EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement ("***Agreement***") is made as of November 27, 2019 (the "***Effective Date***") by and between Appili Therapeutics Inc., a corporation incorporated under the laws of the Province of Nova Scotia, Canada whose office is at 1344 Summer Street, Suite 21, Halifax, Nova Scotia, Canada B3H 0A8 ("***Licensor***") and Saptalis Pharmaceuticals, LLC, a New York limited liability company whose office is at 45 Davids Drive, Hauppauge, New York 11788 ("***Licensee***"). Each of Licensor and Licensee are hereinafter referred to individually as a "***Party***" and collectively as the "***Parties.***"

RECITALS

WHEREAS, Licensor owns certain intellectual property relating to a taste-masked liquid suspension form of metronidazole, designed to enable broader use of metronidazole;

WHEREAS, Licensee is engaged in the development, manufacture, and commercialization of pharmaceutical products in the Territory;

WHEREAS, Licensor wishes to exclusively license such intellectual property to Licensee and Licensee wishes to obtain an exclusive license to such intellectual property in the Territory, all on the terms and subject to the terms and conditions contained herein;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the receipt and sufficiency of which is hereby irrevocably acknowledged by the Parties, the Parties to this Agreement mutually agree as follows:

ARTICLE I
DEFINITIONS

1.1 Definitions. The following terms shall have the following meanings as used in this Agreement (other capitalized terms shall have the meanings ascribed to them in this Agreement):

"***Adjusted Product Gross Margin***" means, with respect to any period, the Net Sales for such period less (i) Royalties payable to Licensor for such period, (ii) the Cost of Goods Sold of the Product billed or invoiced for sale in such period, and (iii) the Direct Selling Expenses incurred in connection with the sale of Product in such period, determined in accordance with GAAP and to the extent not inconsistent with Licensee's past practice, as modified hereby. For clarity, no costs or expenses incurred with respect to the Animal Product shall be included in the determination of Adjusted Product Gross Margin.

"***Affiliate(s)***" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by, or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of 50% or more of the voting stock of such entity, or by contract or otherwise.

"***AG Product***" means an authorized generic version of the Product Developed and Commercialized by Licensee, upon written approval by Licensor, following the launch of Generic Competition in the Territory.

"***AG Royalties***" has the meaning set forth in Section 6.3(b).

"***Agreed iPSP***" means an initial pediatric study plan agreed to by the FDA and to be included in an NDA in accordance with Section 505B(a)(3)(A)(ii)(II) of the FD&C Act.

"***Agreement***" has the meaning set forth in the preamble to this Agreement.

"***Animal Field***" means with respect to the Animal Product, all uses approved and authorized by the applicable Regulatory Authority as necessary for the importation, marketing, use, distribution, promotion, and/or sale of the Animal Product on a commercial basis within the Territory.

"***Animal Product***" means any Product Developed for the Animal Field.

"***BA/BE Studies***" means bioavailability and bioequivalence studies with respect to the Product required for the submission of the NDA.

"***Batch***" means, with respect to the Product, a specific quantity of such Product that is intended to have uniform character and quality, within specified limits, and is produced according to a single Manufacturing order during the same cycle of Manufacture.

"***Business Day***" means any day other than Saturday, Sunday, or any statutory holiday in the Territory.

"CDI" means Clostridium difficile infection.

"***Commercialization***" means any and all activities related to the Development, obtaining Regulatory Approval, pricing, marketing, sales, and distribution of the Product, including pre-marketing advertising, educating, planning, marketing, promoting, and distributing and post-marketing safety, surveillance, and reporting. When used as a verb, "***Commercialize***" means to engage in Commercialization.

"***Commercialization Plan***" has the meaning set forth in Section 5.7.

"***Commercially Reasonable Efforts***" means, with respect to the Product, efforts and resources used for a product of a similar market potential at a similar stage of its product life taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory status, the profitability, as well as other relevant factors and corresponding at least to the same type (quality and quantity) of channels, methods, investments, and staff (including, without limitation, sales force), which are used by reputable pharmaceutical companies in the marketing, promotion, and sales of products with a reasonably similar potential in the Territory.

"***Commercially Viable***" means, with respect to the Product, the commercial sale of the Product results in zero or positive Adjusted Product Gross Margin. For purposes of this Agreement, the Product shall be deemed to no longer be Commercially Viable in the event that, [redacted]

"***Competing Product***" means any liquid suspension or compounding kit of Metronidazole, irrespective of dosage or formulation, [redacted] approved by Licensor in accordance with this Agreement.

"***Confidential Information***" has the meaning set forth in Section 9.1.

"***Control***" or "***Controlled***" means with respect to any (i) material, item of information, method, data, or other Know-How, or (ii) intellectual property 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 access

and/or a license as provided herein under such material, item of information, method, data, or other Know-How or right without violating the terms of any agreement or other arrangement with any Third Party existing on, before, or, to the extent negotiated and executed in good faith, after the Effective Date.

"***Cost of Goods Sold***" means with respect to the Product and any period, (i) the sum of (A) the inventory cost of the Product at the beginning of such period, plus (B) Cost of Goods Manufactured in such period, less (ii) inventory cost at the end of such period; *provided*, that "inventory cost" shall include only the Cost of Goods Manufactured for such inventory.

"***Cost of Goods Manufactured***" means with respect to the Product and any period, the total cost of raw materials (including packaging) and direct labor required to Manufacture such Product for commercial sale, but, for clarity, shall not include the allocation of any other Development or Commercialization costs or expenses, factory or similar overhead, or any other indirect costs.

"***Data Package***" means with respect to a Product, the data generated for such Product (both clinical and non-clinical) and compiled for submission to and to satisfy the requirements of the applicable Regulatory Authorities in the Territory.

"***Data Review***" has the meaning set forth in Section 3.6.

"***Designated Senior Officer***" shall mean, with respect to Licensor, [redacted], and with respect to Licensee, [redacted], or such other senior official of such Party as such Party may designate in writing to the other Party from time to time.

"***Development***" means non-clinical and clinical research and drug development activities, including without limitation toxicology, test method development, and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre- and post-approval studies), regulatory affairs, and product approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals). When used as a verb, "***Develop***" means to engage in Development.

"***Development Data***" has the meaning set forth in Section 3.5.

"***Development Plan***" has the meaning set forth in Section 3.3.

"***Direct Selling Expenses***" means with respect to a quantity of Product billed or invoiced for sale, the total cost of shipping supplies, delivery charges, sales commissions, marketing, distribution and other direct costs incurred solely in connection with the commercial sale of such Product. For clarity, Direct Selling Expenses shall not include the allocation of any administrative expenses, facility costs, rent, supervisory costs, or other indirect costs.

"***Effective Date***" has the meaning set forth in the preamble to this Agreement.

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

"***FD&C Act***" means the United States Food, Drug & Cosmetic Act, as amended, and all Laws promulgated thereunder.

"***Field***" means with respect to the Product, all human therapeutic uses approved by the applicable Regulatory Authority as contained in the Regulatory Approval.

"***First Commercial Sale***" means the first commercial sale of the Product by Licensee, its Affiliates, or its Sublicensees after receipt of Regulatory Approval, it being understood and agreed that sales for clinical studies and compassionate use shall not constitute First Commercial Sale.

"***GAAP***" means generally accepted account principles in the United States set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants, statements and pronouncements of the Financial Accounting Standards Board, or such other principles as may be approved by a significant segment of the accounting profession in the United States, that are applicable to the circumstances as of the date of determination, consistently applied.

"***Generic Competition***" means an AB-rated Competing Product.

"***GCP***" means the then current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording analyses, and reporting of clinical trials, including those relating to pediatric clinical practice as promulgated and amended by applicable Regulatory Authorities from time to time.

"***GMP***" or "***Good Manufacturing Practice***" means the then current regulations, standards, principles, and guidelines of good manufacturing practice as promulgated and amended by FDA from time to time.

"***Governmental Authority***" means governments, regulatory authorities, governmental departments, agencies, commissions, bureaus, officials, ministers, courts, bodies, boards, tribunals, or dispute settlement panels, or other law, rule, or regulation-making organizations or entities (a) having or purporting to have jurisdiction on behalf of any nation, state, territory, or other geographic or political subdivision of any of them, or (b) exercising, or entitled or purporting to exercise any administrative, executive, judicial, quasi-judicial, legislative, policy, regulatory, or taxing authority or power.

"***Facility Approval***" means any and all permits, certificates, licenses, authorizations, or other approvals from the applicable Governmental Authorities which are necessary for the Manufacture of the Product at a Manufacturing Facility.

"***Initial Sales Milestone***" has the meaning set forth in Section 6.2.

"***IP Developments***" has the meaning set forth in Section 7.2.

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

"***Know-How***" means all unregistered intellectual property, scientific, technical, manufacturing, marketing, production, sales, and other information relating to the Product that is known, owned, or Controlled by Licensor or any of its Affiliates and which is reasonably necessary for the Development, Manufacture, or Commercialization of the Product in the Territory.

"***Law***" or "***Laws***" means the laws, statutes, rules, codes, regulations, orders, judgments, and/or ordinances of a Governmental Authority including, without limitation, the FD&C Act, as any of the foregoing may be amended from time to time, and directives, regulations, promulgations, guidance and guidelines promulgated thereunder having jurisdiction over or related to the Development, registration, approval, Manufacture, Commercialization, and use of Product in the Territory, as may be in effect from time to time.

"***Licensee***" has the meaning set forth in the preamble to this Agreement.

"***Licensor***" has the meaning set forth in the preamble to this Agreement.

"***Manufacture***" means all activities related to the manufacturing of the Product, including, but not limited to, manufacturing supplies for Development, manufacturing supplies for commercial sale, packaging, quality control, storage, and in-process and finished Product testing.

"***Manufacturing Facility***" or "***Manufacturing Facilities***" means, with respect to the Product, those Licensee facilities for which any required Facility Approvals has been obtained and remains in effect.

"***Marketing Authorization***" means the marketing authorization issued by a Governmental Authority, including, but not limited to, the FDA, for the Product in the Territory.

"***Material Subcontractor***" means a contract sales organization, Third Party distributor/marketer of the Product in the Territory, or Third Party Manufacturer of the Product.

"***Milestone Event***" has the meaning set forth in Section 6.2.

"***Milestone Payment***" has the meaning set forth in Section 6.2.

"***NDA***" means a New Drug Application filed with the FDA under Section 505(b)(2) of the FD&C Act or as otherwise approved by the JSC with respect to the Product, and all supplements or amendments filed pursuant to the requirements of the FDA.

"***Net Sales***" means, with respect to a given period of time, the gross amount (calculated in United States dollars) billed or invoiced by Licensee or Sublicensees to independent Third Party customers (other than Sublicensees) for sales of the Product during such period, less, without duplication (a) reasonable and customary quantity, trade, or cash discounts or allowances (including customer rebates) actually taken, (b) any adjustments on account of price adjustments, billing errors, rejected goods, damaged goods, and returns (but not goods damaged while under the control of Licensee or its Affiliates or Sublicensees), price protection and shelf stock adjustments, reprocurement charges and other similar charges or allowances, and inventory management fees, (c) credits, chargebacks, and rebates, reimbursements, administrative fees, and wholesaler fees for service given to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations, or other customers, (d) rebates or other price reductions, based on sales of the Product to any Governmental Authority or Regulatory Authority in respect of any state or federal Medicare, Medicaid, or similar programs.

"***Net Sales Measurement Period***" means the Partial Net Sales Measurement Period and each successive fiscal year during the Term.

"***Orange Book***" means the FDA publication entitled "The Approved Drug Product with Therapeutic Equivalence Evaluations."

"***Partial Net Sales Measurement Period***" means the period of time from the date of the First Commercial Sale through the end of the fiscal year in which the First Commercial Sale occurred.

"***Party***" or "***Parties***" has the meaning set forth in the preamble to this Agreement.

"***Patent***" means all patents, including all current and future patent applications, divisional patents, re-examined patents, and reissued patents owned or Controlled by or licensed to Licensor (regarding licensed patents only to the extent Licensor is permitted to sublicense same), as listed in Schedule B.

"***Person***" means any individual, corporation, company, partnership, trust, limited liability company, association, or other business entity.

"***Pharmacovigilance***" has the meaning set forth in Section 4.6.

"***Pharmacovigilance Agreement***" has the meaning set forth in Section 4.6.

"***Product***" means the liquid suspension formulation of Metronidazole incorporating Licensor's taste-masking technology as further described in Schedule A and, subject to the provisions of this Agreement, any derivative, modification, reformulation, improvement, or alteration thereof Developed by Licensee and/or any permitted Sublicensee, or that results from practicing or using the Patent and/or Know-How in the Field. In the event an AG Product has been approved in accordance with this Agreement, unless otherwise provided herein, the term "Product" shall also include the AG Product. For clarity, the term "Product" shall not include any Animal Product.

"***Product Trade Dress***" means any trade dress (a) Controlled by Licensee on the Effective Date or (b) comes within Licensee's Control during the Term, which is used for any Product in the Territory.

"***Product Trademark***" means any trademark (a) Controlled by Licensee on the Effective Date or (b) comes within Licensee's Control during the Term that is used for any Product in the Territory.

"***Promotional Materials***" means all written, printed, video or graphic advertising, promotional, educational, and communication materials (other than Product labels and package inserts) for marketing, advertising, and promotion of Products, including, without limitation, copyrights in any such materials and all designs, industrial designs, design patents, design registrations, and design patent applications developed in connection with such materials for Commercialization in the Territory.

"***PDUFA***" means the Prescription Drug User Fee Act of 1992 as amended, and all Laws promulgated thereunder.

"***PDUFA Recovery Period***" has the meaning set forth in Section 6.3(a).

"***Registration Batch***" means one or more Batches necessary to support the filing of the NDA.

"***Regulatory Approval***" means any approval and regulatory authorization by any Regulatory Authority, including without limitation the FDA, including the Marketing Authorization, of the Territory on an application filed with respect to the Product that are necessary for the importation, marketing, use, distribution, promotion, and sale of the Product on a commercial basis within the Territory.

"***Regulatory Activities***" means all activities reasonably required in connection with obtaining or maintain Regulatory Approval.

"***Regulatory Authority***" means any applicable Governmental Authority body or other agency responsible for granting Regulatory Approval in a country or jurisdiction in the Territory.

"***Reversion***" has the meaning set forth in Section 5.4.

"***Royalties***" has the meaning set forth in Section 6.3(a).

"***Royalty Payment Date***" has the meaning set forth in Section 6.6.

"***Royalty Period***" has the meaning set forth in Section 6.6.

"***Royalty Statements***" has the meaning set forth in Section 6.6.

"***Second Sales Milestone***" has the meaning set forth in Section 6.2.

"***Specifications***" means the then current technical specifications of the Product as documented in the applicable Marketing Authorization and as amended from time to time.

"***Sublicense***" has the meaning set forth in Section 2.2.

"***Sublicensee***" has the meaning set forth in Section 2.2.

"***Tax***" or "***Taxes***" means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge, or interest) imposed by, or payable to, any Governmental Authority anywhere in the world, including without limitation any value added tax or any form of consumption tax levied by a relevant tax authority, as well as all other forms of consumption taxes levied by the relevant tax authority on the purchase of a good or a service, including but not limited to sales tax and good and service tax.

"***Tax Authority***" means any Governmental Authority anywhere in the world, authorized to levy Tax.

"***Term***" has the meaning set forth in Section 12.1.

"***Territory***" means the continental United States and its territories, commonwealths, and possessions, including, but not limited to, the District of Columbia and the Commonwealth of Puerto Rico, and any other territory over which the United States exerts extrajudicial control.

"***Third Party***" shall mean any Person other than the Parties and their Affiliates.

ARTICLE II
GRANT OF LICENSE RIGHTS

2.1 **License Grant**. Subject to all terms and conditions of this Agreement, Licensor grants to Licensee, and Licensee accepts, for the Term, the exclusive (including as to Licensor), non-assignable, non-transferrable license, with the limited right to grant sublicenses in accordance with Section 2.2, under the Patent and Know-How of Licensor, to (a) engage in Development of the Product and the Animal Product for the Territory, (b) seek, obtain, and/or maintain Regulatory Approval for the Product and the Animal Product in the Territory, (c) Commercialize the Product and the Animal Product in the Territory, and (d) Manufacture the Product for Commercialization in the Territory (including, without limitation, as required for all Development activities).

2.2 **Permitted Sublicensees**. Licensee shall not sublicense any of its rights under this Agreement, whether in whole or in part ("***Sublicense***"), to an Affiliate of Licensee or to a Third Party, without the prior written consent of Licensor, which consent shall not be unreasonably withheld, conditioned, or delayed, and

in such case Licensee shall be solely responsible for the expenses and actions of, and shall be liable for the performance of, any responsibilities sublicensed to any such Affiliate or Third Party ("***Sublicensee***") as if they had been performed by Licensee. Licensee will provide a copy of all executed Sublicenses to Licensor within 10 days of their execution. Each Sublicense will include substantially the same terms and conditions of this Agreement and will specify that: (a) it will automatically terminate upon the termination of this Agreement; and (b) no further sublicenses are permitted.

2.3 Liability for Affiliates, Sublicensees, and Subcontractors.

(a) Performance by Affiliates. Subject to the provisions of Section 2.2, the Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates without the prior approval of the other Party; *provided, however*, that each Party shall remain responsible for the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power, or remedy, or proceed against an Affiliate, for any obligation or performance hereunder prior to proceeding directly against such Party. Wherever in this Agreement the Parties delegate responsibility to Affiliates, the Parties agree that such Persons may not make decisions inconsistent with this Agreement, amend the terms of this Agreement, or act contrary to its terms in any way.

(b) Performance by Other Subcontractors. Subject to the provisions of Section 2.2, Licensee may cause some of its obligations under this Agreement to be performed through subcontractors, but only upon (i) in the case of a Material Subcontractor, the written approval of Licensor, which approval shall not be unreasonably withheld, or (ii) in the case of a subcontractor that is not a Material Subcontractor, prior notice to Licensor. In the event such approval is given, Licensee shall ensure that each of its subcontractors accepts and complies with all of the terms and conditions of this Agreement as if such subcontractors were a party to this Agreement and Licensee shall guarantee subcontractors' performance under this Agreement. Licensee hereby expressly waives any requirement that Licensor exhaust any right, power, or remedy, or proceed against a subcontractor, for any obligation or performance hereunder prior to proceeding directly against Licensee.

2.4 Restrictions on Off-Label Promotion. Licensee and its permitted Sublicensees, distributors, and/or other Third Parties that sell or supply the Product in the Territory as a result of an arrangement with Licensee permitted hereunder shall not promote the use of the Product in the Territory for uses outside the Field. Licensee shall take appropriate and reasonable action with respect to each of such Third Parties in an effort to ensure that there is no off-label use being promoted in the Territory for the Product outside the Field. Upon notification by Licensor that Licensee or any of such Third Party is promoting off-label use of the Product for uses outside the Field, Licensee shall take prompt and reasonable action in a good faith effort to discontinue, prevent, and preclude any and all of such off-label promotion activities.

2.5 Non-Compete. During the period commencing on the Effective Date and continuing for the Term of this Agreement (or, in the event that either (i) no First Commercial Sale occurs or (ii) Licensee terminates this Agreement in accordance with Section 12.5, continuing until the expiration of the enforceable term of the Patent), Licensee shall not by itself or through its Affiliates or a Third Party Develop or Commercialize, directly or indirectly, any Competing Product in the Territory or any country outside of the Territory for which Licensee is entitled to receive payment from Licensor pursuant to Section 2.6 or Section 7.2.

2.6 Right to Purchase Products. Licensee hereby grants to Licensor the right to purchase Products that have been Manufactured by Licensee for resale by Licensor outside of the Territory. Such purchases shall be at Licensee's direct costs of manufacture and appropriate markup of not greater than [redacted] of direct cost of manufacture, subject to and in accordance with the terms of a product purchase agreement to be negotiated between the Parties. In the event Licensor uses the Development Data to obtain any required

regulatory authorization to Commercialize the Product in a country outside of the Territory, Licensor shall pay to Licensee a fee equal to [redacted].

2.7 No Implied License. Except as expressly provided in this Agreement, neither Party grants to the other Party any right or license in any intellectual property right, whether by implication, estoppel, course of conduct, or otherwise. No implied licenses or other rights are granted under this Agreement.

ARTICLE III
JOINT STEERING COMMITTEE; DEVELOPMENT

3.1 Joint Steering Committee.

(a) General. The general purpose of the collaboration described in this Agreement will be to Develop the Product for Commercialization in the Territory. The Parties desire to establish a specialized committee to oversee the Parties' collaboration under this Agreement and to facilitate communications between the Parties with respect to the Development of the Product within the Territory. Such committee shall have the responsibilities and authority allocated to it in this Section 3.1 and shall have the obligation to exercise its authority consistent with its respective purpose as stated herein and any such decisions shall be made in good faith.

(b) Joint Steering Committee Formation and Purpose. Promptly following the Effective Date (but in no event later than 30 calendar days thereafter), the Parties shall create a joint steering committee (the "***JSC***") for the Product to manage the overall Development for the Product for the Territory pursuant to the terms of this Agreement. The purpose of the JSC shall be to, in accordance with the provisions of this Article, (i) review and approve the overall development strategy for the Product, (ii) facilitate the management and implementation of the Parties' Development activities hereunder for the Product, (iii) review and coordinate the overall strategy and filings with Regulatory Authorities necessary for the authorized Manufacture and supply of the Product, and (iv) to ensure on the terms contained in Section 4.11 that there is no interruption in supply of the Product.

(c) JSC Responsibilities. In addition to its overall responsibilities described in Section 3.1(b), the JSC shall specifically:

(i) oversee the Development of the Product, including monitoring the progress of activities undertaken by the Parties pursuant to the Development Plan for the Product;

(ii) manage the flow of information with respect to Development of the Product;

(iii) review and finalize the Data Package for the Product;

(iv) provide a forum for consensual decision making;

(v) review and approve with respect to the Development Plan for the Product and any amendments thereto;

(vi) review the forecasting and order planning process and to adopt and amend the process as required;

(vii) approve the pursuit by Licensee of orphan designation for the Product if Licensee has elected to so purse such designation as provided in Section 4.2;

(viii) discuss and implement appropriate performance measures for supply and quality measurement; and

(ix) review, discuss, and assess any impact of operational activities (for example, forecast development, growth, changes, variances) manufacturing process improvements, equipment/new facility introduction, capacity improvements, cycle time and lead time reduction, improvement in shelf life, inventory management, complaints, and in-market quality/performance reports, etc.

(d) JSC Membership. The Parties shall each designate an equal number of representatives who are employees of such Party or an Affiliate of such Party with appropriate expertise to serve as members of the JSC. The JSC shall be comprised of 2 senior decision-making representatives of each Party; ***provided, however***, that each Party's representatives shall in combination be experienced in (i) clinical development, (ii) regulatory matters, and (iii) manufacture and supply of pharmaceutical products or in quality assurance as required. Each Party may replace its JSC representatives at any time upon written notice to the other Party, provided that the Parties will use reasonable efforts to keep such replacements to a minimum. The JSC shall have a chairperson selected by Licensee. The chairperson of the JSC shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting based upon the agenda items proposed by each Party's representatives, and preparing and issuing minutes of each meeting within 30 days thereafter; ***provided, however***, that the chairperson shall call a meeting of the JSC promptly upon the written request of a representative of the other Party to convene such a meeting. Such minutes will not be finalized until a representative of the other Party on the JSC has reviewed and confirmed the accuracy of such minutes in writing.

(e) JSC Meetings. The JSC shall hold meetings at such times as it elects to do so; ***provided, however***, that it shall hold meetings no less frequently than once every 6 months. Meetings may be held in person or by means of telecommunication (telephone, video, or web conferences); ***provided, however***, that at least 1 meeting per year will be held in person. The Parties will alternate in designating the location for in-person meetings, with Licensor selecting the first meeting location. Other employees of each Party or any of its Affiliates involved in the Development or Commercialization of the Product may attend meetings of the JSC as nonvoting participants, and, with the consent of each Party, consultants, representatives, or advisors involved in the Development or Commercialization of the Product may attend meetings of such Committee as nonvoting observers; ***provided, however***, that such third-party representatives must be subject to obligations of confidentiality and non-use applicable to the Confidential Information of each Party and that are at least as stringent as those set forth in this Agreement. Each Party shall be responsible for all of its own expenses of participating in a meeting. For purposes of clarity, no meeting of the JSC shall be held or be valid without at least 1 member of each Party being present at such meeting.

(f) JSC Meeting Agenda. Each Party is permitted to propose agenda items hereunder and will disclose to the other proposed agenda items along with appropriate information at least 7 Business Days in advance of each meeting of the JSC; ***provided, however***, that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting.

(g) Limitations of Powers. The JSC shall have only such powers as are specifically delegated to it hereunder and shall not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, the JSC shall not have any power to amend this Agreement.

(h) JSC Decision-Making. Subject to the terms of this Section 3.1, the JSC will take action by unanimous vote with each Party having a single vote, irrespective of the number of representatives actually in attendance at a meeting, or by a written resolution signed by all of the designated representatives of each of the Parties. If the JSC is unable to reach unanimous consent on a particular matter, then either Party may provide written notice of such dispute to the Designated Senior Officer of the other Party. The Designated Senior Officers of each Party will meet at least once in person or by means of telecommunication (telephone, video, or web conferences) to discuss the dispute and use their good faith efforts to resolve the dispute. In the event that such dispute cannot be so resolved within 15 Business Days after initial discussion or meeting between such officers, then the Designated Senior Officer of Licensee shall have the authority to finally resolve any such dispute, acting in good faith; ***provided, however***, that any resolution that could reasonably be expected to have a material and adverse effect on Licensor's ability to Develop or Commercialize the Product outside of the Territory or outside of the Field (whether or not outside the Territory) may not be made by Licensee without Licensor's prior written consent. Notwithstanding the foregoing, no Party shall exercise its right to finally resolve a dispute of the JSC in accordance with this Section 3.1 in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement or in a manner that negates any consent rights or other rights specifically allocated to a Party under this Agreement.

3.2 Development Overview. Subject to the role of the JSC, Licensee will be primarily responsible, at its sole cost except as otherwise specifically provided herein, for designing and conducting all Development (including conducting clinical trials, creating the protocols, defining the end points, selecting investigators, reviewing and approving data, and preparing such data for filing) necessary to receive Regulatory Approval for the Product in the Territory. Licensee shall provide an initial draft to the JSC of a Development Plan for the Product to generate the Data Package in accordance with Section 3.5 below. Prior to implementing such Development Plan, unless otherwise determined by the JSC, Licensee shall submit the Development Plan to such Regulatory Authority for comments.

3.3 Development Plan. The Development of the Product for Regulatory Approval in the Territory shall be governed by a development plan ("***Development Plan***"). Licensee shall prepare the Development Plan and submit it to the JSC for its review and approval. From time to time during the Term, the JSC shall have the right to propose amendments to and amend the Development Plan.

3.4 Diligence. Licensee will carry out the Development activities (including generating any additional data other than the Data Package) necessary for obtaining Regulatory Approval in the Territory.

3.5 Reporting and Data. At each meeting of the JSC, each Party will present a report describing the Development activities performed hereunder by such Party (if any) with respect to the Product since the last such report. Each Party shall provide to the other Party copies of all substantive or material information with respect to the Development, including clinical data compiled with respect to the Product and all information and data filed with any Regulatory Authority with respect to the Product, as soon as reasonably practicable after such information, data, or results become available or compiled, including any drafts and final versions of any study reports (the "***Development Data***"). All Development Data shall be jointly owned and shall be the Confidential Information of both Parties. Subject to the terms and conditions of this Agreement, Licensee shall have the exclusive right to use the Development Data or any portion thereof for the sole purpose of Developing and Commercializing the Product in the Field in the Territory.

3.6 Data Review. Prior to Licensee making a filing for Regulatory Approval, Licensor's authorized representatives may, during regular business hours (giving at least 2 Business Days' prior written notice), subject to applicable Law and any Third Party confidentiality restrictions and obligations, inspect all data, documentation, and work products relating to the activities performed by Licensee, including, but not limited to, the medical records of any patient participating in any clinical study, in each case generated pursuant to the Development activities hereunder ("***Data Review***").

3.7 Assistance.

(a) General. Subject to the terms of this Article III, each Party agrees to provide the other with all reasonable assistance in a timely manner and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Law applicable to each Product, including, but not limited to, meeting, reporting, and other obligations to maintain and update any Regulatory Approvals for such Product.

(b) Technology Transfer; iPSP Assistance. Without limiting the generality of Section 3.7(a), Licensor shall grant Licensee any licenses and transfer (at Licensee's reasonable expense) such technology, Know-How, and other applicable data owned or Controlled by Licensor as of the Effective Date, and during the 180 day period immediately following the Effective Date, be available to consult with and advise Licensee with respect to such transferred technology, Know-How, and other data, as reasonably needed to: (i) facilitate Licensee's ability to Manufacture Batches as reasonably required to complete Development of the Product and obtain Regulatory Approval of the Product; and (ii) assist Licensee in obtaining an Agreed iPSP prior to the submission of the NDA by Licensee.

(c) Acknowledgement. To the extent that Licensee is in compliance with its payment obligations to Licensor hereunder, Licensor acknowledges that it shall be available on a commercially reasonable basis to assist Licensee as set forth in this Section 3.7. N/A

3.8 AG Product. In the event that Generic Competition exists, Licensee may Commercialize an AG Product; ***provided, however***, that Licensee shall not commence such Commercialization without the prior written approval of Licensor, which approval shall not be unreasonably withheld, conditioned, or delayed following the commercial sale of such Generic Competition in the Territory.

3.9 Veterinary Market. The Parties acknowledge and agree that in the event Licensee elects to pursue Development or Commercialization of the Animal Product for use in the Animal Field, Licensor shall have no obligations with respect thereto, it being expressly understood and agreed that (a) such Development or Commercialization shall be at Licensee's sole expense, and (b) Licensor shall not receive any royalties with respect to, or otherwise share in any of the revenues associated with, sales of the Animal Product in the Animal Field.

3.10 Compliance with Laws. Each Party or its permitted Third Party contractors shall perform its responsibilities under this Agreement, including those set forth in a Development Plan, in accordance with all applicable Laws.

ARTICLE IV
REGULATORY MATTERS

4.1 Regulatory Approvals.

(a) Except as otherwise expressly provided in this Agreement, Licensee shall be responsible for all actions and costs required to obtain and maintain the Marketing Authorization for the Product in the Territory, including, but not limited to, (i) performing all necessary studies to finalize the "Chemistry, Manufacturing, and Controls" and other sections of the NDA, and (ii) submitting the NDA to the FDA and providing ongoing regulatory support during the review process. Licensee shall use Commercially Reasonable Efforts to file for Regulatory Approvals for the Product in the Territory no later than 180 days after receipt of the Data Package or receipt or completion of requisite data needed for such filing, as applicable, and thereafter maintain such Regulatory Approvals, including filing reports with the applicable Regulatory Authorities. Licensee shall be responsible for the expenses incurred in connection with each

Regulatory Approval that it holds. Notwithstanding the foregoing or anything contained herein to the contrary, (x) the costs of any BA/BE Studies required by the FDA as a condition of approval of the NDA shall be conducted by or at the direction of Licensee (as approved by the JSC) and borne 50% by Licensor and 50% by Licensee at the time such studies are conducted, and (y) the Third Party costs of any PK Studies set forth in the Agreed iPSP shall be paid for by Licensee, but such costs and expenses will be deemed to be a reduction to Net Sales until such time as Net Sales exceed, on a cumulative basis, such costs and expenses.

(b) Licensee shall hold all Regulatory Approvals in its own name for the Products in the Territory or in the name of its local designee if so required by applicable Law; ***provided, however***, that in the event that Licensee's rights granted hereunder revert back to Licensor in accordance with the provisions of Section 5.4 of this Agreement, then with respect to the Product in the Territory, or in the event that this Agreement is terminated pursuant to Article XI or in its entirety for any reason, each Party shall, at its own expense, cooperate with the other Party to cause the Regulatory Approvals for the Product in the Territory to be assigned to Licensor. Notwithstanding the foregoing, Licensor shall be responsible for all filing fees to be paid to any Regulatory Authority with respect to the recording of Licensor's ownership of the Regulatory Approvals.

4.2 Orphan Drug Designation. Upon approval by the JSC, Licensee shall have the option, at its sole expense, to seek orphan designation for the Product for treatment of CDI in pediatric populations.

4.3 Pricing. Licensee shall be responsible to communicate and file reports for applicable pricing regulations and guidelines. Licensee shall ensure compliance with any pricing regulations under applicable Laws in the Territory.

4.4 Professional Undertakings. Licensee warrants and represents to have and allocate the appropriate qualified and trained personnel in order to carry out the Regulatory Activities in a timely, professional, and competent manner. Licensee shall perform the Regulatory Activities in accordance with the provisions of this Agreement and the applicable Laws in the Territory.

4.5 Communication with Regulatory Authorities in the Territory. Each Party shall promptly provide the other Party with copies of any and all material written, or electronic correspondence received from Regulatory Authorities (or any other sources) relating to the Product and/or the Marketing Authorization in the Territory. Each Party shall promptly inform the other Party of any notification of any action by, or notification or other information which it receives from, any Governmental Authority (together with copies of correspondence related thereto), which (a) raises any material concerns regarding the safety or efficacy of the Product, (b) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with the Product, or (c) indicates a reasonable potential for a recall or market withdrawal of a Product.

4.6 Pharmacovigilance. All processing of information related to any adverse events, including, without limitation, any information regarding such adverse events that is received from a Third Party, related to each Product in the Territory and for all expedited and periodic reporting of such events to the applicable Governmental Authority in the Territory in accordance with applicable Laws ("***Pharmacovigilance***") shall be performed by Licensee at its expense on behalf of Licensor on the terms and subject to the conditions of the Pharmacovigilance Agreement attached hereto as Schedule C ("***Pharmacovigilance Agreement***"), to be entered into by the Parties as of date the Regulatory Authority shall have granted Regulatory Approval of the Product.

4.7 Changes Required by Regulatory Authority. Licensee shall promptly inform Licensor of any mandatory change of packaging and packaging materials required by the Regulatory Authority in the Territory.

4.8 Compliance with Regulatory Approvals. Licensee shall exercise its rights under this Agreement in strict compliance with the Regulatory Approvals.

4.9 Clinical Data. Each Party shall provide to the other Party any and all clinical data related to the Product in its possession for further Development and Commercialization of the Product. Licensee shall post any data arising from any clinical trial conducted or sponsored by Licensee, to the applicable clinical trial registry.

4.10 Recalls and Withdrawals.

(a) Notification and Determination. In the event that any Governmental Authority threatens or initiates any action to remove the Product from a market in the Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately, but in no event later than 1 Business Day, after receipt thereof. In all cases, Licensee shall determine whether to initiate any recall or withdrawal of such Product in the Territory, including the scope of such recall or withdrawal (e.g., a full or partial recall, or a temporary or permanent recall); ***provided, however***, that before Licensee initiates a recall or withdrawal, the Parties shall promptly meet and discuss in good faith the reasons therefor, provided further that such discussions shall not delay any action that Licensee reasonably believes has to be taken in relation to any recall or withdrawal. In the event of any such recall or withdrawal, Licensee shall implement any necessary action, with assistance from Licensor as reasonably requested by Licensee, to conduct such recall or withdrawal.

(b) Cost Allocation. All direct costs and expenses associated with implementing a recall or withdrawal of a Product in the Territory shall be allocated between Licensor and Licensee as follows:

(i) in the event, and to the extent, that the recall or withdrawal arises as a result of a material breach of this Agreement by a Party, then the breaching Party shall bear the costs and expenses for implementing the recall or market withdrawal; and

(ii) in the event, and to the extent, that the recall or withdrawal arises out of any event other than those set forth in Section 4.10(b)(i), such costs and expenses shall be borne by Licensee.

(c) Product Recall Outside the Territory. Nothing in this Agreement shall restrict Licensor, its Affiliates, licensees, and distributors in deciding upon a recall or market withdrawal of or other corrective action related to a Product outside the Territory in their own discretion. Notwithstanding the foregoing, Licensor shall inform Licensee of any Product recalls outside the Territory and provide Licensee with reasonable details regarding the recall as soon as reasonably practicable.

4.11 Manufacture of Product. Licensee will Manufacture and supply, at Licensee's sole expense, all requirements of Product for Development activities, Regulatory Activities, and Commercialization activities to be performed by Licensee under this Agreement in accordance with and subject to the following:

(a) Approvals. Licensee shall, at Licensee's expense, be responsible for obtaining and maintaining any and all Facility Approvals.

(b) Manufacturing Facilities. The Product, or any components thereof, shall only be Manufactured at the Manufacturing Facilities. Licensee shall not change Manufacturing Facilities for the Product for the Territory, or any component thereof, except in accordance with the authorization of the competent Governmental Authority (if required) and upon prior written notice to Appili. All costs incurred in connection with the change of a Manufacturing Facility during the Term shall be the sole responsibility of Licensee. The Parties will cooperate to obtain any required Facility Approvals. Upon 90 days' reasonable notice per calendar year

(c) Inventory. Licensee shall maintain an inventory of the Product and the materials necessary to Manufacture the Product in accordance with its normal practices and so as to ensure satisfaction of its obligations with respect to the Development and Commercialization hereunder. Licensee shall be solely responsible for the costs associated with acquiring and importing (including the associated costs of any necessary licenses or clearances) the components and other materials required to Manufacture the Product.

(d) Recordkeeping and Storage.

(i) Licensee shall, and shall cause all permitted Sublicensees to, retain samples and maintain records from each Batch of Products for a period required by applicable Laws for record keeping, testing, and regulatory purposes.

(ii) Licensee shall maintain complete and accurate documentation of all validation data, stability testing data, Batch records, quality control, and laboratory testing, and any other data required under GMP, applicable Laws, and other requirements of any relevant Governmental Authority in connection with the performance of any Manufacturing hereunder. Licensee shall provide Licensor with access to such documentation at Licensee's Manufacturing Facility promptly upon Licensor's request (but no later than 7 Business Days after such request).

(iii) When storing Products, Licensee shall, and shall cause all permitted Sublicensees to, comply with and maintain all storage facilities in accordance with Regulatory Approval, GMP, and all applicable Laws, and perform ongoing stability testing of the Product during such storage.

(e) Manufacturing Standards. In Manufacturing the Product, Licensee agrees to, and shall cause all permitted Sublicensees to, adhere to all quality standards and processes (i) required by any Law applicable to the Manufacture of the Product, (ii) set forth in the Regulatory Approval, (iii) in accordance with GMP, or (iv) as may be agreed to in writing by the Parties. Throughout the Term and for so long thereafter as is required by applicable Law, Licensee shall monitor and maintain reasonable records confirming its compliance with GMP including through the establishment and implementation of such operating procedures as are reasonably necessary to assure such compliance. Licensee shall promptly advise Licensor of any information arising out of Manufacturing activities that have adverse regulatory compliance and/or reporting consequences concerning the Product. In the event a Manufacturing facility is inspected or audited by a Governmental Authority, Licensor shall be kept fully informed by Licensee regarding such inspection, all related correspondence with such Governmental Authority, and any notice of observations or potential observations of violations provided by such Governmental Authority.

(f) Personnel. Licensee shall ensure and document that each Person engaged in the Manufacture of Products shall have education, training, and experience sufficient to enable such Person to perform the assigned functions in such a manner as to provide assurance that the Product has the safety, identity, strength, quality, and purity that it is represented to possess.

(g) Technology Transfer. Upon the termination of this Agreement (including without limitation by Reversion) for any reason other than material breach by Licensor, Licensee shall grant Licensor any licenses and, at Licensor's reasonable expense, transfer such technology and Know-How as may be required for Licensor to assume responsibility for Manufacture and supply of the Product and, upon request, immediately effect any transfer of applicable data and information.

ARTICLE V
COMMERCIALIZATION OF PRODUCT

5.1 Commercialization. Licensee shall use, and shall cause any permitted Sublicensee to use, Commercially Reasonable Efforts to Commercialize the Products in the field in the Territory pursuant to the terms and conditions of this Agreement. Licensee represents and warrants that as of the Effective Date, Licensee holds all licenses, approvals, qualifications, registrations, certificates, authorities, and permits to engage in the Commercialization of the Product in the Territory. During the Term, Licensee shall maintain all Governmental Authority and other licenses and permits required for the Commercialization of the Product as provided for in this Agreement in the Territory and, upon request, shall provide Licensor copies of such licenses and permits. Licensee shall inform Licensor about any changes to the Governmental Authority and other licenses and permits required for the Commercialization of the Product in the Territory. Licensee will be solely responsible for Commercialization of the Products in the Territory.

5.2 Compliance with Laws. Licensee undertakes, and shall be solely responsible to ensure, that Licensee's performance of its obligations under this Agreement shall at all times comply with all applicable Laws, GMP, the Regulatory Approvals, and PhRMA Code of Practice.

5.3 Diligence in Commercialization. Licensee will use Commercially Reasonable Efforts to Commercialize the Product after receiving Regulatory Approval (including, to the extent applicable, pricing and reimbursement approvals) for such Product in the Territory. Notwithstanding anything herein, Licensee shall use its Commercially Reasonable Efforts to achieve First Commercial Sale of the Product in the Territory no later than [redacted] after the receipt of Regulatory Approval of such Product including commercially acceptable pricing and reimbursements.

5.4 Reversion. In the event Licensee fails to achieve First Commercial Sale of the Product in in accordance with Section 5.3, or in the event that Licensee fails to file for or maintain Regulatory Approval in the Territory within [redacted] of the same being eligible for filing or within the allowable timeframe for maintaining such Regulatory Approval, as the case may be, barring a failure to file for or maintain Regulatory Approval that is solely the result of changes in FDA Law or similar circumstances beyond the reasonable control of Licensee, (a) Licensee's licenses and rights hereunder shall terminate upon written notice from Licensor to Licensee, and (b) Licensee shall have the rights and obligations to Licensor under Section 12.6 of this Agreement (a "***Reversion***").

5.5 Promotional Materials. Licensee will create and develop, or arrange for a Third Party to create and develop, Promotional Materials for the Territory in accordance with the Regulatory Approvals and applicable Laws. During the Term, Licensee shall own all right, title, and interest in and to any Promotional Materials relating to Products to be Commercialized within the Territory, including without limitation applicable copyrights and trademarks used or registered with respect to Products, but excluding trademarks owned by Licensor (including without limitation the Product Trademarks).

5.6 Expiry. Licensee shall ensure rotation of inventory and dating to ensure that all quantities of the Products Commercialized in the Territory are in good saleable condition.

5.7 **Commercialization Plans**. On an annual basis, before the end of the third quarter, Licensee shall deliver to the JSC a commercialization plan for the Product for the following year in the Territory. Such plans to include the pricing and reimbursement strategy, promotion and medical education activities, and sales forecast for the [redacted] ("***Commercialization Plan***").

ARTICLE VI
PAYMENTS AND ROYALTIES

6.1 **License Fee**. As partial consideration for the grant of the license under this Agreement, Licensee shall pay Licensor [redacted] on the Effective Date.

6.2 **Milestone Payments**. As further consideration for the grant of the rights and licenses to Licensee in this Agreement, within 30 calendar days of the first achievement of each milestone event listed below with respect to the Product (each, a "***Milestone Event***") Licensee shall make a one time lump sum payment of the corresponding amount listed alongside such Milestone Event (the "***Milestone Payment***"):

[redacted]

(1) *In the event this Milestone Payment exceeds 30% of the Adjusted Product Gross Margin for the respective Net Sales Measurement Period, such Milestone Payment shall be reduced to an amount equal to 30% of the Adjusted Product Gross Margin for the respective Net Sales Measurement Period.*

6.3 Royalty Payments.

(a) In consideration of the rights and licenses granted under this Agreement, beginning on the date of First Commercial Sale of the Product and continuing for a period of [redacted] (the "***Royalty Period***"), Licensee shall pay to Licensor quarterly royalty payments based on Net Sales of the Product ("***Royalties***") as follows:

(i) Commencing at the start of the Royalty Period until such time that Licensee receives cumulative Adjusted Product Gross Margin equal to the lesser of [redacted]

(ii) Following the [redacted]

(b) In the event Licensee launches an AG Product, in addition to the payment of Royalties in accordance with subsection (a) above during the Royalty Period, Licensee shall pay to Licensor quarterly royalty payments based on Net Sales of the AG Product ("***AG Royalties***") [redacted]

(c) For purposes of calculating Royalties, (i) in the event a Sublicense is granted under this Agreement, Licensee shall be responsible for paying Licensor Royalties with respect to all sales by the Sublicensee as if sales by the Sublicensee were sales by Licensee; *provided*, *however*, that solely for purposes of (1) [redacted]

6.4 Taxes. In addition to the amounts owed to Licensor, Licensee shall pay any and all Taxes that Licensee or its Sublicensees are required by the applicable Law to collect and/or pay. It is the responsibility of Licensee to determine Tax status of itself and its Sublicensees and to pay to Licensor the applicable Taxes in addition to the payments required by this Agreement. Licensor shall be responsible for and shall pay its own share of any and all Taxes on net income that Licensor is required to pay under applicable Law in connection with the receipt of Royalties under this Agreement.

6.5 Interest and Administrative Charges. Interest is payable on all overdue amounts. Interest on overdue amounts is calculated and compounded monthly at a rate of [redacted] and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by Licensor.

6.6 Payment; Royalty Statements. All Royalties and AG Royalties, if applicable, owed to Licensor pursuant to Section 6.3 are due and payable within 60 calendar days after the end of each fiscal quarter during the Royalty Period (each, a "***Royalty Payment Date***"). On each Royalty Payment Date, Licensee will also deliver to Licensor reports detailing the determination of such Royalties and AG Royalties ("***Royalty Statements***"). Royalty Statements must be certified accurate and correct by the Chief Financial Officer or an equivalent senior officer of Licensee, and must include the following information, with the requested documentation supporting the Royalties, for the period up to the Royalty Payment Date or since the last Royalty Payment Date: (a) the quantity of Products (including, if applicable, AG Products) made; (b) Net

Sales of Products and AG Products; (c) calculation of the Royalties and AG Royalties due to Licensor; (d) such additional information that Licensor may request from time to time prior to the end of fiscal quarter and (e) where applicable, identical information required in items (a) through (e) from all Sublicensees, certified as accurate and correct by the Chief Financial Officer or some other senior officer of the Sublicensee.

6.7 **Records**. Licensee shall, and shall require Sublicensees to:

(a) keep accurate, detailed, and complete records in accordance with generally accepted accounting principles, at its expense, which shall be retained and available at its principal place of business in respect of Products, Milestone Payments, Net Sales, Royalties, and any other amounts which may require a payment to Licensor;

(b) provide Licensor, upon request and without charge, with audited annual financial statements and other records in sufficient detail to confirm the accuracy of amounts due to Licensor pursuant to this Agreement; and

(c) keep all such records intact during the Term of the Agreement and continuing for a period of not less than 5 years after the termination or expiration of this Agreement.

6.8 **Audit Rights**. Upon 90 days prior written notice to Licensee, and once per calendar year (except as otherwise provided in this Section 6.8), Licensee shall make all relevant records relating to payments required under this Agreement available at its premises during normal business hours, upon reasonable notice, and permit Licensor, its authorized representatives, and an independent Third Party certified public accounting firm selected by Licensor and reasonably acceptable to Licensee to audit, inspect, and copy such records in order to verify the accuracy of any expenses shared or paid under this Agreement or the calculation of Net Sales or sums paid under this Agreement for any calendar year. In such circumstances, Licensee shall afford all facilities and cooperation to Licensor and its representatives, and furnish all information necessary to the understanding of such records. If Licensor's audit reveals that payments made by Licensee are less than [redacted] of the amount that should have been paid, Licensee shall reimburse Licensor's costs of the audit which becomes a debt due immediately, along with the shortfall in Royalties with interest from the date on which the payments should have been made, and Licensor shall be permitted to conduct an additional audit in accordance with this Section 6.8 in the calendar year in which the shortfall was identified. The rights granted herein shall survive the termination or expiration of this Agreement for a period of 5 years.

6.9 **Inspection Rights**. Licensor or its appointees shall, 60 days prior notice be entitled to inspect during normal business hours, all of Licensee's and its permitted appointees facilities (including, without limitation, the Manufacturing Facilities) where the Products are being handled, transported or stored, so as to ascertain compliance by Licensee with its related legal and contractual obligations. Licensee or its appointees shall, upon 60 days prior notice be entitled to inspect during normal business hours, all of Licensor's and its permitted appointees facilities (including, without limitation, the Manufacturing Facilities) where the Products are Manufactured, handled, transported, or stored and to inspect the manufacturing, packaging, and quality control records relating to the Product, so as to ascertain compliance by Licensor with its related legal and contractual obligations.

6.10 **Payment Method**. All amounts due to either Party hereunder will be payable in United States dollars by wire transfer of immediately available funds to an account designated by such Party.

ARTICLE VII
INTELLECTUAL PROPERTY RIGHTS

7.1 **General Principle**. All intellectual property rights Controlled by Licensor or its Affiliates including, without limitation, the Patent, proprietary Know-How, and information of Licensor and its Affiliates, and all labels, designs, trademarks, denominations, forms or wording, which pertain to the Product, as well as the goodwill appertaining thereto, or connected directly or indirectly therewith, are, and shall at all times remain, the exclusive property of Licensor or its Affiliates, as the case may be, and neither Licensee nor any Party claiming through it, nor any other person shall be entitled to or acquire any ownership, or title to, or interest in, the same.

7.2 **Independent Developments**. Any and all intellectual property developed solely by a Party during the Term, whether by or for itself or any of its Affiliates relating to the subject matter of this Agreement ("***IP Developments***") shall be the sole and exclusive property of such Party, subject to the licenses granted hereunder. To the extent any IP Developments are made by Licensee, Licensee agrees to grant and hereby grants to Licensor a semi-exclusive license to such IP Developments and all Intellectual Property rights in and to such IP Developments outside of the Territory. [redacted]

7.3 **Joint Developments**. Any and all intellectual property developed jointly by the Parties (including by Affiliates of the Parties) during the Term relating to the subject matter of this Agreement, shall be the exclusive property of Licensor and Licensee hereby assigns, transfers and conveys, and agrees to assign, transfer and convey, and shall execute an assignment of, all rights, title and interest in and to such intellectual property to Licensor, subject to the licenses granted hereunder.

7.4 **Prosecution of Intellectual Property Rights Covering the Product**. Licensor shall be responsible for, and make all decisions concerning, patent prosecution activities (including, without limitation, the Patent) and pay for all patent prosecution costs. Licensor shall conduct and have logistical control over the prosecution and issuance of its intellectual property; *provided*, *however*, that Licensor shall have no obligation to prosecute or maintain any intellectual property rights outside of the Product or the Field. Licensee shall render Licensor all reasonable assistance required for that purpose; *provided*, *however*, that Licensee shall be obligated to cover the cost of any of its own legal counsel.

7.5 **Enforcement**.

(a) Enforcement by Licensor. Licensee shall observe the market in the Territory regarding any infringements or potential infringements, or challenges to the validity of Licensor's intellectual property rights covering the Product (including without limitation the Patent) and shall advise Licensor, promptly and well within any deadlines for starting litigation, of any such infringements or potential infringements or challenges to validity, including but not limited to receipt of any notices of allegation.

(b) Initiating Enforcement Actions. In the event that Licensor fails to initiate an enforcement action under Section 7.4 to enforce the Patent against a misappropriation by a Third Party in the Territory, which misappropriation consists of the Development or Commercialization of a misappropriated Product, Licensee may deliver to Licensor a written request for consent for Licensee to initiate such enforcement

action against such misappropriation. In the event Licensor approves such request, Licensee may initiate an Enforcement Action against such misappropriation. In such case, Licensee shall pay for all costs incurred and Licensor shall cooperate with Licensee in such enforcement action. The Party initiating or defending any such enforcement action shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the right to participate with counsel of its own choice at its own expense. In the case of any enforcement action by mutual consent, all legal costs will be shared equally by the Parties.

(c) Recoveries. Any recovery received as a result of any enforcement action under this Section 7.5 shall be used first to reimburse the Parties for the costs and expenses (including reasonable attorneys' and professional fees) incurred in connection with such enforcement action, and the remainder of the recovery shall be allocated and paid 50% to Licensee and 50% to Licensor.

(d) Consultation. The Party assuming the lead role in the enforcement action (the "***Controlling Party***") shall consult with the non-Controlling Party on all material aspects of the enforcement. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. Each Party agrees to be joined as a party plaintiff if necessary and shall provide all reasonable cooperation (including any necessary use of its name) required to prosecute such litigation, provided that the Controlling Party shall indemnify the non-Controlling Party in relation to any costs awards made against it. The non-Controlling Party shall be entitled to be represented by an independent counsel of its own choice at its own expense.

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

7.6 Defense of Third Party Claims. If any Product becomes the subject of a Third Party's claim or assertion of infringement, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant. Neither Party shall enter into any final settlement of any claim described in this Section 7.6 that adversely affects the other Party's rights or interests without such other Party's prior written consent, not to be unreasonably withheld or delayed. In any event, the Parties shall reasonably assist one another and cooperate in any such litigation at the other Party's request and expense; *provided*, *however*, that in the event that one Party is named as a defendant in any Third Party suit and the other Party is not, the Parties agree that all costs of defending such litigation shall be allocated and paid 50% to Licensee and 50% to Licensor.

7.7 Notification of Drug Submission. Licensee shall notify Licensor prior to the filing of any drug submission related to the Product, and provide copies of any such proposed filing.

7.8 No Warranties of Non-Infringement of Third Party Rights. Without limiting the generality of Section 10.2, any warranties by Licensor for non-infringement of Third Party patents or trademarks or other intellectual property rights, whether express or implied, are hereby expressly excluded.

7.9 **No Contest**. Licensee agrees not to contest the validity of the Patents licensed hereunder during the Term, either directly or indirectly by assisting other parties.

7.10 **Trademarks**.

(a) Maintenance of Trademarks. The Parties acknowledge that Licensor has not applied for nor is currently using any trademarks or trade dress with respect to the Product. Accordingly, any Product Trademarks and Product Trade Dress will be developed for use in connection with the Product or, if applicable, the AG Product in the Territory by Licensee, subject to approval by the JSC. Following such approval during the Term, Licensee will maintain and enforce the Product Trademarks and Product Trade Dress, at its sole costs and expense, and will not allow any Product Trademark or Product Trade Dress to expire or otherwise be abandoned without the prior approval of the JSC. Licensee shall not during the Term of this Agreement assign any Product Trademarks or Product Trade Dress to any Third Party.

(b) Infringement and Enforcement. In the event either Party becomes aware of any infringement of a Product Trademark or Product Trade Dress by a Third Party in the Territory, such Party shall promptly notify the other Party. In such event of a Third Party infringement of a Product Trademark or Product Trade Dress, Licensee shall have the initial right (but not the obligation) to take legal action with respect to such infringement of such Product Trademark or Product Trade Dress at its own sole expense (a "***Trademark Enforcement Action***"). In the event that Licensee fails to initiate a Trademark Enforcement Action to prevent infringement of such Product Trademark or Product Trade Dress by a Third Party in the Territory, within thirty 30 days of a request by Licensor to initiate such Trademark Enforcement Action, Licensor may initiate a Trademark Enforcement Action against such Third Party at Licensor's sole expense. In each case, the other Party shall cooperate with such Party pursuing a Trademark Enforcement Action at such Party's expense. The Party initiating or defending any such Trademark Enforcement Action shall keep the other Party reasonably informed of the progress of any such Trademark Enforcement Action, and such other Party shall have the right to participate with counsel of its own choice and at its own expense. Any recovery received as a result of any Trademark Enforcement Action under this Section 7.10(b) shall be used first to reimburse the Parties for the costs and expenses (including reasonable attorneys' and professional fees) incurred in connection with such Trademark Enforcement Action, and the remainder of the recovery shall be allocated and paid 50% to Licensee and 50% to Licensor.

ARTICLE VIII
COMPLIANCE

8.1 **General Compliance with Law**. Licensee undertakes to comply, and to cause its Sublicensees to comply, with all applicable Laws. To the extent that this Agreement requires any recommendation or approval of Licensor, any such recommendation or approval shall not relieve Licensee of its aforementioned duty of compliance under this Section 8.1, and any such recommendation or approval of Licensor notwithstanding, Licensee shall refrain from any Commercialization if there are reasonable doubts as to the compliance of such activities with applicable Laws. Licensee shall take such steps as are necessary, including implementing and maintaining (at a minimum) a robust internal compliance program, so as to ensure that its business and practices and the Commercialization it shall perform under this Agreement are carried out in accordance with all applicable Laws, codes of conduct, and any reasonable ethical and compliance principles. Licensor undertakes to comply with all applicable Laws in the performance of its obligations under this Agreement.

8.2 **Anti-Bribery/Anti-Corruption**. Without limiting the generality of Section 8.1, in performing this Agreement, Licensee and its employees and agents (a) shall not offer to make, make, promise, authorize, or accept any payment or giving anything of value, including but not limited to bribes, either directly or indirectly to any public official, Regulatory Authority, or anyone else for the purpose of influencing,

inducing, or rewarding any act, omission, or decision in order to secure an improper advantage, or obtain or retain business, and (ii) shall comply with all applicable anti-corruption and anti-bribery Laws. Licensee and its employees and agents shall not make any payment or provide any gift to a Third Party in connection with Licensee's performance of this Agreement, except as may be expressly permitted in this Agreement.

8.3 **Company Assistance; Notice of Government Inspection**. Both Parties shall promptly comply with any request for information and assistance to ensure, audit, and confirm compliance with applicable Laws. Each Party shall immediately notify the other Party upon becoming aware of any governmental or regulatory review, audit, or inspection of items related to the Product or any other activities in connection with this Agreement.

8.4 **Obligation to Notify**. Licensee shall notify Licensor immediately upon becoming aware of any breach of Licensee's obligations under this Article VII.

ARTICLE IX
CONFIDENTIALITY

9.1 **Confidential Information**. For the purposes of this Agreement, the term "***Confidential Information***" shall mean any and all information of a Party hereto that may be exchanged between the Parties at any time and from time to time before and during the Term in relation to the subject matter covered by this Agreement. Confidential Information as defined herein shall in particular be deemed to include all notes, analyses, compilations, studies, interpretations, or other documents, whether in tangible form or on electronic or other data storage media, prepared by the receiving Party and its Representatives which contain, reflect, or are based on, in whole or in part, Confidential Information furnished to the receiving Party or its Representatives by the disclosing Party or its Representatives hereunder. The Parties agree that the terms of this Agreement shall be considered the Confidential Information of both Parties. Without limitation, if transmitted by or for Licensor, Confidential Information of Licensor shall include the registration dossier, testing methods, research, laboratory and clinical results and data, Know-How, trade secrets, business forecasts, and procurement requirements for the Product.

9.2 **Duties of Confidentiality and Restricted Use**. During the Term, and for a period of 10 years thereafter, each Party hereto will maintain in strict confidence all Confidential Information disclosed to it by the other Party and make no use of Confidential Information except for the purposes of this Agreement; *provided*, *however*, that any trade secret information of a Party shall be maintained in strict confidence for as long as such information remains a trade secret of such Party. Neither Party shall use, disclose, or grant use of such other Party's Confidential Information except as required under this Agreement. To the extent that disclosure is authorized by this Agreement, the disclosing Party shall place its employees, agents, consultants, Affiliates, subcontractors, and Sublicensees (collectively, the "***Representatives***") to whom disclosure is to be made under the same written obligations of confidentiality and restricted use as are contained herein. Each Party shall promptly notify the other upon discovery of any unauthorized use or disclosure of Confidential Information by it or its Representatives.

9.3 **Exceptions**. Confidential Information shall be deemed not to include any information which the receiving Party can prove by credible and pre-dated or contemporaneously-dated written records:

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

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

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

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the other Party not to disclose such information; or

(e) was independently developed by the receiving Party without reference to, use of, or reliance on the disclosure by the other Party.

9.4 Disclosure Required by Law. The receiving Party may disclose Confidential Information belonging to the disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary to comply with applicable Laws, court order, or requests of Regulatory Authorities, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is necessary for such compliance. To the extent reasonably possible, the receiving Party shall notify the disclosing Party of the receiving Party's intent to make such disclosure sufficiently prior to making such disclosure so as to allow the disclosing Party time to apply for an appropriate protective order it may deem appropriate to protect the confidentiality of the information. The receiving Party will fully cooperate (at the disclosing Party's expense) in connection with the disclosing Party's efforts to obtain any such order or other remedy. The receiving Party shall disclose only that portion of the Confidential Information that it is legally required to disclose. If and whenever any Confidential Information is disclosed in accordance with this Section 9.4, such disclosure shall not cause any such information to cease to be Confidential Information.

9.5 Public Announcements. No Party shall originate any publicity, news release, or public announcement relating to this Agreement, whether to the press, stockholders, or otherwise, without the prior written consent of the other Party, except for such announcements which are required by Law or applicable stock exchange rules in which event such Party shall give the other Party a reasonable opportunity to review the form and content of such announcement prior to its scheduled release.

ARTICLE X
REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that as of the Effective Date:

(a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation;

(b) it has legal power, authority, and right to enter into this Agreement and perform its obligations hereunder;

(c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound;

(d) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement, and that this Agreement has been duly authorized, executed, and delivered by that Party;

(e) this Agreement is a valid, binding, and legally enforceable obligation of that Party;

(f) no broker, finder, or investment banker is entitled to any brokerage, finder's, or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf;

(g) except for Regulatory Approvals, manufacturing approvals, and/or similar approvals necessary for the Commercialization of the Product, it holds and will make Commercially Reasonable Efforts to hold and maintain all licenses, approvals, qualifications, registrations, certificates, authorities, and permits required by Law to perform the activities under this Agreement; and

(h) it has not granted any right to any Third Party that would conflict with the rights granted to the other Party hereunder.

10.2 No Other Licensor Representations or Warranties. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND LICENSOR AND LICENSEE EACH SPECIFICALLY DISCLAIM ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS, STATUTORY OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. ADDITIONALLY, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, LICENSOR MAKES NO REPRESENTATIONS AND WARRANTIES OF ANY KIND WHATSOEVER TO LICENSEE REGARDING THE CHARACTERISTICS, QUALITY, FREEDOM FROM DEFECTS, EFFICACY, PERFORMANCE, MARKET READINESS, MERCHANTABILITY, OR FITNESS FOR PURPOSE OF THE PRODUCT, THE KNOW-HOW, AND/OR THE PATENTS (INCLUDING WITHOUT LIMITATION THE VALIDITY OF THE PATENTS OR THE NON-INFRINGEMENT OF RIGHTS OF THIRD PARTIES BY THE PATENTS), ALL OF WHICH ARE LICENSED TO LICENSEE HEREIN "AS-IS" AND "WITH ALL FAULTS", AND WHICH MAY CONTAIN ERRORS, DEFECTS, OR OTHER PROBLEMS. LICENSOR HAS NOT MADE AND DOES NOT MAKE ANY REPRESENTATIONS TO LICENSEE AS TO THE SCOPE OF ANY PROPRIETARY RIGHTS IN RESPECT OF THE PATENTS OR THE PRODUCTS OR THAT SUCH RIGHTS MAY BE EXPLOITED WITHOUT THE POSSIBLE INFRINGEMENT OF PROPRIETARY RIGHTS OF OTHERS. LICENSEE ACKNOWLEDGES AND AGREES THAT IT IS ENTERING INTO THIS AGREEMENT BASED SOLELY ON ITS OWN DUE DILIGENCE INVESTIGATIONS OF THE PRODUCT, THE KNOW-HOW AND/OR THE PATENTS.

ARTICLE XI
INDEMNIFICATION; LIABILITY

11.1 Indemnification by Licensor. Licensor hereby agrees to defend Licensee, its Affiliates, and their respective directors, officers, employees, and agents (the "***Licensee Parties***") against any and all claims and suits of a Third Party and to indemnify and hold the Licensee Parties harmless from and against any and all losses, damages, costs, penalties, liabilities (including strict liabilities), judgments, amounts paid in settlement, fines, and expenses (including court costs and reasonable fees of attorneys and other professionals) of Licensee caused by or resulting from such claims or suits of a Third Party (individually and collectively, the "***Losses of Licensee***") for (a) the gross negligence or willful misconduct or wrongdoing of Licensor or any person for whose actions or omissions Licensor is legally liable, (b) a breach by Licensor of any of its representations, warranties, or obligations under this Agreement, and (c) any Development activities conducted by Licensor (directly or indirectly); *provided, however*, Licensor shall have no liability

to Licensee for any Losses of Licensee to the extent that such Losses of Licensee are attributable to Licensee under Section 11.2.

11.2 Indemnification by Licensee. Licensee hereby agrees to defend Licensor, its Affiliates, and their respective directors, officers, employees and agents (the "***Licensor Parties***") against any and all claims and suits of a Third Party and to indemnify and hold the Licensor Parties harmless from and against any and all losses, damages, costs, penalties, liabilities (including strict liabilities), judgments, amounts paid in settlement, fines, and expenses (including court costs and reasonable fees of attorneys and other professionals) of Licensor caused by such claims or suits of a Third Party (individually and collectively, the "***Losses of Licensor***") for: (a) bodily injury, personal injury, death, and property damage caused by the negligence or willful misconduct of Licensee; (b) the gross negligence or wilful misconduct by Licensee or any person for whose actions or omissions Licensee is legally liable; (c) any Development or Commercialization activities conducted by Licensee (directly or indirectly), (d) any matter relating to an Animal Product, including the Development or Commercialization thereof by Licensee, and (e) a breach by Licensee of any of its representations, warranties, or obligations under this Agreement; *provided*, *however*, that Licensee shall have no liability to Licensor for any Losses of Licensor to the extent that such Losses of Licensor are attributable to Licensor under Section 11.1.

11.3 Duty to Coordinate. Any Party seeking to be indemnified hereunder (the "***Indemnified Party***") shall provide prompt written notice to the other Party ("***Indemnifying Party***") no later than 30 days after becoming aware of any actual or potential claim in respect of which indemnification may be sought; *provided*, *however*, that the failure by the Indemnified Party to provide such prompt notice to the Indemnifying Party shall only be a bar to recovering Losses of Licensor or Losses of Licensee, as the case may be (the "***Loss***"), to the extent that the Indemnifying Party was prejudiced by such failure. In the event of any such actual or threatened Loss or claim therefor, each Party shall provide the other Party information and assistance as the other Party shall reasonably request for purposes of defense and each Party shall receive from the other Party all necessary and reasonable cooperation in such defense including, but not limited to, the services of employees or agents of the other Party who are familiar with the transactions or occurrences out of which any such Loss may have arisen. The primary responsibility for defending any such Loss or claim shall be with the Indemnifying Party; *provided*, *however*, that the Indemnified Party shall have the right to participate in and with respect to the defense of any Loss with counsel of its own choosing, whose fees shall be borne by the Indemnified Party unless the Indemnifying Party shall have failed to assume the defense as provided herein. If the Indemnifying Party has not assumed the defense as provided herein, the Indemnified Party shall not be entitled to settle any claim or agree to the entry of any judgment or other relief without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed. If the Indemnifying Party has assumed the defense of the claim, the Indemnifying Party will not settle or agree to the entry of any judgment or other relief without the prior written consent of the Indemnified Party (which shall not be unreasonably withheld or delayed); *provided*, *however*, that if a firm offer is made to settle a claim that solely involves the payment of money damages, that will not result in the Indemnified Party becoming subject to injection or other relief, that will not adversely affect the business of the Indemnified Party in any manner, and that includes a complete and unconditional release of the Indemnified Party with respect to such claim, the Indemnifying Party will have the sole right to enter into such settlement on such terms as the Indemnifying Party, in its reasonable discretion, will deem appropriate.

11.4 Limitation of Liability. EACH PARTY SHALL COMPENSATE THE RESPECTIVE OTHER PARTY FOR ANY DAMAGE SUFFERED BY THE OTHER PARTY DUE TO SUCH PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT. HOWEVER, EXCEPT FOR EACH PARTY'S OBLIGATION UNDER SECTION 10 AND INDEMNIFICATION OBLIGATIONS PURSUANT TO THIS SECTION, NEITHER PARTY SHALL HAVE ANY LIABILITY TO THE

OTHER PARTY, ITS AFFILIATES, OR THEIR RESPECTIVE ENTITLED PERSONS FOR ANY DAMAGES INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS, SPECIAL, INDIRECT, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATING TO THIS AGREEMENT HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (INCLUDING NEGLIGENCE), WHETHER OR NOT A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, UNLESS SUCH DAMAGES HAVE BEEN CAUSED BY THE WILLFUL MISCONDUCT OR GROSS NEGLIGENCE OF SUCH PARTY OR ANY PERSON FOR WHOSE ACTIONS OR OMISSIONS SUCH PARTY IS LEGALLY LIABLE. NOTHING IN THIS AGREEMENT SHALL LIMIT ANY PARTY'S LIABILITY FOR DEATH OR PERSONAL INJURY CAUSED BY THE GROSS NEGLIGENCE OF SUCH PARTY OR FOR FRAUDULENT MISREPRESENTATION BY SUCH PARTY.

THE FOREGOING LIMITATIONS WILL NOT LIMIT EITHER PARTY'S OBLIGATIONS TO THE OTHER PARTY UNDER ARTICLE IX AND SECTION 11.2.

11.5 **Insurance**. Each Party will obtain and keep in force, through self-insurance or otherwise, in a form reasonably acceptable to the other Party hereto, insurance in scope and amount as required by Law applicable to a Party's activities hereunder and such additional amounts as may be reasonably necessary to cover such Party's indemnity obligations under this Agreement with scope and coverage as is normal and customary in the biotechnology/pharmaceutical industry generally for parties similarly situated. It is understood that such insurance will not be construed to limit a Party's liability with respect to its indemnification obligations under this Article XI. Each Party will, except to the extent self-insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Article XI. Such certificate will provide that such insurance will not expire or be cancelled or modified without at least 30 days' prior notice to the other Party.

11.6 **Survival**. The provisions of this Article XI shall survive the termination or expiration of this Agreement.

ARTICLE XII
TERM AND TERMINATION

12.1 **Term**. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue until such time as Licensee ceases to have any obligation to make payments to Licensor pursuant to Section 6.3 (the "***Term***"). Upon expiration (but not, in the case of the following subclause (a), earlier termination) of the Agreement: (a) all licenses granted hereunder for the Product in the Territory shall become fully paid up, non-exclusive, and irrevocable; (b) Licensee will provide Licensor with full disclosure of, and hereby grants to Licensor, subject to the provisions of Sections 2.6 and 7.2 hereof, a perpetual, worldwide license to Commercialize outside of the Territory any improvements, enhancements, upgrading, and/or functional changes that Licensee and its Sublicensees have made to the Product up to the date of such expiration of this Agreement; (c) all amounts owing by one Party to another Party under this Agreement outstanding at the time of expiration shall be paid to the Party owed money within 30 days after expiration or the date as of which the applicable payment has become calculable, whichever occurs first; and (d) except in connection with the exercise by a Party of any rights that survive the expiration of this Agreement under Section 12.7, each Party shall cease using Confidential Information received from the other Party and each Party shall, at Disclosing Party's request, either return to Disclosing Party or its appointee or destroy any and all advertising materials and all documents and embodiments incorporating Confidential Information in possession of each Party under this Agreement, including, without limitation, any technical and scientific documents, any promotional materials, samples, Know-How, or other information, without retaining copies thereof; *provided*, *however*, that each Party may retain 1 copy of Confidential Information for the purpose of determining its obligations under this Agreement or as necessary

to comply with record keeping obligations under applicable law. Obligations of confidentiality and restricted use shall continue to apply to such retained Confidential Information for the term defined in Section 9.1.

12.2 Termination for Breach. Without prejudice to any remedy or claim hereunder or under applicable Laws it may have against the other Party for material breach or non-performance of this Agreement, each Party shall have the right to terminate this Agreement with immediate effect in the event that the other Party fails to materially comply with or perform any material provision of this Agreement and, in case of a curable material breach, in the further event that such other Party, after having been given written notice, should fail to discontinue and to remedy such violation within a remedy period of 15 Business Days after receipt of such notice; ***provided, however***, that in the case of any default by Licensee other than with respect to the failure to make undisputed payments due hereunder, the remedy period shall automatically increase to 30 Business Days after receipt of notice upon Licensee's delivery of evidence to Licensor that Licensee has taken action to remedy such breach.

12.3 Termination for Insolvency. Each Party may terminate this Agreement with immediate effect if the other Party becomes insolvent or is subject of a petition in bankruptcy, whether voluntary or involuntary, or of any other proceeding under bankruptcy, insolvency, or similar Laws, makes an assignment for the benefit of creditors, is named in, or its property is subject to a suit for the appointment of a receiver, is dissolved or liquidated, or terminates its business activities.

12.4 Termination for Force Majeure. In the event that a force majeure event pursuant to Article XIII should persist for a period of time exceeding 90 days, each Party shall be entitled to terminate this Agreement with immediate effect, by giving the other Party written notice.

12.5 Termination by Licensee. Licensee shall be permitted to terminate this Agreement upon 90 days written notice in the event that the Product is no longer Commercially Viable.

12.6 Consequences of Termination.

(a) General. Upon termination of this Agreement, in its entirety or in part, for any reason (including without limitation by Reversion in accordance with Section 5.4 of this Agreement):

(i) except for specific provisions that the Parties agreed to remain in effect, the respective rights granted to Licensee, and by Licensee to any Sublicensees, under this Agreement shall likewise terminate, and Licensee and Sublicensees shall no longer be entitled to avail themselves of such rights, including any IP Development rights, and shall further refrain from all activities in the Territory relating to the Products;

(ii) except in connection with the exercise by a Party of any rights that that survive the termination of this Agreement under Section 12.7, each Party shall cease using Confidential Information received from the other Party and each Party shall, at Disclosing Party's request, either return to Disclosing Party or its appointee or destroy any and all advertising materials and all documents and embodiments incorporating Confidential Information in possession of each Party under this Agreement, including, without limitation, any technical and scientific documents, any promotional materials, samples, Know-How, or other information, without retaining copies thereof; ***provided, however***, that each Party may retain 1 copy of Confidential Information for the purpose of determining its obligations under this Agreement or as necessary to comply with record keeping obligations under applicable law. Obligations of confidentiality and restricted use shall continue to apply to such retained Confidential Information for the term defined in Section 9.1;

(iii) upon written request, Licensee shall sell to Licensor or Licensor's nominee all remaining stocks of the Product, which are in good saleable condition and with a minimum of 18 months expiry date as well as all customer trade returns and expiring or near expiry stocks in Licensee's warehouse shelves at Licensee's cost of purchase, or if Manufactured by Licensee, at Licensee's cost of Manufacturing;

(iv) Licensee will provide Licensor with full disclosure of, and will grant to Licensor a license to Commercialize outside of the Territory any improvements, enhancements, upgrading, and/or functional changes that Licensee and its Sublicensees have made to the Product up to the date of such termination of this Agreement, to the extent not assigned to Licensor hereunder; and

(v) subject to any offset for losses caused by or resulting from a material breach, all amounts owing by one party to another party under this Agreement outstanding at the time as of which the termination of this Agreement becomes effective shall be paid to the party owed money within 30 days after termination or the date as of which the applicable payment has become calculable, whichever occurs first.

(b) Breach. Upon termination of this Agreement due to material breach by Licensee, Licensee shall, and shall cause its Sublicensees and permitted subcontractors to, upon Licensor's first request and as soon as possible, to take all actions necessary in order to effect the most expeditious transfer to Licensor or its appointee, in the form required in the Territory, of all rights relating to the Product, Product Trademarks, and Product Trade Dress, including any Regulatory Approvals (including Marketing Authorizations), registrations, scientific dossiers, governmental authorizations, the Development Data, and all other rights or benefits in the possession of Licensee, its Sublicensees, or its subcontractors, which may be attached to the Products in the Territory. Such assignment shall be at the cost of Licensee.

(c) Reversion; Commercially Viable; Force Majeure. Upon (i) a Reversion, (ii) termination of this Agreement by Licensee in accordance with Section 12.5 because the Product is no longer Commercially Viable, or (iii) termination by a Party due to Force Majeure, Licensee shall, and shall cause its Sublicensees and permitted subcontractors to, upon Licensor's first request and as soon as possible, to take all actions necessary in order to effect the most expeditious transfer to Licensor or its appointee, in the form required in the Territory, of all rights relating to the Product, Product Trademarks, and Product Trade Dress, if Licensor so desires. Such assignment shall be at the cost of Licensor.

12.7 Survival. The expiration or termination of this Agreement for any reason whatsoever shall be without prejudice to any obligations or rights on the part of either Party which have accrued prior to such expiration or termination and shall not affect or prejudice any provision of this Agreement, which is expressly or by implication provided to come into effect on, or continue in effect after such expiration or termination. The provisions of Sections 2.5, 3.5, 12.6, 13.1, and 14.1 and the provisions of Article VI, Article IX, Article X, Article XI (but only the portions of such Articles that would reasonably be expected to survive) shall survive expiration or termination of this Agreement. The provisions of Sections 2.6 and 7.2 regarding Licensor's obligations to pay Licensee a portion of the consideration received by Licensor in connection with sales of the Product outside the Territory shall survive the expiration or termination other than termination by Licensor due to a material breach by Licensee of this Agreement for such period of time that Licensor remains entitled to receive such amounts.

ARTICLE XIII
FORCE MAJEURE

13.1 **Force Majeure**. Except for the payment of any amount due hereunder (other than any amount disputed in good faith), Licensor and Licensee shall each be excused for any delay or default in performing any of their respective obligations hereunder if such delay or default is caused by conditions beyond its reasonable control including, but not limited to, acts of God, government restrictions (including import and export restrictions), wars, insurrections, terrorism, labor disturbances, shortages of equipment, fuel or labor, destruction of facilities or materials by fire, earthquake, storm or other casualty, judgment or injunction of any court, epidemic, or failure of public utilities or common carrier; *provided, however*, that the Party suffering such delay or default shall promptly notify the other Party in writing of the reasons for the delay or default. If such force majeure event continues for longer than 90 calendar days, each Party has the right to terminate this Agreement by providing the other Party with written notice of its intention to terminate; *provided, however*, that the non-affected Party shall no longer be entitled to terminate this Agreement and such notice of termination shall be ineffective, if the affected Party has resumed performance of its obligations hereunder prior to the conclusion of such 90 day period.

13.2 **Losses Resulting from Force Majeure**. In the event of such delay, default, or termination attributable to a force majeure event, each Party shall bear its own losses resulting therefrom.

ARTICLE XIV
GENERAL

14.1 **Governing Law and Legal Jurisdiction**. This Agreement shall be exclusively governed by, construed, interpreted, and enforced pursuant to the laws and courts of the State of New York applicable therein without reference to conflict of laws principles. The Parties hereto agree that all proceedings arising in connection with this Agreement shall be initiated and tried exclusively in the state and federal courts located in the County of New York, State of New York. The aforementioned choice of venue is intended by the Parties to be mandatory and not permissive in nature, thereby precluding the possibility of litigation between the Parties with respect to or arising out of this Agreement in any jurisdiction other than that specified in this Section 13.1. Each Party hereby waives any right it may have to assert the doctrine of forum non conveniens or similar doctrine or to object to venue with respect to any proceeding brought in accordance with this section, and stipulates that the courts located in the State of New York, County of New York shall have personal jurisdiction and venue over each of them for purposes of litigating any dispute, controversy, or proceeding arising out of or related to this Agreement. Each Party hereby authorizes and agrees to accept service of process sufficient for personal jurisdiction in any action against it as contemplated by this section by registered or certified mail, return receipt requested, postage prepaid, or overnight courier to its address for the giving of notices as set forth in this Agreement. Any final judgment received against a Party in any action or proceeding shall be conclusive as to the subject of such final judgment and may be enforced in other jurisdictions in any manner provided by applicable Law. Notwithstanding anything to the contrary in this Agreement, either Party will have the right to seek injunctive relief in any court of competent jurisdiction as may be available to such Party under the laws and rules applicable in such jurisdiction with respect to any matters arising out of the other Party's performance of its obligations under this Agreement, including without limitation Sections 2.4, 5.4, and 12.6 and Articles VII and IX of this Agreement. The UNICITRAL Convention for the International Sale of Goods, as well as any other unified laws relating to the conclusion and implementation of contracts for the international sale of goods, will not apply.

14.2 **Entire Agreement**. This Agreement, including the Exhibits and Schedules attached hereto, constitutes the entire understanding of the Parties with respect to the subject matter hereof and supersedes and replaces all prior understandings.

14.3 **Assignment**. Neither Party shall be entitled to assign its rights and duties under this Agreement without the prior written consent of the other Party, which consent may be unreasonably withheld or delayed; *provided*, *however*, that a Party shall be entitled to assign this Agreement (or any of its rights or obligations hereunder) to any Person to which such Party has sold all or substantially all of its assets relating to this Agreement provided that the acquiring corporation or other Person agrees to be bound by the terms of this Agreement.

14.4 **Modifications and Amendments**. Modifications and amendments to this Agreement shall be effective only if made in writing executed by both Parties.

14.5 **Severability**. In the event of the invalidity of any provisions of this Agreement, the Parties agree that such invalidity shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision with valid provisions that most closely approximate the purpose and economic effect of the invalid provision. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. In the event that the Parties are unable to agree to any of the foregoing, the judicial or other competent authority making such determination shall have the power to limit, construe, or reduce the duration, scope, activity and/or area of such provision and/or delete specific words or phrases necessary to render such provision enforceable in such jurisdiction. Nothing in this Agreement shall be interpreted so as to require the Parties to violate any applicable Laws.

14.6 **Waiver and Estoppel**. Failure of the Parties to insist upon a strict and punctual performance of any of the provisions hereof shall not constitute a waiver nor an estoppel against asserting the right to require such performance, nor shall a waiver or estoppel in one instance constitute a waiver or estoppel with respect to a later breach, whether of similar nature or otherwise. The observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) by the Party entitled to enforce such term, but any such waiver shall be effective only if in writing signed by the Party against whom such waiver is to be asserted.

14.7 **Notices**. Unless otherwise provided for in this Agreement, any notice or request required or permitted to be given under or in connection with this Agreement or the subject matter hereof, shall be given in the English language in writing by prepaid registered or first-class airmail, international courier or email to the recipient at its address as set forth hereunder or to such other address or addressee as may have therefore been furnished in writing by the recipient to the sending party in accordance with this Section. Any such aforementioned notice or request shall be deemed to be effective upon receipt by the Party to which it is addressed. Any notice to be sent by Licensor or Licensee pursuant to this Agreement shall be addressed:

To Licensor:	Appili Therapeutics Inc. 1344 Summer Street, Suite 21 Halifax, Nova Scotia, Canada B3H 0A8 [redacted]
with a copy to:	White and Williams LLP 1650 Market Street, Suite 1800 Philadelphia, PA 19103 [redacted]
To Licensee:	Saptalis Pharmaceuticals LLC 45 Davids Drive

Hauppauge, NY 11788
[redacted]

with a copy to: Pharma Tech Law LLC
300 Main Street #202
Madison, NJ 07928
[redacted]

14.8 **No Agency**. Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership, or similar relationship between the Parties, and this Agreement shall not be deemed a partnership agreement. Notwithstanding any of the provisions of this Agreement, neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur on behalf of the other Party, any commitment, expense, or liability whatsoever, and all contracts, expenses, and liabilities undertaken or incurred by one Party in connection with or relating to the Development, Manufacture, or Commercialization of Products shall be undertaken, incurred, or paid exclusively by that Party, and not as an agent or representative of the other Party.

14.9 **Headings; Construction; Certain Conventions**. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof. The exhibits and schedules to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular will include the plural, and vice versa, (d) the words "include", "includes" and "including" will be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import, (e) the word "or" will be deemed to include the word "and" and (f) references to "Article", "Section", "Subsection" ,"clause" or other subdivision, or to a schedule or exhibit, without reference to a document are to the specified provision, schedule, or exhibit of this Agreement. This Agreement will be construed as if it were drafted jointly by the Parties and shall not be strictly construed against either Party.

14.10 **Further Assurances**. Each Party shall, as and when requested by the other Party, do all acts and execute all documents as may be reasonably necessary to give effect to the provisions of this Agreement.

14.11 **Counterparts**. This Agreement may be executed in one or more counterparts, including in the form of a PDF or electronic file, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.

14.12 **Independent Status**. Neither Party is an agent, employee, or representative of the other. Neither Party shall have the authority to make any statements, representations, or commitments of any kind, nor to take any action, which shall be binding on the other Party, except as may be explicitly authorized by the other Party in writing. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or formal business organization of any kind.

[Signature Page Follows]

IN WITNESS WHEREOF, Licensor and Licensee hereto have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

APPILI THERAPEUTICS INC.

By: _____
Name: [redacted]

SAPTALIS PHARMACEUTICALS LLC

By: _____
Name: [redacted]

Schedule A - Product

Product:	ATI-1501 liquid suspension formulation of Metronidazole incorporating Licensor taste-masking technology
Strength:	50mg/mL
Supplied:	200 mL bottle/measuring cup/carton

Schedule B - Patents

"Redacted"

Schedule C – Form of Pharmacovigilance Agreement

"Redacted"