time to time), who is suitably qualified to enable Manufacturer to perform and discharge its quality management obligations as required by Current Good Manufacturing Practice or other Applicable Laws.

1.36 "**Quality Agreement**" means the future document outlining the Parties' respective responsibilities on quality matters, as the same may be amended by written agreement between the Parties.

1.37 "**Quality Control Procedure**" means the analytical testing of a Batch according to written testing instruction including in-process-control testing and analytical testing of the Product.

1.38 "**Regulatory Authority**" means any multinational, federal, state, local, municipal or other Governmental Authority in the Territory having jurisdiction over any aspect of the activities contemplated by this Agreement, including to the extent applicable, in the United States, the United States Food and Drug Administration ("**FDA**"), and in the European Union, the European Medicines Agency.

1.39 "**Services**" means Development Services and Commercial Manufacturing Services.

1.40 "**Services Related Requirements**" means all provisions of the Specifications which describe or require a certain minimum conduct and/or level of performance of Manufacturer when performing a Service as further described in this Agreement and the Quality Agreement as opposed to "**Product Related Requirements**" which describe a certain measurable property of a deliverable (such as impurities allowed in the Product) resulting from Manufacturer's performance of a Service.

1.41 "**Specifications**" means with respect to each Product the technical specifications for the required quality and characteristics of the Product agreed between the Parties in writing in the Quality Agreement (as the same may be amended from time to time in accordance with this Agreement).

1.42 "**Steering Committee**" means within thirty (30) days alter the Effective Date, the Parties will establish a joint steering committee to oversee and manage the Parties activities under this Agreement. The Steering Committee will continue to be in effect throughout the Term of the Agreement and will disband following termination of the Agreement.

1.43 "**Territory**" means as of the Effective Date any country of the European Union and the United States of America. Merck shall be entitled to include further countries into the Territory including, without limitation, China and Japan by written notice to Manufacturer provided (a) Manufacturer, acting reasonably, is able to fulfil any additional regulatory or other requirements of any such further country, and (b) Merck agrees to bear all additional costs of Manufacturer arising from the inclusion of any such further country.

1.44 "**Third Party**" means any person or entity other than a Merck or Manufacturer or their Affiliates or [***] or any other third party having signed an agreement with Merck in relation to the Trial.

1.45 "**Trial**" means the Phase III clinical trial of the Product conducted or sponsored by Merck or a Merck's designated third party described in the recitals above.

1.46 "**Trial Authorizations**" means all regulatory and ethical authorizations and approvals required for the lawful conduct of the Trial by Merck or by a Merck's designated third party.

1.47 "**Trial Subject**" means an individual enrolled into the Trial in accordance with the Protocol.

1.48 "**Work Order**" means Merck's order for Manufacturing Runs which are part of the Development Services.

1.49 "**Working Day**" means a day other than Saturday or Sunday or a day that is a public holiday in the jurisdiction in which the Manufacturing Site is located.

1.50 **Other Terms**. The definition of each of the following terms is set forth in the section of the Agreement indicated below:

Defined Term	Section
Acceptance	**9.3**
Average Yield	**5.11**
Background IP	**3.1**
BCP	**21**
Consequential damages	**18.3**
Designated Vendors	**2.10(a)**
Effective Date	**Preamble**
FDA	**1.38**
Firm Zone	**4.2**
Green Zone	**4.2**
Initial Term	**19.1**
KPIs	**5.9**
Manufacturer Background IP	**3.1**
Manufacturer Confidential Information	**16.8**
Manufacturing Problem	**5.7**
Manufacturing Problem Notice	**5.8**
Merck Arising IP	**3.2**
Merck Background IP	**3.1**
Non-Escalable Dispute	**22.1**
Payee	**6.19**
Payer	**6.19**
Payments	**6.19**
Product Event	**15.1**
Purchase Order	**4.5**
Punitive Damages	**18.3**
REACH	**13.11**
Renewal Term	**19.1**
Required Manufacturing Change	**12.3**
Rolling Forecast	**4.1**
Taxes	**6.18**
Technical Change	**12.1**
Term	**19.1**
Third Party Claims	**18.1**
Yearly Capacity Reservation	**2.6**

ARTICLE 2
MANUFACTURER'S OBLIGATIONS

2.1 **Scope of the Agreement**. Manufacturer agrees to provide Merck with both Development Services and Commercial Manufacturing Services including the manufacture and sale to Merck of Products ordered by Merck in accordance with ARTICLE 4 in consideration of Merck paying the Price for the Services.

2.2 Notwithstanding the execution of this Agreement, the commencement of certain Services described herein below is subject to and conditional an satisfaction or waiver by Merck of the following conditions:

i For the start and continuation of GMP manufacturing of at least [***] [***] Batches : (i) the Manufacturer has transferred the process from Merck to his relevant site(s) without any major deviation from the agreed timelines under**Project Timelines** and the Product Specifications, and (ii) the Parties have signed the Quality Agreement.

ii For the start of the manufacturing of at least [***] [***] Batches: the Manufacturer has successfully supplied Merck with at least [***] [***] Batches without any major deviation from the Project Timelines and according to the Product Specifications

iii For the start of the Commercial Manufacturing Services: (i) Manufacturer shall have successfully manufactured and supplied to Merck at least [***] [***] Batches without any major deviation from the Project Timelines and according to the Product Specifications, (ii) Merck Phase III Clinical Trials data package can support a successful BLA registration and (iii) Merck has decided to go on with the commercial manufacturing of the Products.

For the purpose of this Section 2.2 a major deviation from the Project Timelines herein consists of a delay from such Project Timelines equal to or longer than [***].

2.3 In case one of the conditions under Section 2.2 is not met, Merck shall have the right to terminate the Agreement in accordance with Section 19.2.

2.4 **No General Terms and Conditions**. The supply of the Product shall be exclusively governed by the terms and conditions of this Agreement. General terms and conditions of the Parties shall not apply even if mentioned by routine in a Work Order or Purchase Order of Merck or in any of Manufacturer's order confirmations.

2.5 **Project Timelines**. Manufacturer will provide Merck with the Services within the Project Timelines indicated in **Schedule 5** ("**Project Timelines**"). Table 1 of **Schedule 5** indicates some binding timelines to be complied with by Manufacturer and Table 2 of **Schedule 5** indicates some indicative timelines, which will be further discussed and agreed upon by the Parties. In case Manufacturer does not comply with a binding Project Timeline or does not use Commercially Reasonable Efforts to comply with an agreed indicative timeline, Merck, without prejudice to Sections 9.8 and 9.9 as applicable, may either request the payment of a late performance penalty in accordance with Section 5.6 (where applicable) and/or terminate this Agreement in accordance with ARTICLE 19.

2.6 **Capacity Reservation of Products in the performance of Commercial Manufacturing Services**. Following Manufacturer's letters to Merck dated [***] and [***] about capacity expansions (attached in **Schedule 7**), in view of performing the Commercial Manufacturing Services Manufacturer hereby commits on a yearly capacity reservation ("**Yearly Capacity Reservation**") as shown in the table below. Such reservation shall terminate automatically in case Merck does not place Purchase Orders with the Manufacturer, observing the agreed lead time. Unless otherwise agreed, the Yearly Capacity Reservation from [***] onwards shall be of [***] Manufacturing Runs. In case Manufacturer foresees that it will not be able to fulfil the below Yearly Capacity Reservation, Manufacturer shall send to Merck a written notice at least [***] in advance. In this event, Manufacturer shall bear the technology transfer costs of the transfer of the Manufacturing of the Products to another manufacturer.

Year	2022	2023	2024	2025
Yearly Capacity Reservation ([***])	[***]*	[***]*	[***]*	[***]*

* The specific number of reserved Manufacturing Runs at [***] scale will be defined according to the Rolling Forecasts provided by Merck.

2.7 **Expansion of the Manufacturing Capacities**. In order to meet a potential increase of Product demand by Merck from [***] Manufacturing Run in [***] to the [***] Manufacturing Runs from [***] onwards as shown in the table under Section 2.6, Manufacturer undertakes to expand at its own cost its manufacturing capacity accordingly in [***]. In the event Merck requires more than [***] and up to [***] Manufacturing Runs, Manufacturer shall set up a fully dedicated line for Merck. In such case, Merck shall inform Manufacturer at least [***] in advance of its additional Product requirements to allow Manufacturer to plan the investment and discuss necessary changes to this Agreement which may then include annual minimum order quantities in order to ensure utilization of the dedicated line.

2.8 **Restrictions on Competing Products**. During the Term, Manufacturer shall not manufacture on its own or for any Third Party or engage in the performance of services for a product which competes with the Product in the [***].

2.9 **Standards Applicable to the Manufacture of the Product**. Manufacturer shall manufacture the Products at the Manufacturing Site in accordance with Current Good Manufacturing Practice, the Specifications, the Manufacturing License, the Quality Agreement, Merck's Labelling and all Applicable Laws relevant to the Manufacture of the Products and with personnel that are knowledgeable, qualified and trained to perform the activities required to Manufacture the Products in accordance with the terms and conditions of this Agreement.

2.10 **Designated Vendors**

(a) Approval of Designated Vendors. If Merck elects, at its sole discretion, to require Manufacturer to procure Materials from Third Parties designated and approved by Merck in writing ("**Designated Vendors**") which are not then under contract with Manufacturer, Merck shall so advise Manufacturer in writing, and Manufacturer shall establish supply arrangements with such Designated Vendors (which supply arrangements shall comply with the terms of this Agreement, the Quality Agreement and any other related agreements) and the terms and conditions of such supply shall be subject to the approval of Merck. If Merck elects that Materials need to be purchased by vendors which are not qualified vendors of Manufacturer, Merck shall bear the cost for contracting, qualification and auditing of those vendors. Manufacturer shall allow Merck to agree with Designated Vendors an indemnification of Merck and Manufacturer by such Designated Vendors with respect to risks or liabilities created by such Designated Vendors, and include Merck as a Third Party beneficiary of these provisions. Manufacturer has to qualify such Designated Vendors according to cGMP requirements and establish the related contractual framework (including a Quality Agreement) also to support the terms of this Agreement and ancillary agreements hereto.

(b) Notification. Manufacturer shall immediately advise Merck if it encounters supply problems, including delays and/or delivery of non-conforming Materials from Designated Vendors and (except to the extent Materials are provided by Merck) Manufacturer shall use Commercially Reasonable Efforts to reduce and eliminate any supply problems from such Designated Vendors (and Merck shall provide Manufacturer with reasonable assistance in connection therewith).

(c) Audits and Assessment. Manufacturer shall maintain an adequate system, which functions as a risk-based assessment of Designated Vendors that provide Materials to ensure compliance with the terms of this Agreement and any ancillary agreements hereto, cGMPs and Applicable Laws. Furthermore, Merck may, at its option, independently conduct audits or participate in Manufacturer audits (including, but not limited to, quality, safety, social responsibility and environment) of such Designated Vendors, on a routine or for-cause basis. As a result of such audits, if necessary, Merck shall have the right to direct Manufacturer to disqualify a Designated Vendor as a source of Materials. Manufacturer shall use Commercially Reasonable Efforts to identify a new supplier as a source of Materials and replace the disqualified supplier with such new supplier, pursuant to the provisions set forth in Section 2.10 (a) above at Merck's expense.

2.11 **Use of Affiliates and Subcontractors**. Manufacturer may not, without the prior written consent of Merck, use Affiliates or Third Party sub-contractors to perform the Services. For any subcontract authorized by Merck, Manufacturer shall ensure that the subcontractor complies with the obligations and restrictions applicable to Manufacturer under this Agreement and shall further ensure that its subcontractor protects Merck's interests in Confidential Information, Merck Background IP and Merck Arising IP. Manufacturer (a) shall manage the performance of the subcontractor at its sole cost and expense and (b) shall remain responsible to Merck for all acts and omissions of any subcontractor and the performance of those subcontracted activities just as though Manufacturer had performed them itself and for purposes of this Agreement such acts or omissions and the performance of those subcontracted Services shall be deemed to be Manufacturer's. Manufacturer shall be Merck's sole point of contact regarding the Services, including with respect to payment. Merck hereby agrees that the external [***] services will be provided by the service providers listed in the Quality Agreement, being Manufacturer's sole subcontractor as of the Effective Date. For the avoidance of doubt, the costs for any external [***] services are not included in the Price for the Product and will be passed on to Merck plus a [***] handling fee.

2.12 **Responsibility**. Unless otherwise specified herein or expressly consented to in writing by Merck, as between the Parties, Manufacturer shall be solely responsible for performance of all Services necessary for Merck to be supplied with Products as agreed hereunder including the ordering and purchasing all of the Materials to enable Manufacturer to meet its manufacturing and delivery obligations under this Agreement.

2.13 **Safety Stock**. During the Term, Manufacturer shall maintain at all times a safety stock of Materials (list of Materials to be agreed in writing between the Parties) sufficient to meet the Manufacturing Runs set out in the Firm Zone, unless mutually agreed to in writing by Merck Manufacturer shall notify Merck immediately whenever the inventories of Materials become insufficient to Manufacture enough Product to meet the Manufacturing Runs set out in the Firm Zone. Manufacturer will pay the Materials. However, all Materials will then be invoiced by Manufacturer to Merck upon their receipt. Manufacturer shall send to Merck an invoice with a copy of the invoice paid by Manufacturer for the Materials. Merck shall pay this invoice within [***] after its receipt.

2.14 **Development Services**

(a) **Performance**. Manufacturer shall perform the Development Services set out in **Schedule 5** to this Agreement pursuant to and consistent with the terms of this Agreement, any applicable Specifications and **Schedule 5,** all reasonable written directions and instructions from Merck, generally accepted professional standards of care and all Applicable Laws of each country where Development Services shall be conducted, including without limitation cGMPs. Manufacturer shall perform all Development Services in a competent, professional and in a timely manner. Manufacturer shall perform all quality reviews, quality controls and process checks necessary in their performance of Development Services and as outlined in **Schedule 5** in accordance with the quality standards agreed upon by Merck and Manufacturer in **Schedule 5** and the Quality Agreement.

(b) **Purchaser Obligations**. Merck shall provide to Manufacturer (in a timely manner) such assistance, information and co-operation as reasonably requested by Manufacturer in connection with the performance of the Development Services.

(c) **Change Orders**. Merck may, from time to time, submit to Manufacturer a request for changes to **Schedule 5**. Unless, in Manufacturer's reasonable judgment, Manufacturer can implement the requested changes without requiring additional Manufacturer time or resources and without affecting Manufacturer's ability to maintain the Project Timeline, Manufacturer will implement the change at Merck's expense. Manufacturer will provide Merck with a written change order proposal for the additional work, including: (i) price change, (ii) impact an Project Timelines, and (iii) revised **Schedule 5**, including additional requirements of Merck, if any. Merck may, at its discretion, accept or reject Manufacturer's change order proposal. Each Party will use Commercially Reasonable Efforts to respond as expeditiously as possible to change order proposals.

(d) **Work Location**. Manufacturer shall perform the Development Services to be provided under this Agreement at the location indicated in **Schedule 5**, or, if no such location is indicated, at the Manufacturing Site unless mutual agreement to the contrary has been made and stipulated by the Parties.

(e) **Project Staffing**. Manufacturer shall perform the Development Services with highly qualified, trained and educated personnel knowledgeable and trained as appropriate for a particular Development Service in cGMPs, applicable regulatory requirements, fraudulent practices, project management, and pharmaceutical drug development and related services. Manufacturer is responsible for the training of its staff in order to maintain their knowledge to the standards of the industry and to perform their obligations under this Agreement and **Schedule 5**. All costs and expenses for such training will be fully paid by Manufacturer.

ARTICLE 3
INTELLECTUAL PROPERTY

3.1 **Background IP**. Each Party shall, at all times throughout and after the Term, remain the owner of any and all Intellectual Property that it owned (or was licensed to use) by the effective date of the signed CDA, and which Intellectual Property shall, for the purposes of this Agreement, be defined as "**Background IP**". Manufacturer acknowledges that Intellectual Property relating to the Products shall remain vested solely and exclusively in Merck or its relevant Affiliate. Merck acknowledges that Intellectual Property relating to manufacturing processes, including testing and packaging, which are generally used at the Manufacturing Site (to the extent existing prior to the Effective Date, or developed independently of this Agreement without the use of Merck's Confidential Information), shall remain vested in Manufacturer or its relevant Affiliate. For the purposes of this Section, Background IP vested in Merck (or its Affiliates) shall be defined as "**Merck Background IP**" and Background IP vested in Manufacturer (or its Affiliates) shall be defined as "**Manufacturer Background IP**".

3.2 **Merck Arising IP**. Neither Manufacturer, its Affiliates, nor any of their respective subcontractors shall acquire any rights of any kind whatsoever with respect to the Products by conducting Manufacturing activities hereunder. All rights to any Intellectual Property (whether or not patentable) conceived (whether or not reduced to practice) in the performance of work conducted under this Agreement by Manufacturer's or its Affiliates' employees, or independent contractors, either solely or jointly with employees, agents, consultants or other representatives of Merck exclusively or primarily relating to the Products or the manufacturing, processing, testing, packaging, storing thereto, will be owned solely and exclusively by Merck ("**Merck Arising IP**").

3.3 **Use of Intellectual Property**. Manufacturer will not use, or allow others to use, any Merck Background IP or Merck Arising IP for any other purpose than the Manufacture of the Products for Merck. Merck hereby grants Manufacturer and any Affiliates and subcontractors approved by Merck a non-exclusive and royalty free license for the Term to use the Merck Background IP and Merck Arising IP to the extent necessary to Manufacture the Products under this Agreement. Manufacturer hereby grants Merck and its Affiliates an irrevocable, worldwide, non-exclusive, and royalty free license to use the Manufacturer Background IP to the extent necessary for Merck or its Affiliates to further manufacture, commercialize, distribute, market, export, sell and otherwise exploit the Products.

3.4 **Assistance**. Manufacturer shall fully cooperate in the preparation, filing, prosecution and maintenance of all trademarks, copyrights, patents or other intellectual Property of any Merck Arising IP at Merck's cost and expense. Such cooperation shall include execution of all papers and instruments appropriate so as to enable Merck to prepare, file, prosecute and maintain such rights in any country.

ARTICLE 4
FORECASTS AND ORDERS

4.1 **Forecast**. Provided that all conditions under Section 2.2 have been met, in view of the performance by Manufacturer of the Commercial Manufacturing Services Merck shall provide a rolling forecast for [***] (the "**Rolling Forecast**" or "**RF**"). The RF shall be updated on a [***] basis and shall be delivered by Merck to Manufacturer by [***] of each [***]. The minimum order size will be [***] Batches per campaign and the maximum order size will be [***] Batches per [***], i.e. a Purchase Order for one (1) campaign consisting of [***] needs to be spread over [***].

4.2 The first [***] of the RF (e.g. [***] to [***] of the following [***] in a RF provided on [***]) shall be broken down on a [***] basis. The first [***] thereof shall be firm and cannot be changed ("**Firm Zone**"). The [***] of the RF shall constitute a non-binding forecast ("**Green Zone**"), however, the first [***] of the Green Zone may only be changed [***], i.e. the number of Manufacturing Runs forecasted for the first [***] of the Green Zone cannot be [***] without prior agreement between the parties.

4.3 On or before [***] after receipt of the RF by Manufacturer, Manufacturer shall inform Merck in writing if it is able to fulfil such RF, whether related to the Firm Zone or Green Zone as depicted. If no notification is received by Merck within that [***] period then the RF shall be deemed to have been accepted by Manufacturer, unless such RF exceeds the Yearly Capacity Reservation. Upon agreement of a RF Manufacturer shall submit to Merck on or before [***] a plan for Product delivery and tentative production schedule for the [***] of the RF. During the RF negotiations, the Parties shall also discuss any implications with regard to the residual shelf life of Product to be delivered under such RF.

4.4 In the event the Manufacturer cannot fulfil any part of a RF relating to the Green Zone, then the Parties shall discuss and agree on quantities and delivery dates of Product which are mutually acceptable. Manufacturer shall be obliged to supply Merck with commercial supply of the Product in accordance with the agreed upon RF.

4.5 **Orders of Manufacturing Runs for commercial purposes - Purchase Orders**. Provided that all the conditions precedents under Section 2.2 are met and the Commercial Manufacturing Services start, Merck shall throughout the Term, order Manufacturing Runs by delivering purchase orders to Manufacturer (each such order being referred to as a "**Purchase Order**"). Each Purchase Order shall, unless otherwise agreed between the Parties, specify the number of Manufacturing Runs ordered and the required Delivery Date which shall be at least [***] after the date of receipt of the Purchase Order by Manufacturer. Unless otherwise agreed, Merck's Purchase Order must allow for a Manufacturing in maximum [***] campaigns per calendar year.

4.6 **Manufacturer's Response to Purchase Orders**. Purchase Orders under Section 4.5 above shall be issued by Merck either electronically or by such other means, and to such location or contact person or system, as Manufacturer shall specify in writing. Manufacturer shall respond to each such Purchase Order received from Merck within [***] from receipt. Provided that (i) the number of Manufacturing Runs ordered by Merck does not exceed the number of Manufacturing Runs forecasted for the respective [***] in accordance with Sections 4.1 and 4.2 above, (ii) the Purchase Order allows for a Manufacturing in maximum [***] per [***], (iii) Merck complies with the above lead time of [***] under Section 4.5 and (iv) Merck's Purchase Order otherwise complies with this Agreement, Manufacturer shall accept the Purchase Order and its response shall include confirmation of the number of Manufacturing Runs and the Delivery Date. Deliveries confirmed by Manufacturer shall not occur later than [***] from the date indicated in the relevant Purchase Order. A failure of Merck to issue a Purchase Order shall not affect Merck's obligations to purchase the quantities set forth in the Firm Zone and, accordingly, in the event of any such failure, the missing Purchase Order shall be deemed issued by Merck. For the avoidance of doubts, in the event Merck cancels a Purchase Order issued or deemed issued within the Firm Zone, Merck shall pay [***] of the Price of each cancelled Purchase Order.

4.7 **Orders of Manufacturing Runs during the development phase - Cancellation of Work Orders**. In the context of the Development Services Merck shall order the Manufacturing Runs by issuing specific Work Orders to Manufacturer. Each Work Order shall, unless otherwise agreed between the Parties, specify the number of Manufacturing Runs ordered and the required Delivery Date reflecting the timeline under **Schedule 5**. Each Work Order shall be issued and sent to Manufacturer at least [***] prior the Delivery Date of the Manufacturing Runs indicated in such Work Order except for the Work Order for the first [***] Batch for which the Work Order shall be issued and sent to the Manufacturer at least [***] prior to Delivery Date. Provided that Work Orders are in line with the number of Batches agreed under Section 2.2 (i) and (ii) the timelines set forth in **Schedule 5**, Work Orders issued by Merck under this Section 4.7 at least [***] prior the Delivery Date of the Manufacturing Runs indicated in such Work Order shall be accepted the Manufacturer within [***] from the receipt of the Work Order.

4.8 Merck may cancel a Work Order without any obligation or incurring any liability to manufacture at the latest [***] prior to the Delivery Date. If notice of the cancellation or reduction is given by Merck less than [***] prior to the Delivery Date, Merck shall be obliged to make the following payment to Manufacturer:

(a) If notice is given by Merck between [***] and [***] prior to the Delivery Date, Merck shall pay [***] of the Price for each cancelled Manufacturing Run except if these can be used for further campaigns (if the shelf life allows it).

(b) If notice is given by Merck between [***] to [***] prior to the Delivery Date, Merck shall pay [***] of the Price of each cancelled Manufacturing Run.

(c) If notice is given by Merck less than [***] prior to the Delivery Date, Merck shall pay [***] of the Price for each cancelled Manufacturing Run.

4.9 **Reallocation of Manufacturing Runs in case of cancellation of Purchase Orders and Work Orders**. Manufacturer shall use Commercially Reasonable Efforts to re-allocate the manufacturing slot for any such cancelled Manufacturing Run (whether set out in a Work Order or Purchase Order) to customers of Manufacturer for non GMP or GMP Batches, and/or shall consider in good faith a proposal of an alternative project or use for the manufacturing slot by Merck and/or its Affiliates; and if Manufacturer successfully re-allocates the manufacturing slot, Merck shall not be required to make any of the payments above but only for Materials purchased for the cancelled Manufacturing Run which cannot be used for a later Manufacturing Run as well as for any other non-cancellable costs of Manufacturer.

4.10 **Addressees for Correspondence**. All Forecast Schedules, Purchase or Work Orders, written confirmation of Purchase or Work Orders and other notices contemplated under this ARTICLE 4 shall be sent to the attention of such Party as set forth in Section 23.10, or such persons as each Party may identify to the other in writing from time to time.

4.11 **Affiliates of Merck**. Affiliates of Merck may order Products directly from Manufacturer. Manufacturer shall manufacture and supply to such Affiliates the ordered Products in accordance with the terms and conditions of this Agreement.

ARTICLE 5
DELIVERY OF PRODUCT

5.1 **Delivery**. Manufacturer shall provide Merck with authorized electronic copies of the [***] records, the [***], the [***], and when applicable, the [***] at each time point and the invoice for each Manufacturing Run in accordance with the Delivery Terms on the Delivery Date specified in the relevant Work Order or Purchase Order confirmed by Manufacturer pursuant to ARTICLE 4 above. For the avoidance of doubt, punctual "delivery" in terms of this Agreement by Manufacturer does not require the pick-up of the stored Product by Merck but shall occur upon Manufacturer providing the above mentioned documents to Merck. As defined in Section 7.2, in case Manufacturer will store Product [***] at Merck's demand at Manufacturer's premises, payment process will be triggered at the reception of the Batch Documentation.

5.2 **Sample Analysis by Merck**. Delivery dates set out in a Work Order or Purchase Order include [***] for the results (starting from samples arrival at the site in [***] designated by Merck for the performance of the samples analysis) of the sample analysis performed by Merck in accordance with the Manufacturing Process. Any delay of Merck may lead to a potentially much longer delay of the delivery of the respective Batch, in particular if Merck misses the slot reserved at Manufacturer for the final review of the Batch Documentation. Manufacturer shall not be responsible for any delay caused by Merck failure to perform sample analysis within [***]. Upon Merck's notice that sample analysis may be delayed by a certain number of days or weeks, Manufacturer shall inform Merck whether and, if so, to what delay of the delivery of the respective Batch this will lead. If a slot for the final review of the Batch Documentation at Manufacturer is missed due to Merck's delay, Manufacturer shall use the next free slot.

5.3 **Title; Risk of Loss**. Risk and title in the Products shall remain with Manufacturer until delivered in accordance with the Delivery Terms at which point it shall pass to Merck.

5.4 **Accompanying Documentation**. With each shipment of Product, Manufacturer shall provide Merck with the documentation set forth in the Quality Agreement.

5.5 **Retention of Samples**. Provisions covering Manufacturer's obligation to store and retain appropriate samples (identified by Batch number) of Products that it supplies to Merck and access by Merck to the same are set forth in the Quality Agreement.

5.6 **Late Delivery**. Without prejudice to the Merck's rights and Manufacturer's obligations under this Agreement, in the event that the Manufacturer is unable to fulfil the Services, regardless of whether such Services are Development Services or Commercial Manufacturing Services, within the timelines defined under this Agreement, it shall notify Merck as soon as possible and the Parties will work together to agree a mutually acceptable resolution. If conforming Product is not received by Merck within [***] from the Delivery Date, except where Manufacturer can reasonably demonstrate that the delay is not due to its fault (e.g. unavailability of Materials), then Merck shall have the right to claim from Manufacturer payment of a late performance penalty equal to [***] of the Price of such delayed Manufacturing Run per each calendar day beyond the above [***] grace period, up to a total amount of [***] of the Price of such delayed Manufacturing Run in total. The foregoing amounts may be deducted by Merck from any amounts invoiced to Merck. The rights and remedies contained in this Section 5.6 are non-exclusive and without prejudice to Merck's right to terminate this Agreement pursuant to Section 19.8 or any other remedy under this Agreement, however, the above late delivery penalty shall be deducted from any claim of Merck for damages arising from late delivery of a Batch by Manufacturer.

5.7 **Manufacturing Problem**. In the event that Manufacturer or Merck becomes aware of any matter, circumstance or event which (i) would reasonably be expected to give rise to a material delay in the shipment of Product; (ii) reasonably indicate that the quality standards set forth herein and in the Quality Agreement have been materially compromised or (iii) may reasonably give rise to a material breach hereunder or the right of Merck to terminate this Agreement under ARTICLE 19 (each a "**Manufacturing Problem**")**,** Manufacturer shall promptly give written notice to Merck of such Manufacturing Problem, the cause thereof, the anticipated length of such Manufacturing Problem, and the action to be taken to reduce, minimize or remove the adverse effects of any such Manufacturing Problem. Within [***] of receipt of the notice given pursuant to this ARTICLE 5, Merck and Manufacturer shall meet with a view to agreeing to any actions necessary to ensure that no interruption to supply or shortfall in quantities of any Product occurs. For purposes of clarity, a Manufacturing Problem which shall give rise to the remedies set forth in this ARTICLE 5 includes, but is not limited to, (i) receipt by Manufacturer of a warning letter from a Regulatory Authority or a FDA Form 483 affecting a Product, (ii) continuous errors or inadequacies in batch processing or documentation as determined by Merck in its sole discretion, (iii) circumstances which could in the reasonable opinion of Merck likely lead to a warning letter from a Regulatory Authority and (iv) delivery of one or more Batches which do not meet quality standards for the Product as set forth under this Agreement, the Quality Agreement, cGMPs, the Specifications or Applicable Laws.

5.8 **Manufacturing Problem Remediation**. In the event that Merck or the Manufacturer becomes aware of a Manufacturing Problem, the knowledge Party shall give written notice to the other Party of such Manufacturing Problem (the "**Manufacturing Problem Notice**").

(a) In addition to the actions contemplated in the Quality Agreement, Merck shall have the right to physically inspect such areas of the Manufacturing Sites that relate to the Manufacturing Problem and Manufacturer shall provide Merck with reasonable access to all relevant equipment, process, records, appropriate quality system documents and personnel (wherever located) of Manufacturer associated with the Manufacturing Problem.

(b) Within [***] of receipt of the Manufacturing Problem Notice, the Steering Committee shall meet with a view to agreeing on remedial actions in good faith discussions.

(c) In the event that the Steering Committee cannot agree on remedial actions for the Manufacturing Problem within [***] of receipt of the Manufacturing Problem Notice, each Party shall have the right to request that an independent expert examines the root cause for the Manufacturing Problem and renders a respective expert opinion. As soon as possible, the Parties shall agree on an appropriate independent expert to be engaged by Merck.

(d) The fees of the independent expert shall be paid by the Party against whom the independent expert's decision is made.

(e) If the Parties or the independent expert (as the case may be) acknowledges that the Manufacturing Problem cannot be cured within a period of [***] following the Manufacturing Problem Notice and results in a supply shortage in the Territory, Merck shall have the right to initiate the technology transfer with regard to the Product(s) affected by the Manufacturing Problem and this Agreement shall terminate upon successful completion of the technology transfer.

(f) Any and all reasonable costs in fulfilling the technology transfer contemplated by this Section 5.8 shall be borne by Manufacturer except where Manufacturer can reasonably demonstrate that the Manufacturing Problem is not due to its fault (e.g. unavailability of Materials or equipment). Nothing contained in this Section 5.8 shall limit any rights or remedies that may be available to Merck on account of any failure of Manufacturer to supply the Product hereunder.

5.9 **Key Performance Indicators**. The Parties agree to measure Manufacturer's performance of its Development (when applicable) & Commercial Manufacturing Services through the establishment of Key Performance Indicators ("**KPIs**"). As long as Manufacturer only delivers up to [***] commercial Batches per year, Manufacturer shall provide Merck with [***] reports out of its performance based on the KPIs. From [***] Batches per year, the reports should occur [***]. The Parties are currently negotiating these KPIs which will be integrated to this Agreement by way of written amendment signed by both Parties. If the Parties do not manage to agree on reasonable KPIs within six (6) months from the Effective Date, either Party shall have the right to terminate this Agreement with immediate effect upon written notice sent in accordance with Section 23.10 to the other Party. The Parties may agree on additional KPIs by means of further amendments to this Agreement. The Parties shall agree upon the relative importance of the KPIs by classifying each KPI with a designation of "[***]", "[***]" or "[***]". The Parties shall agree in good faith by [***] of each [***], (beginning with the [***] of the Agreement), the performance level objectives of Manufacturer for the following [***]. The performance level objectives shall be established for individual KPIs and for overall performance and on the basis of actual, past performance, and shall be expressed in measurable values. In addition, minimum acceptance levels shall be agreed upon for all critical KPIs and for overall performance. Manufacturer shall use all Commercially Reasonable Efforts to ensure that its performance does not fall below these minimum acceptance levels. Notwithstanding Manufacturer's use of all Commercially Reasonable Efforts, if at any time Manufacturer's overall performance or performance for critical KPIs falls below the established minimum acceptance levels, Manufacturer shall promptly take corrective action to cure such under-performance.

5.10 **Process Improvements and Sharing of Costs Efficiencies**. Manufacturer shall monitor potential cost and quality improvements, including by seeking productivity improvements, by minimizing waste and improving yields, by purchasing quality materials at lower cost, by improving manufacturing processes, by streamlining organizational processes and by reducing cycle times and lead times. [***] per [***] during the Term, the Parties shall meet to discuss potential improvements identified by Manufacturer. Merck shall decide whether or not to implement at Merck's costs necessary changes to achieve the potential improvements. The Parties shall share [***] of any cost savings so achieved.

5.11 **Average Yield**. After the Manufacture of the first [***] successful Manufacturing Runs for validation and commercial purposes, the Parties shall calculate the average yield ("**Average Yield**") of such [***] Manufacturing Runs, disregarding [***]. As from the [***] Manufacturing Run, the price per Manufacturing Run set out in Section 6.2 below shall be adjusted as follows: if the average yield of all Manufacturing Runs in a campaign is more than [***] higher or lower than the Average Yield, the price for all Manufacturing Runs of such campaign shall be increased or reduced by applying a surcharge or discount, as the case may be, of [***] the percentage points beyond such [***] range, e.g. if the average yield of all Manufacturing Runs of a campaign is [***] below the Average Yield, a discount of [***] shall apply for Manufacturing Runs of such campaign. For the avoidance of doubt, in case the investigation of the low yield shows a technical failure due to Manufacturer's fault, then the price for all Manufacturing Runs of such campaign will be reduced by the difference below the [***], i.e, if the average yield of all Manufacturing Runs of such campaign is [***] below the Average Yield, a discount of [***] shall apply for all Manufacturing Runs of such campaign. Price [***] will be discussed and implemented once sufficient data are available.

ARTICLE 6
PRICE

6.1 **Development Services**. In consideration of the performance by Manufacturer of the Development Services, Merck shall pay Manufacturer the amounts specified in **Schedule 1**.

6.2 **Manufacturing Runs for commercial purposes**. In consideration of each Manufacturing Run, Merck agrees to pay to Manufacturer, in addition to the further costs and charges as set out in this Agreement, an amount of

[***] for each of the first [***] Manufacturing Runs in a [***] (based on the agreed Delivery Date),

[***] for each of the [***] to [***] Manufacturing Runs in a [***] (based on the agreed Delivery Date),

[***] for each of the following [***] to [***] Manufacturing Runs in a [***] (based on the agreed Delivery Date), and

[***] for each further Manufacturing Run in a [***] (based on the agreed Delivery Date),

All the above mentioned prices include production costs, Batch Documentation and IPC testings.

6.3 **Raw Materials and Consumables**. Costs of Materials and consumables to be used by the Manufacturer in the performance of the Services are not included in the fees under Sections 6.1 and 6.2 and shall be passed on to Merck at cost plus [***] handling fee. Costs of [***] shall be passed on to Merck at a cost plus [***]. Merck is aware that the consumption and prices of Materials and consumables vary from Manufacturing Run to Manufacturing Run. If an increase of total costs of Materials or consumables by more than [***] occurs, Manufacturer will give Merck sufficient and detailed information about the increase in costs for such Materials or consumables to reasonably demonstrate that the increase of the costs is justified. Upon request of Merck, Manufacturer will share the specific supplier invoices of such Materials or consumables.

6.4 **Packing and Qualification of Columns**. Manufacturer shall be entitled to charge for the packing and qualification of each column a lump-sum amount of [***]. Costs for spare parts for the columns are not included and shall be passed on to Merck at cost plus a [***] handling fee.

6.5 **Filling of Stability Samples**. Manufacturer shall be entitled to invoice for the filling of stability samples required for the performance and testing of stability studies performed at Merck an amount [***] for up to [***] bags. The costs for external testing ([***]) and transport of analytical samples and stability samples are not included and shall be passed on to Merck at cost plus [***] handling fee.

6.6 **Annual Product Review**. Manufacturer shall be entitled to charge for the annual product review an amount [***] per review.

6.7 **Project Management**. Manufacturer shall be entitled to charge for overall project management services [***] per [***].

6.8 **Regulatory Support**. Manufacturer shall be entitled to charge for regulatory support as set out in Section 13.9.

6.9 **External Analytical Testing**. Costs of external analytical testing for [***], [***] and [***] are not included and shall be passed on to Merck at cost plus a [***] handling fee.

6.10 **Transport of the Samples**. In the event Manufacturer organizes the transport of the samples to Merck or any third party including Manufacturer's subcontractors, transport costs shall be passed on to Merck at cost. Manufacturer shall bear the risk of loss during the transport of samples to/from its subcontractors. Merck shall bear the risk of loss during any other transport of samples starting from the moment Manufacturer hands over a sample to the courier service, including but not limited to the transport from Manufacturer to Merck.

6.11 **Storage of Columns**. Manufacturer shall be entitled to charge Merck for storage for columns that are not used during [***] consecutive [***] [***] per [***] per column for each [***] following the [***] period.

6.12 **Potential Extra Costs**. In addition to the above, Manufacturer shall be entitled to charge Merck costs and expenses of (i) changes to documentation, e.g. due to a request of a Regulatory Authority, (ii) the potential requirement of an [***] before production of the Drug Substance, (iii) reporting in the context of the continuous process verification (iv) concurrent lifetime and hold time studies (reports) for [***], and (v) any stability study.

6.13 **Costs of Process-Dedicated Equipment**. Where the performance of the Services requires Manufacturer to purchase any process-dedicated equipment (such as [***]) and when Merck consents in writing to it in advance, such consent not to unreasonably withheld, delayed or conditioned, Manufacturer shall be responsible for purchasing such process-dedicated equipment, for the implementation of such process-dedicated equipment at its facilities as required for the purposes of the Services, and for qualifying and maintaining such process-dedicated equipment. Manufacturer shall only purchase such process-dedicated equipment upon prior approval by Merck, for which Manufacturer shall provide Merck with a quotation from its supplier. Merck shall be responsible for any delay in the performance of the Services caused by a failure on the part of Merck to approve the purchase of such process-dedicated equipment within a reasonable time from being requested to do so by Manufacturer. Manufacturer shall also include the costs of such process-dedicated equipment as a separate item plus a [***] handling fee in its invoices for the Services. It is understood and agreed that, upon Merck paying the invoice that itemizes such process-dedicated equipment, Merck shall become the owner of such process-dedicated equipment, but shall allow Manufacturer to use such process-dedicated equipment for the purposes of the Services. Any process-dedicated equipment shall be used only for the purposes of the Services, and shall promptly be returned to Merck upon termination of this Agreement for any reason. Notwithstanding the above, Manufacturer shall purchase the first set of [***] at its own expense. In the event Merck does not order any commercial Batches under this Agreement, Manufacturer shall be entitled to invoice to Merck such first set of [***] at [***].

6.14 **Storage**. Manufacturer shall be entitled to charge Merck for the storage of Products in accordance with the Storage Agreement, however, only alter the first [***] of storage of Products.

6.15 **Travelling Costs**. Merck shall reimburse travelling expenses as may be reasonably incurred by Manufacturer in the course of the direct performance of the Services provided that (i) such expenses have been previously agreed upon in writing by Merck; (ii) such expenses will be based on 2nd class/economy class travel for all travels within Europe, unless agreed to otherwise in advance and in writing by Merck (with expenses for travel outside Europe to be agreed in advance and in writing); and (iii) that the reimbursement requests are accompanied with appropriate supporting evidence of such expenses.

6.16 **Agreed Hourly Rate**. The initial Agreed Hourly Rate shall be [***]. The hourly rate for formal validation support shall be [***].

6.17 **Indexation**. Except for pass-through costs, all amounts payable to Manufacturer under this Agreement as well as the Agreed Hourly Rate shall be revised upwards or downwards each year in accordance with the increase or decrease, as the case may be, of the harmonized German consumer price index published by the German Federal Statistical Office (*Statistisches Bundesamt*) on their official website (https://www.destatis.de) from January of the previous year to January of the then current year and invoices from Manufacturer to Merck from April onwards shall take such increase or decrease into account, e.g., if such index increases by zero point nine percent (0.9%) between January 2018 and January 2019, all amounts payable to Manufacturer which are invoiced on or after 1 April 2019 shall also increase by zero point nine percent (0.9%). However, just yearly increase or decrease cannot exceed [***] For the avoidance of doubt, the value of such index in December 2017 was 110.6 (on basis 2010 = 100). Manufacturer shall not be entitled to delay an invoice in order to charge the new increased amount instead of the applicable old amount. This clause shall apply for the first time as per [***], taking into account change of the German consumer price index from [***] to [***] and thereafter on a yearly basis.

6.18 **Taxes**. All payments under the Agreement are deemed exclusive of VAT or any other indirect taxes; The invoicing Party shall, if required under applicable laws & regulations, add VAT or any other indirect taxes to the Price at the prevailing rate under applicable laws & regulations; the invoicing Party shall also fulfill all material and formal conditions required from the invoicing Party under applicable laws & regulations to ensure a refund of the VAT or any other indirect taxes charged to the invoiced Party provided a refund is available to the invoiced Party under applicable laws & regulations.

6.19 **Tax Withholding**. The amounts payable by one Party (the "**Payer**") to another Party (the "**Payee**") pursuant to this Agreement ("**Payments**") shall not be reduced on account of any Taxes unless required by law. The Payee alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by the Payer) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Payer shall deduct or withhold from the Payments any Taxes that it is required by law to deduct or withhold. Notwithstanding the foregoing, if the Payee is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it shall promptly deliver to the Payer or the appropriate Governmental Authority (with the assistance of the Payer to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Payer of its obligation to withhold Tax, and the Payer shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be. If, in accordance with the foregoing, the Payer withholds any amount, it shall make timely payment to the proper Governmental Authority of the withheld amount, and send to the Payee reasonable proof of such payment within sixty (60) days following that payment. If Taxes are paid to a tax authority, each Party will provide the other such assistance as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.

ARTICLE 7
INVOICES AND PAYMENT

7.1 **Invoices**. Manufacturer shall invoice Merck in accordance with ARTICLE 6. Each invoice shall specify the Price in respect of the Products delivered, the quantity of Batches of the Products delivered and the amount of sales, use, value added, excise or equivalent indirect tax due in respect of the Products delivered and the Purchase Order reference number. Manufacturer's invoices shall comply with all Applicable Laws.

7.2 **Payment of Invoices**. Merck shall pay the invoices issued by Manufacturer in Euro within [***] from the date of receipt of the invoice by electronic transfer to the account nominated in writing by Manufacturer, except in case of any Product rejected in accordance with ARTICLE 9. In case of rejection, the term of payment will start once the delivery is accepted by Merck. In case Manufacturer will store Product free of charge at Merck's demand at Manufacturer's premises, payment process will be triggered at reception of the Batch Documentation.

ARTICLE 8
QUALITY ASSURANCE

8.1 **Validation Studies**. Manufacturer shall perform validation studies as agreed between the Parties in writing, or to the extent required by the Specifications, cGMP or Applicable Laws to manufacture the Products at the Manufacturing Site.

8.2 **Analytical Reference Standards**. Merck shall provide, without charge to Manufacturer, analytical reference standards for the Products. The reference standards shall be provided in quantities reasonably required for Manufacturer to perform its obligations relating to the manufacture, stability testing or any other testing of the Products under this Agreement.

8.3 **Technical and Quality Matters**. The respective responsibilities of each Party in relation to technical and quality matters connected to the performance of the Services are further set out in the Quality Agreement.

8.4 **Release Testing**. Prior to release of the Products to finished goods inventory, Manufacturer shall test the Products in accordance with the testing procedures for bioburden (external lab), content by[***] described in the Specifications. All other release testing procedures will be performed by Merck.

8.5 **Man-in-Plant**. Manufacturer agrees that, at Merck's option, Merck representatives may be present at the Manufacturing Site (including adequate temporary desk space and other reasonable resources available to these representatives during the periods they are at the Manufacturing Site) during the performance of certain Services and manufacturing of Product(s) for the purposes of inspecting, sampling, check weighing, and documenting the manufacturing of the Product(s) and all associated records in connection therewith. Any Merck employees who are present at the Manufacturing Site shall comply with Manufacturer's site regulations and rules. The Merck representative, if present, does not have responsibility for the supervision of Manufacturer's personnel or the manufacturing of the Product(s). However, if at any time the Merck representative thinks that Manufacturer is operating in a manner not compliant with the know-how or which could adversely affect the manufacturing of Product(s), he/she may recommend that Manufacturer cease operations until such condition is remedied.

ARTICLE 9
DEFECTIVE PRODUCTS AND DEFECTIVE SERVICES

9.1 **Warranty**. Subject to Section 18.3, Manufacturer warrants to Merck that at the time of delivery of any Batch of the Product: (i) as far as Services performed by Manufacturer, its Affiliates and/or subcontractors are concerned, the Batch will have been manufactured in accordance with the relevant conditions applicable hereunder as specified in the relevant Work Order or Purchase Order; (ii) each Batch will only be released by Manufacturer if it has passed the Quality Control Procedure conducted by Manufacturer and Merck whereby Manufacturer may, in the process of its Quality Control Procedure, unconditionally rely on all data provided by Merck; (iii) as far as Services performed by Manufacturer, its Affiliates and/or subcontractors are concerned the Batch will be manufactured using and in accordance with the Manufacturing Process and in accordance with cGMP, the Services Related Requirements of the Specifications, the provisions of the Quality Agreement and Applicable Laws. Further, Manufacturer warrants and represents to Merck (i) that, during the Term of this Agreement, Manufacturer will have obtained and maintained such approvals and licenses as may be required under applicable laws, rules, regulations and requirements to operate its manufacturing facilities for the purposes contemplated by this Agreement, and (ii) as far as Services performed by Manufacturer, its Affiliates and/or subcontractors are concerned that Batch Documentation shall be generated and stored in accordance with cGMP, the Services Related Requirements of the Specifications, the provisions of the Quality Agreement and Applicable Laws.

9.2 **Non-conforming Batch**. Where Manufacturer or Merck, through own sample analysis before delivery of a Batch, finds that any Batch fails or will fall to comply with any Product Related Requirements of the Specifications, including but not limited to the release specifications (i) Manufacturer or Merck, as the case may be, shall notify the other Party thereof within [***], (ii) Manufacturer shall not deliver the Batch, (iii) Manufacturer shall, upon request by Merck in case Manufacturer had not already provided samples, promptly provide Merck with samples of the Batch in order to allow Merck to perform its own analysis of the failed Batch; (iv) at the latest within [***] of the first notification, Manufacturer shall provide Merck with a written report summarizing results of Manufacturer's investigation of the cause of such failure, and (v) the Parties shall thereafter discuss in good faith said failure and consider which optimization or correction shall be implemented by Manufacturer in order to perform another Batch, which additional Manufacturing Run, if mutually decided, shall be subject to the execution of a written amendment to the respective Work Order or Purchase Order which shall set forth the new terms and conditions or such additional Manufacturing Run. In case the non-compliance of said Product is determined to have arisen from Manufacturer's breach of the warranties set out in Section 9.1, Sections from 9.6 to 9.9 shall apply. In case the non-compliance of said Product is determined not to have arisen from Manufacturer's breach of the warranties set out in Section 9.1, Merck may request Manufacturer to perform, at Merck's sole cost, an additional Manufacturing Run and produce a new cGMP Batch replacing the rejected cGMP Batch as soon as reasonably possible. Notwithstanding the foregoing, Merck shall have the unfettered right to discretionary decide not to perform an additional production Service. For clarity: Merck shall pay Manufacturer the applicable Price for a Manufacturing Run despite the fact that a non-conforming Product was generated unless such non-compliance was caused by Manufacturer's breach of the warranties set out in Section 9.1 and rejected by Merck in accordance with Section 9.6. In case the non-compliance of said Product is determined to have arisen from Manufacturer's failure to perform the Services in accordance with the warranties set out in Section 9.1, Section 9.6 shall apply. In case the reason for the non-compliance cannot be determined, Merck shall pay Manufacturer [***] of the applicable Price for the respective Manufacturing Run.

9.3 **Acceptance, Rejection of Product**. Merck will notify Manufacturer in writing of its acceptance or rejection of any shipment of Product hereunder within [***] of the [***] receipt of any [***], including but not limited to the [***], and within [***] of the [***] receipt of [***] to Merck or to the third party designated by Merck or, in the case of any defects not reasonably susceptible to discovery upon receipt, within [***] after discovery by Merck or third party designated by Merck. For clarity: the aforementioned notice periods shall in any case not start during storage of the containers containing the Product at Manufacturer as the containers containing the Product need to be physically received by Merck or a third party designated by Merck. Merck has no obligation to accept such Products if they do not comply with any warranty set out in Section 9.1. In the absence of any such written notification of Merck to Manufacturer within the applicable time period set out above, containing in reasonable detail the reasons of the non-conformance, the applicable Product shall be deemed to comply with and accepted by Merck ("**Acceptance**"). Upon receipt of a Product, Merck shall retain full control and title to the relevant Product and shall transport and store (or shall ensure that the third party designated by Merck shall transport and store) such Product under appropriate and controlled conditions compliant with cGMP requirements. Any other use or processing of such Product by or on behalf of Merck [***] shall be at the sole risk, responsibility and expense of Merck and shall constitute an unconditional Acceptance of such Product. This Section 9.3 shall apply to both (i) the shipment of the Batch Documentation to Merck as well as (ii) the shipment of the Product itself. In the former event, the Acceptance relates to the Batch Documentation, i.e. the compliance of the Product with any warranty as set out in Section 9.1, while in the latter event the Acceptance relates to the primary packaging of the Product.

9.4 **Resolution of Dispute as to Whether a Product is Non-Conforming**. The Parties shall cooperate in good faith to determine whether a rejection of Product is appropriate. If the Parties disagree, a sample of the rejected Product and a sample retained by Manufacturer shall be exchanged between Merck (or a third party designated by Merck reasonably acceptable to Manufacturer) and Manufacturer for a counter-check. If such counter-check does not resolve the dispute, a sample of the rejected Product and a sample retained by Manufacturer shall be submitted to an independent, qualified Independent Expert that is mutually acceptable and selected by Manufacturer and Merck promptly in good faith. Such Independent Expert shall determine whether the rejected deliverable met the warranties set out in Section 9.1 at the time of delivery by Manufacturer to Merck or to the third party designated by Merck, as applicable and such Independent Expert's determinations shall be final, binding upon the Parties and determinative for purposes of this Agreement. The Party against whom the Independent Expert rules, shall bear all costs of the Independent Expert.

9.5 **Conforming Product**. If the Parties have agreed, or if the Independent Expert determines that the Product was conforming in all respect with the warranties set out in Section 9.1 at the time of delivery by Manufacturer then such Product shall be deemed to have been accepted by Merck, and Merck shall make the final payment therefor in accordance with ARTICLE 6.

9.6 **Non-Conforming Product**. If the Parties have agreed or if the Independent Expert determines that the Product was not conforming to the warranties set out in Section 9.1 at the time of delivery by Manufacturer then such Product shall be deemed to have been rejected by Merck, and Manufacturer shall refund to Merck all payments made by Merck therefore in accordance with ARTICLE 6.

9.7 **Responsibility of Manufacturer**. For the avoidance of doubt, Manufacturer shall not be responsible for (and Merck shall pay the Price for such Manufacturing Run in full) if the reason for the non-compliance of the Product is for any other reason but for a breach of the warranties set out in Section 9.1, such other reason being for example [***]. Accordingly, Manufacturer shall also not be responsible for any delay or non-performance of Services of Manufacturer caused by reasons outside of Manufacturer's responsibility (e.g. [***]), if Manufacturer took all reasonable actions to prevent such delay or non-performance of the Services.

9.8 **Sole Remedy**. It is specifically agreed that, in addition and without prejudice to what is set out in Sections 5.6, 18.1 and ARTICLE 19, the actions described in this ARTICLE 9 shall be the sole remedy of Merck in the event any Product supplied by Manufacturer in the context of Commercial Manufacturing Services fails to conform to the warranties set out in Section 9.1. The limitation of remedies set out herein shall not apply in case of failure by the Manufacturer to perform its obligations hereunder due to the Manufacturer's wilfull misconduct or gross negligence unless Manufacturer's gross negligence in the performance of its obligations hereunder has resulted into a Defect in a Batch ordered by Merck and Manufacturer, at Merck's request, offers and successfully performs at its own costs a new Manufacturing Run under the terms and conditions of Section 9.9.

9.9 **Defective Services**. In the event that Manufacturer is not properly performing Development Services pursuant to this Agreement, except where Manufacturer can reasonably demonstrate that such malperformance is not due to its fault (e.g. [***]), Manufacturer shall, at Merck's option, either re-perform as set out below at its own costs the defective Development Services in accordance with the Specifications and this Agreement or refund to Merck the price and/or any advance payments paid for such defective Development Services. For the avoidance of doubt, in the event that Merck opts for the re-performance of defective Development Services consisting in the re-performance of Manufacturing Runs, Manufacturer shall use its best efforts to schedule the start of such new Manufacturing Runs as early as possible and anyway not later than a maximum of [***] from Merck's request for the reperformance of the defective Development Service or, as the case may be, not later than a maximum of [***] after the root cause identification of the Defect affecting the Batch to be replaced. In order to secure a quicker slot, Merck shall also have the option to reserve one or several back-up Manufacturing Runs by issuing one or more Work Orders at least [***] prior the Delivery Date. In case such back-up Manufacturing Run(s) is/are needed due to a failure by the Manufacturer to perform its obligations hereunder, no cost will be charged by the Manufacturer to Merck for such back-up Manufacturing Run(s). If the ordered back-up Manufacturing Run(s) is/are not needed and the relevant Work Order is cancelled by Merck, Merck shall pay in derogation of Section 4.8 a lump-sum of [***] as cancellation fee independently of the time when the cancellation of the Work Order occurred unless the reallocation of such back-up Manufacturing Run(s) is possible under Section 4.9 excluding Merck's obligation to pay a cancellation fee. In addition and without prejudice to what is set out in Sections 5.6, 18.1 (for the case of death and bodily injuries) and ARTICLE 19, the remedies set out in this Section 9.9 shall be Merck's sole and exclusive remedies under this Agreement with respect to any defective Development Services and any delay caused by defective Development Services. The limitation of remedies set out herein shall not apply in case of failure by the Manufacturer to perform a Development Service due to the Manufacturer's wilfull misconduct or gross negligence unless Manufacturer's gross negligence in the performance of its obligations hereunder has resulted into a Defect in a Batch ordered by Merck and Manufacturer, at Merck's request, offers and successfully performs at its own costs a new Manufacturing Run under the terms and conditions of this Section 9.9.

ARTICLE 10
PRODUCT LICENSES

Merck shall, at its expense, obtain and maintain all necessary Product Licenses. Merck shall be responsible for responding to all requests for information related to such Product Licenses made by, and for making all legally required filings relating to such Product Licenses with, any Regulatory Authority having jurisdiction to make such requests or require such filings. If any Product License held by Merck relating directly to the Products is hereafter suspended or revoked, Merck shall promptly notify Manufacturer of the event and shall promptly inform Manufacturer of the Impact an Merck's purchases of the affected Products and Merck's general intentions with respect to the affected Product.

ARTICLE 11
TRIAL AUTHORIZATION

Merck or a Merck's designated third party shall, at its expense, obtain and maintain all necessary Trial Authorizations. Merck or a Merck's designated third party shall be responsible for responding to all requests for information related to such Trial Authorizations made by, and for making all legally required filings relating to such Trial Authorizations with, any Regulatory Authority having jurisdiction to make such requests or require such filings. If any Trial Authorization held by Merck or a Merck's designated third party relating directly to the Products is hereafter suspended or revoked, Merck shall promptly notify Manufacturer of the event and shall promptly inform Manufacturer of the impact on Merck's purchases of the Product and Merck's general intentions with respect to the Trial.

ARTICLE 12
CHANGES TO PRODUCT SPECIFICATIONS

12.1 **Changes Requested by Manufacturer**. Notwithstanding anything herein to the contrary, Manufacturer shall not amend, change or supplement any of the following except in accordance with the change control provisions set forth in the Quality Agreement: (a) the Specifications, (b) the Materials, (c) the source of Materials, (d) the specifications for Materials, (e) the Manufacturing Site or the equipment used in manufacturing the Product, (f) the test methods used to test the Products or Materials, or (g) the process for manufacturing the Products (each of the foregoing a "**Technical Change**").

12.2 **Changes Requested by Merck**. Merck may request a Technical Change by written notice to Manufacturer, and except as prohibited by Applicable Law, Manufacturer shall use Commercially Reasonable Efforts to implement such change within a reasonable period of time.

12.3 **Required Manufacturing Changes**. Each Party shall notify the other Party of any Technical Change which is required by cGMPs or Applicable Laws (a "**Required Manufacturing Change**"). Manufacturer shall use Commercially Reasonable Efforts to implement Required Manufacturing Changes within a reasonable period of time.

12.4 **Cost of Technical Changes** All reasonable out-of-pocket costs associated with Required Manufacturing Changes that relate to the Product or to the performance of any Services (including the cost of any Regulatory Authority filings and any write offs and other similar costs due to such changes associated with obsolete Materials, work-in-process and finished Product inventories, and printed materials, including packaging and labelling materials) shall be borne by Merck, except with respect to Materials purchased by Manufacturer in excess of the amounts needed to fulfil Manufacturing Runs set out in the Firm Zone, unless otherwise procured by Manufacturer in advance with Merck's consent (provided that Manufacturer will use Commercially Reasonable Efforts to minimize the costs associated therewith).

12.5 **Technical Change Implementation**. All Technical Changes (including Required Manufacturing Changes) shall be implemented in accordance with Applicable Laws, cGMP and the Quality Agreement. Prior to implementation of any Technical Change, the Parties shall ensure that any implications on the quality of the Products have been considered and recorded, and the change is approved by the relevant Regulatory Authorities. Manufacturer shall provide Merck with technical assistance at the Agreed Hourly Rate, including through the provision of supporting documentation in order to permit Merck to amend and file any relevant document required to be filed with a Regulatory Authority.

ARTICLE 13
QUALITY & REGULATORY COMPLIANCE

13.1 **Maintenance of Permits**. Manufacturer shall maintain all Manufacturing Licenses and other regulatory and governmental permits, licenses and approvals that may be necessary to Manufacture Product.

13.2 **Notification of Adverse Manufacturing Activities**. Manufacturer shall advise Merck of any information arising out of its Services that has adverse regulatory compliance and/or reporting consequences concerning the Product.

13.3 **Activities at the Manufacturing Site and Machinery Used to Manufacture Products**. Manufacturer shall not carry out any other activities at the Manufacturing Site that may prejudice the quality, safety or efficacy of the Products.

13.4 **Storage**. Manufacturer shall at all times store and warehouse all Materials and Products in premises that are secure, clean, compliant with the Specifications, Manufacturing Licenses and the Quality Agreement and otherwise reasonably acceptable to Merck and shall be physically separated from all other materials and products in Manufacturer's possession. Manufacturer shall be responsible for the safe storage and handling of the Products until delivery to Merck in accordance with the Delivery Terms. The Manufacturer shall keep records of the storage conditions in relation to each Batch of Products in accordance with the requirements set forth in the Quality Agreement. Manufacturer agrees to disclose to Merck from time to time or upon Merck's request, subject to Manufacturer's confidentiality obligations to its other customers, the nature of any relevant products manufactured or packaged by Manufacturer for itself or third parties which use the same machinery as that used by Manufacturer for the Manufacture of Products under this Agreement or that are stored in the same location where the Products or Materials are stored in order that Manufacturer and Merck may identify any potential effects on quality, safety or efficacy of the Products which may result.

13.5 **Requests from and Inspections by Regulatory Authorities**. Provisions covering correspondence, interaction with and provision of information to Regulatory Authorities, including inspections, are set forth in the Quality Agreement.

13.6 **Audits by Merck**. Representatives of Merck may, upon reasonable notice, at times reasonably acceptable to Manufacturer and in accordance with the further terms and conditions agreed in the Quality Agreement, (i) visit, inspect and audit the Manufacturer's facilities where the Services are being performed, and (ii) consult informally, during such visits and by telephone, with personnel of Manufacturer performing work on the Services; provided, however, that Manufacturer shall accompany each on Merck's initial visit to Manufacturer's facilities. Any such visits will be coordinated with a representative of Manufacturer to be designated in writing following execution of this Agreement.

In addition, Merck shall also be entitled, upon prior written notice to Manufacturer, to conduct audits "for cause" which shall include, without limitation, manufacturing or facility issues affecting the Manufacture of the Product or quality of the Product (including cGMP), at times reasonable acceptable to Manufacturer, but in any case no later than [***] from receipt by Manufacturer of said prior written notice. Merck shall not be charged by Manufacturer for any audit made "for cause".

Any information and data disclosed to Merck pursuant to this Section 13.6 shall be deemed Confidential Information subject to the obligations of confidentiality and non-use as provided in ARTICLE 16.

13.7 **Audit and Inspection Fees**. Manufacturer shall be entitled to charge for the costs of audit and inspections at the agreed hourly rate except for [***] audit every [***] which shall be [***]. In addition, Manufacturer shall not be entitled to charge any amounts to Merck where an audit or inspection is "for cause".

13.8 **Handling of Materials; Wastes**. Manufacturer shall inform its employees, contractors and other personnel of any known or reasonably ascertainable chemical hazards associated with the Products or any wastes (including, Hazardous Materials) generated through performance of the Services, and to provide such persons with reasonable training in the proper methods of handling and disposing of such items. In addition, Manufacturer shall handle, accumulate, label, package, ship and dispose of all wastes (including, Hazardous Materials) generated through performance of the Services in accordance with all Applicable Laws.

13.9 **Documentation for Regulatory Authority Requirements**. Manufacturer shall maintain in accordance with and for the period specified in the Quality Agreement (unless cGMP or Applicable Laws require a longer period), complete and accurate records relating to the manufacture of Products and to the performance of Services as it may be required to hold under such Applicable Law. Manufacturer shall provide Merck with such documentation promptly upon Merck's request.

13.10 **Assistance with Regulatory Filing**. Manufacturer shall prepare and provide to Merck, at no additional cost (unless otherwise agreed to in writing by the Parties), the reports agreed and described in **Schedule 5** supporting manufacturing operations for the Products (including, without limitation, [***]) for Merck's use in updating the [***] of the applicable IND/CTA and/or NDA/BLA. The above-mentioned reports might be used as is in regulatory submission or in the framework of response to questions. Assistance to provide response to questions received from authorities should be provided within the due evaluation timelines as appropriate and at Merck's expense as described in **Schedule 5**, except in case of deficiency of Manufacturer's Services in which case Merck shall not pay for such Services. Manufacturer shall provide at the Agreed Hourly Rate mentioned in Section 6.16 further regulatory assistance as may reasonably be required by Merck.

13.11 **Debarment and Exclusion**. Manufacturer represents and warrants that neither it, its subcontractors, nor any individual, corporation, partnership or association engaged in connection with the performance of services under this Agreement, has ever been, are currently, nor during the performance of any services hereunder, shall become:

(i) disqualified or debarred by the FDA or other competent Regulatory Authorities for any purpose pursuant to Applicable Laws (including but not limited to United States law, including but not limited to the statutory debarment provisions at 21 U.S.C. § 335a(a) or (b));

(ii) charged or convicted for conduct relating to the development or approval of, or otherwise relating to the regulation of, any drug product under any Applicable Laws; or

(iii) excluded or threatened with exclusion under state or federal laws, including under 42 U.S.C. § 1320a-7 or relevant regulations in 42 C.F.R. Part 1001, or assessed or threatened with assessment of civil money penalties pursuant to 42 U.S.C. Part 1003.

Manufacturer agrees to notify Merck immediately, in the event that Manufacturer or any of its officers, directors, employees, agents, or parties under contract to perform and work under this Agreement (i) becomes debarred, excluded or convicted, or (ii) receives notice of action with respect to its debarment, exclusion or conviction during the Term. Manufacturer hereby certifies that it has not utilized, and shall not utilize, in any capacity the services of any individual, corporation, partnership or association in the performance of work for Merck under this Agreement that has been (X) debarred, or to its knowledge has received notice of action with respect to debarment, under the Generic Drug Enforcement Act of 1992, 21 United States Code §335a(a) and (b), as amended or any foreign equivalent thereof, (Y) excluded pursuant to 42 U.S.C. § 1320a-7 or relevant regulations in 42 C.F.R. Part 1001 or to its knowledge has received notice of exclusion or any foreign equivalent thereof or (Z) otherwise convicted pursuant to (ii) above, or to its knowledge has received notice of conviction or any foreign equivalent thereof. In the event that Manufacturer receives any notice of actions set forth in this Section 13.110 (with regard to Manufacturer only but not including an individual employee, officer, director, agent or subcontractor), without limiting any other rights or remedies of Merck, Merck shall have the right to terminate this Agreement immediately pursuant to the provisions of this Agreement. Any termination by Merck pursuant to this Section 13.11 shall be deemed to be a termination by Merck for material breach of this Agreement by Manufacturer pursuant to Section 19.7.

13.12 **Compliance with REACH**. Merck Manufacturer shall ensure compliance with the Registration requirements stipulated in Regulation (EC) No. 1907/2006 ("**REACH**") with respect to Products manufactured and Raw Materials required by Manufacturer. Merck shall, at its expense, be responsible for responding to regulatory developments with impact on the manufacturing process, such as the inclusion of Raw Materials in Annex XIV to the Reach regulation ("Authorization"), and to decide on the approach chosen, such as technical changes to substitute substances of concern, or regulatory action to satisfy the requirements.

ARTICLE 14
OPERATIONAL MANAGEMENT; STEERING COMMITTEE

14.1 During the Term, the operational management of the relationship between the Parties shall lie with the Steering Committee established by the Parties in accordance with this ARTICLE 14.

14.2 The Steering Committee shall be composed of [***] representatives of each Party but of at least one member of the management of each Party and one additional representative of each Party. It shall have the general responsibility for the implementation of the Clinical and Commercial Supply Agreement. The Steering Committee's resolutions shall be adopted unanimously, with an escalation to the Parties' senior management in the event of a blockage or tie.

14.3 The tasks of the Steering Committee shall include, without limitation:

(a) periodically review the KPIs outlined in **Schedule 2**, and update such KPIs as may be required;

(b) consider and, when appropriate, approve amendments to the Material Specifications;

(c) periodically review the level of the Manufacturer's Safety Stocks and adjust their level as deemed necessary, as contemplated in Section 2.13;

(d) work on a mutually acceptable resolution to minimize the consequences of a late delivery, as contemplated in Section 5.6; and

(e) agree on remedial actions to address Manufacturing Problems, as contemplated in Section 5.8.

14.4 The Steering Committee shall pass its resolutions:

(a) in meetings on the occasion of which all members are present (either in person or through voice or video conferencing systems); or

(b) by written consent to a proposal submitted by one of their members.

ARTICLE 15
PRODUCT COMPLAINTS AND ADVERSE EVENTS

15.1 **Product Complaints, Adverse Events and Product Events**. Provisions covering complaints or Adverse Events are set forth in the Quality Agreement. Provisions covering voluntary and involuntary recalls, product withdrawals, field corrections, field alerts, or other related actions ("**Product Event**") of Finished Medicinal Products are set forth in the Quality Agreement.

15.2 **Expenses Resulting from a Product Event**. In the event that a Regulatory Authority requires, or Merck decides to, initiate a Product Event with respect to a Finished Medicinal Product using Product manufactured by Manufacturer under this Agreement, Merck shall promptly notify Manufacturer. Manufacturer shall fully cooperate with Merck in implementing the foregoing as Merck or the Regulatory Authority may require. If the Product Event is due to a breach of this Agreement by Manufacturer or Manufacturer's negligence or wilful misconduct, Manufacturer shall replace all Products used for manufacturing recalled Finished Medicinal Products, at Manufacturer's cost.

ARTICLE 16
CONFIDENTIALITY AND DATA PROTECTION

16.1 **Non-Use, Non-Disclosure**. Manufacturer shall use the Confidential Information only for the purpose of providing Development and Commercial Manufacturing Services hereunder. Except as otherwise provided for herein, Manufacturer shall not, at any time (whether during this Agreement or alter its termination) use, for Manufacturer's own or any Third Party's benefit or purposes or disclose, publish or make available all or any portion of the Confidential Information to any other Third Party, without the Prior written consent of Merck. Merck Background IP and Merck Arising IP shall be considered the Confidential Information of Merck.

16.2 **Standard of Care**. Manufacturer shall maintain and protect the confidentiality of Confidential Information and shall use at least the same degree of care to safeguard and to prevent disclosing of Confidential Information as it employs to avoid unauthorized disclosure, publication, dissemination, destruction, lass, or alteration of its own confidential information (or information of its customers of a similar nature), but at all times shall use at least reasonable care. Manufacturer shall implement and maintain appropriate security measures to prevent unauthorized access to, or disclosure of Confidential Information. Manufacturer personnel and approved subcontractors shall have access to Confidential Information Only to the extent necessary for such person to perform his or her obligations under or with respect to this Agreement or as otherwise naturally occurs in such person's scope of responsibility, provided that such access is not in violation of Applicable Law.

16.3 **Required Disclosures**. The obligations of confidentiality, non-disclosure and non-use hereunder shall continue until the relevant Confidential Information falls within the exceptions provided for in Section 16.4 hereof. Notwithstanding the foregoing, Manufacturer shall be entitled to disclose the Confidential Information to the extent required by Applicable Law or court order on the condition that Manufacturer provides Merck with written notice that the Confidential Information is required to be disclosed sufficiently in advance of the disclosure so as to provide Merck with reasonable opportunity to seek to prevent the disclosure of or to obtain a protective order for the Confidential Information; and provided further that Manufacturer shall reasonably assist Merck in obtaining a protective order, shall make any required disclosures in consultation with Merck and shall clarify the confidential nature of the disclosed Confidential Information.

16.4 **Exclusions to Confidentiality**. Manufacturer shall not have any obligation hereunder with respect to any Confidential Information if such Confidential Information (a) is, at the time of disclosure or becomes alter disclosure, general or public knowledge through no breach of the Agreement by Manufacturer; (b) was, at the time of disclosure by Merck, already known by Manufacturer, as established by written record; or (c) is received by Manufacturer from a Third Party having the right to disclose same and who is not bound by a confidentiality agreement in favour of Merck or its Affiliates.

16.5 **Notification**. In the event Manufacturer becomes aware or has knowledge of any unauthorized use or disclosure of Confidential Information under Manufacturer's control, Manufacturer shall promptly notify Merck of such unauthorized use or disclosure and, thereafter, shall take all reasonable steps to assist Merck in attempting to minimize any potential or actual damages or losses resulting from such unauthorized use or disclosure.

16.6 **Return**. Upon receipt of a written request from Merck, or upon termination of this Agreement, Manufacturer shall promptly return to Merck all Confidential Information, including all reproductions and copies thereof together with all internal material and documents generated by Manufacturer containing Confidential Information or references thereto and Manufacturer shall delete all such Confidential Information and references thereto stored electronically. Notwithstanding the above, Manufacturer may retain a single copy of any Confidential Information as is reasonably necessary for regulatory or insurance purposes, subject to Manufacturer's obligations of confidentiality under this Agreement.

16.7 **Public Announcements**. Neither Party shall make any press nor other public announcement concerning any aspect of this Agreement, unless the text of such announcement is first approved in writing by the Parties to this Agreement. Provisions covering inspections and audits of Manufacturer, including with respect to the Manufacturing Site, whether by Merck or a Regulatory Authority, are set forth in the Quality Agreement.

16.8 **Manufacturer Confidential Information**. Merck acknowledges it may receive confidential and proprietary information from Manufacturer including but not limited regarding its methodology, testing processes, packaging and manufacturing techniques, data collection and/or data management techniques, commercial information, prices and contractual terms ("**Manufacturer Confidential Information**"). Merck shall treat any Manufacturer Confidential Information in the same confidential manner as Manufacturer is obliged to treat Confidential Information as set forth in this Agreement, except that Merck may disclose such information as is requested by Regulatory Authorities or as is necessary to be included in regulatory filings or Product Licenses (e.g. Drug Master Files).

16.9 **Data Processing Agreement**. If and to the extent Personal Data is processed on behalf of Merck by Manufacturer so that Manufacturer is acting as a "**Processor**", the Data Processing Agreement attached as **Schedule 6** shall apply.

16.10 **Audit And Inspection Rights**. Additional provisions covering inspections and audits of Manufacturer, including with respect to the Manufacturing Site, whether by Merck or a Regulatory Authority, are set forth in the Quality Agreement.

ARTICLE 17
WARRANTIES

17.1 **Mutual Representations and Warranties**. Merck and Manufacturer each represent and warrant to the other that:

(a) **Organization and Authority**. It has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement;

(b) **No Conflicts or Violations**. The execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of Applicable Laws existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date; and

(c) **Valid Execution**. Such Party is duly authorized, by all requisite corporate action, to execute and deliver this Agreement and the execution, delivery and performance of this Agreement by such Party does not require any shareholder action or approval or the approval or consent of any Third Party, and the person executing this Agreement on behalf of such Party is duly authorized to do so by all requisite corporate action.

17.2 **Manufacturer Representations and Warranties for Manufacturing the Products**. In addition to the warranty pursuant to Section 9.1, Manufacturer represents and warrants to Merck that:

(a) **Good Title, No Encumbrances**. It will convey good title to the Products supplied under this Agreement, free from any lawful security, interest, lien or encumbrances;

(b) **Right to Manufacturer Background IP**. It has the title and/or right to any and all Manufacturer Background IP used to Manufacture the Products in accordance with this Agreement; and the Manufacture of the Products by Manufacturer or its. Affiliates or by Merck or its Affiliates will not infringe the Intellectual Property or any other rights of any Third Party;

(c) **Compliance Obligations**. Merck intends to conduct its business in accordance with environmental, labor and social standards and to abide by the standards set forth in the *Human Rights Charter and Code of Conduct* (including Merck values) referred to under **Schedule 3**. Manufacturer shall comply, and shall ensure that its subcontractors comply, with reasonably comparable environmental, labor and social standards. Manufacturer acknowledges that it is aware of the *OECD Convention an Combating Bribery of Foreign Public Officials in International Business Transactions* and shall comply, and shall ensure that its subcontractors comply, with its principles. Manufacturer shall not offer, promise, give, authorize or consent to the giving of money or anything of material value to any person (i) with the purpose or effect of securing any improper advantage in order to obtain or retain business or (ii) to induce or prevent the performance of an individual's duties in violation of Applicable Law. Should Merck discover that Manufacturer or its subcontractors are in breach of the foregoing, Merck may terminate this Agreement without notice.

(d) **Compliance with Merck's Responsible Sourcing Principles and Customs and Foreign Trade**. It will, and it will endeavour to ensure that its subcontractors, comply with internationally recognized fundamental environmental, labour and social standards, as described in Merck's Responsible Sourcing Principles referred to under **Schedule 3**. Upon request of Merck, Manufacturer shall provide Merck with a supplier declaration as per **Schedule 4**.

(e) **Bribery**. It will neither offer to give nor give money or gifts to Merck employees or members of their families in exchange for business from Merck; and

(f) **Change of Control**. It will provide prompt written notice to Merck in the event of any Change of Control.

17.3 **Manufacturer Representations and Warranties for the Development Services**. Manufacturer represents and warrants to Merck that:

(a) **Performance**. The Services shall be performed in accordance with cGMP and Applicable Laws with respect to the performance of Services;

(b) **Right to Manufacturer Background IP**. It has the title and/or right to any and all Manufacturer Background IP used to perform the Services in accordance with this Agreement; and the use by Manufacturer or its Affiliates of Manufacturer Background IP will not infringe the Intellectual Property or any other rights of any Third Party.

17.4 **Merck Representations and Warranties**. Merck represents and warrants to Manufacturer that it holds all necessary Product Licenses with respect to the Products and that:

(a) **Trial Authorizations**. It holds all necessary Trial Authorizations to conduct the Trial.

(b) **Right to Merck Background IP**. It has the title and/or right to any and all Merck Background IP supplied to Manufacturer in accordance with this Agreement for the Manufacture, labelling and packaging of the Products, and further that it has the title and/or right to grant Manufacturer the right to use such Intellectual Property in accordance with the terms of this Agreement and the use by Manufacturer or its Affiliates of Merck Background IP will not infringe the Intellectual Property or any other rights of any third party.

ARTICLE 18
INDEMNITY

18.1 **Indemnification by Manufacturer**. Manufacturer shall indemnify, hold harmless and, upon request of Merck, defend Merck, its Affiliates and its and their directors, officers, representatives, shareholders, employees and agents, and their respective successors and permitted assigns, from any and all Losses from any Third Party claims, proceedings, actions or causes of actions ("**Third Party Claims**") which arise out of (a) the faire of Products to meet the warranties set forth in Section 9.1 and (b) any other breach by Manufacturer of any of its representations, warranties, covenants, agreements or obligations under this Agreement, or the negligence, recklessness or wilful misconduct of Manufacturer (or its Affiliates or subcontractors) in the performance the Services and any of its obligations hereunder; in each case except to the extent such Third Party Claim arises out of matters contemplated in Section 18.2 (a) or (b) below. In the event a Third Party Claim is caused by both Party's behaviour, the amount of indemnification shall depend on the circumstances, in particular to what extend the Third Party Claim is caused mainly by one or the other Party.

18.2 **Indemnification by Merck**. Merck shall indemnify, hold harmless and, upon request of Manufacturer, defend Manufacturer, its Affiliates and its and their directors, officers, representatives, shareholders, employees and agents, and their respective successors and permitted assigns, from any and all Losses from any Third Party Claims which arise out of (a) a breach by Merck of any of its representations, warranties, covenants, agreements or obligations under this Agreement and (b) the negligence, recklessness or wilful misconduct of Merck (or its Affiliates or subcontractors) in the performance of its obligations hereunder; in each case except to the extent such Third Party Claim arises out of result from matters contemplated in Section 18.1(a) or (b) above. In the event a Third Party Claim is caused by both Party's behaviour, the amount of Indemnification shall depend on the circumstances, in particular to what extend the Third Party Claim is caused mainly by one or the other Party.

18.3 **No Consequential Damages**. EXCEPT WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 18.1 OR SECTION 18.2, AS APPLICABLE, AND/OR EXCEPT IN THE EVENT OF WILFUL MISCONDUCT AND GROSS NEGLIGENCE, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES FOR BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR (I) ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES, OR CLAIMS BROUGHT BY [***] OR ANY OTHER THIRD PARTY HAVING SIGNED AN AGREEMENT WITH MERCK IN RELATION TO THE TRIAL, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. FOR THE PURPOSES OF THIS CLAUSE "**CONSEQUENTIAL DAMAGES**" SHALL BE DEFINED AS LOSS OF PROFIT OR ANTICIPATED PROFIT, LOSS OF PRODUCTION, LOSSES CAUSED BY BUSINESS INTERRUPTIONS, LOSS OF REVENUE AND LOSS OF GOODWILL OR REPUTATION AS WELL AS DAMAGES RESULTING FROM REMOTE EVENTS THAT ARE VERY UNLIKELY TO HAPPEN, "**PUNITIVE DAMAGES**" SHALL BE DEFINED AS COMPENSATION CLAIMS THAT EXCEED THE DAMAGE ACTUALLY INCURRED. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY FROM SEEKING OR OBTAINING ANY REMEDY AVAILABLE UNDER APPLICABLE LAW, INCLUDING EQUITABLE REMEDIES, FOR ANY BREACH OF ITS CONFIDENTIALITY AND NON-USE OBLIGATIONS UNDER ARTICLE 16.

18.4 **Notification of Claims; Conditions to Indemnification Obligations**. As a condition to a Party's right to receive indemnification under this ARTICLE 18, it shall: (a) promptly notify the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defence, settlement or compromise of such claim or suit; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defence counsel. In no event, however, may the indemnifying Party compromise or settle any Claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any indemnitee without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defence of any such suit, claim or demand, such cooperation to include without limitation using Commercially Reasonable Efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this ARTICLE 18 with respect to Claims or suits settled or compromised without its prior written consent.

18.5 **Insurance**. During the Term, each Party shall obtain and maintain, at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts that are reasonable and customary in the pharmaceutical and biotechnology industry for companies engaged in comparable activities in the jurisdiction where such activities are being performed. Manufacturer shall add Merck as an additional insured on any product liability and comprehensive general liability policy carried by Manufacturer. Without prejudice to the foregoing, Manufacturer shall maintain a minimum product liability insurance coverage of [***] per occurrence, with a deductible of a maximum of [***]. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self-insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 18.5.

ARTICLE 19
TERM AND TERMINATION

19.1 **Term**. This Agreement shall commence on the Effective Date and continue for an initial period of [***] (the "**Initial Term**"), and thereafter shall automatically renew for further successive periods of [***] each (the "**Renewal Term**" and together with the Initial Term, the "**Term**"), unless terminated earlier as provided for elsewhere in this Agreement. Either Party shall have the right to terminate this Agreement at the end of the Initial Term or at the end of a Renewal Term by providing the other Party with no less than [***] prior written notice.

19.2 **Termination On Failure of a Condition Precedent under Section 2.2**. In case one of the events described in Section 2.2 is not met, Merck shall have the right to terminate this Agreement with immediate effect by sending a written notice to Manufacturer in accordance to Section 23.10.

19.3 **Termination for Convenience**. Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving [***] advance written notice to Manufacturer.

19.4 **Patient Safety**. Merck may terminate the Agreement (a) at any time if termination is reasonably considered necessary by Merck by giving written notice to the Manufacturer in the interest of the health and well-being of the Trial Subjects, in which case notice of termination shall have immediate effect and (b) on a Product-by-Product basis by giving [***] advance written notice to Manufacturer if Merck decides to withdraw the Product from the market.

19.5 **Change of Control Term**. Manufacturer shall provide notice to Merck as soon as possible after a Change of Control with a company developing or commercializing [***] and upon receipt of such notification Merck shall have the right to terminate this Agreement with immediate effect.

19.6 **Regulatory Authority Warning Letter**. Merck may terminate the Agreement immediately upon written notice to Manufacturer if Manufacturer is subject to any Regulatory Authority warning letter or sanction.

19.7 **Termination for Breach**. If either Party to this Agreement shall have materially breached or defaulted in the performance of any of its obligations and does not remedy the breach within [***] of notice from the other Party to do so (if capable of remedy) the non-breaching Party may terminate this Agreement immediately by written notice to the Party in breach. It is understood and agreed by the Parties that the non-respect by Manufacturer of its Yearly Capacity Reservation obligation as provided for in Section 2.6, is considered a material breach under this Agreement.

19.8 **Termination for Late Delivery**. If Manufacturer becomes more than [***] liable under Section in any calendar year, Merck shall have the right to terminate this Agreement upon written notice to Manufacturer. The provisions of this Section 19.8 are non-exclusive and without prejudice to the payment of penalties pursuant to Section 5.6 above or any other remedy under this Agreement or Applicable Law.

19.9 **Termination for Force Majeure Event**. Notwithstanding anything to the contrary contained in this Agreement, in the event a Force Majeure Event shall have occurred and be continuing for [***], the Party not suffering such Force Majeure Event shall be entitled to terminate this Agreement effective immediately upon written notice to the Party suffering such Force Majeure Event.

19.10 **Termination for Reasons of Insolvency or Termination of Business Activities**. Either Party shall be entitled to terminate this Agreement if the other Party becomes insolvent or is the subject of a petition in bankruptcy whether voluntary or involuntary or of any other proceeding under bankruptcy, insolvency or similar laws, makes an assignment for the benefit of creditors, is named in such a petition, or its property is subject to a suit for the appointment of a receiver, or is dissolved or liquidated. Such termination right may be exercised without the need for written notice within [***] following the date as of which the Party entitled to terminate receives knowledge of such insolvency or termination of business activities by the other Party.

ARTICLE 20
EFFECTS OF TERMINATION

20.1 **Termination Due to Reasons other than Manufacturer Default or Insolvency**. Upon expiration or termination of this Agreement other than in case of termination by Merck pursuant to Sections 19.5, 19.6, 19.7, 19.8 or 19.10, Merck shall, by written notice to Manufacturer: (i) request Manufacturer to execute outstanding Work Orders or Purchase Orders, and, unless the Products delivered to Merck do not comply with the terms of this Agreement due to Manufacturer's breach of the warranties set out in Section 9.1, Merck shall pay Manufacturer in accordance with the terms of this Agreement, or (ii) cancel any outstanding Work Order or Purchase Order, pay the Price for the cancelled Manufacturing Runs and reimburse Manufacturer for any actual costs in executing such Work Order or Purchase Order, provided that Manufacturer shall use Commercially Reasonable Efforts to mitigate such actual costs. For the avoidance of doubt, Section 4.8 shall apply, i.e. Merck shall only be obliged to pay part of the Price for a Manufacturing Run set out in a Work Order depending on the time of receipt of Merck's termination notice.

20.2 **Termination Due to Manufacturer Default or Insolvenc**y. Upon termination of this Agreement by Merck pursuant to Sections 19.5 19.6, 19.7, 19.8 or 19.10, Merck shall, by written notice to Manufacturer: (i) request Manufacturer to execute outstanding Work Orders or Purchase Orders, and provided that the Products delivered to Merck comply with the terms of this Agreement, Merck shall pay Manufacturer in accordance with the terms of this Agreement, or (ii) cancel outstanding Work Orders or Purchase Orders without any liability to Merck.

20.3 **Termination for any Reason**. Upon expiration or termination of this Agreement for any reason, each Party shall return or destroy all of the other Party's Confidential Information which it has in its possession or under its control, unless and to the extent the Party is under a statutory obligation to keep such Confidential Information.

20.4 **Termination On Failure of a Condition Precedent under Section 2.2 or for Convenience**. Termination of this Agreement by Merck pursuant to Section 19.2 or Section 19.3 shall not give rise to any claim for Losses by Manufacturer against Merck. For the avoidance of doubt, termination pursuant Section 19.2, unless due to a Manufacturer's failure to perform its obligations under this Agreement, and Section 19.3 shall not affect Merck's obligation to fully pay for Manufacturing Runs set out in the Firm Zone or Merck's obligations under any open Work Order or Purchase Order in accordance to Sections 4.6 and 4.8.

20.5 **Ongoing Supply Obligations**. In the event of expiration or termination of this Agreement pursuant to ARTICLE 19 hereabove, except if this Agreement is terminated by Merck pursuant to Section 19.1 or by Manufacturer for any reason, Manufacturer shall continue to supply Merck with Merck's new Work Orders or Purchase Orders after the expiration date or termination date of this Agreement, if Merck has not identified and fully registered with the competent Regulatory Authorities a new Manufacturer of a replacement product. Such obligation of Manufacturer shall continue until the earlier of (i) successful completion of the technical transfer pursuant to Section 20.8, and (ii) notification by Merck to the Manufacturer that it has identified and duly registered with the competent Regulatory Authorities a new manufacturer of the Products.

20.6 **Accrued Rights and Surviving Obligations**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination or expiration.

20.7 **Regulatory Assistance**. After expiration or termination of this Agreement, Manufacturer agrees to provide Merck with reasonable support in relation to any investigation required by any Regulatory Authority with respect to Manufacture of the Products carried out at the Manufacturing Site during the Term, provided that Merck shall reimburse Manufacturer for its reasonable costs in providing such assistance (other than in case of Merck's termination under Sections 19.6, 19.7 or 19.10).

20.8 **Technical Transfer Assistance**. For a period of [***] following expiration or termination of this Agreement for any reason, Manufacturer will provide, upon the request of Merck, its reasonable support and cooperation in transferring the then-current manufacturing process of the Product to an alternative site, designated by Merck. Manufacturer shall be entitled to charge Merck for its reasonable costs in supporting the technical transfer of the Products, at the Agreed Hourly Rate based on a written and accepted quotation, provided, however, if the technical transfer is requested by Merck following its termination of this Agreement under Sections 19.6, 19.7 or 19.10 then the Manufacturer shall provide the above technical transfer services free-of-charge. Additionally, in connection with the technical transfer assistance provided pursuant to this Section 20.8, Manufacturer shall grant to Merck and its Affiliates and designees a perpetual, fully-paid, non-exclusive, royalty-free license, with the right to sublicense, under any Manufacturer intellectual Property which is reasonably necessary for the manufacture of each Product. Manufacturer's obligations to support a technical transfer shall continue until such time as Merck, or its designee, successfully manufactures a validated Batch of each Product.

ARTICLE 21
DISASTER RECOVERY AND BUSINESS CONTINUITY

Manufacturer shall provide Merck prior to the commencement of the first Manufacturing Run under a Purchase Order with a true, correct and complete copy of Manufacturer's business continuity plan (the "**BCP**") which provides for, among other things, the high level design and processes for disaster recovery and business continuity for Manufacturer. The BCP shall be revised and updated by Manufacturer from time to time, but in no event less than every [***]. The Parties shall meet periodically, as specified by Merck, to discuss and analysis the status of the BCP. Manufacturer shall provide a written report to Merck for such discussions and analysis which shall analysis the effectiveness of the applicable BCP, propose necessary changes, suggest improvements, and provide an updated risk assessment for the activities to which the BCP relates.

ARTICLE 22
DISPUTE RESOLUTION

22.1 **Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish under this ARTICLE 22 procedures to facilitate the resolution of disputes arising under this Agreement (other than any disputes relating to matters which under this Agreement Merck has sole decision-making authority and/or discretion (each, a "**Non-Escalable Dispute**"), in which case, such matter shall be determined by Merck and shall not be part of the dispute resolution procedure set forth in this ARTICLE 22) in an expedient manner by mutual cooperation and without resort to litigation. In the event that the Parties are unable to resolve such dispute through diligent review and deliberation within [***] from the day that one Party had designated the issue as a dispute in written notice to the other Party, then either Party shall have the right to escalate such matter to the Executive Officers as set forth in Section 22.2.

22.2 **Escalation to Executive Officers**. Either Party may, by written notice to the other Party, request that a dispute (other than a Non-Escalable Dispute) that remains unresolved for a period of [***] as set forth in Section 22.1 arising between the Parties in connection with this Agreement be resolved by the Executive Officers, within [***] alter referral of such dispute to them. If the Executive Officers cannot resolve such dispute within [***] after referral of such dispute to them, then, at any time after such [***] period, either Party may proceed to enforce any and all of its rights with respect to such dispute in accordance with this Agreement.

22.3 **Injunctive Relief**. No provision herein shall be construed as precluding a Party from bringing an action for injunctive relief or other equitable relief prior to the initiation or completion of the above procedure.

ARTICLE 23
MISCELLANEOUS PROVISIONS

23.1 **Relationship of the Parties**. Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.

23.2 **Assignment**.

(a) **Assignment Generally**. Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Manufacturer without the prior written consent of Merck (not to be unreasonably withheld or delayed).

(b) **Assignment by Merck**. Merck may assign this Agreement, in whole or in part, to any Affiliate or Third Party without the consent of Manufacturer. Merck shall give written notice to Manufacturer promptly following any such assignment.

(c) **Continuing Obligations**. No assignment under this Section 23.2 shall relieve the assigning Party of any of its responsibilities or obligations hereunder and, as a condition of such assignment, the assignee shall agree in writing to be bound by all obligations of the assigning Party hereunder. This Agreement shall be binding upon the successors and permitted assigns of the Parties.

(d) **Void Assignments**. Any assignment not in accordance with this Section 23.2 shall be void.

23.3 **Performance and Exercise by Affiliates**. Merck shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates and the performance of such obligations by any such Affiliate(s) shall be deemed to be performance by Merck; provided, however, that Merck shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of Merck hereunder shall be deemed to be a failure by Merck to perform such obligations.

23.4 **Technical Managers**. Each Party will notify the other in writing with the name of a technical manager who will be responsible for dealing with all matters relevant to this Agreement. The appointment of Manufacturer's technical manager shall be subject to approval of Merck, not to be unreasonably withheld or delayed. Manufacturer shall replace its technical manager upon Merck's request for reasonable cause within [***]. Unless otherwise mutually agreed, the technical managers and other appropriate representatives from each Party shall endeavor to meet no less than once every [***] to discuss matters relevant to the Manufacture and supply of Products hereunder.

23.5 **Occurrence of Force Majeure Event**. If any Force Majeure Event occurs in relation to either Party which affects or may affect the performance of any of its obligations under this Agreement, it shall use all Commercially Reasonable Efforts to mitigate the effects of such delay or prevention upon the performance of its obligations under this Agreement, promptly notify the other Party as to the nature and extent of such Farce Majeure event; and resume performance of its obligations as soon as reasonably possible alter the removal of the cause of the delay or prevention. 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 Event of which it has duly notified the other Party, and the time for performance of that obligation shall be extended accordingly. Without limiting Merck's right to terminate this Agreement pursuant to Section 19.9, if the performance by either Party of any of its obligations under this Agreement is prevented or delayed by a Force Majeure Event for a continuous period in excess of [***], 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.

23.6 **No Trademark Rights**. No right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.

23.7 **Entire Agreement of the Parties; Amendments**. This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties in respect of the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. In the event of any conflict or contradiction between this Agreement and a Schedule, the provisions of this Agreement shall prevail, except with respect to conflicts or contradiction for matters of quality or technical nature, in which case the applicable Quality Agreement shall prevail. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

23.8 **Captions**. The captions to this Agreement are for convenience only, and are to be of no forte or effect in construing or interpreting any of the provisions of this Agreement.

23.9 **Governing Law and Arbitration**. This Agreement shall be governed by and interpreted in accordance with the laws of Germany, excluding application of any conflict of laws principles that would require application of the Law of a jurisdiction outside of Germany and further excluding the UN Convention an Contracts for the International Safe of Goods (CISG). All disputes arising out of or in connection with this Agreement or its validity shall be submitted to the International Court of Arbitration and shall be finally settled in accordance with the Arbitration Rules of the International Chamber of Commerce. The place of arbitration shall be Geneva, Switzerland. The number of arbitrators shall be three (3). The language of the arbitral proceedings shall be English.

23.10 **Notice**. Any notice to be given by either Party under or in connection with this Agreement to the other Party must be in writing in English and shall be delivered by hand or by courier. A copy by fax or by email shall be sent to the addresses set out below (or such other address or number as may be notified to the other Party from time to time):

Manufacturer:

Address: Richter-Helm BioLogics GmbH &Co.KG., [***]

Fax: [***]

Email: [***]

Attention: [***]

Merck:

Address: Merck Serono S.A.—[***]

Phone: [***]

Email: [***]

Attention: [***]

With copy to: Legal Department

Unless there is evidence that it was received earlier, notices sent in accordance with this Section 23.10 are to be deemed to have been received: if delivered by hand or by courier, when left at the address referred to above; or if sent by fax or email, when transmitted, provided that if deemed receipt occurs before 9am on a Working Day the notice shall be deemed to have been received at 9am on that day, and if deemed receipt occurs alter 5pm on a Working Day, or on a day which is not a Working Day, the notice shall be deemed to have been received at 9am on the next Working Day.

23.11 **Waiver**. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

23.12 **Severability**. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

23.13 **No Implied License**. Except as set forth in Section 3.3, no right or license is granted to Manufacturer hereunder by implication, estoppel, or otherwise to any know-how, patent or other Intellectual Property owned or controlled by Merck or its Affiliates.

23.14 **Interpretation**. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” All references herein to Articles, Sections, and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require. Unless the context otherwise requires, countries shall include territories.

23.15 **Counterparts**. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

[SIGNATURE PAGE FOLLOWS]

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

Merck KGaA

[***]

By: [***]
Title: [***]

[***]

By: [***]
Title: [***]

Richter-Helm Biologics GmbH & Co. KG

[***]

By: [***]
Title: [***]

[***]

By: [***]
Title: [***]

Exhibit 10.12

Certain confidential information contained in this document, marked by brackets as [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. In addition, certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

AMENDMENT NO.2

TO THE CLINICAL AND COMMERCIAL MANUFACTURING AGREEMENT

This Amendment No.2 (the "Amendment No.2"), is made and entered into, as of November 20th, 2020 ("Effective Date"), by and between:

Richter Helm Biologics GmbH & Co.KG, a corporation organized under the laws of Germany having a place of business at [***] ("**Manufacturer**"), and

Merck Healthcare KGaA, a corporation organized under the laws of Germany and having a place of business at Frankfurter Strasse 250, 64293 Darmstadt, ("**Merck**").

Manufacturer and Merck may be referred to herein individually as a "**Party**" or, collectively, as "**Parties**."

WITNESSETH

WHEREAS, Merck, and Manufacturer have entered into a Clinical and Commercial Manufacturing Agreement dated as of October 15th, 2018 and amended by Amendment No.1 dated as of December 6, 2019 (hereinafter referred to as the "Agreement");

WHEREAS, the Agreement was transferred from Merck KGaA to Merck Healthcare KGaA an 1st April 2019 as part of a business restructuring of Merck KGaA;

WHEREAS, the Parties wish to amend the Agreement in accordance with the terms set forth in this Amendment;

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein contained and eventual addenda, the Parties agree to amend the existing Agreement, with effect from the Effective Date, as follows:

ARTICLE 1— DEFINITIONS

Capitalized terms not otherwise defined herein shall have the meanings given in the Agreement.

ARTICLE 2 — AMENDMENTS

As of the Effective Date of this Amendment No.2, the Agreement shall be amended as follows:

2.1 The Parties hereby acknowledge and agree to delete Article 5.9 (Key Performance Indicators) in its entirety and replace it by the following Article 5.9 (Key Performance Indicators):

5.9 Key Performance Indicators.

The Parties agree to measure Manufacturer's performance of its Development (when applicable) & Commercial Manufacturing Services through the establishment of Key Performance Indicators ("**KPIs**") set forth in Schedule 2. As long as Manufacturer only delivers up to [***] commercial Batches per year, Manufacturer shall provide Merck with [***] reports out of its performance based on the KPIs. From [***] Batches per year, the reports should occur [***]. The Parties may agree on additional KPIs by means of further amendments to this Agreement. The Parties shall agree upon the relative importance of the KPIs by classifying each KPI with a designation of "minor", "major" or "critical". The Parties shall agree in good faith by [***] of each [***], (beginning with the [***] of the Agreement), the performance level objectives of Manufacturer for the following year. The performance level objectives shall be established for individual KPIs and for overall performance and on the basis of actual, past performance, and shall be expressed in measurable values. In addition, minimum acceptance levels shall be agreed upon for all critical KPIs and for overall performance. Manufacturer shall use all Commercially Reasonable Efforts to ensure that its performance does not fall below these minimum acceptance levels. Notwithstanding Manufacturer's use of all Commercially Reasonable Efforts, if at any time Manufacturer's overall performance or performance for critical KPIs falls below the established minimum acceptance levels, Manufacturer shall promptly take corrective action to cure such under-performance."

2.2 The Parties hereby acknowledge and agree to delete in its entirety Schedule 2 (KPIs) and replace it by a new Schedule 2 (KPIs) attached to this Amendment No.2.

2.3 The Parties hereby acknowledge and agree to add to Schedule 5 — DEVELOPMENT SERVICES, DELIVERABLES & TIMELINES an additional sub-section entitled "**Performance of the HSA binding Assay (ELISA)** " as follows:

[***]

ARTICLE 3 — NO OTHER AMENDMENTS

Except as expressly amended hereby, all of the terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties have caused this Amendment No.2 to be executed by their respective duly authorized officers or representatives in two (2) copies, each an original. This Amendment No.2 may be executed via facsimile or ".pdf' file and in counterparts, each of which shall be signed by each of the contracting parties and deemed an original, but all of which together shall constitute one and the same instrument.

MERCK HEALTHCARE KGAA	**Richter Helm Biologics GmbH & Co.KG**
[***]	[***]
By: [***]	By: [***]
Title: [***]	Title: [***]
[***]	[***]
By: [***]	By: [***]
Title: [***]	Title: [***]

Exhibit 10.13

Certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

ASSIGNMENT

This ASSIGNMENT AGREEMENT (the "**Assignment**") is entered into as of 1 July 2021, ("**Assignment Effective Date**") by and among Merck Healthcare KGaA, Frankfurter StraBe 250, 64293 Darmstadt, Germany ("**Merck**"), Richter-Helm BioLogics GmbH & Co. KG, [***] ("**Richter Helm**"), and MoonLake Immunotherapeutics AG, c/o KD Zug-Treuhand AG, Untermuli 7, 6302 Zug, Switzerland (CHE-433.093.536) ("**MoonLake**").

WITNESSETH:

WHEREAS, Merck and the Richter Helm entered into a contract manufacturing agreement dated 15 October 2018, as amended by Amendment No. 1 effective 6 December 2019, by Amendment No. 2 effective 20 November 2020, Amendment No. 3 effective I January 2021 and Amendment No. 4 effective 30 June 2021 (together the "**CMO Agreement**"), with respect to the manufacture of Merck's proprietary ILl7 nanobody named sonelokimab (also known as M1095);

WHEREAS, MoonLake and Merck informed Richter Helm that they have entered into a certain License Agreement on 29 April 2021 (the "**License Agreement**"), pursuant to which Merck agreed to transfer and license, among other things, certain assets and rights related to its Ml095 compound; and

WHEREAS, in connection with the License Agreement, and subject to the terms and conditions of this Assignment, Merck desires to assign to MoonLake, and MoonLake desires to accept and assume, all of Merck's rights, obligations, title and interest in and to the CMO Agreement.

NOW, THEREFORE, in consideration of the promises and mutual agreements set forth in this Assignment, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Effective as of the Assignment Effective Date, (i) Merck hereby assigns to MoonLake, and MoonLake hereby accepts and assumes from Merck all of Merck's rights, obligations, title and interest in and to the CMO Agreement and all purchase orders placed by Merck under the CMO Agreement ("**Purchase Orders**"), and MoonLake and Richter Helm undertake to observe, perform under, and to be bound by the terms of, the CMO Agreement and the Purchase Orders.

2. Effective as of the Assignment Effective Date, Richter Helm hereby releases and discharges Merck from all obligations and liabilities of Merck under the CMO Agreement (provided that Merck shall remain responsible for any obligations under the CMO Agreement that survive such agreement and have occurred or been triggered prior to the Assignment Effective Date), and accepts the performance thereof by MoonLake in place of performance by Merck.

3. The CMO Agreement shall remain in full force and effect, subject to the terms set forth in this Assignment and the Amendment No. 5, which is currently being negotiated by Richter Helm and MoonLake.

4. Representations and Warranties. Merck hereby represents and warrants to MoonLake the following: (i) the CMO Agreement is currently in force, valid and enforceable; and (ii) to its knowledge, Merck and Richter Helm each fulfilled and performed their obligations under the CMO Agreement and neither Merck nor Richter Helm are in a material breach of the CMO Agreement.

5. Each Party will keep confidential and will not disclose to any third party (other than its advisors who are under a duty of confidence) the terms of this Agreement. For the avoidance of doubt, Merck undertakes to continue to be bound by the obligations of confidentiality contained in the CMO Agreement, unless Richter Helm and MoonLake agree otherwise in writing. As of the Assignment Effective Date, confidential information disclosed by Merck to Richter Helm under the CMO Agreement shall be deemed to have been disclosed by MoonLake to Richter Helm.

6. Richter Helm and MoonLake are currently negotiating the Amendment No. 5 to the CMO Agreement and will, in addition, negotiate in good faith a Quality Agreement (as defined in the CMO Agreement) within ninety (90) days of the Assignment Effective Date (but in no event later than ninety (90) days prior to the anticipated start of the first GMP manufacturing campaign) which shall essentially correspond to the existing Quality Agreement between Merck and Richter Helm.

7. Each party hereto covenants and agrees to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary or desirable in order to consummate or implement expeditiously the transactions contemplated by this Assignment.

8. This Assignment shall be binding upon and inure to the benefit of the parties hereto and their respective successors.

9. For the convenience of the parties hereto this Assignment may be executed in three or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages with signatures (in form of handwritten, non-certified electronic or certified electronic signatures), will be deemed an original.

10. An amendment of any of the provisions of this Assignment is only valid if it is in writing and signed by each Party or authorized representatives. Any provision contained in this Agreement may only be waived by a document signed by the Party waiving such provision.

11. This Assignment shall be governed by and interpreted in accordance with the laws of Germany, excluding application of any conflict of laws principles that would require application of the Law of a jurisdiction outside of Germany and further excluding the UN Convention on Contracts for the International Sale of Goods (CISG).

12. All disputes arising out of or in connection with this Assignment or its validity shall be submitted to the International Court of Arbitration and shall be finally settled in accordance with the Arbitration Rules of the International Chamber of Commerce. The place of arbitration shall be Geneva, Switzerland. The number of arbitrators shall be three (3). The language of the arbitral proceedings shall be English.

13. Should one or several provisions of this Assignment be or become invalid, then the Parties hereto shall substitute valid provisions for such invalid ones. The substituted provision(s) shall in their economic effect come so close to the invalid provision(s) that it can be reasonably assumed that the Parties would have contracted on the basis of the new provision(s). If such provision(s) cannot be found, the invalidity of one or several provisions of this Assignment shall not affect the validity of the Assignment as a whole, unless the invalid provision(s) is of such essential importance for this Assignment that it is reasonably assumed that the Parties would not have entered this Assignment without the invalid provision(s).

14. The validity of this Assignment is subject to the execution of the Amendment No. 5 to the CMO Agreement which is currently being negotiated by Richter Helm and MoonLake. For the avoidance of doubt, the assignment of the CMO Agreement to MoonLake shall only become effective if and when the Amendment No. 5 has been executed.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first set forth above.

Merck Healthcare KGaA

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

Merck Healthcare KGaA

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

Richter-Helm BioLogics GmbH & Co. KG

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

Richter-Helm BioLogics GmbH & Co. KG

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

MoonLake Immunotherapeutics AG

By: /s/ A. Ploos van Amstel
Name: A. Ploos van Amstel
Title: Chief Operating Officer