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

FORM 10-Q/A
(Amendment No. 1)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 30, 2017

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**000-28508**	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Block 10-1, Blanchardstown Corporate Park
Ballycoolin
Dublin 15, Ireland
(Address of Principal Executive Office and Zip Code)

+353-1-485-1200
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated	☐	(Do not check if a smaller reporting company)	
		Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

At November 2, 2017, 39,762,209 ordinary shares, nominal value $0.01 each, of the Company were outstanding.

Explanatory Note

Avadel Pharmaceuticals plc (the "Company") is filing this Amendment No. 1 (this "Form 10-Q/A") to Quarterly Report on Form 10-Q to amend the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017, as filed with the Securities and Exchange Commission (the "SEC") on November 9, 2017 (the "Original Filing"). This Form 10-Q/A is being filed solely to re-file Exhibit 10.7 to the Original Filing (the "Exhibit"). Due to a clerical error, certain paragraphs under Section 8.2 (Milestone Payments) of the Exhibit in the Original Filing contained incorrect sequential paragraph numbering. Specifically, the paragraph titled "Tier One Commercialization Milestone Payments" should be marked as Section 8.2(b); the paragraph titled "Tier Two Commercialization Milestone Payments" should be marked as Section 8.2(c); and the paragraph titled "Change of Control Payment" should be marked as Section 8.2(d). The Exhibit, as re-filed in this Form 10-Q/A, contains the correct sequential paragraph numbering. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, new certifications by the Company's principal executive officer and principal financial officer are filed as exhibits to this Form 10-Q/A.

No other changes have been made to the Original Filing. This Form 10-Q/A continues to speak as of the original filing date of the Original Filing, does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update any related disclosures made in the Original Filing.

ITEM 6. EXHIBITS.

Exhibit No.	Description
10.1*±	Employment Agreement by and between Avadel Management Corporation and Michael S. Anderson dated August 15, 2017.
10.2*±	Employment Agreement by and between Avadel Management Corporation and Gregory J. Divis dated September 5, 2017.
10.3*±	Employment Agreement by and between Avadel Management Corporation and Sandra Hatten dated August 15, 2017.
10.4*±	Employment Agreement by and between Avadel Management Corporation and Michael F. Kanan dated September 5, 2017.
10.5*±	Employment Agreement by and between Avadel Management Corporation and Phillandas T. Thompson dated August 15, 2017.
10.6*‡	Exclusive Right of Negotiation Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of August 11, 2017.
10.7**‡	Exclusive License and Assignments Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of September 1, 2017.
10.8A*‡	Manufacturing Agreement by and between Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC) and Serenity Pharmaceuticals, LLC dated as of July 14, 2014.
10.8B*	Renaissance Agreements Assignment and Assumption Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of September 1, 2017.
10.9*	Master Manufacturing Services Agreement by and between Patheon UK Limited and Éclat Pharmaceuticals L.L.C. dated as of November 8, 2012.
31.1**	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act.
31.2**	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act.

32.1***	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2***	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

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* Previously filed as an exhibit to Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 filed with the Securities and Exchange Commission on November 9, 2017.

** Filed herewith.

*** Furnished herewith.

\+ Indicates management contract or compensatory plan or arrangement.

‡ Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

AVADEL PHARMACEUTICALS PLC
(Registrant)

Date: November 17, 2017

By: /s/ Michael F. Kanan
Michael F. Kanan
Senior Vice President and Chief Financial Officer (Duly Authorized Officer and *Principal Financial Officer)*

Exhibit 10.7

Execution Copy

EXCLUSIVE LICENSE AND ASSIGNMENT AGREEMENT

Contents

CONFIDENTIAL TREATMENT REQUESTED THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS ("[***]") HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

Exhibits and other Agreements (in the order in which they appear in the Agreement):

(1) attached to this Agreement upon its execution
(2) to be drafted following execution of this Agreement
(3) to be provided separately

Schedules (in the order in which they appear in the Agreement):

EXCLUSIVE LICENSE AND ASSIGNMENTS AGREEMENT

This Exclusive License and Assignments Agreement (this "Agreement") is made as of September 1, 2017, by and among SERENITY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensor"), with offices at 105 Hawk Court, Milford, PA 18327, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensee"), with offices at16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005. Licensor and Licensee are each sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Licensor has developed the Product (herein defined) for treating certain medical conditions characterized by abnormalities or disorders in voiding and other urinary functions, and the FDA (herein defined) has approved a New Drug Application (herein defined) for treating certain of these medical conditions (herein defined as the "First Approved NDA);

WHEREAS, Licensee is engaged in the business of the development, distribution, sale and marketing of pharmaceutical products;

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to grant to Licensee, and Licensee desires to be so granted, an exclusive license and sublicense to the Licensed Rights (herein defined) and the Sublicensed Rights (herein defined), respectively, for the purpose of: (a) Commercializing (herein defined) Products in the Field (herein defined) throughout the Territory (herein defined) and (b) Developing (herein defined) and Commercializing the Product for the PNE Indication and Additional Indications (herein defined) in the Field and Territory;

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to assign and to delegate to Licensee, and Licensee desires to be so assigned and delegated, all of Licensor's right, title, and interest in and to, and the related regulatory obligations in respect of, the First Approved NDA and the related IND (herein defined); and

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to assign and delegate to Licensee, and Licensee desires to be so assigned and delegated, all of Licensor's right, title, and interest in and to, and the related obligations under, the Renaissance Supply Agreements (herein defined),

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the Parties intending to be legally bound agree as follows:

1. DEFINITIONS.

When used in this Agreement each of the following terms whether used in the singular or plural shall have the following meanings.

1.1 "A/B Rated" means, (a) inside the United States, "therapeutically equivalent" as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations", and (b) outside the United States, such equivalent determination by the applicable Regulatory Authorities as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law.

1.2 "Acceptance" and its correlative "Accepted" means with respect to an NDA submitted to the FDA, receipt by the sponsor thereof of written notice from the FDA that the FDA deems such NDA to be sufficiently complete for filing and filed by the FDA pursuant to 21 C.F.R. 314.101 and any regulation successor thereto.

1.3 "Additional Indications" means any other Indication for the Product in the Field in the Territory other than the PNE Indication.

1.4 "Adverse Drug Experience" has the meaning set forth in 21 CFR Sec. 314.80 and any regulation successor thereto.

1.5 "Affiliate" means any Person who, directly or indirectly through one or more intermediates, controls or is controlled by or is under common control with another Person, but only for so long as such relationship exists. For purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means the possession, directly or indirectly through one or more intermediates, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Such power will be deemed to exist in the case of ownership, directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, or status as a general partner in any partnership. The Parties acknowledge that, in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity.

1.6 "Agreement" has the meaning set forth in the Preamble.

1.7 "Alliance Manager" means, with respect to each of Licensor and Licensee, the individual designated by such Party in accordance with Section 3.2(h).

1.8 "Applicable Law" means, with respect to any action taken or omitted to be taken by a Party under this Agreement, the Laws in any country and any jurisdiction therein that are applicable to such action or omission.

1.9 "Bankruptcy Code" means the United States Bankruptcy Code, as amended and set forth in Title 11 of the United States Code.

1.10 "Branding Strategy" means the strategy, including messaging, for branding the Product for use in the Field in the Territory, to be set forth in the Commercialization Plans for each combination of Product and Indication.

1.11 "Business Day" means a day other than any Saturday, Sunday or other day on which banking institutions in New York, New York are required by Applicable Law to remain closed.

1.12 "Calendar Quarter" means each calendar quarter ending on the last day of each March, June, September and December during the Term of this Agreement; *provided, however,* that (a) the first Calendar Quarter of the Term of this Agreement will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the term of this Agreement will end upon the expiration or termination of this Agreement.

1.13 "Calendar Year" means each calendar year ending on December 31 of such year; *provided, however,* that (a) the first Calendar Year of the Term of this Agreement will extend from the Effective Date to and including December 31, 2017; and (b) the last Calendar Quarter of the term of this Agreement will end upon the expiration or termination of this Agreement.

1.14 "CFR" means the United States Code of Federal Regulations.

1.15 "Change of Control" means with respect to Licensee:

(a) Licensee enters into a merger, consolidation, stock sale or sale or transfer of all or substantially all of its assets to which this Agreement relates, or other similar transaction or series of transactions with a Third Party, unless, following such transaction or transactions, (i) the individuals and entities who were the beneficial owners of the outstanding voting securities of Licensee immediately prior to such transaction beneficially own, directly or indirectly, at least fifty percent (50%) of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors or similar governing persons of the corporation or other entity resulting from such transaction ("Successor") in substantially the same proportions as their ownership immediately prior to such transaction of such outstanding voting securities, (ii) at least fifty percent (50%) of the members of the Board of Directors or similar governing body of the Successor were members of the Board of Directors of Licensee at the time of the execution of the initial agreement, or the action of the Board of Directors of Licensee, providing for such transaction, (iii) Licensee retains title ownership after the transaction or transactions to properties and assets (x) representing more than fifty percent (50%) of such Third Party's consolidated total assets or (y) from which more than fifty percent (50%) of such Third Party's consolidated operating income for its most recent fiscal year was derived, and (iv) Licensee is the surviving entity in such transaction or transactions; or

(b) any transaction or series of related transactions in which any Third Party or group of Third Parties acquires beneficial ownership of securities of Licensee representing more than fifty percent (50%) of the combined voting power of the then outstanding securities of Licensee.

Notwithstanding subsections (a) or (b), above, a stock sale to underwriters of a public or private offering of Licensee's capital stock shall not constitute a Change of Control.

1.16 "Clinical Study" means (a) a Phase 1 Clinical Study, a Phase 2 Clinical Study, a Phase 3 Clinical Study, (b) variations of such studies and/or trials (for example, a Phase 2/3 Clinical Study), as such terms are defined and understood by the FDA, and (c) such other tests and studies in human patients that are required by Applicable Law, or otherwise recommended by applicable Regulatory Authorities in the Territory, to obtain or maintain Regulatory Approvals, but excluding Post-Market Approval Studies not required to be conducted under an IND.

1.17 "CMC" means, as required by the context, the chemistry, manufacturing and controls processes applicable to the manufacture of a product or the section of an IND or NDA that contains information on such processes.

1.18 "Combination Product" means any product that comprises (a) the Compound and (b) at least one clinically active therapeutic, or prophylactic ingredient or component (whether packaged together or in the same formulation) that is not the Compound.

1.19 "Commercialize", "Commercializing" or "Commercialization" means, with respect to any drug product, any and all activities directed to using, launching, marketing, market researching, detailing, promoting, advertising, educating, importing, exporting, distributing, selling, offering for sale, post-market approval pharmacovigilance and safety reporting, legal, customer service, securing from both government agency payors and non-government third-party payors reimbursement of such drug product after Regulatory Approval has been obtained (including, without limitation, obtaining pricing and reimbursement approvals), regulatory compliance, planning with respect to each of the foregoing, and reporting. For clarity, "Commercialization" shall not include any activities related to clinical research or Development of Products or to Manufacturing of Products.

1.20 “Commercialization Activities” means any of the activities described in the definition of “Commercialize”.

1.21 “Commercialization Plan” means, from time to time and with respect to any period during the Term, Licensee’s plan then in effect for Commercializing the Product during such period.

1.22 “Commercially Reasonable Efforts” means, from to time to time with respect to the performance at such time of any Development, Commercialization or other obligation of a Party under this Agreement that expressly requires efforts characterized as such, the performance by such Party of such obligation by expending reasonable, diligent, good faith efforts to accomplish such obligation as a similarly situated pharmaceutical company would use to accomplish a similar obligation under similar circumstances through the exercise of reasonable business judgment, where the assessment of being similarly situated would be undertaken by reference to company size and financial position, competitive factors in the relevant market relating to the proprietary position of the relevant product in terms of market and profit potential, the safety and effectiveness profile of the relevant product, strategic value, and applicable regulatory matters; provided, that, with respect to the Development and Commercialization of the Compound or the Product, such efforts shall be substantially equivalent to those efforts and resources that a pharmaceutical company would generally devote to its own internally discovered compounds or products of similar market and profit potential, safety and effectiveness profile, strategic value, and regulatory matters at a similar stage in their development or life cycle, with respect to which it does not owe license payments, milestone payments, royalties or similar financial obligations to licensors or other Persons, and based on conditions then prevailing, with the goal of maximizing the revenue potential of such compounds or products. Commercially Reasonable Efforts shall be determined on a country by country basis.

1.23 “Compound” means “(a) the compound designated as Desmopressin (1-desamino-8-D-arginine vasopressin) and (b) any and all functionally equivalent analogues thereof having antidiuretic activity disclosed in a patent or patent application within the Patent Rights licensed and sublicensed hereunder.

1.24 “Confidential Information” has the meaning set forth in Section 13.1.

1.25 “Control” or “Controlled” means, with respect to any Know-How or Patent Right, the possession by a Party, whether by ownership, license, sublicense or otherwise (other than pursuant to a license granted under this Agreement), of the ability to grant the right to access or use, or to grant a license or a sublicense under, or to grant the right to disclose or transfer, such Know-How or Patent Right, without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party. For clarity, the Patent Right or Know-How licensed to Licensee under this Agreement shall be deemed to be Controlled by Licensee.

1.26 “Cover”, “Covered”, or “Covering” means, (a) with respect to an issued patent, that, in the absence of a license granted to a Person under a Valid Claim included in such patent, the practice by such Person of an invention claimed in such Patent Right would infringe such Valid Claim, or (b) with respect to a patent application, that, in the absence of a license granted to a Person under a Valid Claim included in such patent application, the practice by such Person of an invention claimed in such patent application would infringe such Valid Claim if such patent application were to issue as a patent.

1.27 “CPEX” means CPEX Pharmaceuticals, Inc. (formerly Bentley Pharmaceuticals, Inc.), a corporation organized under the laws of Delaware.

1.28 “CPEX License Agreement” means that certain Development and License Agreement, dated February 4, 2008 and as amended March 31, 2010, by and among Licensor and CPEX.

1.29 “Detail” means a meeting (either in person or through live video conferencing) in respect of the Product (i) with one or more physicians and other persons included in other medical professional categories (where, in the case of group presentations, each such physician or other person participating in a group presentation shall be counted as a separate Detail), who are permitted under the Applicable Law of the country in which they work to prescribe the Product and (ii) in which key attributes of the Product are orally presented, but shall not include merely a reminder or a Sample or promotional material drop). When used as a verb, “Detail” and “Detailing” shall have correlative meanings.

1.30 “Develop” or “Development” means the undertaking of all activities relating to obtaining Regulatory Approval for a product and all Manufacturing Activities reasonably required for development of CMC processes. For the sake of clarity, such activities include preclinical testing, toxicology, formulation, Clinical Studies, and regulatory affairs required for Regulatory Approval, and activities relating to the manufacture of Products that relate to regulatory matters are included in the definition of Manufacturing.

1.31 “Development Activities” means any of the activities described in the definition of “Develop”.

1.32 “Development Budget” means, for any Development Activities to be undertaken with respect to the Product, the PNE Indication and any Additional Indications, the detailed budget for all Development Costs for the Development Activities set forth in any Development Plan in respect of such Development Activities.

1.33 “Development Costs” means, in respect of the Development Activities described in any Development Plan, the following costs: (i) Out-of-Pocket Costs attributable to such Development Activities and (ii) FTE Costs of Licensee’s internal personnel that are attributable or reasonably allocable to such Development Activities. Such costs shall be determined in accordance with GAAP.

1.34 “Development Plan” means, in respect of the Product, the PNE Indication and each Additional Indication, from time to time during the Term of this Agreement, any plan then in effect for the conduct of Development Activities in respect thereof, and includes, without limitation, the Development Budget for such Development Activities.

1.35 “Disclosing Party” means, with respect to any disclosure by a Party of any of its Confidential Information to the other Party, the Party so disclosing such Confidential Information.

1.36 “Disposition” means any disposition by Licensee of any of its assets, including any direct or indirect sale, lease, exchange, transfer, contribution, license, spinoff, recapitalization, dividend, grant or other disposition, with or without value; provided, however, that any sale of inventory by a Licensee Change of Control Party in the ordinary course of business, an offering of debt or equity securities in a public financing, or any pledge of assets to secure acquisition debt financing on customary terms which would not involve the issuance of equity that would otherwise result in a Change of Control, shall not be deemed a Disposition hereunder.

1.37 “Dispute” has the meaning set forth in Section 15.8(b).

1.38 “Dollars” or “$” means U.S. dollars.

1.39 “Drug Master File” or “DMF” has the meaning set forth in 21 CFR Section 314.420 (and any regulation successor thereto).

1.40 [***].

1.41 “Effective Date” shall mean the later of: (i) the date of this Agreement set forth in the Preamble or (ii) the expiration of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

1.42 “Enforceable IP Right(s)” shall mean any Patent Rights, Trademarks, Copyrights, or other intellectual property rights within the Licensed Rights or the Sublicensed Rights that would be infringed by any Exploitation of any product in the Territory in the absence of a valid and enforceable license, sublicense, or other right to engage in such Exploitation.

1.43 “Exploit” and, with correlative meaning, “Exploitation”, means to Develop, Commercialize, Manufacture, and otherwise exploit.

1.44 “FDA” means the United States Food and Drug Administration and any agency successor thereto.

1.45 “FDCA” means the United States Food, Drug and Cosmetic Act of 1938, as amended, and any law successor thereto.

1.46 “Field” means the use of the Product for the Treatment in humans and animals of medical conditions characterized by abnormalities or disorders in voiding and other urinary functions of a subject to control urination**.**

1.47 “First Approved NDA” means U.S. NDA #201656, dated and received by the FDA on February 4, 2016 and as thereafter amended, and approved by the FDA, as evidenced by that certain letter, signed March 3, 2017, from the FDA to Serenity.

1.48 “First Approved Product” means the Product that is the subject of the First Approved NDA.

1.49 “First Commercial Sale” means, with respect to the Product in each country in the Territory, the first sale in such country by Licensee or any Third Party Distributor for consumption or use. Sales or transfers of reasonable quantities of the Product for Clinical Study purposes or for compassionate or similar use, shall not be considered a first sale for consumption or use.

1.50 “First Position” means, with respect to the Detail of an applicable product, that the product is presented in such Detail before any other product, such that the average time spent on all Details in any Calendar Quarter during the First Position Period is approximately fifty (50%), excluding any Detail to a person or group of persons where for good reason Detailing of the Product should either not be made or, if made, made substantially shorter than such average.

1.51 “First Position Period” has the meaning set forth in Section 14.3(b).

1.52 “Force Majeure” has the meaning set forth in Section 15.12.

1.53 “FTE” means the hours of work devoted to or in support of Commercialization, Manufacture, or Development, as applicable, of the Product, in accordance with the applicable Commercialization Plan, Manufacturing Plan, or Development Plan, that is carried out by one or more employees, contract personnel or consultants of a Party, measured in accordance with such Party’s normal time allocation practices from time to time. In no event shall an individual account for more than one FTE year in any Calendar Year.

1.54 “GAAP” means United States Generally Accepted Accounting Principles as applied in the United States.

1.55 "Generic Product" means, with respect to the Product, any product Commercialized by a Third Party in any country in the Territory, that meets the following criteria: (i) such product contains a Low Dosage formulation of a compound that is an active pharmaceutical ingredient in a product that is A/B Rated with respect to the Licensed Product (including, without limitation, any salt, free acid or base, hydrate, isotopic, deuterated, solvate, polymorphic, crystalline, or non-crystalline form of such Compound), and (ii) is A/B Rated with respect to the Product.

1.56 "Generic TRxs-to-Total TRxs Percentage" means, with respect to any Calendar Quarter during the Term of this Agreement in each country in the Territory, the quotient, expressed as a percentage, of (a) total TRxs for Generic Products during such Calendar Quarter in such country DIVIDED BY (b) the sum of total TRxs for Generic Products during such Calendar Quarter in such country PLUS total TRxs for Products during such Calendar Quarter in such country.

1.57 "Governmental Authority" means any legislative, executive, judicial, regulatory, or administrative unit of any governmental entity (multinational, foreign, federal, state, or local) or any department, commission, board, agency, bureau, ministry, official, arbitrator (public), or other similar body exercising executive, legislative, regulatory, administrative, or judicial authority or functions of or pertaining to government to perform any such functions.

1.58 "IND" means, with respect to any investigational product, an Investigational New Drug Application filed with the FDA under 21 CFR Part 312 (and any regulation successor thereto) or similar foreign application or submission in any country in the Territory for permission to conduct human clinical investigations of such investigational product.

1.59 "Indemnification Claim" has the meaning set forth in Section 11.2.

1.60 "Indication" shall mean any human disease or condition, and any subcategories thereof, or sign or symptom of a human disease or condition, and any subcategories thereof.

1.61 "Inventions" means any and all inventions made, conceived, or discovered solely by employees, independent contractors, or agents of either Party or their respective or jointly by employees, independent contractors, or agents of each of the Parties or their respective Affiliates.

1.62 "Joint Steering Committee" or "JSC" means the committee formed by designees of Licensor and Licensee for the purpose of monitoring the Development, Commercialization, and Manufacture of the Product as contemplated by this Agreement and governed in accordance with Article 3.

1.63 "JSC Subcommittee" means any subcommittee established by the JSC in accordance with Article 3.

1.64 "Know-How" means any nonpublic information, ideas, data, inventions, works of authorship, trade secrets technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissues, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, and whether stored or transmitted in oral, documentary, electronic or any other form, including all Regulatory Documentation.

1.65 "Launch" means, with respect to the Product or any Generic Product for an Indication in a country in the Territory, the Product or such Generic Product first becoming available for commercial sale.

1.66 "Law" means any law, statute, rule, regulation, ordinance, regulatory guidance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision in each country in the Territory, including, without limitation, (a) the FDCA in the United States and counterparts thereof in each other country in the Territory, (b) good clinical practices and adverse event reporting requirements and all other rules, regulations and requirements of the FDA and Regulatory Authorities that are counterparts of the FDA, as applicable, (c) the Foreign Corrupt Practices Act of 1977, as amended, in the United States and any comparable laws in each other country in the Territory, and (d) all export control laws in any country in the Territory.

1.67 "LIBOR Rate" means, for any applicable interest period, the rate per annum equal to the average of the one month US Dollar Rate Intercontinental Exchange London Interbank Offered Rate, as published by Thomson Reuters (or, if Thomson Reuters does not publish quotations of such rate, another commercially available source providing quotations thereof as reasonably selected by agreement of the Parties), with the average determined by adding such rate for each day on which such rate is published during the applicable period, divided by the number of such days during such period. If such rate is not available at such time for any reason, then the rate for that interest period will be determined by such alternate method as reasonably selected by agreement of the Parties.

1.68 "Licensed CPEX Patent Rights" means the Patent Rights set forth in Exhibit 1.68.

1.69 "Licensed Reprise Know-How" means the Know-How licensed by Reprise to Serenity under the Reprise License Agreement.

1.70 "Licensed Reprise Patent Rights" means the Patent Rights set forth in Exhibit 1.70.

1.71 "Licensed Reprise Rights" means the Licensed Reprise Patent Rights and the Licensed Reprise Know-How.

1.72 "Licensed Rights" means the rights under the licenses granted by Licensor to Licensee in Sections 2.1(a),(b), and (c).

1.73 "Licensed Serenity Copyrights" means the copyrights set forth in Exhibit 1.73.

1.74 "Licensed Serenity Know-How" means the Know-How described in Exhibit 1.74.

1.75 "Licensed Serenity Patent Rights" means the Patent Rights in the issued patents and patent applications set forth in Exhibit 1.75.

1.76 "Licensed Serenity Trademarks" means the trademarks set forth in Exhibit 1.76.

1.77 "Licensee" has the meaning set forth in the Preamble.

1.78 "Licensee Change of Control Party" means Licensee or any Affiliate of Licensee to the extent Licensee or such Affiliate of Licensee, as applicable, is the subject of a Change of Control.

1.79 "Licensee Insurance Policies" has the meaning set forth in Section 11.3.

1.80 "Licensee Indemnitee(s)" means any of Licensee and its directors, officers, employees, agents, contractors and agent of Licensee and its Affiliates (including without limitation Avadel Pharmaceuticals plc).

1.81 "Licensee Inventions" means any and all Inventions with respect to the Product, Controlled by Licensee and not made, conceived, or discovered by any employees, independent contractors, or agents of Licensor or any of its Affiliates, contractors, or agents.

1.82 "Licensee's Sales and Marketing Force" means, from time to time, Licensee's sales and marketing personnel responsible for managing, coordinating and overseeing the Commercialization of the Product in the Field in the Territory.

1.83 "Licensor" has the meaning set forth in the Preamble.

1.84 "Licensor Indemnitee(s)" means any of Licensor and its directors, officers, employees, agents, contractors and agents of Licensor and its Affiliates (including, without limitation, Serenity).

1.85 "Long Term Care" or "LTC" means the provision of health care in skilled nursing and other long-term care and assisted living facilities.

1.86 "Losses" means, with respect to any Claim for which one Party as an Indemnitee hereunder seeks indemnification hereunder from the other Party as an Indemnitor hereunder, any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and reasonable attorneys' fees) of any kind payable to Third Parties (including attorneys for such Indemnitees) incurred by the Indemnitees and arising out of such Claim.

1.87 "Low Dosage" means, with respect to any product containing the Compound, that such product produces a peak blood concentration (measured as a Cmax) equal to or less than [***] per milliliter of blood plasma or serum ([***]), where "Cmax" means the maximum concentration of the Compound measured in blood plasma or serum following administration of the product and prior to a subsequent administration of the product."

1.88 "LTC Activities" means, for each combination of Product, Indication, and country in the Territory, (a) meetings (either in person or through live video conferencing), other than Details, with one or more physicians, administrators, and other medical or other professional categories identified in the Annual Commercialization Plan for the purpose of marketing and promoting such combination of Product and Indication to LTC organizations in such country and (b) activities connected with pricing, rebate and other contract-related negotiations, contracting, and processing and implementation of agreements with LTC organizations.

1.89 "Manufacture", "Manufacturing", or "Manufacturing Activities" means, as applicable, all activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, and storage of bulk and finished forms of bulk and finished forms of Products and/or any components thereof, including, without limitation, process and formulation development, process validation, stability testing, manufacturing scale-up, manufacture for preclinical and clinical studies and Commercialization, analytical development, product characterization, quality assurance and quality control development, testing and release, and any technical support activities that are necessary for Regulatory Approval and Commercialization of Products.

1.90 "Manufacturing and Supply Plan" means the plan attached as Exhibit 5.5 and relating to the manufacture by or for Licensee of quantities of the Product and subsequent supply thereof for Commercialization and Development Activities by Licensee, as such plan may be modified from time to time for the Territory.

1.91 "Marketing Authorization Application" or "MAA" means, with respect to any product and each country in the Territory, an application to the applicable Regulatory Authority for approval to commercially market and sell the product in such country. For the sake of clarity, this term (and its abbreviation) includes NDAs and sNDAs in the United States.

1.92 "New Drug Application" or "NDA" means, with respect to any product, the application referred to as such by FDA and that must be approved by FDA before such product can be commercially marketed and sold in the United States, and such term includes, without limitation, and, unless the context otherwise states to the contrary, any supplemental NDAs ("sNDAs"), each such application having the form and containing the substance specified by the FDA for such applications and supplemental applications.

1.93 "Net Sales" means, with respect to a given period of time, gross sales of the Product in such period to unrelated Third Parties in bona fide arm's length transactions, (excluding sales or dispositions for use in Clinical Studies or other scientific testing or reasonable quantities of samples, in each case for which Licensee and any such Third Party Distributors receive no revenue), less the following deductions which are actually incurred, allowed, paid, accrued or specifically allocated to such gross sales amounts of the Product and not separately invoiced:

(a) credits or allowances actually granted for damaged Product, returns or rejections of Product, price adjustments, and billing errors;

(b) governmental and other rebates (or equivalents thereof) granted to: managed health care organizations; pharmacy benefit managers (or equivalents thereof); federal, state/provincial, local and other governments, their agencies and purchasers and payors, including, without limitation, any state or federal Medicare, Medicaid or similar program); or trade customers;

(c) normal and customary trade, cash and quantity discounts, allowances and credits actually allowed and taken specifically with respect to sales of other dispositions of the Product;

(d) distribution services agreement fees allowed or paid to Third Party distributors;

(e) transportation costs, including without limitation insurance, for outbound freight related to delivery of the Product to the extent included in the gross amount invoiced;

(f) excise and sales taxes, tariffs, duties, value added taxes, and other taxes applied to the sale of the Product imposed upon and paid directly with respect to such sales or (reduced by any refunds of such taxes deducted in the calculation of Net Sales for prior periods and, for the avoidance of doubt, no deduction shall be permitted for income, withholding, corporate or similar taxes); and

(g) any other items that reduce gross sales amounts as required by GAAP.

Transfers and sales of the Product between or among a Party and its Affiliates or Third Party Distributors shall be excluded from the computation of Net Sales, but the subsequent final sales of the Product to Third Parties by such Affiliates or Third Parties shall be included in the computation of Net Sales.

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. The deductions set forth above in this definition of Net Sales shall be determined in accordance with GAAP, as consistently applied by Licensee and such Third Party Distributors across all of their products. The amounts set forth in clauses (a) through (g) above shall only be deducted from gross invoiced sales where gross invoiced sales before deductions are non-discounted gross sales amounts.

In the event Licensee or such Third Party Distributors sell the Product together with other products to Third Parties in a particular country in the Territory and the price attributable to the Product is less than the average price of "arm's length" sales of the Product alone in the particular country for the reporting period in which such sales occur (such sales to be excluded from the calculation of the average price of "arm's length" sales of the Product alone), Net Sales for any such sales shall be the average price of "arm's length" sales by Licensee or Third Party Distributors, as applicable, of the Product alone and in the country during the reporting period in which such sales occur. If the average price of "arm's length" sale of the Product cannot be determined in any given country, the Net Sales will be determined by the value of the Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities. Any dispute as to the determination of fair market value that cannot be resolved through discussion between the Parties shall be determined in accordance with Section 3.2(i). Notwithstanding the foregoing, in the event the Product is sold as a Combination Product, for purposes of determining the royalties payable by Licensee to Licensor hereunder, Net Sales shall be calculated by the Net Sales for such Combination Product in a manner to be negotiated and agreed upon by Licensor and Licensee, reasonably and in good faith, prior to any sale of such Combination Product, which shall be based upon the respective fair market values of the active pharmaceutical ingredients in such Combination Product; provided that in no event shall the royalty rate payable by Licensee to Licensor for such Combination Product be greater than the royalty rate of the Product containing the Compound as the sole active ingredient.

1.94 “Noctiva Launch” shall mean the date the Noctiva Product has been supplied, to wholesalers, retail chains and pharmacy benefit managers and is widely available for commercial sale to patients.

1.95 “Noctiva Product” shall mean .83mcg or 1.66mcg desmopressin acetate nasal spray product.

1.96 “Nocturia Indication” means an Indication characterized by urination in a human aged 18 years or older wherein, during a defined period of such human’s normal period of sleep at night, two or more non-incontinent urinary void(s) of any volume during such period of sleep, each such void following an initial period of sleep and, thereafter, followed by sleep or an attempt to sleep.

1.97 “Out-of-Pocket Costs” means the direct expenses paid or payable by Licensee to any Third Parties in respect of any Development Activities or Commercialization Activities, as applicable, performed for such Party (or its Affiliates) by such Third Party.

1.98 “Party” means Licensor or Licensee; “Parties” means Licensor and Licensee.

1.99 “Patent Rights” means, with respect to each country in the Territory (except as otherwise stated to be with respect to any country in or outside the Territory), (a) patent applications (including provisional applications) pending in such country, (b) any patents issuing in such country from such patent applications (including certificates of invention), (c) all patents and patent applications issued or pending, as applicable, in such country based on, corresponding to or claiming the priority date(s) of any of the foregoing, (d) rights in such country derived from any of (a), (b) or (c), including any substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations in part, reexaminations, renewals, revalidations, revivals, patents of addition, and (e) all patents and patent applications issued or pending, as applicable, in such country claiming overlapping priority therefrom.

1.100 “Person” means any individual, corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, or any other entity or body.

1.101 “Pharmacovigilance Agreement” means the pharmacovigilance agreement to be entered into by Parties, Third Party Distributors, and any Third Parties which such Third Parties are licensed or sublicensed to Commercialize the Product in countries outside the Territory.

1.102 “Phase 1 Clinical Study”, with respect to any investigational drug product, means a human clinical study that provides for the introduction into humans of such investigational drug product and that is intended to initially evaluate the safety, tolerance or pharmacological effects of such investigational drug product in human subjects, or that is otherwise described in 21 CFR Sec 312.21 (a) or its foreign counterpart.

1.103 "Phase 2 Clinical Study" means a human clinical study that is intended to initially evaluate the dosing and effectiveness of the Product, and to further evaluate the safety of the Product, or that is otherwise described in 21 CFR Sec. 312.21(b) or its foreign counterpart.

1.104 "Phase 3 Clinical Study" means a human clinical study that is prospectively designed to demonstrate statistically whether the Product is safe and effective to control, mitigate, prevent, treat or cure a particular Indication in a manner sufficient to obtain Regulatory Approval to market the Product, or that is otherwise described in 21 CFR Sec. 312.21(c) or its foreign counterpart.

1.105 "PNE Indication" means the Primary Nocturnal Enuresis Indication and is characterized by the occurrence of one or more incontinent urinary voids occurring during sleep in a person under the age of eighteen (18) years.

1.106 "Post-Market Approval Study" means a human clinical study in respect of the Product for a specified Indication that is conducted under the Applicable Law of any country in the Territory after Regulatory Approval of the Product for such Indication has been obtained from the applicable Regulatory Authority in that country, and includes trials conducted (a) voluntarily for the purpose of enhancing marketing or scientific knowledge of such Indication or (b) at the request or requirement of the applicable Regulatory Authority.

1.107 "Product" means any product for a specific Indication within the Field that contains the Compound in any form, presentation, formulation and dosage form, and (a) is at any time during the Term of this Agreement Covered by a Licensed Serenity Patent Right, Licensed CPEX Patent Right, or Licensed Reprise Patent Right. For purposes of this Agreement, Net Sales of any such Product so Covered by any such Patent Right at any time during the Term of this Agreement will continue to be treated, from and after the time that the Product is no longer Covered by any Valid Claim of any such Patent Right, as a Product for purposes of calculating any payments to be made to Licensor under Article 8. For the sake of clarity, the term "Product" includes the First Approved Product.

1.108 "Product Regulatory Approvals and Documentation" means all Regulatory Approvals and Regulatory Documentation in respect of the Product and each country in the Territory (including, without limitation, the First Approved NDA and any INDs in respect of the Product open as of the Effective Date).

1.109 "Promotional Materials" means any printed or other materials bearing the name (trade name or generic name) used to promote the Product in any country in the Territory, including brochures, journal ads, selling aids, posters, reprints, video or audio tapes, press releases, Internet pages and websites, radio or television advertisements and textbooks.

1.110 "Publication" means any publication in a scientific journal, any abstract to be presented to any scientific audience, any presentation at any scientific conference, any other scientific presentation and any other oral, written or electronic disclosure directed to a scientific audience which pertains to the Product or the use of the Product.

1.111 "Receiving Party" means, with respect to the receipt by a Party of any Confidential Information from the other Party, the Party so receiving such Confidential Information.

1.112 "Regulatory Approval" means, with respect to a drug product and a specified country in the Territory, the act of the applicable Regulatory Authority in such country necessary for the marketing and commercial sale of such drug product in such country (including pricing and/or reimbursement approval in such country in which such pricing and/or reimbursement approval is required by Applicable Laws), including, without limitation, the approval of an NDA for the Product by the FDA and other regulatory agencies in the Territory.

1.113 “Regulatory Authority” means, in any country in the Territory, any applicable government regulatory authority involved in the granting of Regulatory Approval for the Product in such country or regulatory jurisdiction, including the FDA in the United States and counterparts thereof in other country in the Territory.

1.114 “Regulatory Documentation” means, with respect to the Product, all INDs, NDAs (including, without limitation, sNDAs), MAAs or other regulatory applications submitted to any Regulatory Authority, preclinical and clinical data and information, regulatory materials, drug dossiers, master files (including, without limitation, Drug Master Files), and any other reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of the Product, including, without limitation, those materials necessary to Develop, Manufacture, Commercialize and otherwise Exploit the Product, including, without limitation, any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database.

1.115 “Regulatory Exclusivity” means, with respect to a country, any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority with respect to the Product in such country, other than a Patent Right.

1.116 “Regulatory Rights Assignment and Assumption Agreement” means that certain agreement of even date herewith entered into by Licensor and Licensee, relating to the assignment by Licensor to Licensee of the Product Regulatory Approvals and Documentation relating to the Commercialization and Development of Products in each country in the Territory, including, without limitation, U.S. IND 076667 and U.S. NDA 201656 (also referred to herein as the First Approved NDA), and the assumption by Licensee of all of the obligations under Applicable Law as the sponsor thereunder.

1.117 “Remedial Action” means any recall, market withdrawal, safety alert, corrective action or other regulatory action taken with respect to the Product by virtue of Applicable Laws.

1.118 “Renaissance” means Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC), a limited liability company organized under the laws of the State of Delaware.

1.119 “Renaissance Agreements” means (a) that certain Manufacturing Agreement, dated July 14, 2014, between Serenity and Renaissance, relating to the manufacture by Renaissance of Product and supply thereof to Serenity or any third party designated by Serenity and (b) that certain Quality Agreement, dated January 16, 2015, between Serenity and Renaissance, relating to compliance with current Good Manufacturing Practices guidances and directives applicable to the manufacture by Renaissance of Products.

1.120 “Renaissance Agreements Assignment and Assumption Agreement” means that certain agreement of even date herewith entered into by Licensor and Licensee, relating to the assignment by Licensor to Licensee and the assumption by Licensee of the Renaissance Agreements.

1.121 “Reprise” means Reprise Biopharmaceutics, LLC, a limited liability company organized under the laws of the State of New York.

1.122 “Reprise License Agreement” means that certain license agreement, effective as of May 28, 2017, by and between Reprise and Serenity, relating to the grant by Reprise to Serenity of an exclusive license under the patent rights and know-how specified therein.

1.123 “Right of Reference or Use” has the meaning set forth in 21 CFR Sec. 314.3(b) with respect to the United States, and any provisions equivalent thereto in the Applicable Laws of any other country in the Territory.

1.124 "Royalty Term" means, with respect to the Product and each country in the Territory, the period of time commencing on the date of First Commercial Sale by Licensee or its Sublicensees of the Product in such country and ending upon the termination of this Agreement in accordance with Article 14.

1.125 "Serenity" has the meaning set forth in the Preamble.

1.126 "Serenity Trademark Standards" means the set of policies, specifications, directions, and standards for use of the Licensed Serenity Trademarks to be prepared in accordance with Section 4.4 and to be attached hereto as Exhibit 1.124.

1.127 "Sublicensed Rights" has the meaning set forth in Section 2.2(b).

1.128 "Term" means the period commencing on Effective Date and ending upon the termination of this Agreement in accordance with Article 14.

1.129 "Territory" means the United States, Canada, and each of their respective territories and possessions.

1.130 "Third Party" means any Person other than the Parties and their Affiliates.

1.131 "Third Party Distributor" means any Third Party engaged and authorized by Licensee Party to distribute, import, market, promote and sell the Product in any country in the Territory.

1.132 "Third Party Infringement Claim" has the meaning set forth in Section 9.4(a).

1.133 "Third Party License(s)" has the meaning set forth in Section 8.3(b)(ii)(A).

1.134 "Third Party Supply Agreements" means the agreements originally executed by and between Serenity and the Third Parties named therein, relating to the manufacture and supply of certain components of the First Approved Product (including, without limitation, the applicable drug substance, ingredients for formulating the applicable drug product, and intranasal delivery device) and the manufacture and supply of the First Approved Product in finished form, including, the Renaissance Agreements and the other agreements set forth in Exhibit 1.134.

1.135 "Toll Period" has the meaning set forth in Section 14.2(b).

1.136 "TRx" shall mean total prescriptions of a product for a specified period.

1.137 "Treatment" (or, when required by the context, "Treat" or "Treats") means, with respect to an Indication, the diagnosis, prevention, palliation, amelioration, control, mitigation, treatment, cure, or prognosis of such Indication.

1.138 "Unexpected Adverse Drug Experience" has the meaning set forth in 21 CFR Section 314.80 and any regulation successor thereto.

1.139 "Valid Claim" means, with respect to a particular country in the Territory, a claim within an issued patent or patent application included in the Licensed Serenity Patent Rights, Licensed Reprise Patent Rights, or Licensed CPEX Patent Rights that has not expired, lapsed, or been abandoned, and that has not been held unenforceable, invalid, or been cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including without limitation through opposition, re-examination, reissue, or disclaimer.

2. LICENSES AND ASSIGNMENTS.

2.1 **Licenses of Patent Rights, Know-How, Trademark, and Copyrights.**

(a) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor's right, title, and/or interest in or to the Licensed Serenity Patent Rights and the Licensed Serenity Know-How, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (subject to Section 2.5, even as to Licensor) license to make, have made, use and have used, offer to sell, sell and have sold, import and have imported, and to otherwise Commercialize the Product in the Field throughout the Territory.

(b) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor's right, title, and/or interest in or to the Licensed Serenity Trademarks, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (even as to Licensor) license to use the Licensed Serenity Trademarks to Commercialize the Product in the Field throughout the Territory.

(c) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor's right, title, and/or interest in or to the Licensed Serenity Copyrights, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (even as to Licensor) license to use, copy, publish, and distribute the content that is the subject of the Licensed Serenity Copyrights for the purpose of Commercializing the Product in the Field throughout the Territory.

(d) The license in, to, and under the Licensed Patents granted in Sections 2.1(a), (b) and (c) includes, without limitation,

(i) the right to sue for past and future infringement, violation, or misappropriation of any of such Licensed and any invention claimed therein and all applications for industrial property protection hereafter filed for any such invention, including, without limitation, all applications for patents, utility models, and designs which may be filed for any such invention in any country or countries in the Territory,

(ii) the right to file such applications in such countries in the Territory,

(iii) the right to claim for such applications the priority rights derived from the corresponding patent application under the patent laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or the domestic laws of the country in which any such application is filed, as may be applicable; and

(iv) all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for any such invention in any country or countries in the Territory and all extensions, renewals and reissues thereof.

2.2 **Grant of Sublicenses to Licensee.** Subject to the terms and conditions of this Agreement, the CPEX License Agreement, and the Reprise License Agreement, Licensor hereby grants Licensee under Licensor's rights in the Licensed CPEX Patent Rights and the Licensed Reprise Rights (collectively, the "Sublicensed Rights") a transferable (subject to Section 15.2), sublicenseable (subject to the terms of Section 2.4, and each of the CPEX License Agreement and the Reprise License Agreement, as applicable), royalty-, fee-, and milestone payment-bearing, exclusive (even as to Licensor) sublicense to make, have made, use and have used, offer to sell, sell and have sold, import and have imported, and to otherwise Commercialize the Product in the Field throughout the Territory.

2.3 **Assignments.**

(a) ***Assignment of Supply Agreement.*** Simultaneously with the execution and delivery of this Agreement, the Parties will execute and deliver to each other the Renaissance Supply Agreement Assignment and Assumption Agreement.

(b) ***Assignment of Regulatory Rights.*** Simultaneously with the execution and delivery of this Agreement, the Parties will execute and deliver to each other the Regulatory Rights Assignment and Assumption Agreement.

2.4 **Sublicensing by Licensee.**

(a) Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant to Third Parties sublicenses under the license to the Licensed Rights granted to Licensee in Sections 2.1(a), (b) and (c) and the sublicense to the Sublicensed Rights granted to Licensee in Section 2.2; provided that Licensee hereby covenants that it will not grant any such sublicense unless (i) in the case of any such sublicense of the Licensed Rights or the Sublicensed Rights, Licensor has consented thereto, which such consent shall not be unreasonably withheld, conditioned or delayed, (ii) in the case of any such sublicense of the Sublicensed Rights, such sublicense complies with the terms and conditions set forth in the CPEX License Agreement or Reprise License Agreement, as applicable; and provided, further, that except for sublicenses granted in respect of Development and Commercialization of the Product in Canada, Licensee will not grant any such sublicenses during the first two (2) years immediately following the Effective Date.

(b) Licensee will be solely responsible for the performance of any sublicensee under each such sublicense agreement granted in accordance with this Section 2.4.

(c) Each such sublicense granted by Licensee in accordance with this Section 2.4 will be set forth in a sublicense agreement that includes provisions that obligate the sublicensee thereunder to abide by and be subject to all of the terms and conditions of (i) this Agreement as are applicable to Licensee as licensee hereunder and (ii) the CPEX License Agreement and the Reprise License Agreement as are applicable to Licensee as a sublicensee thereunder.

(d) Licensee will provide Licensor with a copy of each such executed sublicense agreement within ten (10) days after the execution and delivery thereof.

(e) The existence and any and all of the contents of any such executed sublicense agreement will be deemed to be Confidential Information of each Party under this Agreement (except to the existence of any obligations to disclose such sublicense agreement to the licensors under CPEX License Agreement or the Reprise License Agreement, as applicable).

(f) Each such sublicense granted by Licensee will terminate immediately upon the termination of this Agreement, unless:

(i) such sublicensee is not in material breach of its obligations thereunder,

(ii) if this Agreement was terminated for Licensee's material breach of the terms and conditions hereof, such sublicensee cures such material breach by Licensee within thirty (30) days after such termination; and

(iii) such sublicensee agrees in writing to be bound directly to (A) Licensor as licensee under the Licensed Rights and sublicensee under the Sublicensed Rights in accordance with the terms and conditions of this Agreement and (B) CPEX and Reprise in accordance with terms and conditions of the CPEX License Agreement and the Reprise License Agreement, respectively.

2.5 **Licenses Granted by Licensee to Serenity.**

(a) ***License for Development and Commercialization Activities.*** Subject to the terms and conditions of this Agreement Licensee hereby grants to Serenity and its Affiliates, under Licensee's rights in any and all intellectual property (including, without limitation, Know-How and any Patent Rights, trademarks, and copyrights) with respect to the Product that Licensee or any of its Affiliates owns or otherwise controls by license or otherwise,

(i) an exclusive (even as to Licensee), sublicenseable (subject to Section 2.5(b)), transferable (subject to Section 15.2), sublicense to Develop, Commercialize, and Manufacture outside the Territory Products for any Indications, which such sublicense (A) in the case of any such intellectual property not originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall bear royalties, fees, and/or milestone payments to be mutually agreed upon by the Parties and (B) in the case of any such intellectual property originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall not bear any royalties, fees, or milestone payments;

(ii) in the event that Licensor engages, in accordance with Section 2.6, Section 6.2, Article 14, or otherwise under the terms and conditions of this Agreement, in any Development, Commercialization, or Manufacture of Products in the Territory for any Indications, an exclusive (even as to Licensee), sublicenseable (subject to Section 2.5(b)), transferable (subject to Section 15.2), sublicense to so Develop, Commercialize in the Territory, and Manufacture such Products for such Indications, which such sublicense (A) in the case of any such intellectual property not originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall bear royalties, fees, and/or milestone payments to be mutually agreed upon by the Parties and (B) in the case of any such intellectual property originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall not bear any royalties, fees, or milestone payments; and

(iii) in the event that Licensor engages in any Development of Products in the Territory for any Indications in connection with any Development Activities contemplated by Article 6, a non-exclusive sublicense to Develop such Products for such Indications, which such sublicense shall not bear any royalties, fees, or milestone payments.

(b) ***Sublicensing by Licensor.***

(i) Subject to the terms and conditions of this Agreement, Licensor shall have the right to grant to Third Parties sublicenses under the license granted to Licensor under Section 2.5(a); provided that Licensor hereby covenants that it will not grant any such sublicense unless Licensee has provided its consent, which consent shall not be unreasonably withheld or delayed and such sublicense complies with the terms and conditions set forth in this Agreement.

(ii) Licensor shall be solely responsible for the performance of any sublicensee under each such sublicense agreement granted in accordance with this Section 2.5(b).

(iii) Each sublicense agreement granted by Licensor in accordance with this Section 2.5(b) will be set forth in a sublicense agreement that includes provisions that obligate the sublicensee thereunder to abide by and be subject to all of the terms and conditions of this Agreement as are applicable to the intellectual property so licensed by Licensee to Licensor under Section 2.5(a).

(iv) Licensor will provide Licensee with a copy of each such executed sublicense agreement within ten (10) days after the execution and delivery thereof.

(v) The existence and any and all of the contents of any such executed sublicense agreement will be deemed to be Confidential Information of each Party under this Agreement.

(vi) Each such sublicense granted by Licensor in accordance with this Section 2.5(b) shall terminate immediately upon the termination of this Agreement, unless:

(A) such sublicensee is not in material breach of its obligations thereunder,

(B) if this Agreement was terminated for Licensor's material breach of the terms and conditions hereof, such sublicensee cures such material breach by Licensor within thirty (30) days after such termination; and

(C) sublicensee agrees in writing to be bound directly to Licensee as licensee under the intellectual property sublicensed under such sublicense.

(c) Right of Reference or Use.

(i) Licensee hereby grants to Licensor a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation (for purposes of this Section 2.5(c), "Licensee Regulatory Approvals and Regulatory Documentation") relating to the Compound and any Products in respect of which Licensee is the sponsor for purposes of:

(A) Licensor's Development, Commercialization, or Manufacture of Products outside the Territory and

(B) Licensor's Development, Commercialization, or Manufacture of Products for any Indications inside the Territory in the event that Licensor engages in any such Development, Commercialization, or Manufacture of Products in the Territory for such Indications in accordance with Section 2.6, Section 6.3, and/or Article 14, or otherwise under the terms and conditions of this Agreement.

(ii) The Parties agree that prior to any exercise by Licensor of the Right of Reference or Use granted by Licensee to Licensor under Section 2.5(c)(i), the Parties will mutually agree upon the amount and timing of one or more payments by Licensor to Licensee as consideration to Licensee for the grant of such Right of Reference or Use, which such payments shall be fair and reasonable in respect of the expenditures that Licensee incurs to obtain such Regulatory Approvals and Regulatory Documents and only payable in the event that such Regulatory Approvals and/or Regulatory Documents are referenced or used by Licensor to support a Regulatory Approval of the Product that is granted by the applicable Regulatory Authority.

(iii) The Parties agree that for purposes of Section 2.5(c)(ii),

(A) [***]; and

(B) to the extent Licensor licenses or sublicenses the Commercialization of any Products pursuant to any arrangement that becomes effective following the first anniversary of the Effective Date and in respect of which the applicable Regulatory Approval has been supported at least in part by any Regulatory Approvals or Regulatory Documents of Licensee that are referenced or used as contemplated by this Section 2.5(c), payments of such consideration in respect of any Calendar Quarter will not exceed more than [***] percent ([***]%) of the consideration received by Licensor from any sublicensee of Licensor in respect of such Commercialization.

2.6 **Right of First Negotiation.** Licensee covenants and agrees that if at any time during the Royalty Term with respect to any country in the Territory, Licensee decides to seek to negotiate an agreement with any Third Party relating to the Commercialization of Generic Products in such country by such Third Party, Licensee will not enter into any such negotiations with any such Third Party before providing Licensor prior written notice thereof, whereupon Licensor will, upon written notice to Licensee within thirty (30) days after the receipt of such notice from Licensee, have the right to enter into good faith, exclusive negotiations with Licensee with respect to Licensor obtaining the right to so Commercialize in such country Generic Products, and further provided that as a condition to Licensee agreeing to grant Licensor any rights to so Commercialize any Generic Products for any Indications in any country in the Territory, Licensor must demonstrate that Licensor possesses or otherwise has access to the resources required to so Commercialize any such Generic Products and Licensor agrees not to otherwise Commercialize any Generic Products in the Territory. Notwithstanding anything to the contrary set forth herein, Licensee has the right to Develop and Commercialize Generic Products in any country in the Territory and the TRxs in respect of such Commercialization of Generic Products by Licensee will be included in TRxs of Generic Products for purposes of the definition of Royalty Term, provided that if Licensee Launches any such Generic Product prior to the Launch of a Generic Product in any country in the Territory prior to the Launch in such country of a Generic Product by a Third Party, then Licensee must obtain the written consent of Licensor prior to such Launch.

With respect to Products, Licensor from time to time may notify and demonstrate to Licensee that Licensor possesses or has access to the resources required for performing Commercialization Activities in respect of such Products in the Territory. Licensee agrees that upon demonstration that Licensor possesses or has access to such resources, Licensee will in good faith consider Licensor to perform such Commercialization Activities prior to negotiating an agreement with a Third Party related to such Commercialization Activities.

2.7 **No Implied Rights or Licenses.** No Party grants to the other Parties any rights or licenses in or to any intellectual property right or regulatory right whether by implication, estoppel, or otherwise, except to the extent expressly provided in this Agreement. Nothing in this Agreement shall in any manner limit the activities of Licensor or its Affiliates with respect to the Product outside the Territory.

3. JOINT STEERING COMMITTEE AND ALLIANCE MANAGERS.

3.1 **Generally.**

(a) ***Joint Steering Committee.*** Licensor and Licensee shall form the Joint Steering Committee. The JSC will have only such powers as are specifically delegated to it in this Agreement, and such powers shall be subject to the terms and conditions set forth in this Agreement.

(b) ***JSC Subcommittees.*** The JSC is hereby authorized to appoint one or more JSC Subcommittees to which the JSC may assign responsibility for specific matters (including, without limitation, matters arising with respect to Development, Commercialization, and Manufacturing. Each JSC Subcommittee will have only such powers as are specifically delegated to it by the JSC, and the delegation of any such powers to any JSC Subcommittee shall be subject to the terms and conditions set forth in this Agreement.

(c) ***Limitation of Power of JSC and JSC Subcommittees.*** Without limiting the generality of Sections 3(a) and 3(b), neither the JSC nor any JSC Subcommittee shall have any power to amend this Agreement or bind or incur liability on behalf of either Party without such Party's express prior written authorization.

(d) ***Compliance with JSC and JSC Subcommittee Decisions.*** Each Party will comply with the decisions of the JSC and any JSC Subcommittee to the extent such decisions arise from the JSC or such JSC Subcommittee, as applicable, carrying out its powers and responsibilities as set forth in this Agreement and not otherwise inconsistent with the terms and conditions of this Agreement. Notwithstanding the foregoing, and is expressly set forth herein, Licensee shall have the sole and absolute right and discretion to decide matters related to the Commercialization, Manufacturing, or Development of the Product.

3.2 **Membership and Governance of JSC and JSC Subcommittees.**

(a) ***Membership.***

(i) The JSC will be comprised of six (6) members who, except as otherwise provided in clause (iii) of this Section 3.2(a), are employees of the Parties (each a "JSC Member"), with three (3) JSC Members designated by Licensor and three (3) JSC Members designated by Licensee.

(ii) Each JSC Subcommittee will be comprised of the total number of members (each a "JSC Subcommittee Member") as is designated by the JSC in forming such JSC Subcommittee, with the number of JSC Subcommittee Members appointed to such JSC Subcommittee from each Party to be designated by the JSC in forming such JSC Subcommittee. In determining the number of JSC Subcommittee Members to serve on any JSC Subcommittee formed by the JSC, the JSC will provide that the number of such JSC Subcommittee Members to be designated by each Party will be reasonable with respect to the experience and expertise of the human resources of each such Party in respect of the matters for which such JSC Subcommittee is responsible.

(iii) Each of Licensor and Licensee, upon prior written notice to the other Party, may (i) replace each person such Party has designated as a JSC Member or a JSC Subcommittee Member for any reason at any time, upon prior written notice to the other Party, (ii) designate a substitute for each person such Party has designated as a JSC Member or JSC Subcommittee Member, and (iii) appoint non-employees of such Party as JSC Members and JSC Subcommittee Members only upon the prior consent and approval of the other Party.

(b) ***Decision-Making.*** While the JSC and each JSC Subcommittee will seek to decide matters under their respective consideration by consensus of all of its members, Licensee reserves the right to decide each such matter in its sole and absolute discretion.

(c) ***Meetings.*** The JSC and each JSC Subcommittee will meet as agreed upon by the JSC Members or the applicable JSC Subcommittee Members, respectively, in person or by teleconference or video-teleconference; provided that the first meeting of the JSC Committee or such JSC Subcommittee, as applicable, will be within ninety (90) days after the Effective Date.

(d) ***Observers.*** Except for matters in respect of which the JSC or any JSC Subcommittee needs to meet in executive session, the meetings of the JSC and any JSC Subcommittee may be attended by non-Member observers at the invitation of an executive officer of either Party (the "Inviting Party"), provided that (i) the Inviting Party provides reasonable prior notice of such invitation to the other Party, (ii) the other Party has consented to such invitation in advance of the applicable meeting, which such consent shall not be unreasonably withheld, delayed or conditioned and (iii) any such observer has agreed in writing to obligations to safeguard the confidentiality and restrictions on use of Confidential Information that are no less restrictive than the obligations in Section 13.2.

(e) ***Chairperson.***

(i) *Of JSC*. At the first meeting of the JSC following the Effective Date and at the first meeting of the JSC in each calendar year beginning after the Effective Date, the JSC Members will select a chairperson to serve until such person's successor has been designated in accordance herewith. The chairperson of the JSC shall rotate annually between JSC Members designated by Licensor and those designated by Licensee. The first chairperson of the JSC shall be selected from the JSC Members designated by the Licensee.

(ii) *Of Each JSC Subcommittee*. Each JSC Subcommittee shall have a chairperson appointed in accordance with the directions of the JSC in establishing such JSC Subcommittee.

(f) ***Secretary*.**

(i) *Of JSC*. The chairperson of the JSC shall designate a secretary of the JSC who will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and circulating minutes within thirty (30) days after each meeting of such committee setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JSC. Such minutes shall be effective only after being approved by both Parties. Definitive minutes of all committee meetings shall be finalized no later than sixty (60) days after the meeting to which the minutes pertain.

(ii) *Of Each JSC Subcommittee*. Each JSC Subcommittee shall have a secretary appointed in accordance with the directions of the JSC in establishing such JSC Subcommittee.

(g) ***Term of JSC and JSC Subcommittees.***

(i) The JSC shall continue to exist for the Term of this Agreement or upon its termination upon mutual agreement of the Parties.

(ii) Each JSC Subcommittee shall continue to exist for the term to be set forth by the JSC in establishing such JSC Subcommittee, but in no event for a period extending beyond the Term of this Agreement

(h) ***Alliance Managers.***

(i) Each of Licensor and Licensee shall appoint an Alliance Manager, who shall be an individual authorized to act as such Party's point of contact for communications between and among the Parties relating to the Commercialization, Manufacturing and Supply, and any Development Activities contemplated by this Agreement. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. The Alliance Manager of a Party may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

(ii) Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between and among the Parties and within the JSC and each JSC Subcommittee.

(iii) Each Alliance Manager will also: (i) be the point of first referral in all matters of conflict resolution; (ii) identify and bring disputes to the attention of the JSC or the relevant JSC Subcommittee, as applicable, in a timely manner; (iii) plan and coordinate cooperative efforts and internal and external communications; and (iv) take responsibility for ensuring that governance activities, such as the conduct of required JSC and JSC Subcommittee meetings and production of meeting minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed

(i) Dispute Resolution.

(i) In the event that any dispute arises with respect to matters falling within the scope of the role and the powers and responsibilities of the JSC or any JSC Subcommittee as set forth in or contemplated by this Article 3 or elsewhere in this Agreement, then either Licensor or Licensee or any of the Members of such Committee may notify the Alliance Managers of such disputed matter.

(ii) The Alliance Managers shall discuss in good faith any such disputed matter referred to them in accordance with Section 3.2(i)(i). If the Alliance Managers are unable to resolve any such matter, either Licensor or Licensee may refer the matter to the Chief Executive Officer or President of Licensor and the Chief Executive Officer, President, or an Executive Vice President of Licensee, which such two individuals shall meet at an agreed location or by telephone to resolve the matter within twenty (20) days after the meeting at which such matter arose.

(iii) If such two officers of the Parties are unable to resolve the disputed matter so referred to them in accordance with Section 3.2(i)(ii) within an additional thirty (30) day period, then the following procedures shall apply:

(A) in the case of matters with respect to which Licensee is authorized hereunder to decide in its sole and absolute discretion, including, without limitation, any Commercialization or Manufacturing and Supply matter, Licensee shall have final decision-making rights with respect thereto and shall promptly provide written notice to Licensor of its final position regarding such matter and Licensor will comply with the position taken by Licensee on such matter unless compliance with such position would result in the incurrence of a direct material financial expenditure or imposition of some other non-financial burdensome obligation upon Licensor that would be greater than would have been the case absent compliance with such position, which in such case shall be referred for dispute resolution under Section 15.8 and

(B) in the case of matters with respect to which Licensee is not authorized hereunder to decide such matters in its sole and absolute discretion, such matters shall be referred for dispute resolution under Section 15.8.

3.3 **Committee Oversight of Commercialization Activities.**

(a) Role. The JSC and any JSC Subcommittee established for the purpose of oversight of Commercialization Activities, will monitor, assess, and make recommendations to Licensee in respect of the Commercialization of the Product contemplated in Article 4 of this Agreement.

(b) ***Powers and Responsibilities.*** With respect to Product Commercialization Activities, the powers and responsibilities of the JSC and any JSC Subcommittee established for the purpose of oversight of such Commercialization Activities are limited to the matters set forth in this Section 3.3 and Article 4. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify, or waive compliance with this Agreement with respect to Commercialization Activities required to be undertaken by Licensee under this Agreement, including, without limitation, the Commercialization Plans for the Product and any Indications. Notwithstanding the foregoing, Licensee reserves the right to decide each such Commercialization matter in its sole and absolute discretion, including amending or modifying any Commercialization Plan.

(c) ***Annual Review of Commercialization Plan***. On an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities will review, analyze, and comment on the Annual Commercialization Plan then in effect and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(i) an assessment of whether the Commercialization Activities contemplated by the Annual Commercialization Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Commercialization Plan;

(ii) an assessment of whether the strategic objectives set forth in the Annual Commercialization Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties;

(iii) the submission to Licensee of any recommended revisions to the Annual Commercialization Plan then in effect and any revisions then proposed by Licensee or Licensor, in order to reflect the aforementioned assessments.

(d) ***Regulatory Exclusivity.*** The JSC and any JSC Subcommittee responsible for oversight of Commercialization Activities shall monitor the process of applying for and securing Regulatory Exclusivity that may be available under the applicable Law of countries in the Territory, including, without limitation, any data or market exclusivity periods such as those periods listed in the FDA's Orange Book. Each of Licensor and Licensee shall use Commercially Reasonable Efforts to cooperate with each other and to take such reasonable actions to obtain such Regulatory Exclusivity in each country in the Territory.

3.4 **Oversight of Manufacturing and Supply Activities.**

(a) ***Role.*** The JSC and any JSC Subcommittee responsible for oversight of Manufacturing and Supply Activities will monitor, assess, and make recommendations to Licensee in respect of the manufacture and supply of the Product as contemplated in Article 5 for purposes of Commercializing the Product for any Indications that are the subject of Regulatory Approvals and any Development Activities in respect of the Product for the PNE Indication, any Additional Indications and the Nocturia Indication throughout the Territory.

(b) ***Powers and Responsibilities.*** With respect to Product Manufacturing Activities, the powers and responsibilities of the JSC and any JSC Subcommittee responsible for oversight of such Manufacturing Activities are limited to the matters set forth in this Section 3.4 and Article 5. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify or waive compliance with this Agreement with respect to Manufacturing Activities required to be undertaken by Licensee under this Agreement, including, without limitation, the Manufacturing and Supply Plan for the Product. Notwithstanding the foregoing, Licensee reserves the right to decide each such manufacturing and supply matter in its sole and absolute discretion, including amending or modifying any Manufacturing and Supply Plan.

(c) ***Annual Review of Manufacturing and Supply Plan.*** On an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC or any JSC Subcommittee responsible for oversight of Manufacturing Activities will review, analyze, and comment on the Manufacturing and Supply Plan then in effect, and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(i) an assessment of whether the Manufacturing Activities contemplated by the Manufacturing and Supply Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Manufacturing and Supply Plan; and

(ii) an assessment of whether the strategic objectives set forth in the Manufacturing and Supply Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties.

3.5 **Oversight of Development Activities.**

(a) ***Role.*** The JSC and any JSC Subcommittee responsible for oversight of any Development Activities contemplated in Article 6 of this Agreement will monitor such Development Activities. In this role the JSC or such JSC Subcommittee, as applicable, will (i) assist Licensee in overseeing any Development of, Clinical Studies for, and preparation and submission of Regulatory Documentation for obtaining Regulatory Approval of the Product contemplated by any Development Plan, including, without limitation, review of any relevant Regulatory Documents and Regulatory Documentation and (ii) provide a forum for sharing advice, progress, and results and documents, including, without limitation, relevant Clinical Study designs, protocols, study reports, and any other material information with respect to any such Development Activities.

(b) ***Powers and Responsibilities.*** With respect to any Product Development Activities, the powers and responsibilities of the JSC and any JSC Subcommittee responsible for oversight of such Development Activities are limited to the matters set forth in this Section 3.5 and Article 6. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify or waive compliance with this Agreement with respect to Development Activities, including, without limitation, any Development Plan in effect from time to time. Notwithstanding the foregoing, Licensee reserves the right to decide each such Development matter in its sole and absolute discretion, including amending or modifying any Development Plan.

(c) ***Annual Review of Development Plan.*** If Licensee determines to engage in any Product Development Activities in accordance with Article 6, on an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC and any JSC Committee responsible for oversight of Development Activities that Licensee may so determine to undertake in accordance with Article 6 will review, analyze, and comment on the Development Plan then in effect, and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(A) an assessment of whether the Development Activities contemplated by the Development Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Development Plan;

(B) an assessment of whether the strategic objectives set forth in the Development Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties;

(C) the submission to Licensee of any recommended revisions to the Development Plan then in effect and any revisions then proposed by Licensee or Licensor, in order to reflect the aforementioned assessments.

4. COMMERCIALIZATION.

4.1 **Preparation and Scope of Commercialization Plan.**

(a) ***Preparation.*** Licensee agrees to prepare and provide to Licensor within one hundred twenty (120) days immediately following the Effective Date the initial Commercialization Plan.

(b) ***Scope.*** The Commercialization Plan for the Product in respect of the Nocturia Indication, PNE Indication and any Additional Indication will consist of a Pre-Launch Commercialization Plan, an Annual Commercialization Plan, and, in respect of the initial three-year period following the Effective Date, the three-year Commercialization Plan described below.

4.2 **Timing of Product Launches.** The initial Commercialization Plan will set forth the timing of the Launch of the Product in the United States for the Nocturia Indication. To the extent, Licensee or any sublicensee intends in accordance with Article 6 to engage in any Development Activities in order to (a) Commercialize the Product for the Nocturia Indication in Canada, the Commercialization Plan then in effect will be amended to include such Commercialization at such time and (b) Commercialize any Product for the PNE Indication and any Additional Indication in either country in the Territory, the Commercialization Plan then in effect will be amended to include such Commercialization at such time.

4.3 **Diligent Commercialization of the Product in the Territory.**

(a) Licensee covenants that at all times during the Term of this Agreement it will use Commercially Reasonable Efforts to Commercialize the Product in each country in the Territory, including, without limitation, the making and implementation of decisions and allocation of Licensee's resources for the purpose of achieving the objectives set forth in the Commercialization Plan, which such objectives will include, without limitation, the placement of the Product in First Position in all Detailing of the Product with the Sales Representatives for the Product for the First Position Period achieving the timing and geographic extent of Detailing of the Product set forth in the Commercialization Plan, and the continued optimization of such Detailing to maximize Net Sales of the Product. Failure by Licensee to use Commercially Reasonable Efforts to Commercialize the Product will be deemed to be a material breach of this Agreement for purposes of Section 14.3.

(b) The term "First Position Period" means the four (4) year period commencing upon the Launch of the Product in the United States; *provided, however*, that if Licensee has not been the subject of a Change of Control prior to the end of such four-year period, the First Position Period shall be extended to the earlier of (x) the fifth (5^{th}) anniversary of the commencement thereof and (y) any such Change of Control; and *further, provided, however,* that if any such Change of Control occurs prior to the fourth (4^{th}) anniversary of the commencement of the First Position Period, then the party surviving such Change of Control will be obligated to continue Detailing of the Product in First Position until such fourth (4^{th}) anniversary and Licensee will use Commercially Reasonable Efforts to obtain the agreement of the party surviving such Change of Control to continue Detailing of the Product in First Position until the fifth (5^{th}) anniversary of the commencement of the First Position Period, and if such Change of Control occurs after the fourth (4^{th}) anniversary of such commencement of the First Position Period but before the fifth (5^{th}) such anniversary, then Licensee will use Commercially Reasonable Efforts to obtain the agreement of the party surviving such Change of Control to continue Detailing of the Product in First Position until such fifth (5^{th}) anniversary.

4.4 **Commercialization Plan and Budgets, Generally.**

(a) ***In General.*** Subject to the terms of this Agreement, the preparation of the Commercial Plan and any and all updates, revisions, amendments, and the like thereof will be the responsibility of Licensee, and Licensee will bear the expense of the preparation of the initial Commercial Plan and any and all updates, revisions, amendments and the like thereof. The Commercialization Plan for the Product for each Indication for which Regulatory Approval is obtained in each country in the Territory will include the following:

(i) prior to the Launch of a Product, a detailed Pre-Launch Commercialization Plan covering the period from the date such pre-Launch Commercialization Plan as approved by the JSC or the JSC Subcommittee responsible for oversight of Commercialization and adopted by Licensee (generally, upon commencement of the first Phase 3 Clinical Studies in respect of such combination through the end of the second (2^{nd}) full Calendar Year following Launch of the Product for such Indication in such country (the "Pre-Launch Commercialization Plan"), provided that the Pre-Launch Commercialization Plan for the Product for the Nocturia Indication for the United States is set forth in the Commercialization Plan in Exhibit 4.4 to be attached hereto following its preparation and adoption in accordance with the provisions of this Agreement);

(ii) an annual Commercialization plan and budget for such Product (the "Annual Commercialization Plan") for each full Calendar Year following the end of the period of time covered in the Pre-Launch Commercialization Plan for such Product, each of which such annual Commercialization Plans shall be reviewed and analyzed by the JSC (or the JSC Subcommittee responsible for oversight of Commercialization) in accordance with Section 3.3(c)(ii);

(iii) a three-year Commercialization plan and budget (the "Long-Term Commercialization Plan") that sets forth the Branding Strategy for the Product for the initial three year period, the anticipated Commercialization programs and funding requirements for the Commercialization of the Product for such combination during such three-year period, and anticipated gross sales and Net Sales of the Product during each quarter in such three-year period, and which such Long-Term Commercialization Plan will be used to guide the formulation of the applicable Pre-Launch Commercialization Plan and the Annual Commercialization Plan for such Product.

(b) ***Content of Commercialization Plan, More Specifically.*** The Commercialization Plan will specify in detail the content of the Commercialization Activities contemplated hereby.

(c) ***Preparation of Serenity Trademark Standards.*** As part of the preparation of the initial Commercialization Plan, Licensee will prepare a proposed set of Serenity Trademark Standards for review and approval by the JSC (or the JSC Subcommittee responsible for Commercialization matters) in accordance with Section 3.3(b).

4.5 **Annual Commercialization and Pre-Launch Commercialization Plans.**

(a) ***Interim Updating Annual Commercialization Plan***. Each Annual Commercialization Plan shall be updated by Licensee as frequently as needed during a Calendar Year to take into account developments in the Commercialization of the Product for the applicable Indication and country.

(b) ***Pricing and Reimbursement Approvals.***

(i) Where pricing and reimbursement approvals are required for Commercialization of the Product in any country in the Territory, Licensee, will be responsible for obtaining such approvals in a timely manner, and shall consider in good faith any suggestions and comments from or on behalf of Licensor with respect thereto.

(ii) As part of its responsibility for oversight of Commercialization Activities, the JSC and any JSC Subcommittee responsible for oversight of Commercialization Activities shall review and comment on matters relating to pricing and reimbursement approvals in respect of the Product. Such review shall include review of any materials, presentations, documents, agendas, and other relevant information to be presented or followed in meetings and communications with Regulatory Authorities and third party payors to the extent the timing of such meetings and communications reasonably allows for such review and the outcome of any such meetings.

(iii) Following any meetings or material communications with Regulatory Authorities and third party payors relating to pricing and reimbursement approvals, Licensee will provide to the members of the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities, copies of any materials, presentations, documents, agendas, and other relevant information to be presented or followed at such meetings, to the extent not previously provided to the members of the JSC or such JSC Subcommittee pursuant to clause (ii) of this Section 4.5(b), and a summary of the outcome of such meetings.

4.6 **Sales Training.**

As specified in the Commercialization Plan and in accordance with dates specified therein, Licensee, at its expense, will develop a sales training plan and sales training materials for the Product for the Nocturia Indication in the United States and, if Licensee determines to Develop, directly or indirectly through a sublicensee, the Product for the Nocturia Indication in Canada, a sales training plan and sales training materials therefor. The JSC or the JSC Subcommittee responsible for oversight of Commercialization Activities, as applicable, will review such training materials and make recommendations for any revisions and updates thereto as the JSC or such JSC Subcommittee, as applicable, may deem appropriate. Thereafter, Licensee, at its expense, will train its Sales Representatives in accordance with such sales training plan and sales training materials in sufficient time to ensure that the Sales Representatives are fully trained prior to the date specified in the Commercialization Plan for the Launch of the Product for the Nocturia Indication in the United States and, if applicable, Canada.

4.7 **Advertising and Promotional Materials and Promotional Policies**.

(a) Tools, Materials, and Samples.

(i) Licensee, at its expense, and in accordance with the Commercialization Plan, will develop all advertising and promotional tools and materials relating to the Commercialization of the Product in the Territory.

(ii) The JSC or the JSC Subcommittee responsible for oversight of Commercialization Activities shall monitor Licensee's use of such tools and materials.

(b) Use of Promotional Materials by Sales Representatives. Licensee agrees that:

(i) it will instruct its Sales Representatives to use, and will use Commercially Reasonable Efforts to train and monitor its Sales Representatives to ensure that such Sales Representatives use, only promotional materials, the Product Samples, and literature approved for use under this Section 4.6 for the promotion of the Product in the Territory;

(ii) any promotional material, promotional literature, and the Product Samples supplied to it shall not be misbranded, changed, altered or adulterated by it or any of its agents in any way prior to their distribution or use by such Party or its Sales Representatives; and

(iii) it will instruct its Sales Representatives to do, and will use Commercially Reasonable Efforts to train its Sales Representatives to do, and will establish appropriate internal systems, policies and procedures for the monitoring of its Sales Representatives with the goal of ensuring that such personnel do, the following:

(A) limit claims of efficacy and safety for the Product to those that are (1) consistent with approved promotional claims in, and not add, delete or modify claims of efficacy and safety in the promotion of the Product in any respect from those claims of efficacy and safety that are contained in, the then effective Pre-Launch Commercialization Plan and Annual Commercialization Plans and Budgets, (2) consistent with Applicable Law, and (C) consistent with the Product labeling approved by the FDA and other Regulatory Authorities;

(B) (1) refrain from making any changes in promotional materials and literature provided in accordance with this Section 4.6, and (2) use promotional materials, literature, and Samples within the Territory only in a manner that is consistent with (I) the then effective Pre-Launch Commercialization Plan and Annual Commercialization Plans and Budgets, (II) applicable Law and (III) the Product labeling approved by the FDA or other applicable Regulatory Authorities; (3) promote the Product in compliance with applicable legal and professional standards that are generally accepted by the pharmaceutical industry in the applicable market, such as the FDA Guidance for Industry-Supported Scientific and Educational Activities; the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals; the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers; the Accreditation Council for Continuing Medical Education Standards for Commercial Support of Continuing Medical Education; the American Medical Association Gifts to Physicians From Industry Guidelines; the Pharmaceutical Marketing Research Group Guidelines on market research activities; the Prescription Drug Marketing Act of 1987, as amended, and the rules, regulations and guidelines promulgated thereunder; federal, state and local agencies and all "fraud and abuse", and consumer protection and false claims statutes and regulations, including the Medicare and State Health Programs Anti- Kickback Law (42 USC Sec 1320a-7b(b)) and the "Safe Harbor Regulations" which are found at 42 CFR Sec 1001_952 et seq.; the U.S. Foreign Corrupt Practices Act (and foreign equivalents); the U.S. Physician Payments Sunshine Act of 2010; and, to the extent not inconsistent with the foregoing, such Party's policies communicated in writing to its Sales Representatives in accordance with this Article 4; and (4) not to, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any government, or of any agency or instrumentality of any government, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or improper use of the Product.

(c) ***Detailing.***

(i) Licensee will use Commercially Reasonable Efforts to Detail the Product in accordance with the Commercialization Plan.

(ii) All written, electronic and visual communications provided by Licensee to its Sales Representatives Detailing the Product regarding Product strategy, positioning, Regulatory Approval, or selling messages for use by such personnel in Detailing the Product will be subject to being monitored by the JSC or the JSC Subcommittee responsible for oversight of Commercialization.

(d) ***Medical Education Activities.*** Funding for Medical Education Activities for the Product in the Territory will be set forth in the applicable Annual Commercialization Plan.

(e) ***Direct-to-Consumer Advertising.*** In each country in the Territory, Licensee will observe any and all Applicable Law relating to direct-to-consumer advertising for the Product in such country.

(f) ***Obligations in Respect of Product Samples.***

(i) Licensee will: (i) maintain an investigation, corrective and preventive action program for the handling of Product Samples in accordance with its internal policies and procedures; (ii) maintain monitoring and auditing programs capable of detecting losses, potential diversion and falsification of records related to Product Samples; (iii) implement processes for the inventory, distribution reconciliation and storage of Product Samples; (iv) review with the JSC its practices with respect to its contacts and communications with Regulatory Authorities with respect to matters relating to the Product Samples; and (v) administer the Product Samples program described in any applicable Annual Commercialization Plan in accordance with such standard operating procedures for product sampling that comply with “best practices” in the pharmaceutical industry.

(ii) Licensee will be responsible for compliance with Applicable Law with respect to its Product Samples program.

4.8 **Sales and Distribution.** Licensee will be responsible for warehousing and distributing in the Territory the Product and will perform related distribution activities. Licensee will also be solely responsible for handling all returns, recalls (in accordance with Section 4.11), order processing, invoicing and collection, distribution and inventory and receivables.

4.9 **Sales Representatives**.

The following provisions shall apply to each Party's Sales Representatives in the Territory:

(a) Licensee will use Commercially Reasonable Efforts to ensure that it has the appropriate number of Sales Representatives and managers to Commercialize the Product.

(b) Except as otherwise provided in this Article 4, Licensee's Sales Representatives will be full-time employees of Licensee or its Affiliates or an individual acting as an independent contractor as permitted below.

(c) Licensee may engage individuals as independent contractors to provide the Details to be provided by it in a country in the Territory and may use such independent contractors as Sales Representatives for the Product in a country in the Territory. Licensee will inform the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities of the extent to which Licensee engages such independent contractors for purposes of Detailing.

(d) Licensee will be responsible for the compliance by its independent contractors engaged pursuant to this section with applicable terms and conditions of this Agreement and shall be jointly and severally liable with any independent contractors who serve as Licensee's Sales Representatives for any breach of this Agreement or failure by independent contractors to perform such delegated duties (as well as for any breach by such independent contractors of its agreement with Licensee), and shall use Commercially Reasonable Efforts to cause such independent contractor to perform his, her or its services as a Sales Representative in compliance with the provisions of this Agreement. All compensation, reimbursement of costs and other payments to be made to any of such independent contractors shall be solely a matter between Licensee and such independent contractor.

(e) Licensee may from time to time use part-time employee Sales Representatives to sell the Product on behalf of Licensee in a country to the extent that such use is consistent with Licensee's practice in such country with respect to the majority of its other pharmaceutical products.

(f) Licensee will use Commercially Reasonable Efforts to provide full training (both general and Product-specific training) to its Sales Representatives, to deploy such number of Sales Representatives as may be necessary to fulfill its duties to Commercialize the Product and, consistent with its normal business practices, to minimize turnover of its Sales Representatives Detailing the Product and to cause its Sales Representatives to adhere to the sales call plan included in the Annual Commercialization Plan. Licensee will establish reasonable qualifications and experience levels (measured in years of experience selling or promoting ethical pharmaceutical products to health care professionals with actual prescribing authority) for Sales Representatives, and Licensee will use Commercially Reasonable Efforts to provide Sales Representatives that meet such qualifications and experience levels. Unless the JSC establishes a different time, within forty-five (45) days after the end of each Year, Licensee will provide Licensor and the JSC with a report with respect to the number of its Sales Representatives assigned to the promotion of the Product and the length of time each such Sales Representative has been assigned to the promotion of the Product to the extent not previously provided to the JSC.

(g) In the event that information comes to Licensor's attention that provides it a reasonable basis to believe that Licensee's Sales Representatives may have (i) violated any Applicable Law, or (ii) failed to provide satisfactory service or to comply with this Agreement, Licensor will have the right to request that Licensee immediately assess the performance of such individual, and to exercise any other rights or remedies available to Licensor under this Agreement, at law or in equity. Licensee will promptly use Commercially Reasonable Efforts to evaluate and resolve such issue in accordance with its policies or as it may otherwise deem appropriate, will (to the extent permitted by Applicable Law) keep Licensor informed of the progress of, and information learned during, its evaluation, and within fifteen (15) Business Days after Licensor first brought such information to Licensee's attention will provide Licensor, to the extent possible in compliance with Applicable Law, with a reasonably detailed written report summarizing any steps taken toward resolution of the matter.

(h) Licensee will comply with all Applicable Laws, rules and regulations applicable to the hiring, employment, and discharge of its Sales Representatives and its employees involved in marketing and promoting the Product. Licensee represents to Licensor that Licensee is an equal opportunity employer and does not discriminate against any person because of race, color, creed, age, sex, or national origin.

(i) Licensee will be responsible for any failure of its Sales Representatives or employees to comply with the terms of this Agreement.

(j) Licensee will be solely responsible and liable for all probationary and termination actions taken by it with respect to its Sales Representatives, as well as for the formulation, content, and for the dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its Sales Representatives.

(k) Licensee shall in its sole discretion have the right to determine the configuration of its sales force(s) including, the geographical assignments of its Sales Representatives.

4.10 **Incentive Plans for Sales Representatives**. Licensee, in its sole discretion, will establish and implement a target bonus or sales incentive program whereunder Licensee's Sales Representatives are compensated for their efforts with respect to the Product in a manner consistent with such Party's other programs for similar products (and taking into consideration the commercial life cycle of the Product). All such programs shall be in compliance with all Applicable Law.

4.11 **Product Claims**. Licensee will not, and will cause each of its Sublicensees, contractors, and other agents not to, make any medical or promotional claim for the Product beyond the scope of the relevant Regulatory Approvals then in effect for the Product; provided, that Licensee may, subject to Section 13.7, distribute any information concerning the Product or its use, including scientific articles, reference publications and healthcare economic information, in accordance with Applicable Law**.**

4.12 **Recalls and Withdrawals.**

(a) Following consultation between Licensee and Licensor (or its designee), Licensee shall have final decision-making authority with respect to any recall or withdrawal of the Product from any market.

(b) The costs of any such recall or withdrawal will be borne by Licensee.

(c) In the event of any recall or withdrawal, Licensee shall implement any necessary action, with assistance from Licensor as reasonably requested by Licensee.

5. MANUFACTURE AND SUPPLY OF PRODUCTS.

5.1 **Manufacture and Supply of the Product, Generally.** Licensee will be responsible for the manufacture and supply of the Product for Commercialization and any Development.

5.2 **Scope of Manufacturing and Supply Plan.** In accordance with Article 5, the Manufacturing and Supply Plan for the Product in respect of the Nocturia Indication, the PNE Indication and any Additional Indication will address manufacturing and supply requirements for both the Commercialization Activities and any Development Activities contemplated by this Agreement.

5.3 **Existing Inventory.** Upon request of the Licensee, Licensor agrees to sell to Licensee at Licensor's cost, any and all inventory of Product, both in bulk drug and finished product form, existing as of the Effective Date. Licensee will make payment for any such inventory of Product requested by Licensee in two equal installments each at the time Licensee makes it first and second royalty payments to Licensee, respectively, in accordance with Article 8.

5.4 **Manufacturing for Licensor.** Licensee agrees that following any written request from Licensor during or after the Term of this Agreement, Licensee will within sixty (60) days after the date of such request, will use Commercially Reasonable Efforts to enter into an agreement with Licensor (which shall be transferable and sublicensable by Licensor to the same extent as contemplated in Section 2.5 in respect of sublicenses granted under this Agreement by Licensee to Licensor) containing fair and reasonable terms and conditions to be negotiated by Licensor and Licensee pursuant to which Licensee will designate under each of the Third Party Supply Agreements (and any successor agreements thereto and additional agreements entered into by Licensee relating to the manufacture and supply of Products and any components thereof) Licensor (and any transferee, sublicensee, or subcontractor of Licensor) as a party for which the applicable Third Party under such Third Party Supply Agreement (and any such successor agreements and any such additional agreements) will manufacture and supply Products thereunder on terms and conditions no less favorable to Licensor as those applicable to Licensee under such Third Party Supply Agreement (and any such successor agreements and any such additional agreements), subject to the agreement of such Third Party. Licensor acknowledges and agrees that any use of such Product so manufactured and supplied will only be used by Licensor for purposes not in conflict with Licensee's rights under this Agreement. With respect to any such additional agreements entered into by Licensee relating to the manufacture and supply of Products and any components thereof, Licensee will use Commercially Reasonable Efforts to cause to be included in such additional agreements provisions that so allow Licensee to so designate Licensor (and any transferee, sublicensee, or subcontractor of Licensor) to so obtain Products and any components thereof in accordance with this Section 5.3.

5.5 **Manufacturing and Supply Plan.** The Manufacturing and Supply Plan for the First Approved Product will be set forth in Exhibit 5.5 to be attached to this Agreement. The JSC or any JSC Subcommittee responsible for reviewing, assessing, and revising this Plan in accordance with Section 3.4(c), including, without limitation, such revision as are necessary to address Development and Commercialization of Products for the Nocturia Indication in Canada, the PNE Indication and any Additional Indications in the United States and/or Canada.

6. DEVELOPMENT ACTIVITIES BY LICENSEE.

6.1 **Determination by Licensee to Engage in Development Activities.**

(a) Within one hundred eighty (180) days immediately following the Effective Date, Licensee will provide written notice to Licensor of Licensee's decision to undertake Development of the Product for the Nocturia Indication in Canada and the PNE Indication in the United States and/or Canada. For any such Indication and country in respect of which Licensee timely provides such notice of its decision to undertake Development of the Product, Licensor and Licensee hereby agree to engage in good faith negotiations in respect of the consideration to be received by Licensor from Licensee from the Commercialization of the Product for the Indication and the country for which Regulatory Approval is obtained as a result of such Development, including, without limitation, consideration in the form of licensing fees, development and commercialization milestone payments, and royalties. Upon mutual agreement of the Parties, such time period which Licensee must provide its written notice of its decision pursuant to this Section 6.1 may be extended.

(b) As part of the process by which Licensee determines whether to engage in Development of the Product for the Nocturia Indication in Canada and the PNE Indication and any Additional Indications in the United States and/or Canada, the Parties will engage in good faith discussions as to Development Activities that Licensor can undertake to support and collaborate with Licensee with respect to Licensee's undertaking of such Development.

6.2 **Development Plan.** In respect of any Development of the Product specified in Section 6.1 that Licensee decides to undertake in accordance with Section 6.1, Licensee shall include with the notice specified in Section 6.1 a copy of the initial Development Plan in respect of such Development, which such Development Plan will describe the Development Activities necessary or advisable to obtain Regulatory Approvals of the Product for the Nocturia Indication in Canada and/or the PNE Indication and in the United States and/or Canada, as the case may be.

6.3 **Licensor's Rights to Develop and Commercialize.** For the PNE Indication in either country in the Territory and the Nocturia Indication in Canada in respect of which Licensee does not decide in accordance with Section 6.1 to undertake Development, Licensor has the right, as contemplated by Section 2.5(c), to engage in such Development and the Commercialization of the Product for such Indication and country for which Regulatory Approval is obtained as a result of such Development. To the extent that Licensor engages in any such Development Activities and Commercialization Activities under this Section 6.3, Licensor will keep Licensee informed thereof. To the extent that Licensee believes in good faith that such Commercialization Activities by Licensor would compete with the Commercialization of the Product by Licensee contemplated by this Agreement, the Parties will discuss such matter in good faith and seek to agree upon such measures as are reasonable to minimize any adverse impact of such Commercialization Activities by Licensor on such Commercialization of the Product in the Territory by Licensee.

7. REGULATORY MATTERS.

7.1 **Ownership of Product Regulatory Approvals and Documentation.** Licensee shall own all Product Regulatory Approvals and Documentation in respect of each country in the Territory.

7.2 **Conduct and Management of Regulatory Activities.** Licensee will use its Commercially Reasonable Efforts:

(a) to maintain the First Approved NDA in the United States;

(b) to obtain Regulatory Approval for the Product for the Nocturia Indication in each other country in the Territory in accordance with the Development Plan;

and

(c) to obtain Regulatory Approval for the Product for the PNE Indication in each country in the Territory in accordance with the Development Plan.

Any breach by Licensee of its obligations under Section 7.2(a) shall be deemed to be a material breach of this Agreement for purposes of Article 14.

7.3 **Transfer to Licensee of Product Regulatory Approvals and Documentation.** Following the transfer to Licensee of ownership of the Product Regulatory Approvals and Documentation in each such country in the Territory pursuant to Section 2.3(b),

(a) Licensee or its designee shall be the owner of any and all Product Regulatory Approvals and Documentation in each such country in the Territory, subject to the Right of Reference or Use hereby granted by Licensee to Licensor in Section 2.5(c) for purposes of Development and Commercialization of Products outside the Territory;

(b) Except for the Development and Commercialization of Products by Licensor in the Territory pursuant to Section 6.3, Licensee shall have the responsibility, at its expense, for all regulatory activities (including, without limitation, Development Activities undertaken to support obtaining or maintaining Regulatory Approvals) and interactions relating to the Product in each country in the Territory, including without limitation preparing, obtaining, and maintaining Regulatory Approvals in each country in the Territory and all substantive interactions with such Regulatory Authorities relating thereto; and

(c) Licensee shall determine, in its sole discretion, the content of all such submissions and of all correspondence with Regulatory Authorities relating to the Product in the Territory.

(d) To the extent Licensor has not undertaken any Product Development Activities in the Territory under Section 2.5(c), Section 2.6, Section 6.1 and/or Article 14, Licensor hereby grants to Licensee a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation in respect of the Compound and any Products in respect of which Licensor is the sponsor for purposes of Licensee's Development and Commercialization of Products in the Field and in the Territory. In consideration of such grant, Licensee will make one or more payments to Licensor determined in accordance with the same provisions set forth in clauses (ii) and (iii) in Section 2.5(c) in respect of Licensee's grant of the Right of Reference or Use set forth in clause (i) of Section 2.5(c).

7.4 **Regulatory Documentation for Generic Products.**

(a) Each Party shall deliver written notice to the other Party of any notice it receives as to the submission, filing, or approval of an application, including, without limitation, an Abbreviated New Drug Application in the United States or the equivalent thereof in any other country in the Territory, in respect of a Generic Product within three (3) days after receipt or such notice thereof.

(b) Licensee shall have the sole right to respond to each such application, provided that Licensee shall consult with Licensor regarding any such application and the response thereto.

7.5 **Audits.** Licensor will have the continuing right during the Term of this Agreement, upon reasonable prior written notice to Licensee, to inspect, audit, and investigate any facilities, equipment, record-keeping procedures, and records utilized by Licensee and its subcontractors in connection with the Manufacture and Commercialization of the Product and any Development (including, without limitation, the conduct of Clinical Studies) of the Product.

7.6 **Regulatory Authority Communications Received by a Party.**

(a) Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection, or communication by or from any Person, including, without limitation, any Regulatory Authority in any country in the Territory, that may affect the safety or efficacy claims of the Product, have a material adverse effect on the Commercialization of the Product, or that otherwise suggests the Product may be in violation of Applicable Laws in such country.

(b) Upon receipt of such information described in Section 7.7(a), the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for Licensee to take at Licensee's expense.

(c) Each Party shall keep the other Party informed, in a timely manner consistent with the reporting requirements of Regulatory Authorities, of notification of any action by any Regulatory Authority, or notification or other information that the Party receives (directly or indirectly) from any such Regulatory Authority, and provide to such other Party copies of all documents, if any, it received from such Regulatory Authority.

(d) Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to in this Section 7.7.

7.7 **Adverse Event Reporting and Safety Data Exchange.**

(a) Licensee shall be responsible, at Licensee's expense, in each country in the Territory for the monitoring of all clinical experiences, post-marketing experiences, and filing of all required reports with respect to the Product.

(b) Licensor shall transfer to Licensee the patient database, including without limitation the databases, in their entirety, containing pharmacokinetic, pharmacodynamic, efficacy, and safety information, developed in connection with the conduct of Clinical Studies for the Product under U.S. IND 076667, and all information relating thereto, in the format requested by Licensee. Licensor shall have the right to retain a copy of any and all such information transferred to Licensee.

(c) Each Party shall (i) notify the other Party immediately, but in no event later than three (3) Business Days, after becoming aware of any information concerning any complaint involving the possible failure of Product to meet any requirement of Applicable Laws, and any Unexpected Adverse Drug Experience or other serious or unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidents associated with the distribution or use of the Product and (ii) with respect to adverse events, comply with the provisions of this Section 7.7, and the applicable agreements described herein. Specific details regarding the exchange and management of information relating to adverse events related to the use of the Product shall be delineated and product labeling personnel of each Party shall work in good faith together during such time to negotiate an agreement that:

(i) identifies which safety information shall be exchanged, which shall include without limitation all adverse events for any Indication or condition;

(ii) identifies when such information shall be exchanged (which SAE information shall be provided within two (2) Business Days after notification of such SAE);

(iii) provides that Licensee shall (i) have regulatory reporting responsibilities, (ii) manage the global safety database, (iii) be obligated to obtain follow-up information on incomplete safety reports, (iv) review the literature for safety report information, and (v) prepare required periodic safety updates;

(iv) sets forth the roles and responsibilities of the Parties related to review and approval of safety information for inclusion in the Product labeling; provided that Licensee shall have the final decision-making authority with respect to any disputes regarding such activities with respect to Product in accordance with the terms and conditions hereof;

(v) identifies any other details required to appropriately manage safety information for the Product; and

(vi) as soon as reasonably practicable following the Effective Date, but in no event later than sixty (60) days thereafter Licensor and Licensee will agree upon the terms and conditions of the Pharmacovigilance Agreement and will thereupon execute and deliver to the other Party a copy of such Agreement.

7.8 **Remedial Actions.**

(a) Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Product in the Field may be subject to a Remedial Action.

(b) The Parties will assist each other in gathering and evaluating such information as is required to determine the necessity of conducting a Remedial Action with respect to the Product in the Field in the Territory; *provided, however,* that Licensee shall have sole responsibility for collecting information from its customers in the Territory, including, without limitation, customer complaints, in accordance with the terms and conditions hereof.

(c) Each Party will maintain adequate records to permit the Parties to trace the manufacture of the Product in the Field and the distribution and use of the Product in the Field. In the event Licensee determines that any Remedial Action with respect to the Product in the Field in the Territory should be commenced or Remedial Action is required by any Governmental Authority having jurisdiction over the matter, Licensee will control and coordinate all efforts necessary to conduct such Remedial Action, provided that Licensee shall consult with Licensor or its designee regarding any such Remedial Action.

(d) The cost and expense of a Remedial Action (including the Parties' reasonable costs and expenses in conducting such Remedial Action, but excluding claims described in Article 10) shall be allocated as follows:

(i) If such Remedial Action is due to Licensee's gross negligence or willful misconduct, material breach of this Agreement, or material violation of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensee;

(ii) if and to the extent that such Remedial Action is due to Licensor's gross negligence or willful misconduct, Licensor's material breach of this Agreement, or Licensor's material breach of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensor; and

(iii) if and to the extent that such Remedial Action is due to reasons other than as set forth in Sections 7.8(d)(i) and (ii), then: (A) Licensor shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensor, as Licensor's predecessor in interest; and (B) except for the Development and Commercialization of Product in the Territory by Licensor pursuant to Section 6.3, Licensee shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensee and its contractors; *provided, however,* that nothing in this Section 7.8(d)(iii) is intended to limit or supersede any obligation that Renaissance may have in respect of any such lots of the Product subject to such Remedial Action.

8. PAYMENT OBLIGATIONS.

8.1 **Initial Fee.** In consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall pay to Licensor a one-time, nonrefundable, non-creditable initial fee of Fifty Million Dollars ($50,000,000) on the Effective Date.

8.2 **Milestone Payments.**

(a) ***Launch Milestone Payment.*** Licensee shall notify Licensor promptly of the date of the Noctiva Launch, but in no event later than twenty (20) days thereafter. In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall pay to Licensor a one-time, nonrefundable, non-creditable payment of Twenty Million Dollars ($20,000,000) in respect of such Noctiva Launch on the earlier to occur of: (i) the thirtieth (30^{th}) day immediately following the date of the Noctiva Launch and (ii) June 30, 2018. Such payment shall not require Licensor to provide any invoice in respect thereof.

(b) ***Tier One Commercialization Milestone Payments.*** Licensee shall notify Licensor promptly, but in no event later than thirty (30) days, after the first achievement of the relevant sales milestone for the Product as set forth in the table below in this Section 8.2(b). In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall make the following one-time, nonrefundable, non-creditable milestone payments to Licensor within thirty (30) days after receipt of an invoice from Licensor therefor.

	Milestone Event		Payment (millions of Dollars)
(i)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $50 million on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$	[***]
(ii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $[***] on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$	[***]
(iii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $[***] on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$	[***]
(iv)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $200 million on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$	[***]

(c) ***Tier Two Commercialization Milestone Payments.*** Licensee shall notify Licensor promptly, but in no event later than thirty (30) days, after the first achievement of the relevant sales milestone for the Product as set forth in the table below in this Section 8.2(c). In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, [and the assignments by Licensor to Licensee in accordance with Section 2.3,] Licensee shall make the following one-time, nonrefundable, non-creditable milestone payments to Licensor within thirty (30) days after receipt of an invoice from Licensor therefor; provided, however, in the event that the last of the milestone payments described in the table below becomes payable, the due date for Licensee to make payment to Licensor of such milestone payment will be the first anniversary of the payment of the $[***] milestone payment in the penultimate row of the table below.

	Milestone Event	Payment (millions of Dollars)
(i)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $300 million in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$ [***]
(ii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $[***] in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$ [***]
(iii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $ [***] in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$ [***]
(iv)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $ 1.5 billion in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$ [***]

(d) ***Change of Control Payment.*** If a Change of Control occurs, simultaneously with the consummation of such Change of Control, Licensee shall pay to Licensor the amount of [***] Dollars ($[***]) less the sum of the following allocable portions of any of the milestone payments described in Section 8.2(b) that are paid to Licensor prior to such Change of Control:

(i) [***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (i) of the table in Section 8.2(b);

(ii) [***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (ii) of the table in Section 8.2(b);

(iii) [***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (iii) of the table in Section 8.2(b); and

(iv) [***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (iv) of the table in Section 8.2(b).

For the sake of clarity, in respect of any occurrence of a Change of Control (x) in no event shall any payment by Licensee to Licensor under this Section 8.3(c) in respect of such Change of Control exceed $[***], (y) each Tier One Milestone Payment that is not paid to Licensor prior to such Change of Control, less the allocable portion of the amount of such Tier One Milestone Payment paid to Licensor pursuant to this Section 8.3(c), shall survive such Change of Control, and (z) the Tier Two Milestone payment obligations shall survive such Change of Control.

8.3 **Royalties; Non-Royalty Commercialization Consideration.**

(a) ***Royalties.*** In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, Licensee shall pay Licensor royalties on Net Sales of the Product by Licensee and any of its Sublicensees and Third Party Distributors in accordance with the rates set forth in the tables set forth below in this Section 8.3(a)(i).

Royalty-Bearing Net Sales in each Calendar Year (millions of Dollars)	Royalty Rate
That portion of Annual Net Sales greater than $0 and less than or equal to $ 500 million	28%
That portion of Annual Net Sales greater than $ 500 million and less than or equal to $ 1 billion	30%
That portion of Annual Net Sales greater than $ 1 billion	33%

(b) ***Third Party Royalties.***

(i) *CPEX and Reprise.* Licensor will be responsible for payment of any amounts payable to CPEX and Reprise under the terms of the CPEX License Agreement and the Reprise License Agreement, respectively.

(ii) *Other Third Parties.*

(A) In the event that after the Effective Date Licensee reasonably determines that it is necessary or advisable for Licensee to obtain a license under any Patent Rights from any Third Party in order for Licensee (each a "Third Party License"; collectively, "Third Party Licenses"), its Sublicensees, and any Third Party Distributors to Commercialize the Product in the Field in any country in the Territory as contemplated by this Agreement, the Parties shall discuss the best course of action to resolve such potential license requirement, provided that such discussions shall not limit or delay Licensee's right to obtain any such Third Party Licenses.

(B) With respect to any such Third Party Licenses that Licensor reasonably agrees are necessary for Licensee to be able to Commercialize the Product in the Field in any country in the Territory, Licensee shall have the right to set off an amount equal to [***] percent ([***]%) of the aggregate of any and all payments required to be paid by Licensee to the licensors under such Third Party Licenses in respect of any Calendar Quarter against payments otherwise payable to Licensor under Section 8.3(a) in respect of such Calendar Quarter; *provided, however,* that in no event shall the aggregate set off in any Calendar Quarter resulting from such payments in respect of such Third Party Licenses exceed an amount equal to [***] percent ([***]%) of the royalty payments otherwise payable to Licensor under Section 8.3(a) in respect of such Calendar Quarter.

(c) ***Royalty Term.*** Licensee's obligation under Sections 8.3(a) to pay Licensor royalties on Net Sales of the Product in each country in Territory will apply to any and all sales or other dispositions of such the Product in such country made during the Term of this Agreement.

(d) ***Generic Product.*** If, during the Royalty Term, one or more Third Parties is selling in any country in the Territory any product that is a Generic Product in relation to the Product being sold in such country by Licensee or any of its Sublicensees or Third Party Distributors, Licensee's royalty obligations under Section 8.3(a) for sales in such country of the Product shall be reduced as follows:

If the Generic TRxs-to-Total TRxs Percentage in such country during such Calendar Quarter is:	**Licensee's royalty obligations under Section 8.3(a) shall be reduced by the Percentage Indicated Below**
[***]% or greater	[***]%
[***]%; but less than [***]%	[***]%
[***]%; but less than [***]%	[***]%

8.4 **Reports and Payments.** During the Term of this Agreement following the First Commercial Sale of the Product by Licensee, its Sublicensees, or its Third Party Distributors, within five (5) Business Days after the filing by Licensee of each Form 10-K or Form 10-Q, Licensee shall pay to Licensor the royalty payments payable by Licensee for the Calendar Quarter preceding the Calendar Quarter in which such Form 10-K or 10-Q, as applicable, is filed, and shall provide a report showing, on a country-by-country basis:

(a) the net quantity of the Product sold, total gross sales, an itemized list of the deductions applied to total gross sales, and Net Sales of the Product sold in the Calendar Quarter in respect of which such report has been prepared;

(b) the calculation in Dollars of royalty payments due hereunder with respect to such Net Sales, including any deductions for any offsets in accordance with Section 8.3(b)(ii);

(c) withholding taxes on Net Sales, if any, required by Applicable Laws to be deducted with respect to such royalties; and

(d) the rate of exchange used by Licensee in determining the amount of Dollars payable hereunder.

If no royalty or other payment is due for any period hereunder, Licensee shall so report.

Currency of Payment. All payments to be made under this Agreement shall be made in Dollars by electronic funds transfer to such bank accounts as Licensor may designate from time to time. When Licensee or any of its Sublicensee of Third Party Distributors sells the Product for monies other than Dollars, Licensee will convert any non-Dollar currencies into Dollars with the exchange rate for the purchase of Dollars with such domestic currency as quoted by The Wall Street Journal, New York edition, at an average rate for the Calendar Quarter for which the payment is made.

8.5 **Accounting.**

(a) Licensee shall determine Net Sales with respect to the Product sold using its standard accounting procedures, consistent with GAAP, as if the Product was a solely owned product of Licensee, except as specifically provided in this Agreement. In the case of amounts to be determined by Third Parties (for example, Net Sales by Sublicensees), such amounts shall be determined in accordance with generally accepted accounting principles in effect in the country in which such Third Party is engaged. Licensor and Licensee also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales. Licensor and Licensee agree that, where such changes are economically material to Licensor, adjustments shall be made to compensate Licensor in order to preserve the same economics as are reflected under this Agreement under Licensee's accounting procedures in effect prior to such change. Where the change is or would be material to Licensor, Licensee shall provide an explanation of the proposed change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.

(b) In the event of the payment or receipt of noncash consideration in connection with the performance of activities under this Agreement Licensee shall advise Licensor of such transaction, including without limitation Licensee's assessment of the fair market value of such noncash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by Licensor and Licensee in good faith.

(c) **Withholding Tax.** Notwithstanding anything to the contrary herein, in the event that withholding taxes apply with respect to any amounts due from Licensee hereunder, Licensee shall be entitled to withhold from any payment due to Licensor under this Agreement any taxes that Licensee is required to pay and such withholding shall decrease by an equivalent amount the payment due to Licensor. Licensee shall provide Licensor with notification of any anticipated withholding requirements with as much advance notice as practicable and shall cooperate in good faith with Licensor to legally minimize such withholding taxes. Licensee will timely pay to the proper governmental authority the amount of any taxes withheld and will provide Licensor with an official tax certificate or other evidence of tax obligation, together with proof of payment from the relevant governmental authority sufficient to enable Licensor to claim such payment of taxes.

8.6 **Books and Records; Audit Request.**

(a) During the term of this Agreement and for three (3) years thereafter, Licensee shall keep and maintain, and shall cause each of its Affiliates, and Sublicensees, if any, to keep and maintain, at their respective regular places of business complete and accurate books, records, and accounts in accordance with GAAP, or other accounting standards mandated by the U.S. Securities and Exchange Commission if applicable to Licensee, in sufficient detail to reflect all amounts required to be paid under this Agreement, as well as any other books, records or accounts required to be maintained in connection with the Product under any Applicable Laws, necessary to permit the audits contemplated under Section 8.8(b). Prior to destroying any books, records or accounts which are material to the Parties' rights and obligations under this Agreement, Licensee must seek prior written consent from Licensor, which consent may not be unreasonably withheld.

(b) During the term of this Agreement and for three (3) years thereafter, Licensor shall have access to and the right to examine such relevant records and accounts that Licensee is required to maintain pursuant to Section 8.8(a) at Licensee's premises for the sole purpose of verifying the accuracy of any report or payment made under this Agreement in the three (3) preceding years; *provided, however,* that any such examination: (i) shall not occur more than once during each Calendar Year (except that if as a result of any audit pursuant to this Section 8.8(b), an error in favor of Licensee exceeding five percent (5%) of any payments previously reported as owed by Licensee to Licensor is discovered, the frequency of audits under this Section 8.10(b) shall not be so limited); (ii) shall be during normal business hours upon reasonable prior written notice which shall in no event be less than thirty (30) days; and (iii) shall not unreasonably interfere with Licensee's operations and activities. If Licensor desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to Licensee, to examine such records under conditions of confidentiality with respect thereto at least as stringent as those specified in Article 13. The expense of any such audit shall be borne by Licensor; *provided, however,* that, if an error of more than five percent (5%) in favor of Licensor is discovered as a result of such audit, then such expenses shall be paid by Licensee. If such accountant concludes that additional payment amounts were owed to Licensor during any period, Licensee shall pay such payment amount (including without limitation interest thereon from the date such amounts were payable) within thirty (30) days after the date Licensor delivers to Licensee such accountant's written report so concluding, unless Licensee notifies Licensor of any dispute regarding the audit. If such accountant concludes that Licensee has overpaid any amounts to Licensor during any period, in Licensor's discretion, Licensee may credit such amounts against future payments due Licensor or Licensor may pay such amounts (including without limitation interest thereon from the date such amounts were payable), unless Licensor notifies Licensee of any dispute regarding the audit. Any Information received by Licensor pursuant to this Section 8.10 shall be deemed to be Confidential Information of Licensee for purposes of Article 13.

8.7 **Blocked Currency.** If by Applicable Laws or fiscal policy of a particular country, conversion into Dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, royalties accrued in such country shall be paid to Licensor in the country in local currency by deposit in a local bank designated by Licensor for such deposit, unless Licensor and Licensee otherwise agree.

8.8 **Interest.** If Licensor does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Licensor from the due date until the date of payment at a rate equal to three month Dollar LIBOR Rate, as reported in the online edition of The Wall Street Journal as of Noon (New York Time) on such due date, or the maximum rate allowable by Applicable Laws, whichever is less.

8.9 **Transaction Expenses.** Licensee shall upon execution and delivery of this Agreement pay the documented reasonable fees and expenses of Licensor's advisors and counsel incurred by Licensor in structuring, negotiating, memorializing, and otherwise undertaking the transaction contemplated by this Agreement. Notwithstanding the foregoing, Licensee's obligation under this Section 8.11 shall be limited to an amount not to exceed $2,000,000.

9. INTELLECTUAL PROPERTY MATTERS.

9.1 **Existing Intellectual Property.**

(a) Other than as provided in this Agreement, neither Party grants any right, title, or interest in any Patent Right, information, or other intellectual property right Controlled by such Party to the other Party.

(b) Except as otherwise provided herein, Licensor shall be responsible for the preparation, filing, prosecution (including, without limitation, any interferences, inter partes proceedings, reissue proceedings, cancellations, oppositions, and reexaminations), and maintenance of any and all Licensed Serenity Patent Rights. Licensor shall consult with Licensee, and consider Licensee's comments, in good faith with respect to the preparation, filing, prosecution, and maintenance of any Licensed CPEX Patent Rights or Licensed Reprise Patent Rights to the extent that Licensor has the right, under any agreement with any applicable licensor, to file, prosecute, and maintain such Licensed Patent Rights.

(c) Licensee agrees and acknowledges that Licensor intends to continue to use, in Licensor's discretion, patent counsel currently retained by Licensor to prosecute and maintain the Licensed Serenity Patent Rights. Licensee shall execute, acknowledge and deliver any instruments, and to do all such other acts, as may be necessary or appropriate in order to enable such patent counsel to continue to prosecute and maintain such Licensed Serenity Patent Rights. The Parties shall reasonably consult with each other, and shall consider any comments from each other in good faith, with respect to the preparation, filing, prosecution, and maintenance of such Licensed Serenity Patent Rights and patent strategy for the Licensed Serenity Patent Rights. Licensee shall reimburse Licensor for all costs and expenses incurred by Licensor after the Effective Date in the preparation, filing, prosecution, and maintenance of any Licensed Serenity Patent Rights in the Territory, up to an amount not to exceed [***] Dollars ($[***]), which is the estimated cost set forth on Schedule 9.1(c)**.** Licensor shall provide to Licensee copies of any papers relating to the filing, prosecution or maintenance of the Licensed Serenity Patent Rights promptly upon their being filed or received. Licensee shall not knowingly take any action during prosecution and maintenance of the Licensed Serenity Patent Rights.

(d) Licensor shall not knowingly permit any of the Licensed Serenity Patent Rights to be abandoned in any country in the Territory without Licensor first giving Licensee an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. In the event that Licensee decides not to continue the prosecution or maintenance of a Licensed Serenity Patent Rights in any country in the Territory, Licensor will provide Licensee with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In the event that Licensee elects to assume responsibility for such prosecution and maintenance within thirty (30) days of Licensor's notice, Section 9.1(c) shall thereafter apply to such Licensed Serenity Patent Rights except that the role of Licensee and Licensor shall be reversed thereunder (except further that Licensee will continue to be responsible for all costs and expenses thereafter incurred in the preparation, filing, prosecution, and maintenance of any Licensed Serenity Patent Rights). Any such Serenity Patent Right that is subject to such election by Licensee shall otherwise continue to be subject to all of the terms and conditions of the Agreement in the same way as the other Licensed Serenity Patent Rights.

9.2 **Inventions by Licensee.**

(a) ***Disclosure.*** Licensee shall promptly disclose to Licensor the invention of any Licensee Inventions.

(b) ***Ownership.*** As between the Parties, all Licensee Inventions will be owned and Controlled by Licensee.

(c) Patent Filings.

(i) Licensee, at its expense, will have sole discretion and responsibility to prepare, file, prosecute, and maintain any patent applications and patents claiming Licensee Inventions. The Parties' respective patent counsel shall meet no fewer than once per Calendar Year to discuss strategies for the preparation, filing, prosecution, and maintenance of any such patent applications and patents claiming Licensee Inventions. Licensee shall consider in good faith any comments provided by Licensor with respect to the foregoing. In the event of any dispute between Parties with respect to such strategies, either Party may notify the Alliance Managers for purposes of resolving such dispute; *provided*, *however,* that Licensee shall have the final decision-making authority with respect to any such dispute.

(ii) Licensee shall not knowingly permit any Patent Rights with claims to any Licensee Inventions to be abandoned in any country without Licensee first giving Licensor an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. In the event that Licensee decides not to continue the prosecution or maintenance of any Patent Right claiming a Licensee Invention in any country, Licensee will provide Licensor with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In the event that Licensor elects to assume responsibility for such prosecution and maintenance within thirty (30) days of Licensor's notice, Section 9.1(c) shall thereafter apply to such Patent Right claiming such Licensee Invention except that the role of Licensee and Licensor shall be reversed thereunder.

9.3 **Infringement, Violation, or Misappropriation by Third Parties.**

(a) Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement, violation, or misappropriation by any Third Party of the Licensed Rights or the Sublicensed Rights of which it becomes aware, and following such notification, the Parties shall confer as to any response thereto. The notice shall set forth the facts of such infringement, violation, or misappropriation in reasonable detail.

(b) Response to Infringement, Violation, or Misappropriation by Third Parties.

(i) If a Third Party is infringing, violating, or misappropriating, or either Party reasonably believes a Third Party may be infringing, violating, or misappropriating any Enforceable IP Right in any country in the Territory, Licensee shall have the first right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement, violation, or misappropriation by counsel of its own selection, at its expense. Licensor shall have the right to participate in such action and be represented, if it so desires, by counsel of its own selection and at its own expense. To the extent required by Applicable Laws, Licensor agrees to be joined as a party plaintiff (with Licensor having the right to be represented, if it so desires, by counsel of its own selection and at its own expense) if necessary for Licensee to bring and prosecute such action or proceeding, and to give Licensee reasonable assistance and authority to bring and prosecute such action or proceeding. If Licensee fails to bring an action or proceeding within ninety (90) days after receiving or giving written notice pursuant to Section 9.3(a), then Licensor shall have the right, but not the obligation, to bring and control any such action by counsel of its own selection, at its expense (with Licensee having the right to participate in such action and be represented, if it so desires, by counsel of its own selection and at its own expense). To the extent required by Applicable Laws, Licensee agrees to be joined as a party plaintiff (with Licensee having the right to be represented, if it so desires, by counsel of its own selection and expense therein) if necessary for Licensor to bring and prosecute such action or proceeding, and to give Licensor reasonable assistance and authority to bring and prosecute such action or proceeding. No settlement of any such action or consent judgment or other voluntary final disposition which restricts the scope, or adversely affects the enforceability, of an Enforceable IP Right may be entered into by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned.

(ii) Each Party shall share in any recoveries obtained in connection with any action or proceeding described in Section 9.3(b)(i) as follows:

(A) each Party's costs and expenses incurred in connection with bringing and prosecuting any such action or proceeding, including without limitation attorneys' fees, first shall be reimbursed from such recoveries, and if such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party, and

(B) if Licensee controlled such action or proceeding Licensee shall receive one hundred percent (100%) of such remaining recoveries, provided that such recoveries shall be deemed Net Sales for purposes of Section 8.3(a)(i); and if Licensor controlled such action or proceeding, each Party shall receive fifty percent (50%) of such remaining recoveries, provided that Licensee's portion shall not be deemed as Net Sales for purposes of Section 8.3(a)(i) in such case.

(c) ***Withdrawal.*** If either Party brings an action or proceeding under Section 9.3(b)(i) and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of Section 9.3(b)(i).

(d) ***Oppositions by Parties.*** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, reexamination, inter partes proceeding, or other attack upon the validity, title, or enforceability of any intellectual property right Controlled by a Third Party that Covers the Product in the Field in any country in the Territory, such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Each Party shall be entitled to separate representation in any such action by counsel of its own choice and at its own expense, and shall cooperate fully with the other Party. The costs of any such action shall be borne by the Party bringing the action, and such Party shall retain any recoveries obtained in connection therewith.

9.4 **Infringement of Third Party Rights.**

(a) ***Notice.*** If the Exploitation of the Product pursuant to this Agreement results in a claim, action, suit, or proceeding that such activity infringes or misappropriates the intellectual property rights of a Third Party (**"Third Party Infringement Claim"**), the Party first receiving notice thereof shall promptly notify in writing the other Party thereof. The notice shall set forth the facts of the Third Party Infringement Claim in reasonable detail.

(b) ***Litigation.***

(i) Licensee shall have the sole right, but not the obligation, to defend, at its expense, against any Third Party Infringement Claim. Licensee shall have full control over the defense and settlement of such Third Party Infringement Claim, provided that Licensee shall not settle any Third Party Infringement Claim that is subject to indemnification pursuant to Section 11.1 without the prior written consent of Licensor, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensor shall cooperate with Licensee, at Licensee's expense and reasonable request, in such defense and shall have the right to be represented by counsel of its own choice, at Licensor's expense. Licensee will pay any losses incurred in defense or settlement of, or imposed pursuant to settlement of or judgment on, such Third Party Infringement Claim.

(ii) If Licensee decides not to commence a defense against any Third Party Infringement Claim pursuant to Section 9.4(b)(i), then Licensee will promptly notify Licensor of such decision in a timely manner so as to allow Licensor, who shall have the right, but not the obligation, to commence such a defense by counsel of its own selection, at its expense (with Licensee having the right to participate in such defense and be represented, if it so desires, by counsel of its own selection and at its own expense). Licensor shall thereupon have full control over the defense and settlement of such Third Party Infringement Claim, provided that Licensor shall not settle any Third Party Infringement Claim without the prior written consent of Licensee, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensee shall cooperate with Licensor, at Licensor's expense and reasonable request, in such defense and shall have the right to be represented by counsel of its own choice, at Licensee's expense. Licensor will pay any losses incurred in defense or settlement of, or imposed pursuant to settlement of or judgment on, such Third Party Infringement Claim, subject to Section 11.1.

(iii) Notwithstanding any provisions set forth herein to the contrary, Licensor shall be responsible for continuing to manage, at Licensor's expense, that certain litigation with Ferring Pharmaceuticals that is described in Schedule 10.2. Notwithstanding the foregoing, any settlement of any such action or consent judgment or other voluntary final disposition with respect to the litigation with Ferring Pharmaceuticals described in Schedule 10.2, which restricts the scope, or adversely affects the enforceability, of an Enforceable IP Right may not be entered into by Licensor without the prior written consent of the Licensee, which consent shall not be unreasonably withheld, delayed or conditioned.

(c) ***Oppositions by Third Parties.*** If any patent, trademark, copyright, or other intellectual property right within the Licensed Rights or the Sublicensed Rights becomes after the Effective Date the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference, inter partes proceeding, or other attack upon the validity, title, or enforceability thereof, then Licensee shall control such defense at its sole cost. Licensee shall permit Licensor to participate in the proceeding to the extent permissible under Applicable Laws, and to be represented by its own counsel in such proceeding, at Licensor's expense. If Licensee elects not to defend against such action with respect to any such intellectual property right with the Licensed Rights or the Sublicensed Rights within ninety (90) days after first receiving notice or otherwise becoming aware of such action or proceeding, then Licensor shall have the right to assume defense of such Third Party action at its own expense. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the Parties' expenses in such action, and any remaining amounts shall be retained by the Party defending against such proceeding.

9.5 **Use of Licensed Serenity Trademark.**

(a) Licensee agrees and acknowledges that (i) as between the Parties, Licensor is and shall remain the owner of the Licensed Serenity Trademarks, and (ii) all of the goodwill associated with the Licensed Serenity Trademarks, in all countries of the world, and all uses thereof by Licensee, its Affiliates, sublicensees, and Third Party Distributors shall inure to the benefit of Licensor.

(b) Licensee will cooperate with Licensor for the purpose of protecting, preserving, registering, and enhancing the Licensed Serenity Trademarks and Licensor ‘s interest therein and in furtherance of such obligations, Licensee will promptly execute and deliver to Licensor all documents and instruments that Licensor, acting reasonably, determines are necessary or prudent from time to time. If and to the extent that Licensee, its Affiliates, sublicensees, or Third Party Distributors obtain any rights (other than the licenses granted herein) to the Licensed Serenity Trademarks in any country in the world, at the request of Licensor, Licensee shall immediately and automatically assign, and ensure that its Affiliates, sublicensees, and Third Party Distributors immediately and automatically assign, to Licensor all right, title and interest in and to the Licensed Serenity Trademarks, and all goodwill with respect thereto.

(c) Licensee will use the Licensed Serenity Trademarks (i) only in compliance with all Applicable Law and the express terms of this Agreement and the Serenity Trademark Standards, and (ii) not as part of any composite trademark in close proximity or in combination with any other trademark.

(d) Licensee agrees to conform, and to cause any of its Affiliates, sublicensees and Third Party Distributors to conform, the manner of their respective use of the Licensed Serenity Trademarks with the policies, specifications, directions, and standards for use thereof set forth in the Serenity Trademark Standards, and to maintain the quality standards of Licensor set forth in the Serenity Trademark Standards with respect to the Products sold. Except to the extent that any use of the Licensed Serenity Trademarks by Licensee and any of its Affiliates, sublicensees, and Third Party Distributors is not in accordance with the Serenity Trademarks Standards, Licensee shall not be required to submit to Licensor any materials bearing any Licensed Serenity Trademark for review and approval prior to the use thereof.

(e) To the extent Licensee desires to use any Licensed Serenity Trademark in a manner not expressly permitted under the Serenity Trademark Standards, Licensee will submit to Licensor for Licensor’s review all packaging, advertising, brochures, and other material (including, without limitation, mockups or models thereof), that evidence such use. Within fifteen (15) calendar days after Licensor receives any such material, Licensor will provide Licensee with (i) approval of Licensee’s proposed use of the Licensed Serenity or (ii) comments as to any revisions Licensor reasonably believes are necessary or advisable to achieve compliance with the Licensed Trademark Standards. In each case where Licensor provides any such comments, Licensor and Licensee will promptly discuss and resolve whether any such revisions are necessary or advisable and, if determined to be so necessary or advisable, Licensee will make such revisions. From and after such approval of Licensor of such use, the Serenity Trademark Standards shall be amended or revised to reflect such approved use.

(f) All rights in and to any new version, translation, or arrangement of the Licensed Serenity Trademarks, or other change in the Licensed Serenity Trademarks created by Licensee, with Licensor’s prior written consent or otherwise, will be and will remain the exclusive property of Licensor, and the provisions of this Agreement will apply to the same.

10. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

10.1 **Mutual Representations and Warranties.** Licensor and Licensee (each, a **"Representing Party"**) each hereby represents and warrants to each other, as of the Effective Date and except as otherwise set forth in Schedule 10.2 (in the case of Licensor) and Schedule 10.3 (the case of Licensee), that:

(a) such Representing Party is a corporation or limited liability company, as applicable, duly organized and subsisting under the laws of its jurisdiction of organization;

(b) such Representing Party has the power, authority, and legal right, and is free, to enter into this Agreement on behalf of itself and its Affiliates and to perform its respective obligations hereunder and to cause its Affiliates to perform their respective obligations hereunder;

(c) such Representing Party has the power, authority, and legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;

(d) this Agreement constitutes a legal, valid, and binding obligation of such Representing Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity;

(e) the execution and delivery of this Agreement and the performance of such Representing Party's and its Affiliates' obligations hereunder (i) have been duly authorized and approved by all necessary action by such Representing Party, and all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Representing Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; (ii) do not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws, limited partnership agreement, or any similar instrument of such Representing Party, as applicable, in any material way; and (iii) do not, and will not, conflict with or otherwise interfere with in such a manner as to result in a violation, breach, or default under or require any consent that has not been obtained under any contract between such Representing Party and any Third Party;

(f) there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other agreements that would prevent or impair such Representing Party's or any of its Affiliates' full and complete exercise of the terms and conditions of the Agreement;

(g) such Representing Party and its Affiliates shall at all times comply with all Applicable Laws relating or pertaining to their obligations under the Agreement;

(h) with respect to the services provided hereunder to the other Party, its Affiliates, and their respective employees, officers, contractors and agents who perform such services have the experience, capability, and resources to efficiently and skillfully perform the services, and shall perform, where applicable, all such services in a professional and workmanlike manner and in accordance with the generally accepted then-current standards, forms, procedures, and techniques established from time to time by the industry;

(i) all of such Representing Party's employees, officers, contractors, and consultants have executed agreements requiring assignment to such Representing Party of all inventions created by such persons in the course of their employment by such Representing Party and obligating each such employee, officer, contractor, and consultant to maintain and safeguard the confidentiality of (i) any information that is confidential to such Representing Party or (ii) any information that is confidential to any other Person and that such Representing Party is obligated to maintain and safeguard as confidential; and

(j) neither such Representing Party, nor any of its employees, officers, subcontractors, or consultants who have rendered or will render services relating to the Product: (i) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a.

10.2 **Additional Representations, Warranties, and Covenants of Licensor.** Licensor hereby represents, warrants, and covenants to Licensee, as of the Effective Date and except as otherwise set forth in Schedule 10.2, that:

(a) Licensor is entitled to grant the rights and licenses purported to be granted to Licensee under this Agreement, and to assign the rights purported to be assigned to Licensee under this Agreement, and is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it from granting to Licensee the rights, licenses and sublicenses purported to be so granted in this Agreement;

(b) Licensor is the sole and exclusive owner of all right, title, and interest, in, to, and under the Licensed Rights and has the right under the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights to grant the sublicenses thereunder in accordance with Section 2.2;

(c) the Licensed Rights are free and clear of any liens, charges, encumbrances, or judgments, and Licensor has sufficient rights to grant the licenses and rights purported to be granted herein, free and clear of any security interests, claims, encumbrances, or charges of any kind;

(d) Licensor has not granted, and will not grant during the term of this Agreement, any right, option, license, or interest in or to any of the Licensed Rights that is in conflict with the rights assigned or granted to Licensee under this Agreement;

(e) there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending, or to Licensor's knowledge threatened by, against or involving Licensor, regarding the Licensed Rights, whether at law or in equity, before or by any Third Party, and Licensor has not received any written communications alleging that it has violated, through the manufacture, Development, import, or other exploitation of the Product, any intellectual property rights of any Third Party;

(f) to Licensor's knowledge:

(i) the patents in the issued Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights are valid and enforceable; and

(ii) no Third Party has asserted that any of the Licensed Rights or the Sublicensed Rights is invalid or unenforceable;

(g) all applications, registrations, maintenance and renewal fees due in respect of any of the Licensed Serenity Patent Rights and, to Licensor's knowledge, the Licensed Reprise Patent Rights and the Licensed CPEX Patent Rights, have been paid and all documents and certificates required to be filed with the relevant agencies for the purpose of maintaining such Licensed Serenity Patent Rights, and to Licensor's knowledge, the Licensed Reprise Patent Rights and Licensed CPEX Patent Rights have been filed;

(h) none of the Licensed Serenity Patent Rights, the Licensed Serenity Know-How and, to Licensor's knowledge, none of the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights were developed with funding from any Governmental Authority such that any Governmental Authority has any march in rights or other rights to use the Licensed Serenity Patent Rights, the License Serenity Know-How, the Licensed Reprise Patent Rights, or the Licensed CPEX Patent Rights;

(i) to Licensor's knowledge, no Third Party has infringed or misappropriated any of the Licensed Rights or the Sublicensed Rights;

(j) all inventors of any inventions included within the Licensed Serenity Patent Rights and, to the knowledge of Licensor, the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights have assigned their entire right, title, and interest in and to such inventions and the corresponding patents and patent applications to Licensor, Reprise, or CPEX, as applicable, and have been listed as inventors in the Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights, as applicable;

(k) no agreements that Licensor or its Affiliates may have with any Third Party provide such Third Party with any rights of first offer, rights of first refusal, or any other rights to make, have made, use, conduct Clinical Studies for, sell, offer for sale, have sold, import, export, or otherwise Exploit the Product in the Field in the Territory or the right to use the Licensed Rights or the Sublicensed Rights in connection with the Exploitation of the Product in the Field in the Territory; and Licensor has received no notice from a Third Party of any suit, action, proceeding, or arbitration pending or threatened against it that the proposed terms and conditions of this Agreement, and the Parties' performance in accordance therewith, do or shall conflict or interfere with in a manner resulting in a breach or default under, or other violation of, any agreements that Licensor or its Affiliates may have with any Third Party;

(l) to Licensor's knowledge, (i) each of the CPEX License Agreement and the Reprise License Agreement is valid and enforceable in accordance with its terms, is in full force and effect, and there are no approvals or consents required to make it effective, (ii) Licensor has supplied Licensee with a true and correct copy of the CPEX License Agreement and the Reprise License Agreement , together with all amendments, waivers, or other changes thereto, (iii) Licensor has performed all material obligations required to be performed by it in connection with the CPEX License Agreement and the Reprise License Agreement, (iv) Licensor shall not materially breach and is not in material breach of the CPEX License Agreement or the Reprise License Agreement, (v) Licensor is not in receipt of any claim of default, cure notice, or show cause notice under the CPEX License Agreement or the Reprise License Agreement, and (vi) there is no current material breach or anticipated material breach by any other party to the CPEX License Agreement or the Reprise License Agreement;

(m) (i) Licensor is the named sponsor of the First Approved NDA for the Product; and (ii) with respect to all Regulatory Documentation to obtain Regulatory Approvals for the Product in the Field: (A) the data, information and/or all other documents in Licensor's or its Affiliates submissions were, are and shall be free from fraud or material falsity, and neither Licensor nor its Affiliates has made any material misrepresentation or omission in connection with such data; (B) the Regulatory Approvals have not been and will not be obtained either through bribery or the payment of illegal gratuities by Licensor; (C) the data, information and/or all other documents in Licensor's or its Affiliates' submissions are, were and shall be accurate and reliable for purposes of supporting approval of the submissions; and (D) the Regulatory Approvals shall be obtained without illegal or unethical behavior of any kind by Licensor or its Affiliates; provided that Licensor shall not be deemed to be in breach of this Section 10.2(m) if the violation of this Section 10.2(m) results from the action or omission of Licensee of Licensee's Affiliates, Sublicensees, or contractors (other than Licensor);

(n) Licensor believes in good faith, based on the information set forth in Schedule 10.2(n), that FDA will consider amending or supplementing the First Approved NDA (or the related IND) in the manner described in Schedule 10.2(n); *provided, however,* that Licensor cannot assure that FDA will approve such amendment or supplement.

(o) except as expressly permitted hereunder, Licensor agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product; and

(p) other than the CPEX License Agreement, the Reprise License Agreement, the Renaissance Supply Agreements, and the other Third Party Supply Agreements, Licensor and/or its Affiliates have not entered into any agreements with any Third Party, pursuant to which any Third Party has granted to Licensor, or Licensor has granted to any Third Party, any rights to licenses to, in or under any of the Licensed Rights or the Sublicensed Rights or other intellectual property rights that relate to the Product, or relating to the manufacture of the Product.

10.3 **Additional Representations, Warranties, and Covenants of Licensee.** Licensee hereby represents, warrants, and covenants to Licensor, as of the Effective Date and except as otherwise stated in Schedule 10.3, that:

(a) if, during the term of this Agreement Licensee has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (i) is or will be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (ii) is or will be under indictment under said Section 335a, then Licensee shall immediately notify Licensor in writing;

(b) as of the Effective Date, there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending or, to the knowledge of Licensee's senior management, threatened by, against Licensee regarding this Agreement, whether at law or in equity, before or by any Third Party; and Licensee shall provide notice of any of the foregoing to the extent it affects Licensee's performance of its obligations under this Agreement;

(c) except for information provided by Licensor, its Affiliates or Sublicensees: (i) the data and information in Licensee's submissions and modifications of Regulatory Documentation relating to the Product shall be free from fraud or material falsity; (ii) Regulatory Approvals for the Product hereafter obtained will not be obtained either through bribery or the payment of illegal gratuities by Licensee; (iii) the data and information in Licensee's submissions and modifications of any Regulatory Documentation shall be accurate and reliable; and (iv) any such the Regulatory Approvals will be obtained without illegal or unethical behavior of any kind by Licensee; provided that Licensee shall not be deemed to be in breach of this Section 10.3(c) if the violation of this Section 10.3(c) results from the action or omission of Licensor or its Affiliates, Sublicensees (other than Licensee), or contractors; and

(d) except as expressly permitted hereunder, Licensee agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iv) bring any action or proceeding or otherwise assert any claim under any Applicable Law in the event any licensee (or sublicensee or any entity or person acting on its behalf) initiates any proceeding or otherwise assert any claim in any court, administrative agency, or other forum with jurisdiction over such proceeding or claim, that any of the Licensed Rights or Sublicensed Rights are invalid, unenforceable, or not infringed, violated, or misappropriated. In the event that Licensee or any Affiliate or Sublicensee of Licensee initiates any proceeding or otherwise asserts any claim in violation of clause (iv) of this Section 10.3, and the result thereof is a final decision, ruling, holding, award, or other disposition to the effect that any of the Licensed Rights or Sublicensed Rights are valid, enforceable, or infringed, violated, or misappropriated, then each of the royalty rates set forth in the table in Section 8.3(a) will each be increased by [***] and the party initiating such proceeding or otherwise asserting such claim shall pay the attorneys' fees and expenses incurred by Licensor in defending against such proceeding or claim.

10.4 **Inaccuracies.** Without limiting either Party's rights and remedies at law, in equity or under this Agreement, if, at any point in time (not just at the times when the warranties are deemed granted), either Party becomes aware of any inaccuracies in the foregoing warranties and representations, such Party shall promptly notify the other Party of such inaccuracies, with a detailed written explanation.

11. INDEMNIFICATION AND INSURANCE.

11.1 **Indemnification by Licensee.** Licensee shall defend, indemnify and hold harmless any Licensor Indemnitee from and against any and all Losses arising out of a claim by a Third Party arising out of, resulting from or relating to: (a) the gross negligence or willful misconduct of Licensee and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement; (b) any material breach by Licensee of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) any Development Activities and Commercialization Activities in respect of the Product, undertaken by Licensee or any of its Affiliates, Sublicensees, agents, and contractors (other than Licensor); (d) the failure to comply with Applicable Laws by Licensee, or any of its Affiliates, Sublicensees, agents, or contractors (other than Licensor); and (e) any allegation that personal injury or death, or any damage to any property, was caused or allegedly caused by a manufacturing defect in the Product manufactured by Licensee or for Licensee by Third Parties.

11.2 **Indemnification by Licensor.** Licensor shall defend, indemnify and hold harmless any Licensee Indemnitee from and against any and all Losses arising out of a claim by a Third Party arising out of, resulting from or relating to: (a) the gross negligence or willful misconduct of Licensor and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensor's performance of its obligations or exercise of its rights under this Agreement; (b) any material breach by Licensor of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) any Development Activities and Commercialization Activities in respect of the Product, undertaken by Licensor or any of its Affiliates, Sublicensees, agents, and contractors (other than Licensee); and (d) the failure to comply with Applicable Laws by Licensor, or any of its Affiliates, Sublicensees, agents, or contractors (other than Licensor).

11.3 **Process for Indemnification.** A claim to which indemnification applies under Section 11.1 shall be referred to herein as an **"Indemnification Claim"**. If a Licensor Indemnitee or Licensee Indemnitee (each being an "Indemnitee" for purposes of this Section 11.3) intends to claim indemnification under Section 11.1, such Indemnitee must notify Licensee or Licensor, as the case may be (each in such capacity of providing indemnification hereunder, the "Indemnitor"), in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided, however, that the Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitor and the Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this Section 11.2, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. An Indemnitee shall not settle or compromise any Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise any Indemnification Claim in any manner that would have an adverse effect on the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed, or conditioned. Each Indemnitee shall reasonably cooperate with the Indemnitor at the Licensor's expense and shall make available to the Licensee or Licensor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 13.

11.4 **Insurance.**

(a) At all times during the term of this Agreement and for five (5) years thereafter, Licensee shall at its sole cost: (i) maintain Commercial General Liability, including without limitation product liability insurance (including without limitation bodily injury and property damage coverage) including coverages of: (A) products and completed operations; (B) premises – operations; and (C) broad form contractual liability at limits not less than $5,000,000 per occurrence/$10,000,000 aggregate (collectively, the **"Licensee Insurance Policies"**); (ii) include Licensor as "Additional Insured" under the Licensee Insurance Policies; and (iii) provide Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day notice of cancellation, non-renewal or material change. Licensee will obtain such Licensee Insurance Policies from insurers having A.M. Best's Ratings of–A - VII or equivalent. Any and all deductibles in such Licensee Insurance Policies shall be assumed by Licensee. The policy limits stated above do not limit the obligation of Licensee under this Agreement.

(b) At all times during the term of this Agreement and for five (5) years thereafter, Licensor, to the extent that it is engaged in any Development Activities hereunder, shall at its sole cost: (i) maintain Commercial General Liability, including without limitation product liability insurance (including without limitation bodily injury and property damage coverage) including coverages of: (A) products and completed operations; (B) premises – operations; and (C) broad form contractual liability at limits not less than $1,000,000 per occurrence/$ 2,000,000 aggregate (collectively, the **"Licensor Insurance Policies"**); (ii) include Licensee as "Additional Insured" under the Licensor Insurance Policies; and (iii) provide Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day notice of cancellation, non-renewal or material change. Licensor will obtain such Licensor Insurance Policies from insurers having A.M. Best's Ratings of–A - VII or equivalent. Any and all deductibles in such Licensor Insurance Policies shall be assumed by Licensor. The policy limits stated above do not limit the obligation of Licensor under this Agreement,

12. LIMITATION OF LIABILITY AND DISCLAIMER OF WARRANTY.

12.1 **LIMITATION OF LIABILITY.** EXCEPT FOR BREACH BY EITHER PARTY OF ARTICLE 13, AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING FROM OR RELATING TO THIS AGREEMENT, WHETHER THE BASIS OF THE LIABILITY IS BREACH OF CONTRACT, TORT, STATUTES, OR ANY OTHER LEGAL THEORY, AND WHETHER SUCH FIRST PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR NOT.

12.2 **DISCLAIMER OF WARRANTY.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

13. CONFIDENTIALITY.

13.1 **Confidential Information, Defined; Exclusions.**

(a) ***Definition of Confidential Information.*** The term "Confidential Information" means, with respect to a Disclosing Party, information and material, regardless of the form in which that information or material is constituted, any and all regulatory, technical, manufacturing, business, financial, operational, administrative, marketing or economic information, data, documents, designs, patents, materials, product samples, and Know-How asserted by such Disclosing Party as being confidential to it and disclosed by the Disclosing Party to the Receiving Party, whether orally, in writing, or in pictorial form in hard copy, electronic form or in any other form, in connection with the performance of this Agreement by the Parties, marked in English, or otherwise identified, as confidential or proprietary or secret.

(b) ***Exclusions.*** The term "Confidential Information" does not apply to any portion of information or materials that a Receiving Party can demonstrate by contemporaneous written records was: (i) known to the general public at the time of its disclosure to the Receiving Party, or thereafter became generally known to the general public, other than as a result of actions or omissions of the Receiving Party or anyone to whom the receiving Party disclosed such information or materials; (ii) known by the Receiving Party prior to the date of disclosure by the Disclosing Party; (iii) disclosed to the Receiving Party on an unrestricted basis from a source unrelated to the Disclosing Party and not under a duty of confidentiality to the Disclosing Party; or (iv) independently developed by the Receiving Party by personnel that did not have access to or use of Confidential Information of the Disclosing Party. Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation thereof are published or known to the general public or are in the rightful possession of the Receiving Party.

13.2 **Degree of Care.** Each Party shall take Commercially Reasonable Efforts to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own information and materials of a similar confidential nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including without limitation all copies and derivations thereof, is and shall remain the sole and exclusive property of such Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than as permitted under this Agreement.

13.3 **Required Disclosures.** The obligations of Sections 13.2 and 13.7 shall not apply to the extent that the Receiving Party:

(a) is required to disclose Confidential Information it receives pursuant to (i) an order of a court of competent jurisdiction, (ii) Applicable Laws, (iii) regulations or rules of a securities exchange, including without limitation as required in connection with a public offering of the Receiving Party's stock or to comply with regulations imposed by the United States Securities and Exchange Commission, NASDAQ, or stock exchange disclosure requirements, or (iv) requirement of a governmental agency for purposes of obtaining approval to test or market the Product; provided that, in the case of clauses (i) through (iv) of this subsection (a), the Receiving Party shall provide prior written notice thereof to the Disclosing Party and, where practicable, reasonable opportunity for the Disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefore in a reasonably timely manner, or

(b) discloses such Confidential Information to Affiliates, potential or actual acquirers, merger partners, external advisors, licensees, sublicensees, assignees, subcontractors, investment bankers, investors, lenders, venture capital firms, investment bankers, or other potential financial partners, and their and each of the Parties' respective directors, employees, contractors, and agents; provided that such any such person or entity listed in the first part of this subsection (b) agrees to confidentiality and nonuse obligations with respect thereto at least as stringent as those specified in Section 13.2.

13.4 **Permitted Disclosures.** At each Receiving Party's request, the Disclosing Party shall review and approve in good faith the use by the Receiving Party any packet of Confidential Information of the Disclosing Party that the Receiving Party proposes to disclose, under commercially reasonable confidentiality obligations that are less stringent than those specified in Section 13.2 to actual or potential investment bankers, investors, lenders, venture capital firms, investment bankers, or other potential financial partners, and their and the Receiving Party's respective directors, employees, contractors, and agents for purposes of raising capital.

13.5 **Irreparable Injury.** The Parties acknowledge that either Party's breach of this Article 13 would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach of this Article 13, the nonbreaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity, without necessity of posting a bond.

13.6 **Return of Confidential Information.** Each Receiving Party shall return or destroy, at the Disclosing Party's instruction, all Confidential Information of the Disclosing Party in the Receiving Party's possession upon termination or expiration of this Agreement, except any Confidential Information that is necessary to allow the Receiving Party to perform or enjoy any of its rights or obligations that expressly survive the termination or expiration of this Agreement.

13.7 **Public Disclosure.**

(a) The Parties agree that the initial public announcement of the execution of this Agreement shall be in the form set forth on Exhibit 13.7 (the **"Press Release"**).

(b) During the term of this Agreement, in all cases other than the announcement set forth in the Press Release, Licensor and Licensee shall submit to each other in a reasonably timely manner for review and approval all proposed press releases involving medical or scientific information, academic, scientific, and medical Publications and public presentations, including without limitation any and all abstracts, public presentations at congresses or scientific meetings or other public meetings, and any Publication manuscripts, relating to the Product, the Nocturia Indication, the PNE Indication and any Additional Indication that have not been previously publicly disclosed and that are not otherwise permitted to be disclosed under this Article 13. Such review and approval shall be conducted in a timely manner for the purposes of preserving intellectual property protection and determining whether any portion of the proposed publication or presentation containing the Confidential Information of either Party should be modified or deleted. Notwithstanding the foregoing and for clarity sake, this provision shall not apply for any disclosures or releases required by the SEC or any other Regulatory Authority, which such disclosures and releases will be subject to Section 13.3.

(c) **Effect on Existing Confidentiality Agreement.** The provisions of this Article 13 do not supersede that certain letter agreement, dated April 3, 2017, between Licensor and Licensee.

14. TERM AND TERMINATION.

14.1 **Term.** The term of this Agreement shall commence as of the Effective Date and shall continue in effect until it is terminated as specifically provided in this Agreement.

14.2 **Termination for Material Breach.**

(a) If either Party (the "non-breaching Party") believes the other Party (the "alleged breaching party") is in material breach of any of such alleged breaching Party's obligations under this Agreement, the non-breaching Party may give notice of such breach to the alleged breaching Party, and the alleged breaching Party shall have sixty (60) days in which to remedy such material breach or establish that it is not in material breach hereunder. Subject to Section 14.2(b), if such alleged material breach is not remedied in the time period set forth above, the non-breaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the alleged breaching Party.

(b) If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the non-breaching Party pursuant to Section 14.2(a), and the alleged breaching Party provides notice to the non-breaching Party of such dispute within fifteen (15) days after receipt of such notice, the non-breaching Party shall not have the right to terminate this Agreement unless and until the existence of such material breach by the alleged breaching Party has been determined in accordance with the dispute resolution procedures set forth in Section 15.8 (each such termination delay, a **"Toll Period"**) and the breaching Party fails to cure such default within sixty (60) days following such determination; provided that, if it is determined that such material breach occurred and such breach is not cured within such sixty (60) day period, then, for purposes of Section 14.4(c)(iii), this Agreement shall be deemed to have been terminated as of the date of delivery of notice of such breach under Section 14.2(a). During the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

14.3 **Termination upon Insolvency.** To the extent permitted under Applicable Laws, either Party may terminate this Agreement with respect to the other Party if, at any time, such other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party proposes a written agreement of composition or extension of its debts, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment for the benefit of its creditors.

14.4 **Termination upon Force Majeure.** Either Party may terminate this agreement due to a Force Majeure event pursuant to Section 15.13.

14.5 **Consequences of Expiration or Termination.**

(a) Upon termination of this Agreement by either Party pursuant to Sections 14.2, 14.3, or 14.4,

(i) all of the licenses granted by Licensor to Licensee shall therewith immediately terminate and any sublicenses granted by Licensee thereunder will be subject to the provisions set forth in Section 2.4(f);

(ii) Licensee must assign and transfer to Licensor, and shall cause its Affiliates and Sublicensees to assign and transfer to Licensor, without additional compensation, all of their right, title, and interest in to, and under, subject to any licenses or sublicenses granted by Licensee that expressly survive any such termination pursuant to Section 2.4(f), all clinical and related study data based on use of Products, all Regulatory Filings and Regulatory Approvals for Products in respect of each country in the Territory; and the Renaissance Supply Agreements.

(b) If at the time of any such termination of this Agreement by Licensor pursuant to Sections 14.2 or 14.3 Licensee has in its possession or under its control any inventory of the Product approved and allocated for sale in the Territory, Licensee shall for a period not to exceed six (6) months following the effective date of such termination be permitted to sell any such inventory of the Product in the Field in the Territory, and the licenses hereunder shall continue on a nonexclusive basis until all such units of the Product have been sold, provided that (A) the Product shall not be sold at a discount to a purchaser that is greater than the average discount provided to such purchaser for the Product during the twelve (12) month period preceding such termination and, in addition, such sales shall not result in the applicable wholesaler inventory levels for the Product exceeding the average levels for the twelve (12) month period preceding such termination, and (B) Licensee continues to pay, during the applicable Royalty Term, the applicable royalty and, if applicable, sales milestones, on resulting applicable Net Sales of Product in the Territory by it Licensee, its Sublicensees or any Third Party Distributors.

(c) In the event of a material breach of this Agreement by Licensor that is not successfully disputed or cured by Licensor in accordance with Section 14.2(b), Licensee may elect to terminate this Agreement or continue the Agreement; provided, that in the event Licensee elects to continue the Agreement in lieu of terminating the Agreement in accordance with Section 14.2, Licensee will have the right in its discretion to fully reduce the royalty payments or milestone payments required under Article 8 by the amount of damages suffered by Licensee due to such material breach by Licensor, which such amount will be determined by an independent third party with requisite expertise and agreed upon by the Parties, with any dispute as to the determination being subject to the dispute resolution process set forth in Section 15.8(b).

(d) In the event of the insolvency or bankruptcy of Licensor that gives rise to Licensee's right to terminate this Agreement in accordance with Section 14.3, Licensee may elect to terminate this Agreement or continue the Agreement (subject, to the extent applicable, Section 14.7).

14.6 **General Surviving Obligations.** The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of the Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Expiration or termination of this Agreement for any reason shall not (a) release either Party from any obligation that has accrued prior to the effective date of such expiration or termination (including without limitation the obligation to pay amounts accrued and due under this Agreement prior to the effective date of such termination but that are unpaid or become payable thereafter), (b) preclude either Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (c) terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive expiration or termination. Without limiting the foregoing, the Parties have identified various rights and obligations which are understood to survive, as follows. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: Sections 7.7, 7.8, 9.1(a), 9.2(b), 9.5(a), and Articles 1 (to the extent that any term defined therein is used in any of the sections or articles specified in this list as surviving termination of this Agreement), 8, 11, 12, 13, 14, and 15.

14.7 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by either Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 61 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

15. MISCELLANEOUS.

15.1 **Agency.** Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer, or legal representative of the other Party for any purpose, except as expressly set forth herein. No Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Parties, nor shall either Party be entitled to pledge the credit of the other Parties in any way or hold itself out as having the authority to do so.

15.2 **Assignment.** Except as expressly provided in this Agreement, neither Party may assign any rights or delegate any duties under this Agreement to any Third Party without the prior written consent of the other Party; provided, however, that (a) Licensor may freely assign its right to receive any payments hereunder without such consent of Licensee, (b) in the case where either Party seeks to assign this Agreement as a whole to an Affiliate or to a Successor in connection with a Change of Control of such Party or of that part of such Party's business to which this Agreement relates, such consent shall not be unreasonably withheld, delayed, or conditioned, provided that such Party provides written notice to the other Party of such Change of Control and such Successor agrees in writing to be bound as such Party hereunder. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's Successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or transfer not in accordance with this Section 15.2 shall be null and void.

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

15.4 **Notices.** All notices and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when personally delivered or sent by confirmed facsimile or email (with hard copy to follow); (b) one (1) Business Day after sent by reputable overnight express courier (charges prepaid); or (c) five (5) Business Days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, such notices to Licensor or Licensee shall be sent to the addresses indicated below:

If to Licensor, addressed to:

Serenity Pharmaceuticals, LLC
105 Hawk Court
Milford, PA 18327
Attention: Chief Executive Officer
With a copy to:
email: docsam122@gmail.com>

With a further copy to:
Mr. Alain Kodsi
email: alainkodsi@gmail.com

If to Licensee, addressed to:

Avadel Specialty Pharmaceuticals, LLC
16640 Chesterfield Grove Road, Suite 200
Chesterfield, MO 63005
Attention: Chief Executive Officer
With a copy to: General Counsel

15.5 **Amendment.** No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

15.6 **Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

15.7 **Counterparts; Electronic Delivery.** This Agreement may be executed simultaneously in two counterparts, either of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.8 **Governing Law; Dispute Resolution.**

(a) This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A. without regard to its or any other jurisdiction's choice of law rules that would result in the application of the laws of any jurisdiction other than the State of New York, U.S.A.

(b) Except as otherwise provided in this Agreement, in the event of any dispute, controversy, or claim (**"Dispute"**) between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party providing such notice may, by written notice to the other Party refer such Dispute to the other Party for attempted resolution by good faith negotiation by the Chief Executive Officers or President of Licensor and the Chief Executive Officer, President or an Executive Vice President within thirty (30) days after such notice is received. In the event that any such Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Section 15.8(c). Any Disputes of the type described in Section 3.2(i) shall first be subject to the dispute resolution mechanism set forth in Section 3.2(i) before being subject to this Section 15.8.

(c) In the event such officers of the Parties are not able to resolve any such Dispute, either Party may at any time after such thirty (30) day period submit such Dispute to be finally settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association (**"AAA"**) in effect at the time of submission. The arbitration shall be heard and determined by three (3) arbitrators. Each such Party shall each appoint one arbitrator and the third arbitrator shall be selected by the two Party-appointed arbitrators, or, failing agreement within thirty (30) days following the date of receipt by the respondent of the claim, by the AAA. Such arbitration shall take place in New York, NY. The arbitration award so given shall be a final and binding determination of the dispute, shall be fully enforceable in any court of competent jurisdiction, and shall not include any damages expressly prohibited by Section 12.1. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while the dispute resolution procedures set forth in this Section 15.8(c) are pending.

(d) Notwithstanding anything herein to the contrary, nothing in this Section 15.8 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, including in a court of law, if necessary to protect the interests of such Party. This Section 15.8 shall be specifically enforceable.

(e) Notwithstanding the foregoing, any disputes regarding the validity, scope or enforceability of Patent Rights or trademarks shall be submitted to a court of competent jurisdiction in the territory in which such rights apply.

15.9 **Hart-Scott-Rodino.** Licensee, at its expense, with the reasonable cooperation of Licensor, will be responsible for making any filing with the U.S. Federal Trade Commission ("FTC") in respect of this Agreement and the transaction contemplated hereby under Hart-Scott-Rodino Antitrust Improvements Act of 1976. This Agreement shall not become effective until the expiration of any applicable waiting period under such Act.

15.10 **Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

15.11 **Compliance with Applicable Laws.** Each Party will comply with all Applicable Laws in performing its obligations and exercising its rights hereunder.

15.12 **Remedies.** The exercise of any remedies hereunder shall be cumulative and in addition to and not in limitation of any other remedies available to such Party at law or in equity.

15.13 **Force Majeure**. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of nature, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, or civil unrest (**"Force Majeure"**); provided that the affected Party promptly notifies the other Party and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. In the event any such Force Majeure event continues for three (3) months or more, the unaffected Party shall have the right to terminate this Agreement, effective as of the date of delivery of notice, which notice shall not be delivered prior to the end of such three (3) month period.

15.14 **Interpretation**. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

15.15 **Construction**. In construing this Agreement, unless expressly specified otherwise: (a) unless otherwise specifically provided, any references to Articles, Sections, Exhibits, Schedules, and Appendices are to articles in, sections of, and exhibits, schedules and appendices to, this Agreement; (b) except where the context otherwise requires, use of either gender includes the other gender and use of the singular includes the plural and vice versa; (c) headings and titles are for convenience only and do not affect the construction or interpretation of this Agreement; (d) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words; (e) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (f) except where the context otherwise requires, the word "or" is used in the inclusive sense; (g) all references to "dollars" or "$" herein shall mean US Dollars; (h) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (i) any reference to any Applicable Laws herein shall be construed as referring to such Applicable Laws as from time to time enacted, repealed or amended, and (j) any reference herein to any person or entity shall be construed to include the person's or entity's successors and assigns.

15.16 **Entire Agreement of the Parties**. This Agreement and the exhibits attached hereto constitute and contain the complete, final, and exclusive understanding and agreement of the Parties, and cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including without limitation the Confidentiality Agreement, and neither Party shall be liable or bound to any other Party in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon either Party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided herein. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall control.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date set forth in the first paragraph hereof by their duly authorized representatives as set forth below:

LICENSOR:
SERENITY PHARMACEUTICALS, LLC

By: /s/ Samuel Herschkowitz, M.D.
Name: Samuel Herschkowitz, M.D.
Title: Chief Executive Officer

By: /s/ Alain Kodsi
Name: Alain Kodsi
Title: President

LICENSEE:
AVADEL SPECIALTY PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

Exhibit 4.4
Commercialization Plan

[to be prepared in accordance with Article 4]

Exhibit 5.5
Manufacturing and Supply Plan

[to be prepared in accordance with Article 5]

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

Exhibit __
Development Plan

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Anderson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q/A of Avadel Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2017

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael F. Kanan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q/A of Avadel Pharmaceuticals plc:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2017

/s/ Michael F. Kanan
Michael F. Kanan
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q/A of Avadel Pharmaceuticals plc (the "Company") for the period ended September 30, 2017 (the "Report"), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 17, 2017

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q/A of Avadel Pharmaceuticals plc (the "Company") for the period ended September 30, 2017 (the "Report"), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 17, 2017

/s/ Michael F. Kanan

Michael F. Kanan
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)