Exhibit 10.1  
  
CERTAIN INFORMATION IDENTIFIED WITH THE MARK “(\*\*\*)” HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE SUCH INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.  
LICENSE AGREEMENT  
This License Agreement (this “Agreement”), dated the 29th day of July, 2022 (the “Effective Date”), is by and between Apollo AP43 Limited, a company incorporated under the laws of England and Wales (“Licensee”), and Xxxxx Therapeutics, Inc., a Delaware corporation (“Xxxxx”). Xxxxx and Licensee may each be referred to herein individually as a “Party” and collectively as the “Parties.”  
INTRODUCTION  
WHEREAS, Xxxxx owns or otherwise controls certain intellectual property relating to AVTX-007, a fully human anti-IL-18 monoclonal antibody;  
WHEREAS, Licensee is a pharmaceutical company with a focus on developing and commercializing products for the treatment of various diseases; and  
WHEREAS, Licensee is interested in developing and commercializing products that contain AVTX-007 on the terms and conditions set forth herein.  
NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:  
ARTICLE 1  
  
DEFINITIONS  
  
1.1. Definitions. When used in this Agreement, each of the following terms shall have the following meanings:  
1.1.1. “Accounting Standards” means with respect to a Party, as applicable, (a) United States generally accepted accounting principles (“GAAP”) or (b) International Financial Reporting Standards, in each case consistently applied.  
1.1.2. “Affiliate” means, with respect to any Person, any other Person which controls, is controlled by, or is under common control with such Person as of or after the Effective Date. A Person shall be regarded as in control of another entity if it owns or controls fifty percent (50%) or more of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority) or has the power to control the management and policies of the subject entity, whether through ownership, contract or otherwise.  
1.1.3. “Annual Net Sales” means the combined Net Sales for all Products in the Territory within a Contract Year.  
1.1.4. “Applicable Law” means, with respect to a country in the Territory, its laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities applicable to the Development, Manufacturing or Commercialization of Products, that may be in effect from time to time in such country.  
  
  
  
  
1.1.5. “Assigned Product Agreements” means those agreements between Xxxxx or an Affiliate thereof and certain Third Parties set forth on Schedule 1.1.5 attached hereto.  
1.1.6. “Bankruptcy Code” means Xxxxx 00, Xxxxxx Xxxxxx Code, as amended, or analogous provisions of Applicable Law outside the United States.  
1.1.7. “Biosimilar” means, with respect to a reference brand biologic product and a particular jurisdiction, a biologic product: (a) that is highly similar to such reference brand biologic product notwithstanding minor differences in clinically inactive components; (b) has no clinically meaningful differences from such reference brand biologic product in terms of safety, purity and potency; and (c) for which a Biosimilar Application is approved by the relevant Regulatory Authority of such jurisdiction.  
1.1.8. “Biosimilar Application” means a Regulatory Approval Application for a product claimed to be biosimilar or interchangeable to any Product, or otherwise relying on the approval of such Product, in each case in accordance with Applicable Law in the jurisdiction in which the product is sought to be marketed and sold.  
1.1.9. “BLA” means a Biologics License Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.  
1.1.10. “Blocking Patent” means any Patent Rights owned or controlled by a Third Party (other than Licensed Patent Rights or MedImmune Patent Rights (as defined in the MedImmune License as of the Effective Date)) that are infringed or are reasonably likely to be infringed by the manufacture, use, offer for sale, sale or import of a Molecule that is a part of a Product in the Field in the Territory.  
1.1.11. “Business Day” means a day on which banking institutions in New York, New York are open for business.  
1.1.12. “Change of Control” means, with respect to a Party, (a) a merger, reorganization or consolidation of such Party with a Third Party which results in the stockholders or equity holders of such Party not owning at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation or (b) except in the case of a bona fide equity or debt financing, whether private or public, in which a Party issues (i) new shares of its capital stock, (ii) securities convertible into shares of capital stock of such Party or (iii) debt securities, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all, or substantially all, of such Party’s assets or business (or that portion thereof to which the subject matter of this Agreement relates).  
1.1.13. “CMC” means chemistry, manufacturing and controls.  
1.1.14. “Combination Product” means a Product that is comprised of or contains a Molecule as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units.  
1.1.15. “Commercialization” means any and all activities constituting using, marketing, promoting, distributing, offering for sale, selling and importing a Product in the Field in the Territory and shall include, but not be limited to, promotion, as well as activities required to fulfill ongoing post-approval regulatory obligations, including adverse event reporting and sales force training. When used as a verb, “Commercialize” means to engage in Commercialization.  
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1.1.16. “Commercially Reasonable Efforts” means a measure of effort consistent with Applicable Law and industry standards and practices followed by pharmaceutical companies in the United States of similar size and resources as Licensee and its Affiliates in total with respect to their pharmaceutical products of a similar value, stage, development, life cycle, and commercial potential, taking into consideration safety and efficacy, development costs, the anticipated prescription label and all other relevant factors, including, without limitation, the nature of the Product and the clinical setting in which it is expected to be used.  
1.1.17. “Confidential Information” means, with respect to each Party, proprietary data or information that belongs in whole or in part to such Party, its Affiliates or (sub)licensees, including, without limitation, (a) all information designated as Confidential Information of such Party hereunder, in all cases that, if disclosed in writing, is marked with the words “Confidential,” “Proprietary” or words of similar import, and if disclosed orally or visually, is described in reasonable detail in a written notice sent by the Disclosing Party to the Receiving Party within thirty (30) days of the oral or visual disclosure requesting that such information be treated as Confidential Information hereunder, (b) all information that a reasonable person would reasonably understand to be confidential or proprietary in nature, whether or not marked as such, and (c) all “Confidential Information” (as defined in the Confidentiality Agreement) of such Party. Notwithstanding the foregoing or any provision to the contrary in this Agreement, (i) the existence and terms of this Agreement shall be deemed to be the Confidential Information of both Parties, with each Party being deemed a Receiving Party with respect thereto; (ii) the Licensed Intellectual Property shall be deemed to be the Confidential Information of both Parties with each Party being deemed a Receiving Party with respect thereto; and (iii) as between the Parties, any confidential information disclosed to Xxxxx or its Related Parties pursuant to the MedImmune License or the Novated MedImmune License shall be deemed to be the Confidential Information of both Parties with each Party being deemed a Receiving Party with respect thereto.  
1.1.18. “Confidentiality Agreement” means that certain Mutual Non-Disclosure Agreement, dated June 9, 2022, between Xxxxx and Apollo Therapeutics Group Limited.  
1.1.19. “Contract Quarters” means the successive three (3) month periods in each Contract Year ending on March 31, June 30, September 30 or December 31.  
1.1.20. “Contract Year” means the twelve (12) month period beginning on January 1 and ending on December 31 of each calendar year, provided, however, that the first Contract Year shall be the period of time beginning on the Effective Date and ending on December 31 of that year. Each Contract Year, except the first Contract Year, shall be divided into four (4) Contract Quarters.  
1.1.21. “Control” or “Controlled” means with respect to any (a) material, item of information, method, data or other Know-How or (b) intellectual property right (including any Patent Right), the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party and, to the extent contemplated by this Agreement, its Affiliates, access or a license as provided herein under such item or right without violating any Third Party’s contractual rights thereto or the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.  
1.1.22. “Cover” (in all its verb and adjectival forms, such as “Covered,” “Covering” and “Covers”) means that the use, offer for sale, sale, importation or manufacture of the subject matter in question by an unlicensed entity would infringe a Valid Claim.  
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1.1.23. “Data Room” means that certain virtual data room provided via the Firmex Corp platform to which Licensee was initially granted access on June 9, 2022, as such data room may have been updated prior to the Effective Date.  
1.1.24. “Development” means all pre-clinical, clinical, CMC and regulatory activities with respect to a Product in the Field in a given country in the Territory from the Effective Date until Regulatory Approval of such Product in such country is obtained for the indication under study. When used as a verb, “Develop” means to engage in Development.  
1.1.25. “Executive Officers” means the Chief Executive Officer or President of Licensee (or an executive officer of Licensee designated by such person(s)) and the Chief Executive Officer or President of Xxxxx (or an executive officer of Xxxxx designated by such officer).  
1.1.26. “Existing Regulatory Documentation” means the Regulatory Documentation Controlled by Xxxxx or any of its Affiliates as of the Effective Date.  
1.1.27. “FD&C Act” means the U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time (21 U.S.C. Section 301 et seq.), together with any rules and regulations promulgated thereunder.  
1.1.28. “FDA” means the United States Food and Drug Administration, or a successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.  
1.1.29. “Field” means all indications and uses.  
1.1.30. “First Commercial Sale” means, with respect to a given Product in a country in the Territory, the first commercial sale in an arms-length transaction of such Product to a Third Party by or on behalf of Licensee, its Affiliate or a Sublicensee in such country following receipt of the applicable Regulatory Approval of such Product to Commercialize such Product in such country.  
1.1.31. “Xxxxx-Xxxxxx Act” means the U.S. Drug Price Competition and Patent Term Restoration Act, as amended from time to time.  
1.1.32. “IND” means an Investigational New Drug Application, as defined in the FD&C Act, or similar application or submission inside or outside the United States that is required to be filed with any Regulatory Authority before beginning clinical testing of a Molecule or a Product in human subjects.  
1.1.33. “Indirect Taxes” means value added, sales, consumption, goods and services taxes or other similar taxes required by Applicable Law to be disclosed as a separate item on the relevant invoice.  
1.1.34. “Initiation” means the administration of the first dose of a Product to a human being in a human clinical trial for which Licensee or one of its Related Parties is the sponsor or which is otherwise conducted by or on behalf of Licensee or one of its Related Parties.  
1.1.35. “Know-How” means any non-public, proprietary invention, discovery, process, method, composition, formula, procedure, protocol, technique, result of experimentation or testing, information, data, trade secret, material, drawings, illustrations or other artwork, technology or other know-how, whether or not patentable or copyrightable.  
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1.1.36. “Licensed Intellectual Property” means Licensed Know-How and Licensed Patent Rights.  
1.1.37. “Licensed Know-How” means all Know-How that (a) is Controlled by Xxxxx or any of its Affiliates as of the Effective Date (other than MedImmune Know-How), or comes under the Control of Xxxxx or any Affiliate thereof following the Effective Date as a result of Xxxxx’x development, manufacture, or commercialization of a Molecule or any Product at any time during the Term, (b) is not generally known, and (c) is necessary or reasonably useful to Develop, Manufacture, Commercialize or otherwise exploit any Molecule or any Product in the Field, including Xxxxx’x interest in the Joint Know-How; provided that Licensed Know-How shall not include any Know-How to the extent relating to any active pharmaceutical ingredient other than any Molecule (or the use or manufacture of any such active pharmaceutical ingredient) and not relating to a Molecule (or its use or manufacture). Licensed Know-How includes all Know-How (other than MedImmune Know-How) included under the portions of the Data Room identified in Schedule 1.1.37.  
1.1.38. “Licensed Patent Rights” means all Patent Rights that (a) are Controlled by Xxxxx or any of its Affiliates as of the Effective Date (other than the MedImmune Patent Rights), or come under the Control of Xxxxx or any Affiliate thereof following the Effective Date as a result of Xxxxx’x development, manufacture, or commercialization of a Molecule or any Product, and (b) Cover or are necessary for (or, with respect to patent applications, would, if such patent applications were to issue as patents, Cover or be necessary for) the Development, Manufacture, Commercialization or other exploitation of any Molecule or any Product in the Field, including Xxxxx’x interest in the Joint Patent Rights; provided that Licensed Patent Rights shall not include any Patent Rights to the extent Covering any active pharmaceutical ingredient other than any Molecule (or containing any pending claims in any patent application that cover or claim any such active pharmaceutical ingredient or its use or manufacture) and not Covering a Molecule (or containing any pending claims in any patent application that cover or claim a Molecule or its use or manufacture). Licensed Patent Rights include, as of the Effective Date, all Patent Rights set forth on Schedule 1.1.38.  
1.1.39. “Manufacturing” means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of a Molecule or Products, including process and formulation development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, whether such activities are conducted by a Party, its Affiliates or a Third Party contractor of such Party. When used as a verb, “Manufacture” means to engage in Manufacturing.  
1.1.40. “MedImmune Know-How” means the Know-How Controlled by Xxxxx pursuant to the MedImmune License immediately prior to the novation thereof contemplated by Section 2.3.  
1.1.41. “MedImmune License” means that certain License Agreement, dated August 6, 2019, between Xxxxx and MedImmune Limited (“MedImmune”), as amended, as it exists immediately prior to the novation thereof contemplated by Section 2.3.  
1.1.42. “MedImmune Patent Rights” means the Patent Rights Controlled by Xxxxx pursuant to the MedImmune License immediately prior to the novation thereof contemplated by Section 2.3 (which shall include the “MedImmune Patent Rights” as defined in the MedImmune License).  
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1.1.43. “MedImmune Valid Claim” means any claim in an issued and unexpired patent within the MedImmune Patent Rights which has not been disclaimed, abandoned, revoked, or held unenforceable, unpatentable or invalid by a governmental agency or competent court.  
1.1.44. “Molecule” means (a) the fully human anti-IL-18 monoclonal antibody known at Xxxxx as AVTX-007 (as further described on Exhibit A attached hereto) (the “Original Molecule”) or (b) any derivative thereof that is Covered by a Valid Claim of any of the Licensed Patent Rights or a MedImmune Valid Claim.  
1.1.45. “NDA” means a New Drug Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.  
1.1.46. “Net Sales” means, with respect to a Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates, or Sublicensees (including distributors of authorized generic versions of the Product(s)) to Third Parties for the sale of such Product (the “Invoiced Sales”), less deductions for:  
(a) normal and customary trade, quantity and prompt settlement discounts (including chargebacks and allowances) actually allowed;  
(b) amounts repaid or credited by reason of rejection, return or recall of goods, rebates or bona fide price reductions;  
(c) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced;  
(d) customs and excise duties and other taxes or duties related to the sales to the extent that such items are included in the gross amount invoiced;  
(e) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties’ rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;  
(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Product;  
(g) any actual bad debt expense recorded in accordance with the Accounting Standards from customers related to sales of a Product, such bad debt not to exceed four percent (4%) of the total Invoiced Sales less the deductions set forth above in clauses (a) to (f) above. If any bad debt is subsequently recovered, it shall be included as Net Sales.  
Any of the deductions listed above that involves a payment by Licensee, its Affiliates or Sublicensees shall be taken as a deduction in the Contract Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Product shall be deemed to be sold when invoiced and a “sale” shall not include transfers or dispositions of such Product for pre-clinical or clinical purposes or as samples, in each case, without charge. Licensee’s, its Affiliates’, or Sublicensees’ transfer of any Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Product is consumed or administered by such Affiliate or Sublicensee in the course of its commercial activities. With respect to any Product that is consumed or administered by Licensee, its Affiliates, or Sublicensees, Net Sales shall include any amount billed or invoiced with respect to such consumption or administration, including any services provided in connection therewith.  
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In the event that a Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of “Net Sales” by the fraction A/(A+B), where A is the average invoice price in such country of any Product that contains the same Molecule as such Combination Product as its sole active ingredient(s), if sold separately in such country and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Molecule(s) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country; provided that the invoice price in a country for each Product that contains only such Molecule(s) and each product that contains solely active ingredient(s) other than the Molecule(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency. If either such Product that contains such Molecule(s) as its sole active ingredient(s) or a product that contains an active ingredient (other than a Molecule) in the Combination Product as its sole active ingredient(s) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors reasonably relevant to the relative value of, the Molecule(s), on the one hand and all of the other active ingredient(s), collectively, on the other hand. In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Licensee’s, its Affiliates’, or Sublicensees’ existing allocation method; provided that any such allocation to a Product shall be (i) done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event no greater than a pro rata allocation, such that the portion of each of foregoing rebates, discounts and other forms of reimbursements shall not be included as deductions from Invoiced Sales hereunder in any amount greater than the proportion of the number of units of such Product sold by Licensee, its Affiliates, or Sublicensees to Third Parties hereunder compared to the number of units of all the products sold by Licensee, such Affiliates and such Sublicensees to Third Parties to which such foregoing rebate, discount or other form of reimbursement, as applicable, are granted. Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, its Affiliates, or Sublicensees, which must be in accordance with the Accounting Standards.  
1.1.47. “Novated MedImmune License” means the MedImmune License, as novated to Licensee as contemplated by Section 2.3, as such agreement may be amended from time to time in accordance with the terms thereof and this Agreement following such novation to Licensee.  
1.1.48. “Patent Rights” means all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, revivals or revalidations, supplementary protection certificates and patents of addition) and patent applications (including all provisional applications, continuations, continuations-in-part and divisions).  
1.1.49. “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.  
1.1.50. “Phase 2/3 Clinical Trial” means a human clinical trial of a Product that is designed to evaluate both dosing requirements and the effectiveness of the Product for a particular indication in patients with the disease or condition under study and is consistent with  
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the requirements of 21 C.F.R. §312.21(b) (as hereafter modified or amended) and 21 C.F.R. §312.21(c) (as hereafter modified or amended).  
1.1.51. “Phase 3 Clinical Trial” means (a) a controlled study in humans of the efficacy and safety of a Product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file for Regulatory Approval for human therapeutic, ameliorative, or prophylactic use, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(c), as amended from time to time, or (b) any analogous clinical trial described or defined in Applicable Laws and guidelines for a clinical trial conducted in another country in the Territory.  
1.1.52. “PHS Act” means the Public Health Services Act (Title 42, U.S.C., Chapter 6A). As used herein the PHS Act will refer, more specifically, to 42 USC § 262, which governs the regulation of biological products.  
1.1.53. “Product” means a product containing a Molecule, alone or in combination with one or more other active pharmaceutical ingredients.  
1.1.54. “Product Trademarks” means the Trademarks or indicia of origin used in connection with the distribution, marketing, promotion or Commercialization of any Product in a country in the Territory. For purposes of clarity, the term Product Trademark(s) shall not include the corporate names and logos of either Party, their Affiliates, or Sublicensee(s).  
1.1.55. “Registrational Study” means (a) a Phase 3 Clinical Trial or (b) any other human clinical trial of a Product that is intended to support the submission of an NDA or BLA (or any corresponding foreign application in the Territory to seek Regulatory Approval of a Product in any country or multinational jurisdiction) without conduct of any subsequent human clinical trial.  
1.1.56. “Regulatory Approval” means the approval of the applicable Regulatory Authority necessary for the testing, commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Product in a country in the Territory, including, where required, separate pricing or reimbursement approvals.  
1.1.57. “Regulatory Approval Application” means an application submitted to the appropriate Regulatory Authority seeking Regulatory Approval of a Product in a country in the Territory, including, without limitation, NDAs and BLAs.  
1.1.58. “Regulatory Authority” means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council or other government entity involved in granting of Regulatory Approval for a Product in a jurisdiction within the Territory, including, without limitation, the FDA.  
1.1.59. “Regulatory Documentation” means all (a) applications (including Regulatory Approval Applications) and any amendments, updates and supplements with respect thereto, registrations, licenses, authorizations and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), in each case (a) and (b) directly relating to a Molecule or a Product.  
1.1.60. “Regulatory Exclusivity” means, with respect to a Product, that Third Parties are prevented from legally developing, manufacturing or commercializing a product that could compete with such Product in a country, either through data exclusivity rights, orphan drug  
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designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights.  
1.1.61. “Related Party” means Licensee’s Affiliates and any Sublicensees under this Agreement. For clarity, Xxxxx shall not be deemed to be a Related Party.  
1.1.62. “Royalty Term” means, on a country-by-country and Product-by-Product basis, the period of time commencing on the date of the First Commercial Sale of a particular Product in a particular country and extending until the later of (X) the latest of (a) the date (\*\*\*) years from the date of the First Commercial Sale of the first Product in such country, (b) the first date on which there are no Valid Claims included in the Licensed Patent Rights that Cover such Product in such country, or (c) expiration of Regulatory Exclusivity with respect to such Product in such country or (Y) the expiration of the “Royalty Term” as defined in the MedImmune License (without taking into account any amendments to or termination of the Novated MedImmune License occurring following the Effective Date) for such country and Product.  
1.1.63. “Territory” means worldwide.  
1.1.64. “Third Party” means any Person other than a Party or any of its Affiliates.  
1.1.65. “Trademark” means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.  
1.1.66. “Valid Claim” means any claim in an issued and unexpired patent within the Licensed Patent Rights which has not been disclaimed, abandoned, revoked, or held unenforceable, unpatentable or invalid by a governmental agency or competent court.  
1.2. Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:  
Defined Term  
Section Reference  
“Action”  
11.2.1  
“Agreement”  
Preamble  
“Anti-Bribery Laws”  
10.1.5  
“Applicable Patheon Activities”  
3.4.3  
“Applicable Patheon Proposals”  
3.4.3  
“Assigned Patheon Agreement”  
3.4.3  
“Audited Party”  
6.7.2  
“Xxxxx”  
Preamble  
“Xxxxx Indemnitees”  
10.5.1  
“Xxxxx Material”  
3.3  
“Blocking Patent Claim”  
7.5.3(a)  
“BPCIA”  
7.4.2  
“Competing Product”  
2.6.1  
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“Competitive Activities”  
2.6.2  
“Consulting Activities”  
3.2  
“Continued Existing Clinical Studies”  
4.1.2  
“Disclosing Party”  
8.1  
“Effective Date”  
Preamble  
“embodiments of intellectual property”  
9.5  
“Existing Clinical Studies”  
4.1.2(b)  
“Force Majeure”  
11.6  
“GAAP”  
1.1.1  
“Indemnitee”  
10.5.3  
“Infringement Claim”  
7.5.1  
“Infringement Defense Costs”  
7.5.3(d)  
“Invoiced Patheon Amount”  
3.4.3  
“IP”  
9.5  
“Joint Intellectual Property”  
2.4  
“Joint Know-How”  
2.4  
“Joint Patent Rights”  
2.4  
“Licensee”  
Preamble  
“Licensee Patheon Amount”  
3.4.3  
“Licensee Indemnitees”  
10.5.2  
“Losses”  
10.5.1  
“MedImmune”  
1.1.41  
“Milestone Event”  
6.3  
“Milestone Payment”  
6.3  
“Newly Generated Regulatory Documentation”  
4.2.3  
“Novation Agreement”  
2.3  
“Original Molecule”  
1.1.44  
“Parties”  
Preamble  
“Party”  
Preamble  
“Patent Challenge”  
7.2.2  
“Patheon”  
3.4.3  
“Receiving Party”  
8.1  
“Section 351(k) Applicant”  
7.4.1  
“Study Transfer Plan”  
4.1.2(b)  
“Sublicense”  
2.2.1  
“Sublicensee”  
2.2.1  
“Term”  
9.1  
“Third Party Claim”  
10.5.1  
“Total Patheon Amount”  
3.4.3  
10  
  
  
  
“Transition Plan”  
3.1.1  
“Wind-Down Existing Clinical Studies”  
4.1.2(a)  
  
ARTICLE 2  
  
LICENSES AND INTELLECTUAL PROPERTY OWNERSHIP  
  
2.1. License Grant. Subject to the terms and conditions of this Agreement, Xxxxx hereby grants to Licensee:  
2.1.1. an exclusive (even as to Xxxxx) worldwide license, with the right to sublicense as provided in Section 2.2, under the Licensed Intellectual Property to Develop, have Developed, Manufacture, have Manufactured, make, have made, use, sell, offer for sale, import, Commercialize and have Commercialized Molecules and Products in the Field in the Territory; and  
2.1.2. an exclusive worldwide license and right of reference, with the right to sublicense and grant further rights of reference as provided in Section 2.2, under the Newly Generated Regulatory Documentation, to Develop, have Developed, Manufacture, have Manufactured, Commercialize and have Commercialized Molecules and Products in the Field in the Territory until such time as the respective Newly Generated Regulatory Documentation is actually assigned and delivered to Licensee or its Related Party in accordance with the terms of this Agreement.  
2.2. Sublicenses.  
2.2.1. Right to Sublicense. Licensee may sublicense the rights granted to it under Section 2.1 through multiple tiers to one or more of its Affiliates or Third Parties at any time (each such Affiliate or Third Party, or any subsequent grantee of such a sublicense from a Sublicensee, a “Sublicensee” and each such sublicense, a “Sublicense”). Licensee shall remain responsible for the performance of its Sublicensees under this Agreement, including for all payments due hereunder, whether or not such payments are made by Licensee, its Affiliates or Sublicensees. Licensee shall notify Xxxxx of any sublicense within five (5) Business Days of the grant of the sublicense.  
2.2.2. Terms. Each sublicense granted under this Agreement shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement including, in the case of agreements with any Third Party commercializing Sublicensee, the following provisions: (a) a requirement that such Sublicensee submit applicable sales or other reports consistent with those required hereunder; (b) an audit requirement similar to the requirement set forth in Section 6.7; and (c) a requirement that such Sublicensee comply with confidentiality and non-use provisions at least as stringent as those confidentiality and non-use obligations set forth in ARTICLE 8 with respect to both Parties’ Confidential Information. Notwithstanding any sublicense, Licensee shall remain at all times fully liable for its obligations under this Agreement.  
2.2.3. Effect of Termination on Sublicenses. If this Agreement terminates for any reason, then, on a Sublicensee-by-Sublicensee basis, if (a) a Sublicensee is not, at the time of such termination, in material breach of any of its obligations under the applicable Sublicense and (b) the acts or omissions of such Sublicensee did not cause or result in the termination of this Agreement, then, upon such Sublicensee’s written election delivered to Xxxxx within fifteen (15)  
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Business Days after the effective date of such termination, Xxxxx and such Sublicensee shall promptly enter into a direct license with each other, effective as of the effective date of termination of this Agreement, on substantially the same terms as the applicable Sublicense to the extent such terms (i) relate to the intellectual property rights granted hereunder that are subject to such sublicense and (ii) do not impose obligations on Xxxxx in excess of those imposed on Xxxxx under this Agreement, provided that the financial terms of such direct license will be substantially the same terms as set forth in Sections 6.3, 6.4, 6.5, 6.6, 6.7, 7.3.3(b) and 7.5.3(d) of this Agreement.  
2.3. MedImmune License. Prior to or simultaneously with the execution of this Agreement, the Parties and MedImmune Limited shall enter into that certain novation agreement in substantially the form attached hereto as Schedule 2.3 (the “Novation Agreement”) pursuant to which the MedImmune License will be replaced by the Novated MedImmune License. During the Term, Licensee shall comply with and maintain in full force and effect the Novated MedImmune License for the term thereof, and shall not amend or modify the Novated MedImmune License in any manner that does or would reasonably be anticipated to (a) reduce the duration or amount of any payments to Xxxxx hereunder or (b) otherwise adversely affect (as determined with respect to Xxxxx) Xxxxx’x rights to any payments, or Licensee’s payment obligations to Xxxxx, under this Agreement, in each case ((a) and (b)) without the prior written consent of Xxxxx. In any event, the Parties agree that Licensee’s payment obligations to Xxxxx under this Agreement shall not be affected by any amendment or modification to the Novated MedImmune License and shall be deemed to remain effective in such manner as if such amendment or modification had not occurred. Licensee shall promptly provide Xxxxx copies of any correspondence to or from MedImmune, an Affiliate thereof, or any successor in interest thereto with respect to any actual or alleged breach of the Novated MedImmune License or termination thereof. Licensee shall not terminate this Agreement prior to any termination of the Novated MedImmune License nor terminate the Novated MedImmune License prior to any termination of this Agreement.  
2.4. Ownership of and Rights to Intellectual Property. Subject to the license grants and other rights herein, as between the Parties, each Party shall solely own all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made solely by or on behalf of such Party (or its Affiliates) in the course of activities conducted pursuant to this Agreement, and any and all Patent Rights and other intellectual property rights with respect thereto. Subject to the license grants and other rights herein, as between the Parties, the Parties shall jointly own all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made jointly by or on behalf of Licensee (or its Affiliates) on the one hand, and by or on behalf of Xxxxx (or its Affiliates) on the other hand, in the course of activities conducted pursuant to this Agreement (the “Joint Know-How”) and any and all Patent Rights with respect thereto (the “Joint Patent Rights”) and other intellectual property rights with respect to (including claiming) the Joint Know-How (together with Joint Know-How and Joint Patent Rights, the “Joint Intellectual Property”). The determination of whether Know-How is conceived, discovered, developed or otherwise made by or on behalf of a Party or its Affiliates for the purpose of allocating proprietary rights (including patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with United States patent law, without regard to conflict of law, irrespective of where or when such conception, discovery, development or making occurs. Xxxxx shall promptly disclose to Licensee in writing, and shall cause its Affiliates to so disclose, all Know-How and Patent Rights conceived, discovered, developed or otherwise made solely by or on behalf of Xxxxx (or its Affiliates) in the course of activities conducted pursuant to this Agreement that relate to a Molecule or Product. Each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their licensees and sublicensees to so disclose, all Joint Know-How and Joint Patent Rights. Subject to the licenses granted under Section 2.1 and, in the case of Xxxxx, Section 2.6, each Party shall have  
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the right to independently exploit the Joint Intellectual Property and the right to grant sublicensable, transferable licenses under Joint Intellectual Property to any Person, without a duty of seeking consent of or accounting to the other Party, and to the extent any such consent or accounting is required by any jurisdiction, such consent is hereby granted and the requirement of such accounting is hereby waived.  
2.5. No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest or other right in any, Know-How or Patent Rights of the other Party, including items Controlled or developed by the other Party, or provided by the other Party to the receiving Party at any time pursuant to this Agreement.  
2.6. Exclusivity.  
2.6.1. During the Term, except for activities conducted pursuant to this Agreement in accordance with the terms hereof, neither Xxxxx nor its Affiliates shall (a) directly or indirectly develop, manufacture, commercialize or otherwise exploit any Competing Product anywhere in the Territory or (b) license, authorize, appoint, or otherwise knowingly enable any Third Party to develop, manufacture, commercialize or otherwise exploit any Competing Product anywhere in the Territory; provided that this Section 2.6.1 will not prohibit Xxxxx or its Affiliates from developing, manufacturing, commercializing or otherwise exploiting any Competing Product after the (\*\*\*) anniversary of the first Regulatory Approval of a Product in the Territory unless Licensee (i) determines in writing prior to such (\*\*\*) anniversary and annually thereafter that the restriction set forth in this Section 2.6.1 remains permissible under Applicable Law and (ii) provides notice of such determination to Xxxxx at least thirty (30) days prior to each such anniversary. A “Competing Product” is any molecule, compound, product, or other therapeutic agent that is known to preferentially or selectively bind to, inhibit, activate, or modulate the activity or expression of IL-18.  
2.6.2. Notwithstanding Section 2.6.1, neither Xxxxx nor any Affiliate thereof will be in breach of the restrictions set forth in Section 2.6.1 if Xxxxx is subject to a Change of Control and the Third Party that is party to such Change of Control (or any Affiliate thereof other than (i) Xxxxx or (ii) an Affiliate of Xxxxx existing prior to such Change of Control) (a) is performing at, or has performed within the twelve (12) months prior to, the closing of the Change of Control transaction, any activity that would be in breach of Section 2.6.1 if performed by or on behalf of Xxxxx or an Affiliate thereof (such prohibited activities, “Competitive Activities”) or (b) commences any Competitive Activities after the closing of the Change of Control transaction; and such Third Party and its Affiliates may perform such Competitive Activities as long as (i) no Licensed Intellectual Property is used in connection with the performance of any Competitive Activities and (ii) Xxxxx (or the applicable Third Party, as applicable) institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating reasonably appropriate firewalls.  
2.7. License Grant to Xxxxx. Licensee hereby grants Xxxxx a non-exclusive license under the Licensed Intellectual Property for the sole purpose of conducting any Development or other activities that are allocated to Xxxxx under this Agreement in accordance with the terms thereof. This Section 2.7 will terminate automatically upon the earlier of (a) Licensee’s written notice to Xxxxx thereof or (b) Xxxxx ceasing to conduct any such activities.  
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ARTICLE 3  
  
TECHNOLOGY TRANSFER  
  
3.1. Transition Activities.  
3.1.1. Transition Plan. The Parties will complete, within thirty (30) days following the Effective Date (or such other time frame set forth in the Transition Plan), the activities set forth in the transition plan attached as Schedule 3.1.1 (“Transition Plan”) in accordance with the terms of the Transition Plan and this Agreement, to transfer to Licensee or its designee all Development and Manufacturing activities relating to the Molecules and Products then being undertaken by or on behalf of Xxxxx or its Affiliates  
3.1.2. Transition Activities. Upon Licensee’s request, without limiting Section 3.1.1, without additional consideration to Xxxxx (except as set forth in Section 3.2), and consistent with the Transition Plan:  
(a) Within thirty (30) days after the Effective Date, Xxxxx shall transfer to Licensee (i) copies of all then-existing material data, reports, records, written materials, and other information within the Licensed Know-How and MedImmune Know-How, including all such Know-How constituting adverse event or other safety data resulting from any of Xxxxx’x or its Affiliates’ activities in connection with any Molecule or Product, that is known to or in the possession of Xxxxx or any Affiliate thereof and (ii) to the extent in the possession of Xxxxx or any Affiliate thereof or their respective patent counsel and not constituting freedom-to-operate or infringement analyses or related communications, the file wrappers and other documents and written materials relating to the prosecution, defense, maintenance, validity and enforceability of the Licensed Patent Rights and any Patent Rights that Xxxxx was responsible for prosecuting pursuant to the MedImmune License prior to the novation thereof to Licensee. Thereafter during the Term, from time to time, Xxxxx shall transfer to Licensee copies of (A) any additional Licensed Know-How and (B) any additional materials relating to the prosecution, defense, maintenance, validity and enforceability of the Licensed Patent Rights and any patent rights that Xxxxx was responsible for prosecuting pursuant to the MedImmune License prior to the novation thereof to Licensee, in each case ((A) and (B)), of which Xxxxx becomes aware, that has not been previously transferred to Licensee, that does not constitute freedom-to-operate or infringement analyses or related communications, and is necessary or reasonably useful for Licensee to perform its obligations or exercise its rights under this Agreement;  
(b) Xxxxx shall reasonably assist and cooperate with Licensee, as Licensee may reasonably request, in the transition to Licensee of the prosecution, maintenance, enforcement and defense of the Licensed Patent Rights and any patent rights that Licensee was responsible for prosecuting pursuant to the MedImmune License prior to the novation thereof as contemplated by Section 2.3; and  
(c) Xxxxx shall duly execute and deliver or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be reasonably necessary under or as Licensee may reasonably request in connection with or to carry out more effectively the purpose of, or to better assure and confirm unto Licensee its rights to exploit the Molecules and Products in accordance with, this Agreement.  
3.2. Post-Transition Consulting Activities. Without limiting the foregoing Section 3.1.1 and Section 3.1.2, during the period beginning on the Effective Date and ending on the (\*\*\*) anniversary of the completion of activities under the Transition Plan, Xxxxx will, to the extent  
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such personnel are employed or engaged by Xxxxx or any Affiliate at the time of any applicable inquiry by Licensee, make its employees and consultants previously and materially involved in the Development or Manufacture of a Molecule or a Product reasonably available to respond to Licensee’s reasonable inquiries regarding any Licensed Know-How or activities transferred under the Transition Plan or regarding any Xxxxx Materials (“Consulting Activities”). In the event that Xxxxx ceases to engage any such personnel during such period, Xxxxx will, upon Licensee’s written request, use Commercially Reasonable Efforts, subject to any limitations imposed by any subsequent employment or engagement thereof by any Third Party, to facilitate Licensee’s negotiation of a consulting arrangement between such individual and Licensee in order to facilitate such individual’s continued provision of Consulting Activities, provided that Xxxxx shall not have any obligation to incur any material additional costs or expenses with respect to such obligation. Xxxxx will conduct the first (\*\*\*) person hours of Consulting Activities at its own expense, and Licensee will reimburse Xxxxx for all Consulting Activities conducted by Xxxxx’x or its Affiliates’ employees or consultants beyond the first (1st) (\*\*\*) person hours thereof at the applicable rate(s) set forth on Schedule 3.2 based on the type of employee or consultant performing such activities. Licensee shall pay Xxxxx for any such Consulting Activities within thirty (30) days of receipt of an invoice therefor from Xxxxx.  
3.3. Transfer of Xxxxx Material. Promptly upon Licensee’s request given at any time within ninety (90) days of the Effective Date or at such time as otherwise set forth in the Transition Plan or Study Transfer Plan, Xxxxx or its designee shall deliver to Licensee or its designee quantities of the Molecule(s), Product(s), and other biological and chemical materials related thereto in each case Controlled by Xxxxx or any of its Affiliates, each in the forms and amounts described on Schedule 3.3 (collectively, the “Xxxxx Material”) at no charge to Licensee, provided that Xxxxx shall not have such obligation to the extent Licensee can cause delivery thereof to Licensee or its designee pursuant to the terms of an Assigned Product Agreement (or novated form thereof) to which Apollo or an Affiliate thereof is a party. Any such delivery by Xxxxx (or to be caused by Xxxxx) shall be EXW (Incoterms 2020) the location(s) indicated for the various Xxxxx Materials on Schedule 3.3, unless otherwise agreed to in writing by the Parties. Xxxxx shall maintain, shall ensure that its Affiliates maintain, and that its subcontractors maintain in accordance with the applicable subcontracts, the quality of all Xxxxx Materials until the earliest of (i) such time as responsibility for the shipment of such materials transfers to Licensee pursuant to the terms of this Section 3.3, (ii) the assignment or novation of any Assigned Product Agreement governing such Xxxxx Material to Licensee or an Affiliate thereof as contemplated by this Agreement, or (iii) the ninetieth (90th) day following the Effective Date.  
3.4. Assignment of Product Agreements.  
3.4.1. General. Xxxxx shall assign to Licensee, and Licensee shall and hereby does assume, the Assigned Product Agreements and all rights, obligations, and liabilities thereunder, pursuant to the terms set forth on Schedule 3.4.1, provided that, notwithstanding anything to the contrary, (i) the timing of such assignment and assumption of each Assigned Product Agreement shall, subject to clause (ii) below, be as specified on Schedule 3.4.1 (and the Parties shall, in connection with each assignment, execute a reasonable and mutually acceptable confirmatory document establishing the date of such assignment for each Assigned Product Agreement), (ii) if an Assigned Product Agreement pertains to any product other than a Molecule or Product, such Assigned Product Agreement shall only be assigned and assumed hereunder with respect to Molecules and Products, as applicable, (iii) if the terms of an Assigned Product Agreement do not permit assignment thereof to Licensee (either in its entirety, if solely pertaining to Molecules and Products, or in part, if pertaining to any product other than a Molecule or Product), the Parties shall seek to obtain such permission in a manner consistent with the desired timing for such assignment and assumption set forth in Schedule 3.4.1 and (x) if such permission is obtained, such assignment and assumption shall be effected in a manner consistent with this  
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Section 3.4 and such permission and (y) if such permission is not obtained and the following is elected by Licensee by written notice to Xxxxx, the Parties shall negotiate in good faith and enter into a written arrangement pursuant to which Xxxxx shall otherwise transfer to Licensee, to the extent permitted by such agreement, or otherwise enable Licensee to obtain the benefit of such agreement for the purpose of Developing or Manufacturing Molecules and Products and Licensee shall assume (or perform on Xxxxx’x behalf and indemnify Xxxxx with respect to) all future obligations, payments, and liabilities thereunder (which shall in any event include all payment obligations thereunder incurred after July 31, 2022).  
3.4.2. Previously Undisclosed Agreements. In addition, if Xxxxx becomes aware of any agreement between Xxxxx (or an Affiliate thereof) and a Third Party that (i) was executed prior to the Effective Date, (ii) directly relates to the Development or Manufacture of a Molecule or Product, and (iii) was not included in the Data Room prior to the Effective Date, Xxxxx shall promptly provide written notice thereof (and a copy thereof) to Licensee and, if elected by Licensee by notice to Xxxxx within thirty (30) days of such notice from Xxxxx, promptly assign to Licensee such agreement, provided that, (i) if any such agreement pertains to any product other than a Molecule or Product and assignment in part thereof is permitted by its terms, then Xxxxx shall assign such agreement to Licensee solely to the extent it pertains to a Molecule or Product and (ii) if any such agreement does not permit assignment to Licensee as contemplated hereby, (1) Xxxxx shall promptly seek to obtain permission to assign such agreement as contemplated hereby from such Third Party (and, upon obtaining such permission, so assign such agreement to Licensee) and (2) in the event such permission is not obtained and the following is elected by Licensee by written notice to Xxxxx, the Parties shall negotiate in good faith and enter into a written arrangement pursuant to which Xxxxx shall otherwise transfer to Licensee, to the extent permitted by such agreement, or otherwise enable Licensee to obtain the benefit of such agreement for the purpose of Developing or Manufacturing Molecules and Products and Licensee shall assume (or perform on Xxxxx’x behalf and indemnify Xxxxx with respect to) all future obligations, payments, and liabilities thereunder.  
3.4.3. Patheon Agreement. Xxxxx hereby represents and warrants to Licensee that, as of the Effective Date and with respect to that certain Master Umbrella Development Services Agreement, between Patheon Biologics LLC (“Patheon”) and Xxxxx, effective November 12, 2020, as amended and those certain Project Proposals executed thereunder included in the Assigned Product Agreements (the “Assigned Patheon Agreement”) and all activities through Drug Substance (as referred to in the Applicable Patheon Proposals (as defined below)) manufacturing under the Applicable Patheon Proposals, excluding Drug Product (as referred to in the Applicable Patheon Proposals) manufacturing (the “Applicable Patheon Activities”), (i) Xxxxx has received invoices from Patheon totaling $(\*\*\*) through the latest accounts payable update that occurred on approximately July 20, 2022 (such amount the “Invoiced Patheon Amount”) and (ii) the total amount known to Xxxxx that was, is, or will become due with respect to Applicable Patheon Activities (including corresponding change orders with respect thereto) under the Assigned Patheon Agreement, including the above-referenced $(\*\*\*), is, as of such update, reasonably estimated by Xxxxx to be $(\*\*\*) (the “Total Patheon Amount”). To the extent Xxxxx has not paid any portion of the Invoiced Patheon Amount as of the Effective Date, Xxxxx shall, notwithstanding anything to the contrary in this Agreement, remain and be responsible for paying Patheon that amount, and Licensee shall be responsible for paying (and shall, upon assignment of the Assigned Patheon Agreement to Licensee and, consistent with and without limitation of the terms of Schedule 3.4.1, assume the obligation to pay) any portion of the Total Patheon Amount in excess of the Invoiced Patheon Amount (such excess, the “Licensee Patheon Amount”), provided that if invoices for any portion of the Licensee Patheon Amount are received and paid by Xxxxx prior to the assignment of the Assigned Patheon Agreement to Licensee, then Licensee shall reimburse Xxxxx in the amount of any such payment within thirty (30) days of receipt of an invoice therefor from Xxxxx. For the sake of clarity, the  
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Assigned Patheon Agreement also contains additional potential services for which Licensee will be responsible upon assignment to Licensee of the Assigned Patheon Agreement, pursuant to Schedule 3.4.1. For purposes of this Section 3.4.3, “Applicable Patheon Proposals” means the following included in the Assigned Patheon Agreement: Project Proposal Number OS-02176-R3 (dated March 11, 2021 and also known as Project Proposal OS-01276-P-FEP-260191-R1), Change of Scope COS-08-02 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated July 16, 2021), Change of Scope COS-02-01 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated July 27, 2021), Change of Scope COS-03-R1 to Project Xxxxxxxx Xx. XX-00000-X-XXXXX-000000-X0-XX0 (dated October 22, 2021), Change of Scope COS-04-R1 to Project Xxxxxxxx Xx. XX-00000-X-XXXXX-000000-X0-XX0 (dated January 11, 2022), Change of Scope COS-05-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated March 11, 2022), Change of Scope COS-07-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated June 6, 2022), Change of Scope COS-06-R1 to Proposal No. OS-02176-GROBL-122395-R5-WS2 (June 28, 2022), and Change of Scope COS-08-R1 to Proposal No. OS01276-B-GROBL-122395-R5-WS2 (dated July 8, 2022).  
3.5. Assignment of Regulatory Documentation. Within five (5) Business Days of the Effective Date or such later date as may be (i) consistent with the Transition Plan, Study Transfer Plan, or Schedule 3.4.1 or (ii) otherwise necessary to enable Xxxxx and its Affiliates to perform their obligations with respect to the Existing Clinical Studies without violating Applicable Law or the terms of any applicable agreement with any Third Party, Xxxxx shall and hereby does assign to Licensee all of its right, title and interest in and to all Regulatory Documentation (including all INDs) owned by Xxxxx and its Affiliates relating to each Molecule or Product, and Xxxxx shall deliver such Regulatory Documentation to Licensee in the format reasonably requested by Licensee within thirty (30) days after Licensee’s request therefor. The Parties shall execute and file such documentation (including transfer letters) with the applicable Regulatory Authorities as shall be required to effect such transfer and coordinate such execution and filing as appropriate.  
3.6. Disclaimers. EXCEPT FOR THE IMPLIED WARRANTY OF TITLE OR AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, XXXXX PROVIDES THE XXXXX MATERIAL “AS-IS”, AND XXXXX DISCLAIMS ANY AND ALL IMPLIED WARRANTIES (OTHER THAN THE IMPLIED WARRANTY OF TITLE) CONCERNING THE XXXXX MATERIAL, INCLUDING WARRANTIES CONCERNING THE QUALITY, CONDITION, EFFICACY, SAFETY OR UTILITY OF THE XXXXX MATERIAL, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. FOR THE AVOIDANCE OF DOUBT, EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, XXXXX HAS NO LIABILITY FOR ANY CLAIMS, LOSSES OR CASUALTY ARISING FROM LICENSEE’S USE OF ANY XXXXX MATERIAL.  
ARTICLE 4  
  
DEVELOPMENT, MANUFACTURE AND RELATED DILIGENCE  
  
4.1. Development.  
4.1.1. Responsibility; General Obligation. Except as set forth in Section 4.1.2, Licensee is solely responsible for all Development and regulatory activities, and the expenses related thereto, with respect to the Development of the Molecule(s) and the Product(s) in the Field in the Territory.  
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4.1.2. Existing Clinical Studies.  
(a) Xxxxx shall, as soon as reasonably practicable following the Effective Date, (i) wind-down all remaining activities with respect to those certain clinical studies set forth on Schedule 4.1.2(a) (the “Wind-Down Existing Clinical Studies”) and (ii) conduct any post-completion obligations with respect thereto as required by Applicable Law, in accordance with the timelines set forth on such schedule.  
(b) Xxxxx shall conduct those certain clinical studies set forth on Schedule 4.1.2(b) (the “Continued Existing Clinical Studies”; collectively, with the Wind-Down Existing Clinical Studies, the “Existing Clinical Studies”) in accordance with the protocols therefor and Applicable Law, at Licensee’s expense, until such time as responsibility for performing such studies, has been transferred to Licensee pursuant to the plan therefor set forth on Schedule 4.1.2(b) (the “Study Transfer Plan”), provided that, notwithstanding anything to the contrary, (i) Xxxxx shall not amend, modify or deviate from any existing protocol with respect to the Continued Existing Clinical Studies, as such protocol exists as of the Effective Date, or suspend or terminate the Continued Existing Clinical Studies, in each case without Licensee’s prior written consent (not to be unreasonably withheld or delayed) except solely to the extent required by any Regulatory Authority, Applicable Law, or investigational review board or similar body and (ii) Xxxxx shall not be obligated under this Agreement to enroll any additional patients or subjects in the Continued Existing Clinical Studies. The Parties shall perform and complete the Study Transfer Plan (including but not limited to assignment to Licensee of any applicable Regulatory Documentation owned or controlled by Xxxxx or any Affiliate thereof or, to the extent permitted by the terms thereof or consent to assignment is obtained, agreements between Xxxxx and any Third Parties solely relating to the Continued Existing Clinical Studies, each as set forth in the Study Transfer Plan) in accordance with the timelines set forth therein. Licensee shall reimburse Xxxxx for all internal and external costs incurred by Xxxxx or any Affiliate thereof following the Effective Date with respect to the performance of its obligations under this Section 4.1.2(b) within thirty (30) days of the receipt of any invoice with respect thereto. For clarity, neither Licensee nor its Affiliates will be responsible for any costs or liabilities accrued by Xxxxx or its Affiliates prior to the Effective Date.  
(c) At any time during which Xxxxx or its Affiliate or a subcontractor of either of the foregoing is conducting the Continued Existing Clinical Studies, (i) Xxxxx shall promptly provide Licensee with all information relating to the Continued Existing Clinical Studies coming under the Control of Xxxxx or an Affiliate thereof that is reasonably requested by Licensee and (ii) Xxxxx shall promptly (and in any event, within two (2) days) notify Licensee of any adverse safety event or other material issue relating to the Continued Existing Clinical Studies of which Xxxxx becomes aware.  
(d) Upon reasonable notification by Licensee and at Licensee’s cost and expense, Licensee may conduct an audit of Xxxxx and its Affiliates and, to the extent permitted by the applicable subcontracts or clinical site agreements, subcontractors and all clinical trial sites engaged by Xxxxx or its Affiliates or subcontractors, in each case, to determine whether the Existing Clinical Studies were or are, during any period following the Effective Date during which Xxxxx is responsible for performing such studies, being conducted in compliance with the terms of this Agreement and Applicable Law. Such audit will be conducted no more than once per each six (6)-month period, except with respect to any “for cause” audit, which may be conducted any number of times, provided that, with respect to any such audit of any subcontractor or clinical site, the frequency thereof hereunder shall not exceed such frequency permitted by the applicable subcontracts or clinical site agreements. After preparing or receiving an audit report, Licensee will provide Xxxxx with a written summary of its findings of any  
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material deficiencies or other areas of remediation that Licensee identifies during any such audit. Xxxxx will use best efforts remediate any undisputed deficiencies no later than thirty (30) days after receipt of such report, at Xxxxxx’s cost and expense.  
(e) With respect to any inspection of Xxxxx or its Affiliates or subcontractors by a governmental authority relating to the Existing Clinical Studies, Xxxxx will notify Licensee of such inspection (i) no later than two (2) days after Xxxxx receives notice of such inspection (or in any event with as much advance notice as is possible prior to such inspection if Xxxxx receives notice thereof less than two (2) days in advance of the applicable inspection) or (ii) within two (2) days after the completion of any inspection of which Xxxxx did not receive prior notice. Xxxxx will promptly provide Licensee with all available information known to Xxxxx related to any such inspection. Xxxxx will, will ensure that its Affiliates, and will ensure that its subcontractors will (in accordance with the terms of the applicable subcontract), permit and cooperate with all governmental authority inspections and inquiries relating to the Existing Clinical Studies. Licensee or its designee will, subject to the applicable terms of any subcontract or site agreement, have the right, but not the obligation, to be present at and participate in any such inspection. Following any such inspection, Xxxxx will provide Licensee with an unredacted copy of any findings, notice, or report provided by any governmental authority related to such inspection (to the extent relating to the Existing Clinical Studies) within two (2) days of receiving the same.  
4.2. Specific Development Responsibilities.  
4.2.1. Manufacturing. Except to the extent any applicable Molecule or Product is provided under Section 3.3, and subject to the completion of the applicable transition activities set forth in this Agreement, Licensee is solely responsible for the Manufacture of a Molecule and each Product in the Field in the Territory for clinical Development purposes. To the extent not included in the Licensed Know-How or MedImmune Know-How, Licensee is solely responsible for generating necessary CMC data on a Molecule and each Product for regulatory filings, including any Regulatory Approval Application.  
4.2.2. Regulatory Strategy. With respect to each Product, except for any interaction or communication with a Regulatory Authority that Xxxxx is required to conduct under Applicable Law in connection with Xxxxx’x conduct of the Existing Clinical Studies in accordance with the terms of this Agreement, Licensee and its Related Parties are solely responsible for all interactions and communications with Regulatory Authorities including, without limitation, in relation to INDs, BLAs, label development, advisory committee meetings or their equivalent (if applicable) and negotiation with Regulatory Authorities regarding post-approval requirements/commitments.  
4.2.3. Regulatory Documentation. All Regulatory Documentation (including all Regulatory Approval Applications and Regulatory Approvals) shall, except (a) with respect to such Regulatory Documentation useful or necessary to enable Xxxxx and its Affiliates to perform their obligations and exercise their rights with respect to the Existing Clinical Studies or as otherwise set forth in the Study Transfer Plan and (b) as provided in this Section 4.2.3, be owned by and held in the name of, Licensee or its Related Party. Without limiting Xxxxx’x obligations under Section 3.5, at Licensee’s election, to the extent not already assigned and delivered to Licensee, Xxxxx shall, to the extent permitted under Applicable Law, assign and deliver promptly (in no event later than ten (10) days following receipt of Licensee’s notice electing for such assignment and delivery) to Licensee all or a portion of the Existing Regulatory Documentation and any newly-created Regulatory Documentation arising from any Existing Clinical Studies (“Newly Generated Regulatory Documentation”); provided that (i) with respect to the safety data contained in the Newly Generated Regulatory Documentation with respect to each Existing  
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Clinical Study, during the pendency of such Existing Clinical Study, Xxxxx shall promptly transfer such safety data to Licensee as it becomes available to Xxxxx or its Affiliates on an ongoing basis and in any event no later than ten (10) days after the completion of the applicable Existing Clinical Study and (ii) Xxxxx shall be entitled to delay the transfer of Existing Regulatory Documentation or Newly Generated Regulatory Documentation solely as necessary to permit Xxxxx and its Affiliates to perform their obligations with respect to the Existing Clinical Studies or as otherwise set forth in the Study Transfer Plan. Xxxxx shall duly execute and deliver or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary under or as Licensee may reasonably request in connection with or to carry out more effectively the purpose of, or to better assure and confer unto Licensee its rights under, this Section 4.2.3.  
4.2.4. Records. Each Party shall maintain written scientific records of Development activities conducted pursuant to this Agreement in reasonable detail consistent with such Party’s record keeping for its other products, which practices shall at least be commercially reasonable and consistent with reasonable, customary scientific and pharmaceutical industry standards.  
4.3. Third Parties. Licensee and its Related Parties shall be entitled to utilize the services of Third Parties, including Third Party contract research organizations and service providers to perform their respective Development activities; provided, however, that Licensee shall remain at all times fully liable for its responsibilities under this Agreement. Any agreement with a Third Party to perform Licensee’s Development obligations under this Agreement shall be consistent with Licensee’s obligations under this Agreement including confidentiality and non-use provisions which are no less stringent than those set forth in ARTICLE 8 (provided that the term of such confidentiality and non-use provisions may be shorter than those set forth in ARTICLE 8 to the extent consistent with applicable industry practice).  
ARTICLE 5  
  
COMMERCIALIZATION AND RELATED DILIGENCE  
  
5.1. Commercialization. Licensee is solely responsible for all, and, as between Xxxxx and Licensee, shall record all top line revenues in connection with, Commercialization activities relating to Products in the Field in the Territory.  
5.2. Commercial Manufacturing and Supply. Licensee is solely responsible for the Manufacture of a Molecule and each Product for commercial purposes in the Field in the Territory.  
5.3. Medical and Scientific Affairs. Licensee is solely responsible for medical and scientific affairs and programs, including professional symposia and other educational activities with respect to each Product in the Field in the Territory. Licensee shall have the exclusive right to respond to all questions or requests for information about the Products made by any medical professionals or any other Person in the Field in the Territory.  
ARTICLE 6  
  
FINANCIAL PROVISIONS  
  
6.1. Upfront Payment. Within five (5) Business Days following the Effective Date, Licensee shall pay Xxxxx a nonrefundable, noncreditable amount equal to Five Million Dollars  
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($5,000,000) by wire transfer of immediately available and cleared funds pursuant to wire transfer instructions provided by Xxxxx to Licensee in writing prior to the Effective Date.  
6.2. Payment for Transition Activities. Within five (5) Business Days following the Effective Date, Licensee shall pay Xxxxx a nonrefundable, noncreditable amount equal to Nine Million Five Hundred Sixteen Thousand Five Hundred Forty-Nine Dollars ($9,516,549) as partial consideration for Xxxxx’x transition activities and Consulting Activities and for the transfer of Xxxxx Materials and Assigned Product Agreements, by wire transfer of immediately available and cleared funds pursuant to wire transfer instructions provided by Xxxxx in writing.  
6.3. Milestones. Licensee shall make the following one-time, nonrefundable, and noncreditable milestone payments to Xxxxx (each, a “Milestone Payment”) following the first achievement by Licensee or any of its Related Parties of the milestone event corresponding to such Milestone Payment (each, a “Milestone Event”). Licensee shall notify Xxxxx of the achievement of each Milestone Event as follows: (a) within ten (10) Business Days following the achievement of any Milestone Event labeled a “Development Milestone” below and (b) within thirty (30) days following the end of the Contract Quarter during which the achievement of any Milestone Event labeled a “Sales Related Milestone” below occurs. Xxxxx will invoice Licensee for each Milestone Payment no earlier than the earlier of (i) receipt of such a notice from Licensee with respect to the corresponding Milestone Event or (ii) the date Licensee is required to provide such a notice for the corresponding Milestone Event, and Licensee shall pay such Milestone Payment no later than forty five (45) days following its receipt of the applicable invoice from Xxxxx. For clarity, each Milestone Payment will be payable no more than one (1) time, upon the first achievement of the corresponding Milestone Event by Licensee or any of its Related Parties, regardless of whether the relevant Milestone Event is achieved in respect of more than one (1) Product.  
Development Milestones  
Payment  
1. (\*\*\*) $(\*\*\*)  
2. (\*\*\*) $(\*\*\*)  
3. (\*\*\*) $(\*\*\*)  
Total Development Milestones  
$6,250,000  
  
Sales Related Milestones  
Payment  
Annual Net Sales first exceed $(\*\*\*) $(\*\*\*)  
Annual Net Sales first exceed $(\*\*\*) $(\*\*\*)  
Annual Net Sales first exceed $(\*\*\*) $(\*\*\*)  
Annual Net Sales first exceed $(\*\*\*) $(\*\*\*)  
Total Sales Related Milestones $67,500,000  
  
Notwithstanding anything to the contrary in this Agreement,  
(i) if Milestone Event 2 or 3 or the First Commercial Sale of a Product in the United States occurs prior to the achievement of Milestone Event 1, then Milestone Event 1 shall be deemed to have occurred and the applicable Milestone Payment therefor shall be due (in addition to any Milestone Payment due for Milestone Event 2 or 3); and  
(ii) if Milestone Event 3 or First Commercial Sale of a Product in the United States occurs prior to the achievement of Milestone Event 2, then Milestone Event 2 shall be deemed to  
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have occurred and the applicable Milestone Payment therefor shall be due (in addition to any Milestone Payment due for Milestone Event 3); and  
(iii) if First Commercial Sale of a Product in the United States occurs prior to the achievement of Milestone Event 3, then Milestone Event 3 shall be deemed to have occurred and the applicable Milestone Payment therefor shall be due.  
6.4. Royalties.  
6.4.1. Full Royalty Rate. Licensee shall, subject to any applicable adjustments set forth in Section 6.4.2 below, pay Xxxxx an amount equal to the applicable percentage of Annual Net Sales set forth below:  
Annual Net Sales  
Royalty Rate  
That portion of Annual Net Sales in a given Contract Year that is less than $(\*\*\*) (\*\*\*)%  
That portion of Annual Net Sales in a given Contract Year that is equal to or greater than $(\*\*\*) (\*\*\*)%  
  
6.4.2. Reduced Royalty Rate. On a Product-by-Product and country-by-country basis, Licensee shall pay Xxxxx royalties on Net Sales of a Product in a country at (\*\*\*) % of the rates set forth in the table in Section 6.4.1 during the period in which (a) no Valid Claim of the Licensed Patent Rights and no MedImmune Valid Claim Covers such Product in such country and no Regulatory Exclusivity exists for such Product in such country or (b) a Biosimilar with respect to such Product is commercialized in such country.  
6.4.3. Expiration of Royalty. Net Sales for purposes of calculating the royalties due under this Section 6.4 shall only include Net Sales of a Product in a country occurring during the applicable Royalty Term for such Product in such country.  
6.5. Reports and Royalty Payments. Within sixty (60) days after the end of each Contract Quarter commencing in the Contract Quarter immediately following the Contract Quarter in which there was the First Commercial Sale of any Product, Licensee shall deliver to Xxxxx a report setting forth for the previous Contract Quarter the following information on a Product-by-Product basis: (a) the gross sales and Net Sales of each Product, (b) the number of units sold by Licensee and its Related Parties, (c) the royalty due hereunder, (d) the applicable exchange rate as determined pursuant to Section 6.6.5; and (e) the calculation of any true-up required with respect Net Sales reported and payments made in connection with prior Contract Quarter(s). The total royalty due to Xxxxx for the sale of Products during such Contract Quarter shall be remitted at the time such report is made, but in any event no later than the sixtieth (60th) day after the end of each Contract Quarter.  
6.6. Payment Provisions Generally.  
6.6.1. Taxes and Withholding. All amounts payable under this Agreement shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 6.6, each Party shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from payments and remitted by the other Party) levied on account of, or measured in whole or in part by reference to, any payments it receives. Each Party shall deduct or withhold from the payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if a Party is entitled under any applicable tax treaty to a reduction  
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of rate of, or the elimination of, applicable withholding tax, it may deliver to the other Party or the appropriate governmental authority (with the assistance of the other Party to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve such Party of its obligation to withhold such tax and that Party shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that a Party has received evidence of the other Party’s delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time the payments are due. If, in accordance with the foregoing, a Party withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount and send to the other Party proof of such payment within ten (10) days following such payment.  
6.6.2. Gross Up. If the paying Party transfers (whether by way of legal or equitable assignment, declaration of trust, novation or otherwise) the benefit in whole or in part of this Agreement or, after the Effective Date, changes its tax residence or the permanent establishment to which the rights under the Agreement are allocated and a payment under this Agreement is subject to withholding tax where the payment would not have been subject to withholding tax or would have been subject to a lower rate of withholding tax in the absence of such transfer, change in tax residence or permanent establishment, then the paying Party or its assignee (as the case may be) shall be obliged to pay to the recipient such sum as will after such deduction or withholding has been made leave the recipient with the same amount as it would have been entitled to receive had no transfer, change in tax residence or permanent establishment taken place.  
6.6.3. Anti-Tax Evasion. (a) Each of Licensee and Xxxxx represents, warrants and undertakes that it nor its Affiliates shall commit a UK tax evasion facilitation offence under section 45(5) of the UK Criminal Finances Xxx 0000 in connection with or attributable to this Agreement or the transactions contemplated hereby, (b) each Party shall promptly report to the other Party any apparent breach of Section 6.6.3 clause (a) and shall (i) answer, in reasonable detail, any written or oral inquiry from the other Party related to its and its Affiliates compliance with Section 6.6.3 clause (a), (ii) facilitate the interview of employees of such Party by the other Party (or any agent of such Party) at any reasonable time specified by the inquiring Party related to such Party’s compliance with Section 6.6.3 clause (a) and (iii) co-operate with the inquiring Party or any governmental authority in relation to any investigation relating to the matters referred to in Section 6.6.3 clause (a), in all cases, as reasonably required to enable that other Party to comply with its undertaking in Section 6.6.3 clause (a).  
6.6.4. Indirect Taxes. Notwithstanding anything to the contrary contained in this Section 6.6.4 or elsewhere in this Agreement, the following shall apply with respect to Indirect Taxes. All payments are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, the payer shall pay such Indirect Taxes as the applicable rate in respect of any such payments, following the receipt, where applicable, of an Indirect Taxes invoice issued in the appropriate form by the payee in respect of those payments to which such Indirect Taxes relate. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements, and to the extent any invoice is not initially issued in an appropriate form, the parties shall cooperate to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with Indirect Tax requirements. Xxxxx acknowledges that based on current Applicable Law, Xxxxx does not intend to invoice Licensee for value added taxes in respect of the transactions effected by this Agreement.  
6.6.5. Payment and Currency Exchange. All amounts payable and calculations hereunder shall be in United States dollars and shall be paid by bank wire transfer in immediately  
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available and cleared funds to such bank account as may be designated in writing by Xxxxx from time to time. Whenever for the purposes of calculating royalties payable under this Agreement, conversion from any foreign currency will be required, all amounts will first be calculated in the currency in which the activity was paid or sale was recorded and then converted into United States dollars equivalent using its, its Affiliates, or Sublicensee’s, as applicable, standard conversion methodology consistent with the relevant applicable Accounting Standards. All payments will be non-refundable and not creditable once received by Xxxxx except for any applicable accounting true-ups.  
6.6.6. Overdue Payments. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest compounding on a daily basis) of (\*\*\*) basis points above the U.S. effective federal funds rate, as adjusted each Business Day and published by the Federal Reserve Bank of New York through its website (xxxxx://xxxx.xxxxxxxxxx.xxx/xxxxxxx/xxxxxxxxx/xxx%00xxxxx), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.  
6.7. Maintenance of Records; Audits.  
6.7.1. Record-Keeping. Licensee shall keep, and shall cause its Related Parties to keep, books and accounts of record in connection with the sale of Products and in sufficient detail to permit accurate determination of all figures necessary for verification of royalties to be paid hereunder. Xxxxx shall keep, and shall cause its Affiliates to keep, books and accounts of record in connection with all amounts to be paid to Xxxxx under this Agreement for the conduct of Consulting Activities and Continued Existing Clinical Studies, in order to enable Licensee to verify all amounts to be reimbursed under this Agreement in connection with such activities. Each Party shall maintain, and shall cause its Related Parties to maintain, such records for a period of at least three (3) years after the end of the Contract Year in which they were generated.  
6.7.2. Audits. Upon thirty (30) days’ prior written notice from the other Party, Licensee or Xxxxx, as applicable, (the “Audited Party”) shall permit an independent certified public accounting firm of nationally recognized standing selected by the other Party and reasonably acceptable to the Audited Party, to examine, at the other Party’s sole expense, the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the amounts reported in accordance with Section 6.5 and the payment of royalties hereunder or the amounts invoiced or paid under Section 3.2. An examination by the other Party under this Section 6.7.2 shall occur not more than once in any Contract Year and shall be limited to the pertinent books and records for any Contract Year ended not more than two (2) years before the date of the request. The accounting firm shall be provided access to such books and records at the Audited Party’s facility(ies) where such books and records are normally kept, and such examination shall be conducted during the Audited Party’s normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to the Audited Party’s facilities or records. Upon completion of the audit, the accounting firm shall provide the other Party and the Audited Party a written report disclosing any discrepancies in the reports submitted by the Audited Party or, as applicable, the royalties paid, and in each case, the specific details concerning any discrepancies. No other information pertaining to the Audited Party’s books and records shall be provided to the other Party.  
6.7.3. Underpayments/Overpayments.  
(a) If such accounting firm correctly concludes (such conclusion subject to the dispute resolution procedures set forth in Section 11.17) that additional royalties were due to  
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Xxxxx, Licensee shall, if applicable, pay to Xxxxx the additional royalties within sixty (60) days after the date Licensee receives such accountant’s written report so correctly concluding (unless disputed in good faith hereunder). If such underpayment exceeds five percent (5%) of the royalties that were to be paid for all audited periods, Licensee also shall reimburse Xxxxx for all out-of-pocket expenses incurred in conducting the audit. If such accounting firm correctly concludes that Licensee overpaid royalties to Xxxxx, then Xxxxx shall refund such overpayments to Licensee within sixty (60) days after the date Xxxxx receives such accountant’s report so correctly concluding, or, if mutually agreed by the Parties, during such sixty (60) day period, credit the amount of such overpayments against any existing or future payments due to Xxxxx hereunder, as mutually agreed by the Parties.  
(b) If such accounting firm correctly concludes (such conclusion subject to the dispute resolution procedures set forth in Section 11.17) that Licensee was overcharged for payments relating to the conduct of Consulting Activities and Continued Existing Clinical Studies, then Xxxxx shall refund such overpayments to Licensee within sixty (60) days after the date Xxxxx receives such accountant’s report so correctly concluding, or, if mutually agreed by the Parties, during such sixty (60) day period, credit the amount of such overpayments against any existing or future payments due to Xxxxx hereunder, as mutually agreed by the Parties. If such overpayment exceeds five percent (5%) of the proper amount due for all audited activities, Xxxxx also shall reimburse Licensee for all out-of-pocket expenses incurred in conducting the audit.  
6.7.4. Confidentiality. All financial information of the Audited Party that is subject to review under this Section 6.7 shall be deemed to be the Confidential Information of the Audited Party subject to the provisions of ARTICLE 8, and Xxxxx shall not disclose such Confidential Information to any Third Party and shall not use such Confidential Information for any purpose other than verifying payments to be made by Licensee to Xxxxx hereunder.  
6.7.5. Audit of Third Party Sublicensees. Within thirty (30) days following Licensee’s receipt of a written notice from Xxxxx with respect thereto, Licensee will initiate an audit of a Third Party Sublicensee that is the subject of Xxxxx’x written notice in accordance with the terms of the applicable Sublicense agreement.  
ARTICLE 7  
  
INTELLECTUAL PROPERTY PROTECTION AND RELATED MATTERS  
  
7.1. Filing, Prosecution and Maintenance of Licensed Patent Rights.  
7.1.1. Responsibility. Subject to Section 7.1.4, Licensee shall have, subject to the remainder of Section 7.1, sole responsibility for and control over the prosecution and maintenance of the Licensed Patent Rights throughout the Territory in Xxxxx’x or its applicable Affiliate’s name, all at Licensee’s sole cost and expense.  
7.1.2. Information Sharing; Comment. Licensee shall keep Xxxxx reasonably informed of patent prosecution activities concerning the Licensed Patent Rights in the Territory and provide Xxxxx with copies of material correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution of the Licensed Patent Rights. Licensee shall provide Xxxxx a reasonable opportunity to provide comments and suggestions with respect to any material actions to be taken by Licensee under this Section 7.1, and Licensee shall reasonably consider all comments, suggestions and prosecution actions recommended by Xxxxx.  
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7.1.3. Common Interest. All information provided by or on behalf of Xxxxx to Licensee or its Affiliate or counsel regarding preparation, filing, prosecution or maintenance of the Licensed Patent Rights shall be deemed both Parties’ Confidential Information, with each Party being deemed a Receiving Party with respect thereto. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution and maintenance of the Licensed Patent Rights, the interests of the Parties are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patent Rights, including, without limitation, privilege under the common interest doctrine and similar or related doctrines. To be clear, all information exchanged between counsel to each of the Parties regarding the preparation, filing, prosecution or maintenance of any Licensed Patent Rights shall be subject to the common interest doctrine.  
7.1.4. Election Not to Continue Prosecution; Abandonment. If Licensee elects not to continue the prosecution or maintenance of a Licensed Patent Right in the Territory, then (a) Licensee shall so notify Xxxxx promptly in writing of its intention reasonably (and at least seventy-five (75) days) in advance of any deadlines by which an action must be taken to establish or preserve any such rights in such Patent Rights in the Territory and (b) Xxxxx shall have the right, but not the obligation, upon written notice to Licensee, to file for, or continue to prosecute, maintain or enforce, or otherwise pursue such Licensed Patent Rights in the Territory and, in the event of such notice, Licensee shall cooperate with Xxxxx in regards thereto.  
7.1.5. Cooperation. The Parties shall reasonably cooperate with each other, as reasonably requested by either Party, (a) if necessary and appropriate in gaining patent term extensions and the like wherever applicable to Licensed Patent Rights; and (b) the prosecution and maintenance of the Licensed Patent Rights; both (a) and (b) at Licensee’s sole cost and expense. Further, at Licensee’s sole cost and expense, Xxxxx shall reasonably cooperate with Licensee upon Licensee’s request to execute any such documents and take any such actions to record this Agreement as required under Applicable Law as a prerequisite for the enforceability of this Agreement by Licensee.  
7.2. Invalidity or Unenforceability Defenses or Actions.  
7.2.1. Notices. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patent Rights by a Third Party of which such Party becomes aware.  
7.2.2. Response. In the event that a Third Party challenges any of the Licensed Patent Rights, regardless of the name or procedure including, without limitation, opposition, validity challenge, interference, re-examination, reissue, derivation, supplemental examination, post-grant review, inter-parties review, negotiation, claim, declaratory judgment action or counterclaim or affirmative defense in an infringement suit brought under Section 7.3 (each, a “Patent Challenge”), Licensee shall have the first right, but not the obligation, to: (a) defend and prosecute the Patent Challenge in its own name, at its own expense (provided that such expenses shall be treated as Infringement Defense Costs), and on its own behalf; (b) to the extent applicable to the Patent Challenge, ultimately enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle the Patent Challenge; provided, however, that Xxxxx shall have the second right, but not the obligation, to take such actions at its own expense and in its own name with respect to a Patent Challenge if Licensee chooses not to defend and prosecute such Patent Challenge. Xxxxx shall join any such Patent Challenge if necessary, to avoid dismissal of the Patent Challenge. In all cases, the defending Party agrees to keep the other Party reasonably apprised of the status and progress of the Patent Challenge.  
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7.3. Enforcement of Patent Rights.  
7.3.1. Notification. Each Party shall promptly report in writing to the other Party during the Term any (a) known or suspected infringement of any Licensed Patent Rights or (b) unauthorized use or misappropriation of any Licensed Intellectual Property, in each case ((a) or (b)), by a Third Party of which it becomes aware, and shall provide the other Party with all available evidence supporting such infringement or unauthorized use or misappropriation.  
7.3.2. Rights to Enforce. Licensee shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate to stop infringement or misappropriation of any Licensed Intellectual Property in the Field in the Territory, including (a) initiating or prosecuting an infringement or other appropriate suit or action against and (b) settling or ceasing any such infringement action or other suit, including, but not limited to, granting adequate rights and licenses necessary for continuing such activities in the Territory to any Third Party who at any time has infringed or misappropriated, or is suspected of infringing or misappropriating, any Licensed Intellectual Property. In the event that Licensee elects not to take action pursuant to this Section 7.3.2, Licensee shall so notify Xxxxx in writing of its intention within ninety (90) days after Licensee’s notice of such infringement or misappropriation activities, or within such shorter time as is necessary to enable Xxxxx to meet any deadlines by which an action must be taken to establish or preserve any enforcement rights. Thereafter, the Parties shall consult with one another in an effort to determine whether a reasonably prudent licensee would institute litigation to enforce the Licensed Intellectual Property in question in light of all relevant business and economic factors (including, but not limited to, the projected cost of such litigation, the likelihood of success on the merits, the probable amount of any damage award, the prospects for satisfaction of any judgment against the alleged infringer, the possibility of counterclaims against the Parties or likely Patent Challenges, the impact of any possible adverse outcome on the Parties and the effect any publicity might have on the Parties’ respective reputations and goodwill). If, after such process, it is unanimously determined that a suit should be filed and Licensee does not file suit or commence settlement negotiations forthwith against the infringer, then Xxxxx shall have the right, at its own expense, to enforce the Licensed Intellectual Property in question on behalf of itself and Licensee and Xxxxx shall have the right, but not the obligation, to take any such reasonable measures to stop such infringing or misappropriating activities by the applicable Third Party.  
7.3.3. Procedures; Expenses and Recoveries. The Party having the right to initiate any enforcement action under Section 7.3.2 shall have the sole and exclusive right to select counsel for any such suit and shall pay all expenses of the suit, including attorneys’ fees and court costs and reimbursement of the other Party’s reasonable out-of-pocket expenses in rendering assistance requested by the initiating Party. If required under Applicable Law in order for the initiating Party to initiate or maintain such suit, or if either Party is unable to initiate or prosecute such suit solely in its own name, in each case, the other Party shall join as a party to the suit and shall execute and cause its Affiliates to execute all documents necessary for the initiating Party to initiate litigation to prosecute and maintain such action. In addition, at the initiating Party’s request, the other Party shall provide reasonable assistance to the initiating Party in connection with an infringement suit at no charge to the initiating Party except for reimbursement by the initiating Party for reasonable out-of-pocket expenses incurred in rendering such assistance. The non-initiating Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation), such amounts shall be allocated as follows:  
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(a) in all cases, first to reimburse the initiating Party for all expenses of the suit, including attorneys’ fees and disbursements, court costs and other litigation expenses, and then to reimburse the other Party for its reasonable attorneys’ fees and disbursements, court costs and other litigation expenses;  
(b) if Licensee is the initiating Party, any of the remaining amount that relates to a Molecule or Product shall be treated as if it were Net Sales of Licensee, with Xxxxx receiving a royalty on such remaining amount pursuant to the terms of Section 6.4.1 (without adjustment thereof), and the balance being retained by Licensee; and  
(c) if Xxxxx is the initiating Party, Xxxxx shall pay Licensee an amount equal to (i) the balance of any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation) following the deductions set forth in Section 7.3.3(a) multiplied by (ii) a fraction, the numerator of which is the reasonable attorneys’ fees and disbursements, court costs and other litigation expenses incurred by Licensee in connection with such suit and the denominator of which is the reasonable attorneys’ fees and disbursements, court costs and other litigation expenses incurred by Licensee, Xxxxx, and all Affiliates of the foregoing in connection with such suit.  
7.4. Biosimilar Arrangements.  
7.4.1. Notice of Third Party Applications. In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the type described in Section 7.2 or Section 7.3, the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute (including sharing in and allocating the payment or receipt of damages, license fees, royalties and other compensation) applicable under Section 7.2 or 7.3 will apply. Notwithstanding anything herein to the contrary, within three (3) years after Regulatory Approval is achieved with respect to a Product in the United States (or such shorter time as the Parties agree in the case of a Product in the United States that does not earn reference product exclusivity under the PHS Act), the Parties shall consult as to potential strategies with respect to unexpired Licensed Patent Rights that potentially could be asserted if an unlicensed person engaged in the making, using, offering to sell, selling, or importing into the United States of a product described in a Biosimilar Application filed by a Third Party applicant (a “Section 351(k) Applicant”).  
7.4.2. Cooperation and Enforcement. If Licensee or any Related Party, as the reference product sponsor of the Product within the meaning of section 351(l)(1)(A) of the PHS Act, receives notice of a Biosimilar Application filed by a Section 351(k) Applicant that references such Product and related manufacturing information in accordance with section 351(l)(2)(A) of the PHS Act or receives a notice of commercial marketing in accordance with section 351(l)(8)(A) of the PHS Act, then Licensee shall provide notice thereof to Xxxxx, and the Parties shall discuss and Xxxxx shall reasonably cooperate with Licensee in determining Licensee’s or its Related Party’s course of action with regard to (a) engaging in the information exchange provisions of the Biologics Price Competition and Innovation Act of 2009, Section 351(l) of the Public Health Service Act, as may be amended, supplemented, or replaced (the “BPCIA”), including providing a list of patents that relate to the relevant Product, (b) engaging in the patent resolution provisions of the BPCIA, and (c) determining which patents will be the subject of immediate patent infringement action under section 351(l)(6) of the PHS Act. In the event that the Parties do not agree with respect to the exercise of any such rights, Licensee shall make the final determination with respect thereto, including without limitation with respect to (a), (b) and (c) above provided, however, that Xxxxx’x obligation shall be to reasonably cooperate with Licensee, and Licensee shall bear all out-of-pocket costs and expenses in connection with the exercise of any such rights or actions. If any patent litigation commences with respect to a  
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Biosimilar Application filed by a Section 351(k) Applicant that references such Product, then the provisions of Section 7.3 shall thereafter apply as if such Section 351(k) Applicant were an infringer or suspected infringer.  
7.5. Claimed Infringement of Third Party Rights.  
7.5.1. Notice. In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of such Party’s respective Affiliates or (sub)licensees, claiming infringement of its Patent Rights (including with respect to a Blocking Patent) or unauthorized use or misappropriation of its Know-How, based upon an assertion or claim arising out of the Development, Manufacture or Commercialization of a Molecule or a Product in the Territory, other than any such claim, action, suit, or proceeding by MedImmune Limited, any Affiliate thereof, or any successor in interest thereto with respect to any MedImmune Patent Rights or MedImmune Know-How (“Infringement Claim”), such Party shall promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served.  
7.5.2. Right to Defend. As between the Parties, Licensee shall have the right, but not the obligation, to defend all Infringement Claims brought in the Territory against either Party or any of its Affiliates or (sub)licensees arising out of the Development, Manufacture or Commercialization of a Molecule or a Product in the Territory; provided that the foregoing shall not be construed to require Licensee to defend Xxxxx against a breach of Xxxxx’x representations and warranties set forth herein. For purposes of clarification, but not limitation, to the extent Licensee does not exercise such right with respect to any Infringement Claim against Xxxxx or any Affiliate thereof, Xxxxx and its Affiliates shall be entitled to defend themselves against such Infringement Claim, subject to the terms of Section 7.5.3.  
7.5.3. Procedure.  
(a) To the extent that (i) the Infringement Claim, whether in the form of an assertion by a Third Party or a filed litigation (or other formal dispute resolution procedure), directly relates to a Blocking Patent or (ii) a Blocking Patent is otherwise identified by or on behalf of either Party or its Affiliates (a “Blocking Patent Claim”), as between the Parties, Licensee shall have the sole and exclusive right to control any negotiations and discussions with the Third Party to resolve the Blocking Patent Claim in the Territory with respect to the Development, Manufacture or Commercialization of a Molecule or a Product in the Territory by acquiring a license to engage in such activities under the Blocking Patent or other Patent Rights or Know-How that are the subject of such Blocking Patent Claim, provided that, notwithstanding the foregoing, if Licensee is unable to resolve the Blocking Patent Claim with respect to any actual or potential Blocking Patent Claims against Xxxxx or any Affiliate thereof in a manner that is acceptable to Xxxxx, then Xxxxx shall be entitled to resolve or defend such Blocking Patent Claim with respect to Xxxxx or its Affiliates in any manner in its sole discretion; provided that Xxxxx shall not settle any Blocking Patent Claims that would reasonably be anticipated to adversely impact any of the Licensed Patent Rights (such as invalidation of or narrowing the scope of any claim of any of the Licensed Patent Rights) or purport to impose any obligations on Licensee or any Affiliate of Licensee without obtaining the prior written consent of Licensee, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding any provision to the contrary in this Agreement, any expense incurred by Licensee or its Affiliates in connection with obtaining rights under or to a Blocking Patent, including any ongoing royalties or milestone payments, shall be offset against any royalties or other payments payable under this Agreement as Infringement Defense Costs under Section 7.5.3(d).  
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(b) As between the Parties, Licensee shall have the sole and exclusive right to control any negotiations and discussions with the Third Party to resolve the Infringement Claim in the Territory by acquiring a license under the relevant Patent Rights and Know-How, provided that, notwithstanding the foregoing. if Licensee is unable to resolve an Infringement Claim against Xxxxx or any Affiliate thereof in a manner that is acceptable to Xxxxx, then Xxxxx shall be entitled to settle, resolve or defend such Infringement Claim with respect to Xxxxx or its Affiliates in any manner in its sole discretion; provided that Xxxxx shall not settle any Infringement Claims that would reasonably be anticipated to adversely impact any of the Licensed Patent Rights (such as invalidation of or narrowing the scope of any claim of any of the Licensed Patent Rights) or purport to impose any obligations on Licensee or any Affiliate of Licensee without obtaining the prior written consent of Licensee, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding any provision to the contrary in this Agreement, any expense incurred by Licensee in connection with obtaining rights under or to Patent Rights or Know-How to resolve an Infringement Claim shall be offset against any royalties or other payments payable thereunder as Infringement Defense Costs under Section 7.5.3(d).  
(c) As between the Parties, Licensee shall have the sole and exclusive right to select counsel to defend any Infringement Claim brought via litigation or other formal dispute resolution procedure, provided that (i) with respect to any Infringement Claim brought against Xxxxx or its Affiliates, Licensee shall keep Xxxxx informed, and shall from time to time consult with Xxxxx regarding the status of any such claims and shall provide Xxxxx with copies of all material documents filed in, and all material written communications relating to, any suit brought in connection with such claims and (ii) Xxxxx shall also have the right to participate and be represented in any such claim or related suit against Xxxxx or any Affiliate thereof, at its own expense. Licensee shall not settle any Infringement Claims that would adversely impact any of the Licensed Patent Rights (such as invalidation of or narrowing the scope of any claim of any of the Licensed Patent Rights) or purport to impose any obligations on Xxxxx or any Affiliate of Xxxxx without obtaining the prior written consent of Xxxxx, which consent shall not be unreasonably withheld, conditioned or delayed.  
(d) Except to the extent Xxxxx owes an indemnification obligation to Licensee under this Agreement, as between the Parties, all litigation costs and expenses incurred by Licensee or its Affiliates in connection with Infringement Claims or Patent Challenges, and all damages and settlement payments, including any ongoing royalties or milestone payments negotiated by Licensee or its Affiliates under Sections 7.2.2, 7.5.3(a) or 7.5.3(b), payable by Licensee or its Affiliate to the Third Party in respect of Infringement Claims or Patent Challenges (“Infringement Defense Costs”) shall be borne by Licensee; provided that: (i) Licensee may deduct Infringement Defense Costs as incurred against the royalties and Milestone Payments that become payable to Xxxxx under this Agreement; but (ii) no quarterly payment of royalties or any milestone payment shall be reduced by more than fifty percent (50%) of the amount otherwise payable under Section 6.3 or 6.4, as applicable, solely as a result of this Section 7.5.3(d). For the avoidance of doubt, if Licensee is unable to fully deduct Infringement Defense Costs against any royalties and Milestone Payments payable to Xxxxx because such amounts are less than the then-current balance of the Infringement Defense Costs (as a result of clause (ii) of this Section 7.5.3(d) or otherwise), the un-deducted amount(s) shall carry over to each succeeding accrual of royalties and Milestone Payments until fully deducted.  
7.6. Product Trademarks. Licensee or its Related Parties, as applicable, shall select and, subject to Section 9.4, own the Product Trademarks for each Product and shall be solely responsible for filing and maintaining the Product Trademarks in the Territory (including payment of costs associated therewith). Licensee shall assume full responsibility, at its sole cost and expense, for any infringement of a Product Trademark for a Product by a Third Party and  
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any claims of infringement in the Territory of the rights of a Third Party by the use of a Product Trademark in connection with a Product.  
7.7. Patent Term Extensions in the Territory. The Parties shall use reasonable efforts to obtain all available extensions of Licensed Patent Rights (including those available under the Xxxxx-Xxxxxx Act). Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining such extensions wherever applicable to Licensed Patent Rights. Licensee shall have the sole right to seek extension of any Licensed Patent Right; provided that if Licensee has an option to extend the patent term for only one of several patents, Licensee shall consult with Xxxxx before making the election. If more than one patent is eligible for extension, the Parties shall select, in good faith, a strategy that shall maximize patent protection and commercial value for each Product.  
ARTICLE 8  
  
CONFIDENTIALITY  
  
8.1. Confidential Information. All Confidential Information disclosed by a Party (together with its Affiliates, the “Disclosing Party”) to the other Party (together with its Affiliates, the “Receiving Party”) shall be used by the Receiving Party solely in connection with the activities contemplated by this Agreement (or, in the case of Licensee, as necessary to perform its obligations under the Novated MedImmune License), shall be maintained in confidence by the Receiving Party and shall not otherwise be disclosed by the Receiving Party to any other Person, firm, or agency, governmental or private (other than a Party’s Affiliates or, in the case of Licensee, to MedImmune or its Affiliates under the Novated MedImmune License), without the prior written consent of the Disclosing Party, except to the extent that the Disclosing Party’s Confidential Information (as determined by competent documentation):  
8.1.1. was known or used by the Receiving Party prior to its date of disclosure to the Receiving Party; or  
8.1.2. either before or after the date of the disclosure to the Receiving Party, is lawfully disclosed to the Receiving Party or its Affiliates by Third Party sources other than the Disclosing Party or either Party’s Related Parties, which Third Party sources are rightfully in possession of the Confidential Information; or  
8.1.3. either before or after the date of the disclosure to the Receiving Party, becomes published or generally known to the public (including information known to the public through the sale of products in the ordinary course of business) through no fault or omission on the part of the Receiving Party or its Related Parties; or  
8.1.4. is independently developed by or for the Receiving Party without reference to or reliance upon the Disclosing Party’s Confidential Information.  
8.2. Required Disclosures. Section 8.1 shall not preclude the Receiving Party from disclosing the Disclosing Party’s Confidential Information to the extent such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure. If a public disclosure of Disclosing Party’s Confidential Information is required by any Applicable Laws, including, without limitation, in a filing with the United States Securities and Exchange  
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Commission or submission to an exchange on which any securities of Receiving Party or an Affiliate thereof is listed, the Receiving Party shall provide copies of the disclosure (but shall be permitted to redact or omit portions of any filing, submission or disclosure not relevant to this Agreement) reasonably in advance of such filing or other disclosure, for the Disclosing Party’s prior review and comment and to allow the Disclosing Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. The Receiving Party shall negotiate in good faith with the applicable Regulatory Authority concerning the confidential treatment request. If the disclosure is substantially similar to prior disclosures made by Receiving Party and for which the obligations of this provision have been satisfied, the Receiving Party need not share such disclosure ahead of it being made.  
8.3. Permitted Disclosures. Xxxxx and Licensee each agree that that they shall provide the other Party’s Confidential Information only to their Affiliates and its and their respective directors, officers, employees, consultants, attorneys, vendors, suppliers, (sub)licensees, collaborators and advisors who have a need to know for the Development, Manufacture, and Commercialization of Products in accordance with this Agreement, for prosecution and maintenance of Licensed Patent Rights or to enforce or exercise rights under this Agreement, including in connection with Regulatory Approval Applications and obtaining Regulatory Approvals, or, in the case of Licensee, to MedImmune and its Affiliates as necessary to comply with its obligations under the MedImmune License, provided that such Third Parties are bound by confidentiality obligations at least as strict as this ARTICLE 8 (except that, in the case of agreements with Third Party consultants, attorneys, vendors, advisors and suppliers, the confidentiality term of such obligations may be shorter than that set forth in this Agreement to the extent such shorter confidentiality term is consistent with industry standards). In addition, each Party may not disclose the terms of this Agreement (to the extent such terms are confidential) to any Third Party except to actual or prospective lenders, investors, acquirers, licensees/(sub)licensees or strategic partners or to their respective accountants, attorneys and other professional advisors; provided that such disclosures shall be subject to continued confidentiality obligations at least as strict as this ARTICLE 8 (except that the confidentiality term of such obligations may be shorter than that set forth in this Agreement to the extent such shorter confidentiality term is consistent with industry standards).  
8.4. Public Announcements and Use of Names. No public disclosure of the existence of, or the terms of, this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party in any publicity, news release or public disclosure relating to this Agreement or its subject matter without the prior express written permission of the other Party, except as may be required by Applicable Law or expressly permitted by the terms hereof. A press release agreed upon by the Parties is attached to Exhibit B. If public disclosure of the terms of this Agreement beyond such press release is required by any Applicable Law or the rules and regulations of any securities exchange on which a Party’s securities are traded, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure, but not later than five (5) Business Days prior to the filing, for the non-disclosing Party’s prior review and comment and to allow the other Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. If the disclosure is substantially similar to prior disclosures made by the Party and for which the obligations of this provision have been satisfied, the disclosing Party need not share such disclosure ahead of it being made.  
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ARTICLE 9  
  
TERM AND TERMINATION  
  
9.1. Term. This Agreement shall commence on the Effective Date and, subject to any earlier termination of this Agreement in accordance with this ARTICLE 9, remain in effect until expiration of the last-to-expire Royalty Term (the period from the Effective Date until the expiration or, if earlier, termination of this Agreement, the “Term”). After expiration of the Royalty Term for a Product in a given country, no further royalties shall be payable in respect of sales of such Product in such country, and the license granted to Licensee under Section 2.1 shall be a fully paid-up, perpetual, irrevocable, royalty-free and sublicensable license with respect to such Product in such country.  
9.2. Termination by Xxxxx.  
9.2.1. Breach. Xxxxx will have the right to terminate this Agreement in its entirety, subject to Section 9.2.2, upon delivery of written notice to Licensee in the event of any material breach by Licensee of this Agreement, provided that such breach has not been cured within sixty (60) days after written notice of such breach and Xxxxx’x intention to terminate is given by Xxxxx to Licensee. Subject to Section 9.2.2, any such termination of this Agreement will become effective at the end of such sixty (60) day cure period, unless Licensee has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the sixty (60) day cure period, then, Xxxxx’x right of termination will be suspended only if and for so long as Licensee has provided to Xxxxx a written plan that is reasonably calculated to effect a cure within six (6) months thereafter and such plan is acceptable to Xxxxx (such acceptance not to be unreasonably withheld, conditioned, or delayed), and Licensee commits to and carries out such plan as provided to Xxxxx.  
9.2.2. Dispute. If Licensee reasonably and in good faith disagrees as to whether Xxxxx has a basis for terminating this Agreement pursuant to Section 9.2.1, Licensee may contest the allegation in accordance with Sections 11.2 and 11.17. It is understood and acknowledged that, during the pendency of such a dispute, the remaining cure period shall be tolled and all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by Xxxxx pursuant to Section 9.2.1 will be effective unless and until (a) Xxxxx’x right to terminate this Agreement under Section 9.2.1 has been finally determined by litigation in accordance with Section 11.2 and (b) Licensee fails to cure the breach giving rise to the right to terminate during the cure period that remains following such determination.  
9.2.3. Abandonment. If Licensee, in its discretion, decides to abandon all of its Development or Commercialization efforts with respect to the Products, Licensee shall promptly notify Xxxxx in writing of its intent to do so. Xxxxx will have the right to terminate this Agreement immediately upon receipt of such notice.  
9.2.4. Anti-Shelving. If the Novated MedImmune License is terminated with respect to one or more Products, one or more countries, or in its entirety, respectively, then (a) Licensee shall promptly provide Xxxxx written notice thereof and (b) Xxxxx shall have the right to terminate this Agreement with respect to such Product(s), such country(ies), or in its entirety, respectively, upon written notice to Licensee.  
9.3. Termination by Licensee.  
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9.3.1. Breach. Licensee will have the right to terminate this Agreement in its entirety or on a Product-by-Product or country-by-country basis upon delivery of written notice to Xxxxx in the event of any material breach of this Agreement by Xxxxx including any failure to provide the Xxxxx Material in accordance with this Agreement, and, provided that such breach has not been cured within sixty (60) days after written notice of such breach and Licensee’s intention to terminate is given by Licensee to Xxxxx. Any such termination will become effective at the end of such sixty (60) day cure period, unless Xxxxx has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the sixty (60) day cure period, then, Licensee’s right of termination will be suspended only if and for so long as Xxxxx has provided to Licensee a written plan that is reasonably calculated to effect a cure within six (6) months thereafter and such plan is acceptable to Licensee (such acceptance not to be unreasonably withheld, conditioned, or delayed), and Xxxxx commits to and carries out such plan as provided to Licensee.  
9.3.2. Convenience. Upon ninety (90) days prior written notice in the case where Regulatory Approval has not been obtained for any Product in the Field in a jurisdiction in the Territory or one hundred eighty (180) days prior written notice in the case where Regulatory Approval in the Field in a jurisdiction in the Territory has been obtained for a Product, such termination to be effective at the end of such notice period, Licensee may terminate this Agreement in its entirety or on a Product-by-Product or country-by-country basis for any reason or no reason, including if Licensee decides to cease all of its Development and/or Commercialization efforts with respect to a Product in a jurisdiction.  
9.4. Effects of Termination. Without limiting any legal or equitable remedies of either Party, upon termination of this Agreement for any reason: (a) all licenses granted by Xxxxx under this Agreement shall terminate solely with respect to the Product(s) and country(ies) subject to such termination; and (b) Licensee shall promptly transfer to Xxxxx copies of all Licensed Know-How in Licensee’s or its Affiliate’s possession that relates to the Product(s) or country(ies) subject to such termination. For clarity, in the event that this Agreement is terminated in its entirety, all Products will be deemed to be terminated Products and all countries will be deemed to be terminated countries.  
9.5. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement, including without limitation ARTICLE 2, are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to “intellectual property” as defined under Section 101 of the Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter “IP”). Upon a Party which is a licensor of rights granted under this Agreement entering into any voluntary or involuntary insolvency proceeding during the Term of this Agreement, and notwithstanding any attempted rejection of this Agreement by such Party, or any trustee, administrator or executor of such Party or an applicable bankruptcy court, the Parties agree that: the other Party, as licensee of such rights under this Agreement, shall (a) retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP and (b) retain in perpetuity all rights and licenses herein granted, provided that such Party continues to pay any royalties otherwise due hereunder (subject to any right of set-off hereunder), and the Party which has entered such insolvency proceeding shall have, to the extent required by applicable bankruptcy laws in order to maintain the other Party’s license rights hereunder, no further obligations under this Agreement other than to not interfere with such other Party’s license rights hereunder. Each Party hereby grants to the other Party and its Affiliates a right to obtain possession of and to benefit from a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of intellectual property, which, if not already in the other Party’s possession, shall be promptly delivered to it upon the other Party’s written  
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request therefor. The term “embodiments of intellectual property” includes all tangible, electronic or other embodiments of rights and licenses hereunder, including, without limitation, a Molecule, Product(s), all Regulatory Approval Applications and Regulatory Approvals, and all Know-How and other information related to a Molecule and Product(s), Licensed Patent Rights and Licensed Know-How. Neither Party shall interfere with the exercise by the other Party or its Affiliates of rights and licenses to IP and embodiments of intellectual property licensed hereunder in accordance with this Agreement, and each Party agrees to reasonably assist the other Party and its Affiliates to obtain the IP and embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for the other Party or its Affiliates to exercise such rights and licenses in accordance with this Agreement. The Parties agree that the terms of this Agreement are fair and reasonable, are not overly burdensome and have been negotiated in an arms-length transaction between unrelated parties with each Party represented by legal counsel. If any provision herein is deemed onerous or otherwise unenforceable by any applicable bankruptcy court, the Parties shall use good faith efforts to amend the Agreement (e.g., removing such onerous provision) so as to avoid any consequences thereof under applicable bankruptcy laws.  
9.6. Return of Confidential Information. Except to the extent otherwise required by Applicable Law or useful or necessary to exercise any rights or perform any obligations surviving termination, upon termination of this Agreement, each Party shall promptly return to the other Party, delete or destroy all relevant records and materials in such Party’s possession or control containing Confidential Information of the other Party; provided that such Party may keep copies of such materials in order to satisfy regulatory requirements or obligations under Applicable Law or for archival purposes only. Each Party’s obligations under ARTICLE 8 terminate on the date that is five (5) years after the effective date of termination of this Agreement.  
9.7. Survival. The provisions of ARTICLE 1 (Definitions), ARTICLE 6 (Financial Provisions), ARTICLE 8 (Confidentiality) and ARTICLE 11 (Miscellaneous Provisions) and Sections 2.2.3 (Effect of Termination on Sublicenses), 2.4 (Ownership of and Rights to Intellectual Property), 2.5 (No Other Rights), 3.6 (Disclaimers), 9.4 (Effects of Termination), 9.5 (Rights in Bankruptcy), 9.6 (Return of Confidential Information), 9.7 (Survival), 10.3 (Warranty Disclaimer), 10.4 (No Consequential Damages), and 10.5 (Indemnification and Insurance), any accrued obligation by either Party to make any payment prior to the effective date of termination, and any provision necessary to interpret or give effect to such Sections shall survive any termination of this Agreement in accordance with their respective terms. Except as set forth in this Section 9.7, upon termination or expiration of this Agreement all other rights and obligations cease. Any termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.  
ARTICLE 10  
  
REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION  
  
10.1. Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party, as of the Effective Date, and covenants, as applicable, that:  
10.1.1. Existence and Authority. It is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has full power and authority to enter into this Agreement and the Novation Agreement and to carry out the provisions hereof and thereof.  
10.1.2. Authorized Execution; Binding Obligation.  
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(a) The execution, delivery, and performance of this Agreement and the Novation Agreement and the consummation of the transactions contemplated by this Agreement and the Novation Agreement have been duly authorized and approved by all necessary corporate or company action on its part; and  
(b) This Agreement and the Novation Agreement have been duly executed and delivered by it and constitutes a legal, valid, and binding obligation enforceable against it in accordance with its terms.  
10.1.3. No Conflicts. The execution, delivery and performance of this Agreement and the Novation Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it or its assets may be bound.  
10.1.4. All Consents and Approvals Obtained. All necessary consents, approvals and authorizations of, and all notices to, and filings by such Party with, all governmental authorities and other Persons required to be obtained or provided by such Party in connection with the execution, delivery and performance of this Agreement or the Novation Agreement have been obtained, other than Third Party consents required for the assignment of Product-related agreements as described in ARTICLE 3.  
10.1.5. Compliance with Law. It shall at all times comply with Applicable Laws in all material respects with respect to its activities under this Agreement. Neither it nor any of its Affiliates nor any director, officer, agent, employee, consultant of, or other person associated with, or acting on behalf of, it or its Affiliates has (a) made, authorized, offered or promised to make any payment or transfer of anything of value, directly, indirectly or through a Third Party, to any foreign government official, employee or other representative (including employees of a government owned or controlled entity or public international organization and including any political party or candidate for public office), in violation of any Anti-Bribery Laws, or any law of similar effect in any jurisdiction to which such Person is subject or (b) otherwise taken any action in violation of any Anti-Bribery Laws, or any law of similar effect in any jurisdiction to which such Person is subject. For the purposes of this Section 10.1.5, the acts specified include (x) the making or payment of any illegal contributions, commissions, fees, gifts, entertainment, travel or other unlawful expenses relating to political activity, (y) the direct or indirect payment, gift, offer, promise or authorization to make a payment, gift, offer or promise of, anything of material value to any foreign government representative and (z) the making of any bribe, illegal payoff, influence payment, kickback or other unlawful payment. “Anti-Bribery Laws” means the United States Foreign Corrupt Practices Act of 1977 or any other anti-bribery laws, statutes, rules or regulations of any country that may be applicable to a Party, including the United Kingdom Xxxxxxx Xxx 0000 and any anti-bribery and related prohibitions implemented under the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.  
10.2. Xxxxx Representations and Warranties. Xxxxx hereby represents and warrants to Licensee, as of the Effective Date, or covenants, as applicable, that:  
10.2.1. Xxxxx Intellectual Property; Regulatory Documentation. Xxxxx Controls the Licensed Intellectual Property existing as of the Effective Date and is entitled to grant the licenses specified herein. The Licensed Patent Rights listed on Schedule 1.1.38 constitute all of the Patent Rights Controlled by Xxxxx and its Affiliates as of the Effective Date that, but for the license granted by Section 2.1, would be infringed (or, in the case of patent applications, would be infringed if such patent applications were issued patents) by the Development, Manufacture or Commercialization of a Molecule or a Product, other than the MedImmune Patent Rights. The Licensed Know-How contained in the Data Room under the headings identified on Schedule  
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1.1.37 includes, to the knowledge of Xxxxx, substantially all the Know-How Controlled by Xxxxx and its Affiliates as of the Effective Date with respect to the Molecules other than the MedImmune Know-How. Neither Xxxxx nor any of its Affiliates has previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Licensed Intellectual Property in a manner that conflicts with any rights purported to be granted to Licensee hereunder, and neither Xxxxx nor any of its Affiliates is under any obligation to make any such transfers, conveyances or encumbrances. Xxxxx owns the INDs with the following identifiers with respect to a Molecule or Product in existence as of the Effective Date: AOSD IND #145843 and MM IND #146653. Neither Xxxxx nor any of its Affiliates has granted any rights of reference under any Regulatory Documentation with respect to any Molecule or Product to any Third Party.  
10.2.2. In-License Agreements. There are no agreements between Xxxxx or any Affiliate thereof and any Third Party licensors of either of the foregoing pursuant to which Xxxxx or its Affiliate has in-licensed any rights in the Licensed Intellectual Property as of the Effective Date, other than those Third Party agreements between Xxxxx or its Affiliate and a Third Party contractor that are included in the Data Room. Xxxxx and its Affiliates have, and will have throughout the Term, sufficient rights by ownership or contract to grant Licensee the rights purported to be granted under Section 2.1 to Licensed Intellectual Property.  
10.2.3. Infringement. To the knowledge of Xxxxx, there is no actual or threatened infringement or misappropriation of the Licensed Intellectual Property in the Field in the Territory by any Third Party or any other infringement, misappropriation or threatened infringement or misappropriation that would adversely affect Licensee’s rights under this Agreement.  
10.2.4. Licensed Intellectual Property. The Licensed Patent Rights and MedImmune Patent Rights existing as of the Effective Date are subsisting and, to the knowledge of Xxxxx, are not invalid or unenforceable, in whole or in part and, to the knowledge of Xxxxx, are filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment. The pending applications included in the Licensed Patent Rights and MedImmune Patent Rights are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law and where required by such Applicable Law Xxxxx and its Affiliates have presented all material references, documents and information of which the inventors are aware to the relevant patent office. Each of the Licensed Patent Rights and, to the knowledge of Xxxxx, each of the MedImmune Patent Rights properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Patent Right is issued or such application is pending. To the knowledge of Xxxxx, each Person who has or has had any rights in or to any Licensed Intellectual Property or any Molecule or Product has assigned and has executed an agreement assigning its entire right, title and interest in and to such Licensed Intellectual Property, Molecule or Product. The inventions claimed by the Licensed Patent Rights (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (b) are not a “subject invention” as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401. There are no written claims asserted or, to Xxxxx’x knowledge, threatened against Xxxxx or any of its Affiliates or judgments or settlements against or amounts with respect thereto owed by Xxxxx or any of its Affiliates relating to the Licensed Intellectual Property or a Molecule. No patent or patent application within the Licensed Patent Rights is the subject of any pending or, to the knowledge of Xxxxx, threatened interference, opposition, cancellation, protest, inventorship dispute or other challenge or adversarial  
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proceeding. The Licensed Know-How has been kept confidential by Xxxxx and its Affiliates and has been disclosed by Xxxxx and its Affiliates to Third Parties only under terms of confidentiality. To the knowledge of Xxxxx and its Affiliates, no breach of such confidentiality has been committed by any Third Party. The Licensed Intellectual Property is free of any and all liens, security interests and encumbrances, other than certain reserved nonexclusive rights for the benefit of academic or nonprofit institutions for publication, IRB, regulatory, legal, educational, patient care, and noncommercial research purposes, the nonexclusive nature of Xxxxx’x or its Affiliates’ rights to certain intellectual property rights to which ownership is otherwise retained by a Third Party contractor, and limited, non-exclusive license grants to Third Parties as set forth in those subcontract or clinical trial site contracts between Xxxxx (or its Affiliates) and Third Party subcontractors of Xxxxx or Third Party clinical trial sites, in each case included in the Data Room or established by Applicable Law. No claim or litigation has been brought or, to Xxxxx’x knowledge, threatened by any Third Party alleging that (a) the Licensed Patent Rights are invalid, unpatentable or unenforceable, (b) the Licensed Intellectual Property or the licensing or exploiting of the Licensed Intellectual Property violates, infringes, misappropriates or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party or (c) any Third Party has any right, title, or interest in, to, and under any Licensed Intellectual Property.  
10.2.5. Claims; Judgments. There are no claims, judgments or settlements against or owed by Xxxxx or its Affiliates or pending or, to the knowledge of Xxxxx, threatened claims or litigation relating to the Licensed Intellectual Property.  
10.2.6. Disclosure. To the knowledge of Xxxxx, Xxxxx has made available to Licensee all material information and data (including without limitation all communications with or from the FDA or any other Regulatory Authority) included in the Licensed Know-How and MedImmune Know-How of which it is aware, including that which relates to the results of Xxxxx’x preclinical studies and clinical trials involving a Molecule, as well as all file wrappers and other documents and materials in Xxxxx’x or its Affiliate’s or their respective patent counsel’s possession relating to the prosecution, defense, maintenance, validity and enforceability of the Licensed Patent Rights and MedImmune Patent Rights, other than freedom-to-operate or infringement analyses or related communications. Xxxxx has made available to Licensee all reports and data collections included in the Licensed Know-How containing material information about adverse safety issues (including adverse drug experiences) related to a Molecule of which Xxxxx has knowledge. Xxxxx represents that, to its knowledge, it has not failed to furnish Licensee with any material scientific or Licensed Intellectual Property-related information Controlled by Xxxxx and requested by Licensee that concerns a Molecule or Product. To Xxxxx’x knowledge, there are no scientific or technical facts or scientific or technical circumstances that would reasonably be anticipated to materially adversely affect the scientific, therapeutic, or commercial potential of the Molecules or Products. Xxxxx does not have any knowledge of any material information regarding any Molecule or Product that would reasonably be anticipated to materially adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for any Regulatory Approval with respect to a Molecule or Product.  
10.2.7. Debarment and Compliance. Neither Xxxxx, any of its Affiliates, any of their respective directors, officers, employees, or consultants, nor, to Xxxxx’x knowledge based upon reasonable inquiry, any Third Party (and its directors, officers, employees and consultants), in each case who were responsible for the Development of the Product prior to the Effective Date: (a) is or was debarred under Section 306(a) or 306(b) of the FD&C Act; (b) has been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (i) the development or approval of any drug product or the regulation of any drug product under the FD&C Act; or (ii) a conspiracy to commit, aid or abet the development or  
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approval of any drug product or regulation of any drug product; or (iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or non-procurement programs. Xxxxx will promptly (and in any event, within one (1) Business Day) inform Licensee in writing if Xxxxx, any of its Affiliates, or any of their respective directors, officers, employees, consultants or subcontractors is the subject of any of the foregoing clauses (a) or (b) at any time during the Term. Xxxxx and its Affiliates have conducted and will conduct, and their respective contractors and consultants have conducted and will conduct, all Development of the Molecules and Products, including any and all pre-clinical and clinical studies related to the Molecules and Products, in accordance with, to the extent reasonably applicable, good laboratory, manufacturing and clinical practice and Applicable Law in all material respects. Xxxxx and its Affiliates have employed (and, with respect to such tests and studies that Xxxxx will perform, will employ) Persons with reasonably appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical and clinical studies with respect to the Molecules and Products.  
10.2.8. MedImmune License. Xxxxx has provided Licensee with a complete and accurate copy of the MedImmune License, as such agreement is in effect as of the Effective Date, and Xxxxx has not materially breached and is not aware of any material breach of, the MedImmune License.  
10.2.9. No Untrue Statements of Material Fact. To Xxxxx’x knowledge, the representations and warranties of Xxxxx in this Agreement and the information, documents and materials furnished to Licensee in connection with its period of diligence prior to the Effective Date, do not, taken as a whole, (a) contain any untrue statement of a material fact or (b) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not materially misleading.  
10.2.10. No Conflict. During the Term, neither Xxxxx nor any of its Affiliates will enter into any agreement that would prevent it from granting the rights purported to be granted to Licensee under this Agreement or from performing Xxxxx’x obligations under this Agreement.  
10.3. Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR THE NOVATION AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON- INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL. LICENSEE AGREES THAT, ASSUMING THE ACCURACY OF XXXXX’X REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTION 10.1 AND SECTION 10.2, LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED INTELLECTUAL PROPERTY HAS APPLICABILITY OR UTILITY IN LICENSEE’S CONTEMPLATED EXPLOITATION OF THE MOLECULES OR THE PRODUCTS AND ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.  
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10.4. No Consequential Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS, LOST BUSINESS, LOST OPPORTUNITY, OR LOST GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR TO LIMIT A PARTY’S LIABILITY FOR BREACHES OF ITS OBLIGATION REGARDING CONFIDENTIALITY UNDER ARTICLE 8.  
10.5. Indemnification and Insurance.  
10.5.1. Indemnification by Licensee. Licensee shall indemnify, hold harmless, and defend Xxxxx, its Affiliates, and their respective directors, officers, employees and agents (“Xxxxx Indemnitees”) from and against any and all damages, settlements, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorneys’ fees) or judgments of any kind (collectively, “Losses”) arising out of any Third Party claim, suit or proceeding, whether for money or equitable relief (each, a “Third Party Claim”) against any Xxxxx Indemnitee to the extent arising out of or resulting from, directly or indirectly: (a) any breach of, or inaccuracy in, any representation or warranty made by Licensee in this Agreement or the Novation Agreement, or any breach or violation of any covenant or agreement of Licensee, any of its Affiliates, or any Sublicensees in or pursuant to this Agreement or the Novation Agreement, (b) the negligence, willful misconduct, or failure to comply with Applicable Law by or of Licensee, its Affiliates, any Sublicensees of any of the foregoing, or their respective directors, officers, employees and agents, or (c) the Development, Manufacturing or Commercialization of any Molecule or Product by or on behalf of Licensee, its Affiliates, or Sublicensees (including product liability or claims of intellectual property infringement or misappropriation); provided that Licensee shall not have any obligations hereunder with respect to any Losses or Third Party Claims to the extent resulting from any of the circumstances described in clause (a), (b) or (c) of Section 10.5.2.  
10.5.2. Indemnification by Xxxxx. Xxxxx shall indemnify, hold harmless, and defend Licensee, its Affiliates and their respective directors, managers, officers, employees and agents (“Licensee Indemnitees”) from and against any and all Losses arising out of any Third Party Claims against any Licensee Indemnitee to the extent arising out of or resulting from, directly or indirectly, (a) any breach of, or inaccuracy in, any representation or warranty made by Xxxxx in this Agreement, or any breach or violation of any covenant or agreement of Xxxxx in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of Xxxxx, its Affiliates, and their respective directors, officers, employees and agents, (c) the Development, Manufacture, or Commercialization of any Product by or on behalf of Xxxxx or its Affiliates or licensees prior to the Effective Date, or (d) any Liabilities and Obligations (as defined in the Novation Agreement) arising from performance or non-performance of the MedImmune License by or on behalf of Xxxxx prior to the Novation Effective Date (as defined in the Novation Agreement); provided that Xxxxx shall not have any obligations hereunder with respect to any Losses or Third Party Claims to the extent resulting from any of the circumstances described in clause (a) or (b) of Section 10.5.1.  
10.5.3. Indemnification Procedure. In the event of any Third Party Claim against any Licensee Indemnitee or Xxxxx Indemnitee (respectively, individually, an “Indemnitee”), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the investigation and defense of the Third Party Claim and its settlement; provided that the failure to so notify promptly shall not  
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relieve the indemnifying Party of its obligations under this Section 10.5 except to the extent of the actual prejudice suffered by such Party as a result of such failure. The Indemnitee shall reasonably cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choosing. The indemnifying Party shall not be liable for any settlements or voluntary dispositions of any Third Party Claim entered into by any Indemnitee without the indemnifying Party’s written authorization, such authorization not to be unreasonably withheld. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in Section 10.5.1 or Section 10.5.2 may apply, the indemnifying Party shall promptly notify the Indemnitees, which shall then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party shall be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. The indemnifying Party shall be free to settle or enter into any voluntary disposition of any Third Party Claims subject to indemnification by it hereunder, except for any such settlement or voluntary disposition that adversely affects any Licensed Intellectual Property or imposes non-indemnified liability or admits fault or wrongdoing on the part of any Indemnitee, which will require the consent of the applicable Indemnitee(s).  
ARTICLE 11  
  
MISCELLANEOUS PROVISIONS  
  
11.1. Governing Law. This Agreement shall be construed, and the respective rights of the Parties determined according to the substantive laws of the State of Delaware notwithstanding the provisions governing conflict of laws under the law of any jurisdiction to the contrary.  
11.2. Jurisdiction; Venue; Service of Process.  
11.2.1. Jurisdiction. Each Party by its execution hereof, (a) hereby irrevocably submits to the exclusive jurisdiction of the state courts of the State of Delaware or the United States District Court with jurisdiction over Delaware for the purpose of any claim, controversy, action, cause of action, suit or litigation (“Action”) between the Parties arising in whole or in part under or in connection with this Agreement, (b) hereby waives to the extent not prohibited by Applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such Action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such Action brought in one of the above-named courts should be dismissed on grounds of forum non conveniens, should be transferred or removed to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court and (c) hereby agrees not to commence any such Action other than before one of the above-named courts. Notwithstanding the previous sentence, a Party may commence any Action in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts or to obtain emergency or temporary injunctive relief.  
11.2.2. Venue. Each Party agrees that for any Action between the Parties arising in whole or in part under or in connection with this Agreement, such Party may bring Actions only in the State of Delaware. Each Party further waives any claim and shall not assert that venue should properly lie in any other location within the selected jurisdiction.  
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11.2.3. Service of Process. Each Party hereby (a) consents to service of process in any Action between the Parties arising in whole or in part under or in connection with this Agreement in any manner permitted by Delaware law, (b) agrees that service of process made in accordance with clause (a) or made by registered or certified mail, return receipt requested, at its address specified pursuant to Section 11.5, shall constitute good and valid service of process in any such Action and (c) waives and agrees not to assert (by way of motion, as a defense, or otherwise) in any such Action any claim that service of process made in accordance with clause (a) or (b) does not constitute good and valid service of process.  
11.3. Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior, written consent of the other Party. Notwithstanding the foregoing, (a) Xxxxx may monetize the value of its royalty stream, Milestone Payments and other payments under this Agreement by assigning to a Third Party the right to receive royalties, Milestone Payments and other payments and the right to receive royalty reports from Licensee, provided that Xxxxx gives ten (10) Business Days’ prior written notice to Licensee, and (b) either Party may, without the other Party’s consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of the assigning Party or pursuant to a Change of Control, provided that, in the case of an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by its Affiliate of this Agreement or any obligations hereunder so assigned to such assignee. Without limiting the foregoing, Xxxxx shall not assign any of its rights in or to the Licensed Intellectual Property to any Third Party other than a Third Party to which it is assigning this Agreement in its entirety. Any assignment in violation of this Section 11.3 will be null and void.  
11.4. Amendments. This Agreement, the Novation Agreement, and the Schedules and Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Confidentiality Agreement. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.  
11.5. Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and (a) delivered by hand, or (b) sent by internationally recognized delivery service and shall be deemed to have been properly served to the addressee upon receipt of such written communication or refusal to accept delivery, to the following addresses:  
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If to Xxxxx:  
Xxxxx Therapeutics, Inc.  
0000 Xxxxxxx Xxxxx Xxxxx  
Xxxxx 000  
Xxxxx, XX 00000, X.X.X.  
Attn: (\*\*\*)  
with a copy (which shall not constitute notice) to:  
Xxxxx Therapeutics, Inc.  
0000 Xxxxxxx Xxxxx Xxxxx  
Xxxxx 000  
Xxxxx, XX 00000, X.X.X.  
Attn: CEO  
  
Xxxxxx Xxxxxxx Xxxxx & Xxxxxx LLP  
0000 Xxxx Xxxxx Xxxxx, Xxxxx 000  
Xxxxxxx, XX 00000, U.S.A.  
Attn: (\*\*\*)  
If to Licensee:  
Apollo AP43 Limited  
00 Xxxxx Xxxx  
Xxxxxxxxx, XX0 0XX, XX  
with a copy (which shall not constitute notice) to: Ropes & Gray LLP  
0000 Xxxxxxxxxx Xxxxxx  
0xx Xxxxx  
Xxxx Xxxx Xxxx, XX 00000-0000, U.S.A.  
Attention: (\*\*\*)  
  
Either Party may change its address to which notices shall be sent by giving notice to the other Party in the manner herein provided.  
11.6. Force Majeure. The failure of either Party to timely perform any obligation under this Agreement by reason of epidemic or pandemic, earthquake, riot, civil commotion, fire, act of God, war, terrorist act, strike, flood, or governmental act or restriction, or other cause that is beyond the reasonable control of and without the fault or negligence of the respective Party (such reasons or causes being “Force Majeure”), shall not be deemed to be a material breach of this Agreement, but shall be excused to the extent and for the duration of such Force Majeure, and the affected Party shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and shall use its Commercially Reasonable Efforts to avoid or remove such Force Majeure. If the performance of any such obligation under this Agreement is delayed owing to Force Majeure for any continuous period of more than one hundred eighty (180) days, the Parties shall consult with respect to an equitable solution.  
11.7. Compliance with Export Regulations. Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with US export laws and regulations.  
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11.8. Independent Contractors. It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either Xxxxx or Licensee to act as agent for the other. Nothing in this Agreement shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees for any purpose, including tax purposes, or to create any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.  
11.9. Further Assurances. Each Party shall execute, acknowledge or deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.  
11.10. No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.  
11.11. Performance by Affiliates. Xxxxx recognizes that Licensee may perform some or all of its obligations under this Agreement through Affiliates; provided, however, that Licensee will remain responsible for the acts and omissions of its Affiliates as if such acts omissions were those of Licensee.  
11.12. Construction. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the use of any gender will be applicable to all genders. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein means including, without limiting the generality of any description that precedes such term, and will be deemed to be followed by the phrase “but not limited to,” “without limitation” or words of similar import regardless of whether such words are actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after the word “including” but not others). References to “Article”, “Articles”, “Section”, “Sections”, “Schedule” or “Schedule” “Exhibit” or “Exhibits” are references to the numbered Article(s), Section(s), Schedule(s) or lettered Exhibit(s) of this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, (a) references to a particular law, rule or regulation mean such law, rule or regulation as in effect as of the relevant time, including all rules and regulations thereunder and any successor law, rule or regulation in effect as of the relevant time, and including the then- current amendments thereto; (b) the word “or” has the inclusive meaning that is typically associated with the phrase “and/or”; (c) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (d) references to a particular person or entity include such person’s or entity’s successors and assigns to the extent not prohibited by this Agreement; (e) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; (f) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits); and (g) all references to “will” are interchangeable with the word “shall” and shall be understood to be imperative or mandatory in nature.  
11.13. Headings. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.  
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11.14. No Implied Waivers; Rights Cumulative. No failure on the part of Xxxxx or Licensee to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.  
11.15. Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.  
11.16. No Third Party Beneficiaries. No Person, other than Licensee, Xxxxx and their respective Affiliates and the Indemnitees under ARTICLE 10 and any permitted assignees hereunder, shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.  
11.17. Dispute Resolution. With respect to any disputes between the Parties concerning this Agreement, the dispute shall be submitted to escalating levels of Licensee and Xxxxx senior management for review. If the dispute cannot be resolved despite such escalation, then the matter may be referred by either Party to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. Such resolution, if any, by the Executive Officers shall be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, each Party will be free to pursue all rights available to it under law or equity, provided that it has complied with this Section 11.17. Notwithstanding the foregoing, either Party may seek emergency or temporary injunctive or equitable relief in any court of competent jurisdiction.  
11.18. Entire Agreement. This Agreement (including all exhibits and schedules hereto) and the Novation Agreement constitute the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral and written, among the Parties with respect to the subject matter hereof. This Agreement hereby supersedes the Confidentiality Agreement.  
11.19. Execution in Counterparts. This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Signatures provided by facsimile transmission, in Adobe™ Portable Document Format (PDF) sent by electronic mail, or other reasonable electronic form (e.g., DocuSign™) shall be deemed to be original signatures.  
(Signature page follows)  
  
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IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the Effective Date.  
  
XXXXX THERAPEUTICS, INC. APOLLO AP43 LIMITED  
By: /s/ Xxxxx Xxxx, M.D. By: /s/ Xxxxxxx Xxxxx  
Name: Xx. Xxxxx Xxxx, M.D. Name: Dr. Xxxxxxx Xxxxx  
Title: Chief Executive Officer Title: Chief Executive Officer  
[Signature Page to License Agreement]