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*Execution Copy*

**CONFIDENTIAL**  
**LICENSE AGREEMENT**

This License Agreement (the “Agreement”) is made as of July 30, 2018 (the “Effective Date”) by and between The Population Council, Inc., having a principal place of business of One Dag Hammaraskjold Plaza, New York, NY, 10017 (“Council”) and TherapeuticsMD, Inc., a Nevada Corporation having a principal place of business at 6800 Broken Sound Parkway, NW, 3<sup>rd</sup> Floor, Boca Raton, Florida 33487 (“LICENSEE”).

**RECITALS**

- A. Council is the owner of the Licensed Product (as defined below) and of certain regulatory filings and intellectual property related thereto;
- B. LICENSEE wishes to acquire the regulatory filings and to license from Council the right to develop and commercialize the Licensed Product; and
- C. Council wishes to license such rights to LICENSEE.

NOW, THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

**I. DEFINITIONS AND CONSTRUCTION**

For purposes of this Agreement, the following definitions will apply:

- 1.1 “Act” means the United States Food, Drug and Cosmetic Act of 1938, as amended from time to time, and its implementing regulations.
- 1.2 “Additional Requirements” has the meaning ascribed to that term in Section 4.2.2(c).
- 1.3 “Affiliate” means, with respect to any specified Person, a Person that, directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified Person. For purposes of this definition, “control,” when used with respect to any specified Person, will mean (a) the direct or indirect ownership of more than fifty percent (50%) of the total voting power of securities or other evidences of ownership interest in such Person or (b) the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities, by contract or otherwise; and the terms “controlling” and “controlled” have meanings correlative to the foregoing.
- 1.4 “Agreement” has the meaning ascribed to that term in the first paragraph of this agreement.
- 1.5 “Agreement Patent” means a patent or patent application disclosing and claiming a Program Improvement.
- 1.6 “API” or “Active Pharmaceutical Ingredient” means a substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product and are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body of a patient receiving the drug product.

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1.7 “Applicable Senior Officers” mean the President of LICENSEE or his or her designee, and President of the Council or his or her designee.

1.8 “Application for Regulatory Approval” means each application accepted for filing submitted to a Regulatory Authority to obtain Regulatory Approval in the Territory.

1.9 “Business Day” means any day that banks are open for business in New York City, State of New York, United States of America.

1.10 “Claim” means any action, appeal, petition, plea, charge, complaint, claim, suit, demand, litigation, arbitration, mediation, hearing, inquiry, investigation, or similar event, occurrence, or proceeding made by a Third Party.

1.11 “Commercialize” or “Commercialization” means all activities undertaken with respect to commercialization of a pharmaceutical product in the Territory, including the ongoing process and activities generally engaged in by a pharmaceutical company to establish and maintain a nationwide presence in applicable marketplaces and to sell and market a pharmaceutical product.

1.12 “Commercially Reasonable Efforts” means, in respect of the level of efforts in carrying out an obligation by a Party under this Agreement, within the range of efforts and resources commonly used by pharmaceutical companies of a similar size to such Party to develop and Commercialize in the Territory a product owned by such a pharmaceutical company or to which such pharmaceutical company has rights, which product is at a similar stage in its development or product life and is of similar market potential to the Licensed Product, not taking into account any milestone payments or royalties that may be owed under this Agreement.

1.13 “Confidential Information” means (i) in the case of Council, Council Know-How and financial or other non-scientific or non-technical business information regarding Council or its Affiliates made available to LICENSEE, Program Improvements, and any and all know-how and information relating to the Licensed Product or the use, development, manufacturing, or Commercialization of any of the foregoing; (ii) in the case of LICENSEE, all know-how and information relating to LICENSEE products other than the Licensed Product (whether commercialized or in development), or the use, development, manufacturing, or Commercialization of any of the foregoing; and (iii) in the case of either Party, clinical or regulatory affairs, and financial or other non-scientific or non-technical business information regarding such Party or its Affiliates or its sublicensees made available to the other Party; and in each case, which is owned or Controlled by the applicable Party hereto or any of its Affiliates. Confidential Information may exist in written, electronic or graphic form and may be disclosed orally. Notwithstanding the foregoing, Confidential Information will not include:

(a) information which is or becomes part of the public domain through no breach of this Agreement by the recipient or any of its Affiliates;

(b) information which the recipient can demonstrate by its written records was known by the recipient or any of its Affiliates prior to the disclosure thereof by the disclosing Party;

(c) information which is independently developed by the recipient or any of its Affiliates, so long as such development does not result from use of Confidential Information of the other Party, and such independent development can be demonstrated by written records of the Party claiming such independent development or any of its Affiliates; and

(d) information that becomes available to the receiving Party or its Affiliates on a non-confidential basis, whether directly or indirectly, from a Third Party who is not bound by a duty of confidentiality to the non-disclosing party.

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1.14 “Confidentiality Agreement” means those certain Confidentiality Agreements between Council and LICENSEE dated March 13, 2018 and each such Confidentiality Agreement dated June 28, 2018.

1.15 “Control” or “Controlled” means, with respect to any product, material, information, or intellectual property right, that a Party has the legal right or authority (whether by ownership, license or otherwise), as of the Effective Date or during the Term, to grant to the other Party access to, ownership of, a license or a sublicense (as applicable under this Agreement) under, such product, material, information, or intellectual property right as provided for herein without a need to make payments related to such grant and without violating (i) the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such license or sublicense or misappropriating the proprietary or trade secret information of a Third Party, or (ii) any law or governmental regulation applicable to such license or sublicense.

1.16 “Council” has the meaning ascribed to that term in the first paragraph of this Agreement.

1.17 “Council Technology” means Council Patent Rights and Council Know-How.

1.18 “Council Know-How” means all confidential know-how and information to the extent relating to and necessary for the development, manufacture or Commercialization of the Licensed Product, including clinical, technical, scientific, and medical information, know-how, methods, inventions, practices, and trade secrets, quality control information and procedures, pharmacological, toxicological and clinical test data and results and regulatory information, in each case, which Council Controls as of the Effective Date or at any time thereafter. Notwithstanding the foregoing, Council Know-How will not include (a) information which is or becomes part of the public domain through no breach of this Agreement by LICENSEE; (b) information which LICENSEE can demonstrate by its written records was known by LICENSEE or its Affiliates prior to the disclosure thereof by Council; (c) information which is independently developed by LICENSEE or its Affiliates outside of the Program, so long as such development does not result from use of Council Know-How, and such independent development can be demonstrated by written records; and (d) information that becomes available to LICENSEE or its Affiliates on a non-confidential basis, whether directly or indirectly, from a Third Party who is not bound by a confidentiality obligation to Council. For the avoidance of doubt, the Drug Master File jointly owned by the Council with [\*\*\*] shall not be considered Council Know-How or Council Technology Controlled by Council for purposes of this Agreement until such time as Council may seek and thereafter obtains consent of [\*\*\*] to the licensing thereof hereunder.

1.19 “Council Patent Rights” means: (a) the patents and patent applications that are listed on Exhibit A, and (b) all patents and patent applications Controlled by The Council in the Territory that claim a Licensed Product, or its use or manufacture, in each case, as of the Effective Date or after the Effective Date, including all provisionals, substitutions, continuations, continuations-in-part, divisionals, supplementary protection certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations, patents of addition thereof, PCTs of all such patents and patent applications.

1.20 “Damages” means all damages, losses (including any diminution in value), liabilities, payments, amounts paid in settlement, obligations, fines, penalties, costs, or expenses of any kind or nature whatsoever incurred or paid in connection with any Claim or threatened Claim (including reasonable fees and expenses of outside attorneys, accountants and other professional advisors, and of expert witnesses and other costs of investigation, preparation, and litigation in connection with such Claim or threatened Claim), and specifically excluding all special, punitive, incidental and consequential damages of any kind other than as expressly permitted under Section 13.5.

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- 1.21 “Effective Date” has the meaning ascribed to that term in the first paragraph of this Agreement.
- 1.22 “Exclusivity Term” has the meaning set forth in Section 10.2.1.
- 1.23 “FDA” means the United States Food and Drug Administration or any successors to its responsibilities with respect to pharmaceutical products such as the Licensed Product.
- 1.24 “Field” means human contraceptive indications.
- 1.25 “First Commercial Batch Release” means the first occurrence of the delivery by LICENSEE’s manufacturer of Licensed Product of a batch of Licensed Product to LICENSEE’s distributor’s warehouse (as of the Effective Date, using 3PL (third party logistics)).
- 1.26 “GAAP” means United States generally accepted accounting principles in effect as of the date of determination thereof.
- 1.27 “Generic Equivalent” means, with respect to the Licensed Product which has received Regulatory Approval in the United States of America, a generic version of the Licensed Product which has received Regulatory Approval from the FDA (x) under an abbreviated NDA which refers to the Licensed Product as the Reference Listed Drug (as defined in 21 C.F.R. 314.3(b)), (y) under an NDA described in Section 505(b)(2) of the Act as to which information necessary for approval is contained in the NDA filed as part of the Program for the Licensed Product but as to which the applicant in the NDA for such potential Generic Equivalent does not have a right of reference, or (z) by any means by which such generic version can obtain Regulatory Approval based, in part, on information contained in the NDA filed for the Licensed Product but as to which the applicant in the application for Regulatory Approval for such potential Generic Equivalent does not have a right of reference.
- 1.28 “Joint Product Committee” means the committee described in Section 4.1.1.
- 1.29 “LICENSEE” has the meaning ascribed to that term in the first paragraph of this Agreement.
- 1.30 “Launch” means the occurrence of the first delivery to a pharmacy of the Licensed Product billed or invoiced by LICENSEE (or one of LICENSEE’s Affiliates or permitted sublicensees) to a non-sublicensee Third Party in the Territory following Regulatory Approval.
- 1.31 “Law” means all laws, statutes, regulations, or governmental, regulatory, or judicial orders or judgments.
- 1.32 “License” has the meaning set forth in in Section 2.1.
- 1.33 “Licensed Product” means the Nestorone® (segesterone acetate)/ethinyl estradiol ring that is the subject of the NDA.
- 1.34 “Marketing Plan” means the marketing plan for the Licensed Product in the Territory developed by LICENSEE and reviewed by the Joint Product Committee as described in Section 5.1, as amended from time to time by the LICENSEE and reviewed by Joint Product Committee during the Product Term.
- 1.35 “Marketing Strategy” means the marketing strategy for the Licensed Product in the Territory developed by LICENSEE and reviewed by the Joint Product Committee, including the budget for promotion, product positioning, pricing, education programs, publications, sales messages, and Phase IV clinical studies, as such strategy may be amended by the LICENSEE and reviewed by Joint Product Committee from time to time during the Product Term.

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1.36 “NDA” means, (a) for the Licensed Product, United States New Drug Application #209627, filed with the FDA, as such application may be amended or supplemented from time to time, and (b) generally, a New Drug Application in the United States submitted to the FDA for authorization to market a pharmaceutical Product.

1.37 “NDA Response Date” means the date that the FDA first provides either a complete response letter or approval of the NDA for the Licensed Product.

1.38 “Net Sales” means the amount of gross invoiced sales of the Licensed Product in the Territory for a specified period less the following amounts actually and reasonably incurred by LICENSEE, its sublicensees or any of their respective Affiliates selling such Licensed Product:

- (a) customer directed commissions and quantity, trade and cash discounts actually allowed or given;
- (b) discounts, replacements, credits or refunds actually allowed for the return of rejected, outdated, damaged or returned Licensed Product;
- (c) rebates, chargebacks and price adjustments actually allowed or given;
- (d) sales or similar taxes (including duties or other governmental charges or assessments) levied, absorbed or otherwise imposed on the sale of Licensed Product; and
- (e) charges for freight, handling, postage, transportation, insurance and other shipping charges;
- (f) a reasonable allowance for bad debts to the extent actually written off and not to exceed 5% of such gross invoiced sales during the applicable period;
- (g) provided, however, that:
- (h) sales or transfers of Licensed Product between or among LICENSEE, any permitted sublicensee or any Affiliate of LICENSEE will be excluded from Net Sales calculations for all purposes;
- (i) Licensed Product that is made, sold or used in connection with any pre-clinical or clinical trials, or for any testing, quality control, evaluation or other development purposes, or distributed as samples, will be excluded from Net Sales calculations for all purposes;
- (j) LICENSEE will not, and will cause its Affiliates and permitted sublicensees to not, apply any discount to the price of the Licensed Product for bundled sales of the Licensed Product with any other product Commercialized by LICENSEE its Affiliates and permitted sublicensees; and
- (k) amounts relevant to the determination of Net Sales, and the timing of sales, will be determined from the books and records of LICENSEE (or, as applicable, any permitted sublicensee or any Affiliate of LICENSEE) which will be maintained in accordance with generally accepted accounting principles (GAAP) in the United States.

1.39 “New Product” is defined in Section 10.2.2(b).

1.40 “Other Information” means (a) information relating to a disapproval or cancellation of Regulatory Approval of the Licensed Product by the relevant Regulatory Authority of any jurisdiction; (b) information on modifications required to be made in the contents of a Regulatory Approval of the Licensed Product or an application therefor in any jurisdiction in order to prevent, or to warn against risks of, death, bodily harm, or other severe adverse event; (c) information on withdrawal of the Licensed Product from the marketplace in any jurisdiction; (d) information on important revisions of the warnings or precautions in the usage of the Licensed Product as set forth in the labeling pursuant to a Regulatory Approval or an application therefor in any jurisdiction; and (e) any information about the Licensed Product which would reasonably be expected to adversely impact the continued development or marketing of a Licensed Product in any jurisdiction.

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1.41 “Outreach Plan” is defined in Section 5.4.1.

1.42 “Party” means Council or LICENSEE and “Parties” means Council and LICENSEE.

1.43 “Person” means any individual, corporation (including any nonprofit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, or other entity.

1.44 “Product Term” means the period beginning as of the Effective Date and ending upon the earlier of (i) such time as the Licensed Product is no longer being developed, Commercialized, or sold by LICENSEE or any of its Affiliates, assignees, licensees, sublicensees, transferees, distributors, or marketing partners in the Territory, or (ii) termination or expiration of this Agreement as provided herein.

1.45 “Program” means all activities related to the development, manufacture and Commercialization of Licensed Product performed by or on behalf of Council (or its Affiliates) or LICENSEE (or its Affiliates) pursuant to this Agreement.

1.46 “Program Improvements” means any and all inventions, developments, results, know-how, and information (including clinical, technical, scientific, and medical information, know-how, methods, inventions, practices, and trade secrets, quality control information and procedures, pharmacological, toxicological and clinical test data and results and regulatory information) and all intellectual property relating to any of the foregoing, in each case that is developed by or on behalf of LICENSEE (or its Affiliates) or Council (or its Affiliates) or jointly by LICENSEE and Council or any of their respective Affiliates, in connection with the Program.

1.47 “Program Transfer Provisions” has the meaning ascribed to that term in Section 12.2.3.

1.48 “Protective Action” has the meaning ascribed to that term in Section 7.2.1.

1.49 “Public Organization” will mean the Title X family planning clinics listed in the most recently published Office of Population Affairs Title X Family Planning Directory.

1.50 “Quarter” means a calendar quarter consisting of any of the three-month periods ending on March 31, June 30, September 30 and December 31 in any particular year.

1.51 “Regulatory Approval” means written notice of marketing approval by the FDA based on approval of the NDA.

1.52 “Regulatory Authority” means the agency, if any, of the national government of any country with which a pharmaceutical or biological therapeutic product must be registered or by which a pharmaceutical or biological therapeutic product must be approved prior to its manufacture, use, or sale in such country. Regulatory Authority will include the FDA.

1.53 “Right of Reference” means the “right of reference” defined in 21 CFR 314.3(b), or its equivalents outside the United States, and will in any event include the right to allow the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in regulatory materials (and any data contained therein) filed with such Regulatory Authority.

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1.54 “Royalty Period” will have the meaning described in Section 3.2.1.

1.55 “Royalty Report” will have the meaning described in Section 3.3.4.

1.56 “Territory” means the United States of America including its possessions and territories.

1.57 “Third Party” means any Person other than Council or LICENSEE or an Affiliate or an employee of Council or LICENSEE.

1.58 “Watson Agreement” means that certain License Agreement made as of February 9, 2010 by and between the Council and Watson Pharma Inc.

1.59 “WCG Agreement” means that certain License Agreement made as of October 1, 2015 by and between the Council and WomanCare Global Trading CIC,.

1.60 “Wholesale Acquisition Cost” means the wholesale acquisition cost for the Licensed Product as determined by Licensee and published by First Data Bank, Medispan or other nationally recognized database as of the date the Licensed Product was dispensed.

1.61 Construction. For purposes of this Agreement: (a) words in the singular will be held to include the plural and vice versa as the context requires; (b) the word “including” and “include” will mean “including, without limitation,” unless otherwise specified; (c) the terms “hereof,” “herein,” “herewith,” and “hereunder,” and words of similar import will, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; and (d) all references to “Section,” “Article,” “Schedule” and “Exhibit,” unless otherwise specified, are intended to refer to a Section, Article, Schedule or Exhibit of or to this Agreement.

## II. LICENSE; MANUFACTURING

2.1 License Grant. Subject to the terms and conditions of this Agreement, including the payment by LICENSEE to Council of the payment due for Regulatory Approval of the Licensed Product as set forth in Section 3.1, Council hereby grants LICENSEE the sole and exclusive right and license (even as to the Council except for a retained non-exclusive right to perform research and development activities on Licensed Product as necessary or useful to fulfil Council’s obligations under this Agreement) under all Council Technology and Council’s interest in, to and under all Program Improvements solely to develop, Commercialize, manufacture, make, have made, use, import, export, offer to sell, sell, have sold and distribute Licensed Product in the Field and in the Territory and to make or have made Licensed Product outside the Territory solely for use in the Territory (the “License”).

2.2 Sublicensing.

2.2.1 LICENSEE will have the right to sublicense its rights under the License to LICENSEE Affiliates and to Third Parties only with Council’s prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. The terms of any sublicense permitted under the foregoing sentence will be set forth in a written agreement and fully consistent with the terms of this Agreement, including in the case of any sublicensee obtaining sublicense rights to Commercialize any Licensed Product, that such writing incorporates the terms of Sections 10.2.1, 12.4 and Article XI. With respect to all sublicenses granted under this Agreement, for purposes of determining whether any breach has occurred under this Agreement, the acts and omissions in relation to this Agreement of any sublicensee of LICENSEE hereunder will be attributable to LICENSEE as though taken or omitted by LICENSEE, itself, (ii) LICENSEE will be jointly and severally liable for any damage arising out of the acts or omissions of any of LICENSEE’s sublicensees of the LICENSEE’s licensed rights hereunder and (iii) LICENSEE will remain obligated to perform LICENSEE’s own obligations under this Agreement.

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2.2.2 Any sublicense under the License will automatically terminate upon any termination of the License.

2.2.3 No sublicensee of LICENSEE under the License will have the right to further sublicense its rights under any such sublicensing arrangement without the prior written consent of the Council, which consent will not be unreasonably withheld or delayed.

2.3 Manufacturing.

2.3.1 The Parties acknowledge that (a) Council has entered into that particular Supply Agreement with Crystal Pharma dated [\*\*\*] for the supply of the Active Pharmaceutical Ingredient for the Licensed Product attached as Schedule 2.3.1(a) ("API Supply Agreement") and (b) Council has entered into that particular letter agreement with QPharma AB ("QPharma") dated [\*\*\*] for the optimization of the commercial manufacturing process for the Licensed Product ("Letter Agreement"). It is the intention of the Parties for LICENSEE to enter into agreements with each of Crystal and QPharma for the manufacture and supply of Licensed Product for sale in the Territory. LICENSEE will use Commercially Reasonable Efforts to enter into such agreements promptly after the Effective Date, and Council will use Commercially Reasonable Efforts to assist LICENSEE to enter into such agreements until each such agreement has been entered into by LICENSEE. Upon LICENSEE's reasonable written request to Council, Council will use reasonable efforts at LICENSEE's cost and expense to enforce Council's rights with respect to such negotiation obligations of Crystal Pharma and QPharma, as applicable.

2.3.2 Council hereby consents to a sublicense to QPharma AB for manufacture and supply of Licensed Product to LICENSEE and/or LICENSEE's sublicensees.

2.3.3 Trademarks. Following grant of a registration therefor in the United States by the United States Patent and Trademark Office and upon request by LICENSEE, Council will grant to LICENSEE an exclusive license, on customary terms but without additional consideration above that set forth in this Agreement, to the specific trademarks set forth on Schedule 2.3.3 for use in connection with the Commercialization, marketing, offering for sale and sale of any Licensed Product in the Territory, in each case effective as of the date such trademark is used on such Licensed Product in commerce; provided, however, that nothing herein will require LICENSEE or any sublicensee to market or sell any Licensed Product using a Council Controlled trademark. To the extent LICENSEE Controls any Licensed-Product-specific registered trademarks that are used for Commercialization of the Licensed Product in the Territory and are available for registration in any country or region outside the Territory, Licensee agrees, upon request of Council, to grant a license to Council to such trademarks for use by Council or its designees in Commercialization of the Licensed Product in such country or region outside the Territory.

### III. CONSIDERATION

As partial consideration for the rights and licenses granted to LICENSEE in this Agreement, LICENSEE will pay to Council the following amounts by wire transfer in immediately available funds to an account designated by Council in the United States.



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3.1 Milestone Payments. In addition to (and not in lieu of) the royalty payments due under this Agreement, LICENSEE will pay to Council each of the following one-time milestone non-refundable, non-creditable and no-recourse payments (each a "Milestone Payment") no later than thirty (30) days following the occurrence of each of the following events:

3.1.1 upon the first Regulatory Approval by the FDA of the Licensed Product, twenty million United States Dollars (US \$20,000,000) provided that LICENSEE has not terminated the Agreement in accordance with, and within the applicable time period specified in, Section 4.2.2(c), and further provided that, if LICENSEE has made the five million United States Dollars (US \$5,000,000) payment to Council set forth in Section 4.2.2(c)iv, then such Milestone Payment shall be reduced to fifteen million United States Dollars (US \$15,000,000);

3.1.2 upon the First Commercial Batch Release of a Licensed Product by LICENSEE, a Milestone Payment of twenty million United States Dollars (US \$20,000,000);

3.1.3 upon first achieving two-hundred million United States Dollars (US \$200,000,000) in cumulative Net Sales in the aggregate for all Licensed Product sold by LICENSEE, its sublicensees and their respective Affiliates selling the Licensed Product in the Territory, a Milestone Payment of forty million United States Dollars (US \$40,000,000); and

3.1.4 upon first achieving four-hundred million United States Dollars (US \$400,000,000) in cumulative Net Sales in the aggregate for all Licensed Product sold by LICENSEE, its sublicensees and their respective Affiliates selling the Licensed Product in the Territory, a Milestone Payment of forty million United States Dollars (US \$40,000,000).

3.1.5 upon first achieving one billion United States Dollars (US \$1,000,000,000) in cumulative Net Sales in the aggregate for all Licensed Product sold by LICENSEE, its sublicensees and their respective Affiliates selling the Licensed Product in the Territory, a Milestone Payment of forty million United States Dollars (US \$40,000,000).

3.2 Royalties.

3.2.1 Royalties on Licensed Product. As partial consideration of the licenses granted to LICENSEE hereunder, the royalties described in this Section 3.2.1 will be payable on Net Sales occurring during the period of time beginning on the Effective Date and ending on the date the first arms-length commercial sale of a Generic Equivalent of the Licensed Product is launched by a Third Party unaffiliated with LICENSEE in the Territory (the "Royalty Period"). LICENSEE will pay to Council such royalties equal to the applicable percentages of aggregate annual Net Sales of all Licensed Product sold in the Territory during the applicable calendar year as follows:

(a) five percent (5%) of Net Sales of all Licensed Product aggregated across the Territory in a calendar year during the Royalty Period with respect to such Net Sales in such calendar year that are less than or equal to fifty million United States Dollars (US \$50,000,000); and

(b) ten percent (10%) of Net Sales of all Licensed Product aggregated across the Territory in a calendar year during the Royalty Period with respect to such Net Sales in such calendar year that are greater than fifty million United States Dollars (US \$50,000,000) and less than one-hundred fifty million United States Dollars (US \$150,000,000); and

(c) fifteen percent (15%) of Net Sales of all Licensed Product aggregated across the Territory in a calendar year during the Royalty Period with respect to such Net Sales in such calendar year that are one-hundred fifty million United States Dollars (US \$150,000,000) or greater.

3.2.2 Generic Royalties. Following the expiration of the Royalty Period, LICENSEE will pay to Council the royalties described in Section 3.2.1(a) at a reduced rate equal to fifty percent (50%) of the applicable rate under Section 3.2.1 for the time period beginning on the expiration of the Royalty Period and ending six (6) months thereafter, and (b) after the expiration of the time period described in (a), twenty percent (20%) of the applicable rate under Section 3.2.1 for the remainder of the Term.

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3.2.3 Payment and Reports.

(a) LICENSEE will pay to Council, in United States dollars, not later than forty-five (45) calendar days after the end of each Quarter the royalties owed to Council under the terms of Section 3.2. Each royalty payment will be accompanied by a report in writing (the "Royalty Report") specifying the Quarter to which such royalty payment applies and detailing the calculation of the royalties due to Council for such Quarter, including details as to: gross sales of the Licensed Product; units sold of the Licensed Product; sales and similar taxes paid; refunds made; credits provided; freight and distribution fees paid; other allowable deductions taken; reconciliation, if any, of estimated to actual sales due to timing of financial reporting; computation of Net Sales; computation of royalties; reasonable documentation regarding any amounts deducted pursuant to Section 4.2.2. Except as otherwise expressly permitted in Section 3.4 with respect to taxes, all payments by LICENSEE will be made without set-off or deduction of any kind.

3.2.4 Records. LICENSEE will keep, and will require any Affiliates and sublicensees selling the Licensed Product to keep, for three (3) years from the date of each payment of royalties, complete and accurate records of Net Sales and net units sold of the Licensed Product in sufficient detail to allow the royalties to be determined accurately. Council will have the right for a period of three (3) years after receiving any report or statement with respect to royalties due and payable to appoint an independent Certified Public Accountant reasonably acceptable to LICENSEE to inspect the relevant records solely for the purpose of verifying such report or statement. LICENSEE will make its records and the records of its Affiliates available for inspection by such independent certified public accountant during regular business hours on a reasonably mutually agreed-upon date and at such place or places where such records are customarily kept, upon reasonable notice from Council, to verify the accuracy of the reports and payments. Such inspection right will not be exercised more than once in any calendar year except that, following any audit that reveals an underpayment sufficient to shift the cost of the audit to Licensee, until such time as two consecutive audits show no such discrepancy, Council will have the right to have such audit performed on a quarterly basis. Council will bear all of its and the auditor's costs and expenses associated with an audit conducted pursuant to this Section 3.2.4, provided, however, that if the designated auditor discovers an underpayment of at least the lesser of (i) twenty thousand United States dollars (US \$20,000) and (ii) five percent (5%), for any Quarter between the amount of royalties LICENSEE has paid under this Agreement and the amount of royalties actually owed to Council under this Agreement, then LICENSEE will bear all costs and expenses associated with such audit and, for the avoidance of doubt, such underpayment will be considered a late payment subject to interest pursuant to the terms of Section 14.12. Council agrees to treat all information learned in the course of any audit or inspection as Confidential Information of LICENSEE except to the extent necessary for Council to (i) reveal such information in order to enforce its rights under this Agreement, or (ii) if disclosure is required by law. The results of each inspection, if any, will be binding on both Parties. LICENSEE will include substantially the same audit rights in any sublicense it grants in order to verify the correctness of payments due hereunder.

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3.3 Taxes.

3.3.1 LICENSEE will make all payments to Council under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by applicable Law in effect in the Territory at the time of payment.

3.3.2 Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by LICENSEE on behalf of Council to the appropriate governmental authority, and LICENSEE will furnish Council with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Council.

3.3.3 LICENSEE and Council will cooperate in good faith with respect to all documentation required by any taxing authority or reasonably requested by LICENSEE or Council to secure a reduction in the rate of applicable withholding taxes.

3.3.4 If LICENSEE had a duty to withhold taxes in connection with any payment it made to Council under this Agreement but LICENSEE failed to withhold, and such taxes were assessed against and paid by LICENSEE, then LICENSEE will furnish Council with proof of payment of such taxes (not including any interest or penalty) and Council will reimburse LICENSEE for such amount within forty-five (45) days after Council's receipt of written notice from LICENSEE of such payment by LICENSEE.

3.4 Without limiting Section 2.2.1, in the event that LICENSEE or any successor in interest to LICENSEE sublicenses rights under this Agreement to any Person or Persons in accordance with the terms of this Agreement, LICENSEE or such successor will ensure that any such sublicensee, agrees to provisions whereby the Net Sales of Licensed Product by such sublicensee are considered in determining the royalty rates and milestone and royalty payment amounts owed and paid to the Council hereunder and that such sublicensee is liable for any non-payment of any such amount that related to such Net Sales of such sublicensee.

**IV. JOINT PRODUCT COMMITTEE, PRODUCT DEVELOPMENT,  
CLINICAL TRIALS AND REGULATORY APPROVALS**

4.1 Joint Product Committee.

4.1.1 Formation. Within 30 days of the Effective Date of the Agreement, the Parties will establish a joint product committee (the "JPC"). The JPC will be composed of six (6) members, three (3) members appointed by each Party, including at least one research and development executive or his or her designee from each Party, and will have the right to create subcommittees as needed. Promptly following the Effective Date, each Party will appoint its initial representatives to the JPC. Each Party may replace its JPC representatives at any time upon written notice to the other Party. LICENSEE will designate one of its representatives as the Chairperson of the JPC. The Chairperson will be responsible for scheduling meetings, preparing and circulating an agenda in advance of each meeting, preparing and issuing minutes of each meeting within thirty (30) days thereafter, revising such minutes to reflect timely comments thereon, and overseeing the ratification of such revised minutes.

4.1.2 Meetings. The JPC will meet at such times and such places as will be determined from time to time by LICENSEE and the Council, but in any event, not less than twice in each calendar year. Members of the JPC may participate in meetings of the JPC in person or by conference telephone call. A quorum for the conduct of business by the Joint Product Committee will consist of a majority of the members designated by LICENSEE and a majority of the members designated by the Council.

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4.1.3 Duties of the Joint Product Committee. The JPC will

- (a) Oversee the planning and implementation of development activities, including post-Regulatory Approval activities;
- (b) Review results of the development activities and discuss modifications to any planned development activities;
- (c) Facilitate the exchange of regulatory documents and other regulatory information between the Parties;
- (d) Review the Marketing Plan developed by LICENSEE and its implementation;
- (e) Discuss the state of the markets for Licensed Product in the Territory and opportunities and issues concerning the Commercialization of Licensed Product, including consideration of marketing and promotional strategy, marketing research plans, labeling, Licensed Product positioning and Licensed Product profile issues;
- (f) Monitor the sales efforts of Licensee in the Territory;
- (g) Oversee and update the Outreach Plan; provided that any changes during the Exclusivity Term to Paragraph 4 of the Outreach Plan will not be subject to decision by the JPC and must be made, if at all, by amendment or modification of this Agreement.
- (h) Have authority to establish one or more other committees that report to the JPC and assist the JPC in carrying out its responsibilities, which other committees will be subordinate to the JPC, will have such membership and responsibilities as the JPC will determine, and may be disbanded by the JPC at any time;
- (i) Resolve, or attempt to resolve any disputes not resolved by any subordinate committee created by the JPC; and
- (j) Perform such other functions as appropriate to further the purposes of this Agreement and as allocated to it jointly in writing by the Parties.

4.1.4 Decision Making; Authority. The JPC will make its decisions by consensus, with each Party's representatives collectively having one vote. If the JPC is unable to reach consensus regarding a matter before it, the issue will be presented by the JPC to the Parties' Applicable Senior Officers for resolution. Once an issue has been presented to the Applicable Senior Officers, they will have fifteen (15) days to make a final determination regarding the issue in dispute. In the event that the Applicable Senior Officers are unable to reach a final determination within such fifteen (15) day period, then:

- (a) Council will have authority to make the final decision with respect to all issues relating to all clinical, regulatory, and development matters prior to the NDA Response Date and any matters thereafter for which the Council has sole financial responsibility under this Agreement; and
- (b) LICENSEE will have authority to make the final decision with respect to all issues not set forth in the foregoing (a) or Section 4.2.2(c), subject to LICENSEE fulfilling its obligations under this Agreement, including with respect to using Commercially Reasonable Efforts as required hereunder. For the avoidance of any doubt, LICENSEE will have exclusive right to establish pricing of the Licensed Product in the Territory.

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4.1.5 General Principles.

(a) The JPC and any subordinate committees have no authority beyond the specific responsibilities set forth in this Agreement with respect to such committee. Any subordinate committee created by the JPC will have such duties and responsibilities delegated to such committee by the JPC, so long as such duties and responsibilities do not exceed the power and authority assigned to the JPC hereunder. In particular, and without limiting the generality of the foregoing, no committee may amend or modify the terms or provisions of this Agreement.

(b) Each Party will ensure that its representatives to a committee have appropriate expertise and authority to serve as members of such committee. With the consent of the representatives of each Party serving on a particular committee, other representatives of each Party may attend meetings of that committee as observers. Each Party will be responsible for all of its own expenses of participating in committee meetings. Each Party will use good faith and cooperative efforts to facilitate and assist the efforts of the committees.

(c) Each committee will continue to exist until the first to occur of (i) the Parties mutually agreeing to dissolve it, or (ii) the expiration of all payment obligations described in Article III.

(d) The Parties may form any other committees as they will mutually agree.

4.2 Licensed Product Development.

4.2.1 Prior to the NDA Response Date, the Council in reasonable consultation with LICENSEE will use Commercially Reasonable Efforts to undertake the development and regulatory approval efforts toward obtaining a first approval of the NDA for the Licensed Product in the United States, at Council's cost and expense.

4.2.2 Phase 4 Studies Required upon Regulatory Approval.

(a) To the extent required by the FDA upon Regulatory Approval of the Licensed Product, Council will perform and pay the associated costs and expenses for the four post-approval studies described on Schedule 4.2.2(a).

(b) The Parties anticipate that in order to obtain and/or maintain Regulatory Approval for the Licensed Product a post-approval study may be required by the FDA on such Regulatory Approval to measure risk for venous thromboembolism (VTE) ("VTE Study"), and that as of the Effective Date the scope of the study the FDA has requested is described on Schedule 4.2.2(b). The Parties agree to cooperate in good faith to provide that the scope and cost of a VTE Study is appropriate. To the extent required by the FDA upon Regulatory Approval of the Licensed Product, LICENSEE will perform the VTE Study, provided that (i) fifty percent (50%) of the reasonable and direct costs and expenses incurred by LICENSEE for performance of such Phase IV Study in excess of twenty million United States Dollars (\$20,000,000), after payment thereof by LICENSEE, will be deductible by LICENSEE from the royalties or other payments owed to the Council hereunder to the extent actually paid and not previously deducted by LICENSEE as of the time that the applicable royalty or other payment is owed to Council, and (ii) any costs and expenses below such twenty million United States Dollars (\$20,000,000) will be the sole responsibility of LICENSEE and will not be deductible from royalties or other payments owed by LICENSEE to Council.

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(c) If (x) a complete response letter or continuance of greater than ninety (90) days is received by Council with respect to the Licensed Product, (y) post-marketing requirements or commitments in addition to the studies set forth on Schedule 4.2.2(a) or the VTE Study are required by the FDA upon the initial Regulatory Approval of the Licensed Product (“Additional Requirements”), or (z) the shelf life for the Licensed Product permitted by the FDA upon the initial Regulatory Approval thereof is less than eighteen (18) months, then in each case the Joint Product Committee will meet promptly to determine the strategy to be implemented to address any such issue, provided that:

- i. If a complete response letter or continuance of greater than ninety (90) days is received by Council with respect to the Licensed Product, to the extent that, within thirty (30) days following the notification and sharing by Council to LICENSEE of the complete response letter or notice of continuance, as applicable, the Parties, acting reasonably, are unable to agree on a strategy to address such response or continuance, as applicable (including with respect to each Party’s share of the costs and expenses associated with any such required studies), then each Party will have the right to terminate this Agreement immediately upon written notice by such Party to the other Party delivered not later than the last day of such thirty (30) day period;
- ii. If (A) Additional Requirements are required by the FDA upon Regulatory Approval of the Licensed Product that would involve a Clinical Study or, in the good faith judgment of either Party, would require expenditures in excess of one million United States Dollars (\$1,000,000) in the aggregate, and (B) within thirty (30) days following the notification and sharing by Council to LICENSEE of the Regulatory Approval letter from the FDA, the Parties, acting reasonably, are unable to agree on a strategy to address such additional post-marketing requirements (including with respect to each Party’s share of the costs and expenses associated with any such required additional requirements), then each Party will have the right to terminate this Agreement immediately upon written notice by such Party to the other Party delivered not later than the last day of such thirty (30) day period;
- iii. If the FDA permitted shelf life is less than eighteen (18) months in the Regulatory Approval for the Licensed Product, then LICENSEE shall have the right to terminate the Agreement with immediate effect on written notice to Council made not later than five (5) Business Days following the notification and sharing by Council to LICENSEE of the Regulatory Approval letter from the FDA; and
- iv. If neither Party terminates the Agreement in accordance with Section 4.2.2(c)i above, then LICENSEE shall promptly make a one-time non-refundable, non-creditable (except as set forth in Section 3.1.1) and no-recourse payment to Council of five million United States Dollars (US \$5,000,000).

4.2.3 Subject to Section 4.2.2, LICENSEE (itself or through an Affiliate or permitted Third Party sublicensee) will use Commercially Reasonable Efforts to maintain the NDA for the Licensed Product in the Territory. Without limiting the obligation of LICENSEE in the previous sentence, in the event that LICENSEE determines that LICENSEE will not maintain the NDA for the Licensed Product, LICENSEE will promptly notify COUNCIL of such determination and will provide the Council a reasonable opportunity within five (5) Business Days of such notification to discuss such determination and to offer suggestions regarding potential avenues to maintain the NDA, and if the Parties cannot agree within ten (10) Business Days after such notification on a pathway reasonably likely to permit the LICENSEE to maintain the NDA, then such notification will constitute a notice of Termination by LICENSEE under Section 12.3.1(a) (termination for reason other than for Council’s material breach), provided that the one hundred eighty (180) day notice period for effectiveness of such termination may be shortened by mutual agreement of the Parties to any lesser time period down to an immediate termination as of the expiration of such ten (10) day period following such notification.

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4.2.4 Except as provided in Sections 4.2.1 and 4.2.2, as between the Parties, LICENSEE will be responsible for all development costs with respect to the Licensed Product incurred after the Effective Date by or on behalf of LICENSEE, provided that any costs incurred by Council for development activities under this Agreement shall only be reimbursable by LICENSEE to the extent agreed to by LICENSEE in advance in writing.

4.2.5 Except as provided in Sections 4.2.1 and 4.2.2, LICENSEE will use Commercially Reasonable Efforts to perform the development activities related to the Licensed Product in the Territory. Without limiting the foregoing or Council's other remedies, if Council notifies LICENSEE that it believes LICENSEE is not using Commercially Reasonable Efforts to develop the Licensed Product: (i) the Joint Product Committee will meet within fifteen (15) days of any such notice and, at such meeting, Council will provide its rationale to the Joint Product Committee regarding why it believes LICENSEE has not been using Commercially Reasonable Efforts and LICENSEE will provide its rationale regarding why it believes it has been using Commercially Reasonable Efforts; and (ii) the Parties will use good faith efforts for a period of up to thirty (30) days following such Joint Product Committee meeting to attempt to resolve any such disputes after which time Council may pursue resolution pursuant to the terms of Section 14.3.

4.3 Trademarks. The Joint Product Committee will determine which trademark or trademarks will be used in marketing the Licensed Product in the Territory, provided that no trademark identifying Council will be used on the Licensed Product in the Territory except as required by law or as consented to by Council, such consent to be in Council's sole and absolute discretion. Subject to Section 2.3.3, LICENSEE will be the sole and exclusive owner of any trademark or trademarks used in marketing in a Licensed Product, provided that with respect to any termination of this Agreement that results in reversion of Commercialization rights to Council in relation to the Licensed Product Commercialization in the Territory, upon such termination or reversion, the Council shall be deemed to have a license to the Licensed Product-specific Trademarks in the Territory for purposes of commercializing the Licensed Product therein, and LICENSEE shall thereafter promptly assign all right, title and interest to such Trademarks to the Council.

4.4 Regulatory Activities.

4.4.1 Transfer to LICENSEE.

(a) Council will continue to hold the Investigational New Drug Application ("IND") prior to Regulatory Approval by the FDA.

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(b) Upon Regulatory Approval by the FDA and payment of the associated milestone set forth in Section 3.1.1, LICENSEE will own and hold the NDA and all other Applications for Regulatory Approval, licenses, and authorizations from the FDA, provided that (i) all data and information in the NDA will be owned solely by Council and licensed to LICENSEE in the Territory pursuant to the terms of this Agreement, and (ii) Council and its other licensees will have an irrevocable and perpetual a Right of Reference to such Applications for Regulatory Approval, licenses, and authorizations for (A) purposes of obtaining Regulatory Approval and Commercialization of the Licensed Product and other products outside the Territory, and (B) for all purposes with respect to products other than the Licensed Product (but not including any Generic Equivalent of the Licensed Product) within the Territory. Upon approval by the FDA of the NDA, Council will promptly transfer the NDA to LICENSEE and LICENSEE will accept such transfer from Council. Council agrees to use Commercially Reasonable Efforts in agreements related to licensing the Licensed Product outside the Territory to obtain a Right of Reference for LICENSEE similar to that described for Council above with respect to applications for Regulatory Approval outside the Territory. LICENSEE will not transfer any rights under the Licensed Product NDA to any Affiliate or Third Party (including by granting any Right of Reference thereto) under any circumstance other than as expressly permitted under this Agreement, including (x) in conjunction with an assignment to such Third Party or Affiliate of this Agreement as permitted under Section 14.4, and (y) under a sublicense pursuant to Section 2.2.

(c) Following payment by LICENSEE of the full payment set forth in Section 3.1.1, on an ongoing basis at LICENSEE's expense, Council will provide LICENSEE, in the form specified by the Joint Product Committee, with material relevant information and data that is part of the Council Know-How, including upon approval an electronic copy of the Licensed Product NDA as filed with the FDA. Each Party will provide the other Party with a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference described in this Section 4.1.1.

## V. COMMERCIALIZATION.

5.1 Pre-Marketing Activities. LICENSEE, with input from the Joint Product Committee, will be responsible for pre-marketing activities for the Licensed Product in the Territory. For the avoidance of any doubt, input from the JPC on Commercialization issues is advisory in nature. LICENSEE has sole decision making authority for Commercialization issues.

5.2 Marketing Plan. Not later than ninety (90) days prior to the anticipated Launch for the Licensed Product, LICENSEE, will prepare and submit to the Joint Product Committee for its review and comment a marketing plan for the Licensed Product (the "Marketing Plan") which plan will provide a three-year budget, market assessment, strategic drivers, pricing, and a reasonably detailed summary of operating strategies and tactics, advertising, marketing and educational materials, and sales and marketing promotional materials and activities intended to promote and support sales of the Licensed Product in the Territory (the "Marketing Plan"). The Marketing Plan will be updated by LICENSEE and reviewed by the Joint Product Committee on an annual three-year rolling basis, which update will be submitted to the Council not later than one-hundred eighty (180) days in advance of the first day of the next applicable fiscal year.

5.3 Sales and Marketing. LICENSEE will be responsible for sales, marketing and promotional activities for the Licensed Product in the Territory in accordance with the Marketing Plan and will bear all related costs and expenses. LICENSEE will use Commercially Reasonable Efforts to Commercialize Licensed Product in the Territory in all counties of the Territory, provided that:

5.3.1 if the Licensed Product is not Launched in the United States within sixty (60) days after the date of the First Commercial Batch Release LICENSEE will be deemed to have committed a material breach of its obligations under this Agreement; and

5.3.2 unless determined otherwise by the Joint Product Committee (which determination will be subject to a veto by The Council), (a) by the end of the second year after approval by the FDA of the first Regulatory Approval for a Licensed Product, LICENSEE will ensure that audited detailing visits promoting the Licensed Product are made by its sales representatives not less than once a calendar quarter to the OB/GYN prescribers in the United States that account for at least [\*\*\*] of the prescriptions by OB/GYN prescribers of contraceptive products, (b) in-person detailing visits will be augmented by commercially-reasonable digital efforts and professional education.



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5.4 Public Sector.

5.4.1 LICENSEE (itself or through a permitted sublicensee) will use Commercially Reasonable Efforts (without regard to profitability of the Licensed Product to LICENSEE or any permitted sublicensee) to perform the outreach activities described in the plan attached as Schedule 5.4.1 hereto (“Outreach Plan”). As part of the Outreach Plan, Licensee will publicly announce a reduced price program for underrepresented communities to the extent not already described in the press release described in Section 11.2.

5.4.2 LICENSEE agrees that the price for the Licensed Product charged by or on behalf of LICENSEE to Public Organizations will be no more than [\*\*\*] of the Wholesale Acquisition Cost.

5.5 Medical Inquiries. During the Term, LICENSEE will have responsibility for all correspondence with physicians in the Territory relating to the Licensed Product, and for providing information to physicians in response to medical inquiries, all in accordance with LICENSEE’s standard operating procedures and in compliance with applicable Laws and regulations. Council will promptly refer to LICENSEE all medical or patient questions emanating from the Territory relating to the Licensed Product.

5.6 Distribution and Customer Service. LICENSEE will have the sole responsibility for Licensed Product distribution, inventory, returns, accounts receivable and customer service. All customer complaints and inquiries regarding the Licensed Product will be referred by Council to LICENSEE for response in a timely manner after receipt by Council, and LICENSEE will handle such matters in a timely manner and in compliance with applicable laws and regulations.

5.7 Procedures. Prior to Launch, LICENSEE will prepare and provide to Council reasonable written procedures for Council to follow if Council receives complaints, medical inquiries, adverse event reports or orders for the Licensed Product.

5.8 Licensed Product Recalls. LICENSEE will have the responsibility for, and will bear all costs related to, any total or partial recall or market withdrawal of the Licensed Product (whether voluntary or not).

5.9 Global Coordination. LICENSEE will reasonably cooperate with Council and Council’s other licensees of Nestorone®-containing products other than the Licensed Product with respect to safety, and pharmacovigilance, and will enter into one or more safety and pharmacovigilance agreements as may be necessary or useful to effect such cooperation, and Council will require its other licensees of Nestorone®-containing products other than the Licensed Product to cooperate with LICENSEE, or its permitted sublicensees, as the case may be, with respect to safety and pharmacovigilance, including safety data.

**VI. OWNERSHIP AND INTELLECTUAL PROPERTY**

6.1 Ownership. Subject to LICENSEE’s license rights under the License, Council is and will be sole owner of Council Technology, Council Confidential Information and Program Improvements. Subject to any license granted to Council pursuant to the terms of Article XII, LICENSEE is and will be the sole owner of LICENSEE Confidential Information. Council (or its designated Affiliate) will own any product-specific trademarks set forth on Schedule 2.3.3 used in Commercializing Licensed Product by or on behalf of LICENSEE or its Affiliates or permitted sublicensees in the Territory that are owned by Council as of the Effective Date.

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6.2 Patent Applications on Council Know-How.

6.2.1 With respect to applications for patents that relate to Council Know-How, (a) Council will remain the owner of the application for patent, (b) Council will continue to bear the full costs of and responsibility for preparing, filing, and prosecuting, in its sole discretion, the application and (c) to the extent that any claims of such application for patent cover a Licensed Product, or the manufacture, use or sale thereof, such application for patent and any patents issuing thereon will constitute Council Patent Rights for purposes of this Agreement.

6.2.2 Where applications for patents covering any Council Know-How have not been filed:

(a) Council will, in its sole discretion subject only to the terms of Section 6.2.2(b), determine whether or not to file an application for patent in the Territory for such Council Know-How. If Council elects to file such an application, Council will bear the full costs of preparing, filing and prosecuting the application and maintaining any patents that issue thereon and Council will control the prosecution of such application using counsel reasonably acceptable to LICENSEE.

(b) If Council elects not to file an application for patent in the Territory covering any such Council Know-How that Council reasonably believes is likely to result in a material patent with respect to the License, then the following provisions will apply: (1) Council will notify the Joint Product Committee in writing of its decision not to file such an application for patent; (2) if LICENSEE disagrees with Council's decision not to file such application, LICENSEE will have a reasonable opportunity to consult with Council through the Joint Product Committee in order to convince Council to file such an application; (3) if Council maintains its election not to file such application then (i) the information will remain Council Know-How; and (ii) LICENSEE will not have the right to file any applications for patent disclosing or claiming such Council Know-How anywhere in the world without the prior written consent of Council; and (4) if Council permits LICENSEE to file such application, then LICENSEE will have the right to file such applications for patent.

(c) Council will notify the Joint Product Committee regarding each application for patent filed by Council pursuant to this Section 6.2.2 and any patent issuing thereon that covers a Licensed Product, or the manufacture, use or sale thereof. Each such application and each such patent will constitute a Council Patent Right for purposes of this Agreement and (subject to any restrictions imposed by Third Party transferors or licensors of such Council Know-How) will be licensed to LICENSEE by Council as part of the License without any royalty or other payment other than the royalties and payments specified herein.

(d) In the event that Council decides to abandon an application or not to maintain a patent on an application that falls under Section 6.2.2(c), Council will give written notice to LICENSEE at least sixty (60) days prior to Council allowing such application to go abandoned or prior to Council not taking a necessary step to maintain such patent and LICENSEE will have the option of taking over the prosecution or maintenance of such application or patent at its sole expense. If LICENSEE elects to take over the prosecution or maintenance of such application pursuant to this Section 6.2.2(d), or if Council gives LICENSEE written permission to file any applications for patent pursuant to Section 6.2.2(b), Council will, to the extent permitted by applicable law, assign all its right, title and interest in such application or patent in the Territory to LICENSEE.

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6.3 Patent Applications on Program Improvements. Council will be deemed the sole owner of all Program Improvements, provided that, to the extent any Program Improvement that is made solely by LICENSEE has utility outside the field of reproductive health and contraception in humans, then Council will be deemed hereby to have granted to LICENSEE a perpetual, irrevocable, fully-paid-up sublicensable exclusive license to such Program Improvement to research, develop, make, have made, sale, have sold, import and export products (for avoidance of doubt, other than Licensed Product) in fields outside of reproductive health and contraception in humans. To the extent that a Program Improvement is developed by or on behalf of one Party, that Party will promptly disclose such Program Improvement to the Joint Product Committee in writing with all relevant data supporting such Program Improvement. Council will determine whether or not to file an application for patent in the Territory for all Program Improvements. If Council elects to file such an application, Council will bear the full costs of preparing, filing, and prosecuting such application for patent and maintaining any patents that issue thereon and Council will control the prosecution of such application using counsel reasonably acceptable to LICENSEE.

6.4 Cooperation. Each Party will cooperate, and will cause its employees, consultants and subcontractors to cooperate with all reasonable requests of the other Party for assistance in preparation and prosecution and maintenance of any applications for patent and any patent issuing therefrom and any trademark and any registration issuing therefrom that is owned by the requesting Party hereunder. To the extent that any right, title, or interest in or to any intellectual property conceived, created, developed, or otherwise made by or on behalf of either Party or its Affiliates during the Term vests in a Party or its Affiliates, by operation of Law or otherwise, in a manner contrary to the ownership as set forth in this Article VI, such Party will, and hereby does, on behalf of itself and its Affiliates, irrevocably assign to the other Party any and all of such Party's and its Affiliates right, title, and interest in and to such intellectual property without the need for any further action by any Party. Upon a Party's reasonable request and at its expense, the other Party promptly will execute and deliver to the requesting Party any and all further documents and instruments or take other reasonable actions which may be necessary or appropriate to achieve and confirm the requesting Party's ownership of the intellectual property that is the subject of this Article VI.

6.5 Patent Filing Procedures.

6.5.1 Once a determination has been made by Council to file a patent application for Council Know-How or Program Improvements, each Party will, for patents prosecuted by it pursuant to this Agreement, make Commercially Reasonable Efforts to:

- (a) file applications for letters patent;
- (b) prosecute all pending and new patent applications and defend against oppositions filed against the grant of letters patent for such applications, including by avoiding where reasonably practicable, the use of extensions of deadlines that could reasonably impact the term and potential adjustment to the term of any patent that might issue thereon;
- (c) upon and after the grant of any letters patent, maintain such letters patent in force by duly filing all necessary papers and paying any fees required for such purpose;
- (d) keep the other Party reasonably informed of the status of all such applications for patent in the Territory, including by providing copies of material correspondence with the United States Patent and Trademark Office ("USPTO") regarding such applications far enough in advance to permit such other Party a reasonable opportunity (if available) to comment on any proposed response to any such material correspondence received from the USPTO, which comments, if any and if received by a prosecuting Party in a timely manner, shall be reasonably considered by Council in formulating its response, and if rejected, the Parties shall discuss the Council's reasons for rejecting such comments; to that end, each Party agrees to instruct applicable prosecution counsel to send copies of any material correspondence with the USPTO not later than seven (7) days following receipt by such prosecution counsel thereof; and

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(e) obtain such patent extensions, adjustments or restorations of patent terms as may become available from time to time.

6.6 Council Patent Rights.

6.6.1 Council will use Commercially Reasonable Efforts to (a) prosecute and maintain Council Patent Rights by duly filing all necessary papers and paying any fees required for such purpose by the patent laws of the particular country in which such Council Patent Right was granted, and (b) obtain such patent extensions or restorations of patent terms as may become available from time to time in any country regarding Council Patent Rights.

6.6.2 In the event Council decides not to prosecute or maintain a Council Patent Right or seek a patent extension or restoration, Council will give LICENSEE written notice at least 60 days prior to Council allowing such application to go abandoned or prior to Council not taking a necessary step to maintain such patent or seek such a patent extension or restoration, and LICENSEE will have the option of taking over the prosecution or maintenance of such application or patent or seeking such patent extension or restoration, in each case at its sole expense. If LICENSEE elects to take over the prosecution or maintenance of any application or patent or to seek such a patent extension or restoration, in each case pursuant to this Section 6.2.2, Council will, to the extent permitted by applicable law, assign all its right, title and interest in such application or patent in the Territory to LICENSEE.

6.7 No Challenge. LICENSEE will not and will ensure that its sublicensees and their respective Affiliates and do not challenge the validity or enforceability of any of the patents that are licensed to Licensee hereunder or assist any Third Parties to do the same. If LICENSEE or any of its distributors, or sublicensees or their respective Affiliates challenges or supports a Third Party challenge to the validity or enforceability of any such patent or assists any Third Party to do the same, LICENSEE will pay Council's reasonable costs and expenses (including attorneys' fees) for defending against such challenge, which payments will be made on a monthly basis in arrears.

**VII. INFRINGEMENT BY OR CLAIMS AGAINST THIRD PARTIES**

7.1 Notices. Each Party will advise the Joint Product Committee promptly upon its becoming aware of: (a) any unlicensed activities which such Party believes may be an actual or impending infringement in the Territory of any patent or other proprietary right owned or applied for by it or the other Party and related to the Licensed Product or the development, manufacture, use, importation, or sale thereof; (b) any attack on or appeal of the grant of any patent owned or applied for by it or the other Party and related to the Licensed Product or the development, manufacture, use, or sale thereof; (c) any application for patent by, or the grant of a patent to, a Third Party in respect of rights which may be related to the Licensed Product so as to potentially affect the development, manufacture, use, importation, or sale thereof or which may claim the same subject matter as or conflict with any patent owned or applied for by it or the other Party and related to the Licensed Product, or the development, manufacture, use, importation, or sale thereof; or (d) any application made for a compulsory license under any patent owned or applied for by it or the other Party and related to the Licensed Product or the development, manufacture, use, importation, or sale thereof.

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7.2 Control of Enforcement.

7.2.1 The Parties will determine through discussions at the Joint Product Committee whether or not to take whatever legal or other action is required in response to activities requiring notice under Section 7.1 (“Protective Action”). If the Joint Product Committee determines that such Protective Action is warranted, then, unless the Joint Product Committee determines otherwise, LICENSEE will, at LICENSEE’s expense, commence and prosecute such Protective Action at the direction of the Joint Product Committee or its designee. Council will, at LICENSEE’s expense, cooperate with LICENSEE in such action, including, without limitation, being joined as a Party to such action if such joinder is necessary for standing. Notwithstanding, Council will be responsible for its own internal costs associated with such action. Each Party may be represented by counsel of its own selection at its own expense in such Protective Action. Any recovery obtained as a result of such Protective Action, whether by judgment, award, decree, or settlement, will, after reimbursement of the Parties for their reasonable costs and expenses associated with such Protective Action, be retained by LICENSEE and included in and added to the total gross amounts invoiced for sales of Licensed Product for purposes of calculating royalties under the terms of Section 3.3. To the extent such recovery is insufficient to reimburse the Parties’ associated reasonable costs and expenses fully, then a Party’s share of the recovery will be the product of the total amount recovered with that Party’s reasonable costs and expenses divided by the sum of both Parties’ reasonable costs and expenses.

**VIII. INFRINGEMENT OF THIRD PARTY RIGHTS**

8.1 Third Party Claims. LICENSEE and Council will each promptly notify the Joint Product Committee of any Claim by a Third Party against LICENSEE or Council, or any Affiliate or sublicensee of Council or LICENSEE, alleging infringement of such Third Party’s intellectual property rights as a result of the development, manufacture, marketing, sale, importation, or use of the Licensed Product anywhere in the Territory. As directed by the Joint Product Committee, the Parties will cooperate and use Commercially Reasonable Efforts to resolve such claimed infringement, with each Party entitled to participate in the defense and to be represented by counsel of its choice, with each Party being responsible for the fees of its counsel; provided, however, that if it appears reasonably likely that the claimed infringement will give rise to a Claim for indemnification hereunder, then the Party against whom such Claim for indemnification would be made will have the first right to defend against such Claim in accordance with Article XIII below.

8.2 Payments to Third Parties. If a Third Party has or receives a patent in the United States that covers the development, manufacture, sale, importation, or use of the Licensed Product as the License Product was manufactured and composed as of the Effective Date, and the LICENSEE reasonably determines, after reasonable consultation with the Council and reasonable consideration of any arguments with respect thereto raised by the Council, that LICENSEE is required to obtain a license to such patent as to such Licensed Product for a royalty or other payment to such Third Party (including that any Licensed Product at issue cannot be reasonably manufactured differently so as to avoid the requirement), then LICENSEE may enter into such a license agreement and will pay all costs and expenses associated therewith, provided that LICENSEE will be entitled to deduct from royalties owed to Council hereunder an amount not to exceed [\*\*\*] of the royalties actually paid to such Third Party up to a maximum deduction of [\*\*\*] of the royalties otherwise owed by LICENSEE to Council in the aggregate for all such royalties for which LICENSEE is entitled to make such deduction. To the extent Council has, prior to the Effective Date, entered into any agreement with any Third Party for rights under such Third Party’s intellectual property, Council will be solely responsible for payment of any amounts owed under such agreement to such Third Party as a result of sales of Licensed Product pursuant to this Agreement.

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## IX. REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties of Both Parties. Council and LICENSEE each hereby represents and warrants to the other, as of the Effective Date, as follows:

9.1.1 It is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation and has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.

9.1.2 Neither it, nor any of its employees or consultants who will be undertaking any activities related to this Agreement or the subject matter thereof, has been debarred or is the subject of debarment or other disciplinary proceedings by the FDA or any Regulatory Authority in the Territory.

9.1.3 No consent, approval, order or authorization of, or registration, declaration or filing with, any governmental agency is required to be obtained or made by or with respect to such Party in connection with its execution, delivery and performance of this Agreement.

9.1.4 The execution, delivery and performance by it of this Agreement and the transactions contemplated thereby have been duly authorized by all necessary corporate action and stockholder action and will not (i) violate any applicable laws or regulations or (ii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.

9.1.5 It is not under any contractual obligation to any Third Party that conflicts with the terms of this Agreement or that limits the rights of such Party to fulfill its obligations hereunder.

9.2 Representations and Warranties of Council. Council hereby represents and warrants to LICENSEE, as of the Effective Date, as follows:

9.2.1 Except as set forth on Exhibit A, it owns each of the Council Patent Rights set forth on Exhibit A.

9.2.2 it has sufficient rights and power to grant the exclusive license to LICENSEE which it purports to grant herein.

9.2.3 all inventors of any Council Patents have assigned their entire right, title and interest in, to and under such Council Patents to Council.

9.2.4 the patents and patent applications listed on Exhibit A hereto constitute all the Council Patent Rights in existence as of the Effective Date.

9.2.5 all payments, fees or other obligations to be made or satisfied by Council to any regulatory authority, patent office or Third Party in any jurisdiction have been, and are as of the Effective Date, fully satisfied with respect to each item within the Council Technology and no action with any regulatory authority, patent office or Third Party with respect to the Council Technology is required to be taken within sixty (60) days after the Effective Date.

9.2.6 as of the Effective Date, no patent application or patent within the Council Patent Rights is the subject of any inter partes review, interference, derivation proceeding or other protest proceeding in any patent office in the Territory.

9.2.7 to its knowledge, as of the Effective Date, there is no information, material, fact or circumstance that would constitute inequitable conduct, fraud or misrepresentation with respect to any Licensed Patents.

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9.2.8 Council has received no notice and has no reason to expect such notice of any Claim by any Third Party or any Council employee that (a) such Third Party or employee has any rights to Council Technology or the Licensed Product that prevent Council from granting to LICENSEE the License; (b) manufacture, sale, importation or use of the Licensed Product currently in clinical development within the Field as contemplated hereby infringes any Third Party rights; or (c) Council Patent Rights (to the extent representing issued patents) are invalid or unenforceable.

9.2.9 To Council's knowledge as of the Effective Date, there are no errors in the inventorship set forth in any of the patent applications comprising Council Patent Rights.

9.2.10 the API Supply Agreement attached as Schedule 2.3.1(a) and the Letter Agreement attached as Schedule 2.3.1(b) are true and accurate copies of such agreements other than with respect to redacted terms.

9.2.11 Council is not in breach of (a) the API Supply Agreement or (b) the Letter Agreement.

9.2.12 Council has not received any written notice that the API Supply Agreement or the Letter Agreement has been terminated or breached.

9.3 Representations and Warranties of LICENSEE. LICENSEE hereby represents and warrants to Council, as of the Effective Date, as follows:

9.3.1 LICENSEE has sufficient resources, experience and expertise available to it to enable it to perform its obligations under this Agreement reasonably in accordance with pharmaceutical industry standards and strictly in accordance with all applicable Laws.

9.4 Mutual Limitations on Warranties. OTHER THAN THE REPRESENTATIONS AND WARRANTIES MADE BY THE PARTIES PURSUANT TO SECTIONS 9.1, 9.2 AND 9.3, THE PARTIES DISCLAIM ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES WHETHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY REPRESENTATIONS OR WARRANTY ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

## X. COVENANTS

10.1 Covenants of the Parties.

10.1.1 Throughout the Term, Council and LICENSEE will comply in all material respects with all applicable Laws and regulations, including the Act, concerning the development, manufacture, use and sale of the Licensed Product.

10.1.2 Each of Council and LICENSEE will promptly notify the Joint Product Committee if it becomes aware of any Other Information from sources other than LICENSEE. If any such Other Information relates to fatal, life threatening, or other serious adverse events (as defined in ICH-E2A, Section II.B.), the Party first becoming aware of it will promptly advise the Joint Product Committee by telephone, fax, email, or other instantaneous method of communication and will within fifteen (15) days thereafter provide written confirmation of such Other Information. Council will allow LICENSEE to comply (and LICENSEE will be responsible for complying) with the adverse reaction reporting requirements of the Act, and other comparable applicable Laws outside the United States with respect to the Licensed Product. Prior to the first commercial sale of the Licensed Product by LICENSEE or its designee, the Parties or their designees will enter into a pharmacovigilance and safety agreement concerning their respective reporting and investigation responsibilities.

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10.1.3 The Parties will execute and deliver any further or additional instruments or documents and perform any acts which may be reasonably necessary in order to effectuate and carry out the purposes of this Agreement.

10.2 Exclusivity.

10.2.1 Beginning with the Effective Date and ending on the first to occur of (i) the date of the first commercial sale of the first Generic Equivalent by a Third Party in the Territory, and (ii) six (6) years after the Effective Date ("Exclusivity Term"), neither LICENSEE, nor any sublicensee of LICENSEE that is Commercializing Licensed Product hereunder, nor any of their respective Affiliates that are Commercializing Licensed Product, will enter into contractual arrangements to (a) own, (b) manage or operate, (c) be engaged in, (d) provide services to, or (e) have an economic interest in, in each case, any business that is Commercializing [\*\*\*] other than a Licensed Product (a "Competing Product"). Notwithstanding the foregoing sentence, subject to the terms and conditions of this Agreement:

(a) LICENSEE and any of its Affiliates or sublicensees may, under the license granted, use, distribute, sell, offer for sale, have sold and import Licensed Product as a generic product ("Authorized Generic Product") in the Territory at any time after a Third Party launches a Generic Equivalent in the Territory. LICENSEE will send to the Council any and all verifiable evidence that a Third Party intends to launch a Generic Equivalent in the United States and will notify the Council promptly in writing in the event that LICENSEE or any of its Affiliates or sublicensees decides to use, distribute, sell, offer for sale, have sold and import Technology as an Authorized Generic Product in the Territory.

(b) In the event that LICENSEE or any of its affiliates or sublicensees obtains information showing that it is reasonably likely, based on objective evidence, which may include, without limitation, written notification of filing of an ANDA for such Generic Licensed Product, to the extent such notification is then required by applicable law, or filing of an action challenging Patent(s) pertaining to Council Technology in the United States, or similar verifiable evidence, that a Third Party intends to Commercialize a Generic Licensed Product in the United States, the Joint Product Committee may determine, subject to a veto right of the Council, that LICENSEE and any of its affiliates or sublicensees may, under the license granted, use, distribute, sell, offer for sale, have sold and import Licensed Product as an Authorized Generic Product prior to the launch of a Generic Licensed Product by a Third Party.

(c) In the event that LICENSEE is acquired by or acquires a Third Party through a merger, sale of stock or sale of all or substantially all of LICENSEE's assets, if such Third Party has, prior to and at the time of such acquisition, a Competing Product, then the restrictions described in this Section 10.2.1 shall not apply to such Third Party as long as LICENSEE takes reasonable steps to ensure that no Council Technology or Program Improvements are used in the development, Manufacturing or Commercialization of such Competing Product including as follows: (i) by limiting the access of Council Technology or Program Improvements by LICENSEE personnel that are working on such Competing Product to those such LICENSEE personnel that have a need-to-know such information for the performance of LICENSEE's obligations under this Agreement; and (ii) by conducting the research or Development activities required under this Agreement separately from any research or development activities directed to such Competing Product, including by the maintenance of separate lab notebooks and records (password-protected to the extent kept on a computer network) (except that this requirement shall not apply to personnel who have senior research management roles and not project level research roles, provided such personnel in senior research management roles are not directly involved in the day-to-day activities under such Competing Program).



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(d) LICENSEE shall have the right to engage Third Party manufacturers that are manufacturing Competing Products, provided such Third Party manufacturer is not manufacturing a Competing Product on behalf of LICENSEE during the Exclusivity Term and does not use Council Technology for the manufacture of such Competing Product.

10.2.2 Subject to this Section 10.2.2 (including the exclusive option described herein), LICENSEE acknowledges that, in furtherance of Council's goals, Council will continue to sponsor the development of contraceptive and other products which may, from time to time, compete with the Licensed Product, and that Council may receive compensation from licensees of such competing products in respect of sales thereof.

(a) Council hereby grants LICENSEE an exclusive option ("Option") to negotiate an exclusive license under which LICENSEE would have the exclusive right to develop, Commercialize, manufacture, make, have made, use, import, export, offer to sell, sell, have sold and distribute New Products in the Territory ("New License"). LICENSEE will have the right to exercise the Option at any time beginning on the Effective Date and ending on December 31, 2019 (the "Option Period") by delivery of written notice to Council specifying the category or categories ((i) or (ii) set forth in the definition of New Product) for which LICENSEE is exercising the Option ("Option Exercise Notice"). Upon delivery of the Option Exercise Notice by LICENSEE in accordance with this Section 10.2.2(a) and for the remainder of the Option Period (such time period, the "Negotiation Period", as may be extended by the Parties by mutual agreement), the Parties will negotiate in good faith a definitive written agreement for the New License, (such definitive agreement, the "License Agreement"), provided that the reasonableness and good faith of any position taken by a Party during such negotiation shall not be determined based on the presence or absence of any term or condition contained in this Agreement. During the Negotiation Period, Council will provide to LICENSEE such reasonable additional information in Council's possession and Control regarding the New Product as LICENSEE may reasonably request in writing to assist LICENSEE to make a reasonably informed decision with respect to the execution of the License Agreement, provided that in the event that the Parties do not enter into a License Agreement by the end of the Option Period, LICENSEE shall return to Council all such additional information (and all copies thereof) promptly upon expiration of the Option Period. With respect to each category (i) and (ii) set forth in the definition of New Product, upon the expiration of the Option Period for such category without the Parties' having entered into a License Agreement for such category of New Product, Council will have the right to assign, transfer, convey, license, or otherwise encumber its rights with respect to such category of New Product and any product falling within such category with any Third Party or multiple Third Parties without owing any duty or obligation to LICENSEE with respect thereto. LICENSEE acknowledges and agrees that in the event it does not exercise the Option or the Parties fail to enter in to the License Agreement for one or both of the categories of New Products, that, subject to Council fulfilling its obligations under Section 10.2.2(c) and 10.2.2(d), any development or Commercialization of one or more products within any such category of New Product by or on behalf of Council or a licensee of Council with respect thereto in the Territory may compete with the Licensed Product hereunder.

(b) "New Product" means (i) any vaginal ring product developed by the Council after the Effective Date that contains both and only Nestorone and estradiol as Active Pharmaceutical Ingredients, and (ii) any vaginal ring product that contains both Nestorone and ethinyl estradiol as Active Pharmaceutical Ingredients.

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(c) During the Option Period, the Council will not assign, transfer, convey, license, or otherwise encumber its right, title and interest in the any New Product in any manner that would prevent it from entering into and granting the rights to LICENSEE contemplated under this Section 10.2.2 upon agreement by the Parties, if any, as to the form and substance of the License Agreement and execution thereof.

(d) Council agrees not to license intellectual property rights encompassing or claiming any New Product to any Third Party in a manner that grants rights to market such New Product in the United States prior to the sixth (6<sup>th</sup>) anniversary of the Effective Date.

## **XI. CONFIDENTIAL INFORMATION**

### **11.1 Confidentiality.**

11.1.1 During the Product Term and at all times thereafter, each Party will use commercially reasonable efforts to keep, and cause its Affiliates and permitted sublicensees, if any, to keep confidential all Confidential Information of the other Party, and neither Party nor any of its Affiliates or sublicensees, if any, will use or disclose the Confidential Information of the other Party except as expressly permitted in this Agreement. The Parties acknowledge that Confidential Information may have been disclosed by either Party or its Affiliates to the other Party or its Affiliates pursuant to the Confidentiality Agreement. All information disclosed pursuant to the Confidentiality Agreement will be deemed Confidential Information of the disclosing Party within the meaning of this Agreement and subject to the terms hereof.

11.1.2 The fact that a particular item of information is not or has ceased to be Confidential Information by virtue of one or more of the exclusions specified in the definition of Confidential Information set forth in Section 1.12 (the “Excluded Item”) will not relieve the Party who obtained or received the Excluded Item from that Party’s obligation of confidentiality and non-use (a) as to any other item of Confidential Information of the other Party or (b) as to the relationship of the Excluded Item to any other item of Confidential Information of the other Party.

11.1.3 Each Party hereby acknowledges that the Confidential Information of the other Party is highly valuable, proprietary, and confidential and that any disclosure to any officer, director, employee, trustee, or agent of such Party or any of its Affiliates will be made only to the extent necessary to carry out its responsibilities under this Agreement and only if such officer, director, employee, trustee, or agent is informed of the confidential nature thereof and will have agreed to hold such information in confidence under confidentiality provisions at least as stringent as those provided in this Agreement.

11.1.4 The Parties agree that the obligations of this Section 11.1 are necessary and reasonable in order to protect the Parties’ respective businesses, and that monetary damages alone may be inadequate to compensate a Party for any breach by the other Party of its covenants and agreements set forth herein. The Parties agree that any breach or threatened breach of this Section 11.1 may cause irreparable injury to the injured Party for which Damages may not be an adequate remedy and that, in addition to any other remedies that may be available, in law and equity or otherwise, such Party will be entitled to seek equitable relief against the breach or threatened breach of the provisions of this Section 11.1.

11.1.5 Following termination of the License for any reason and at the request of the other, each Party will destroy all physical records or embodiments of Confidential Information of the other Party or return such information to the other Party, at the returning Party’s expense, and a senior officer of such Party will certify to the other Party that all such items have been so returned or destroyed; provided, however, that each Party will be entitled to maintain one copy of the Confidential Information of the other Party solely for the purpose of monitoring its continuing obligations hereunder.

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11.2 Disclosure to Investors; Public Announcements. Prior to making any public announcement or other disclosure regarding this Agreement, the Parties will agree in writing on an initial press release of the transaction contemplated by this Agreement (the "Initial Press Release"). The Initial Press Release may be issued or used by any Party individually or by the Parties jointly on or after the Effective Date. Other than the Initial Press Release and any information described therein, neither Party will disclose the specific terms described in this Agreement without the prior written approval of the other Party, except such announcements or disclosures, as in the opinion of the counsel for the Party making such announcement or disclosure, are required by law or regulation (including, without limitation, the regulations or rules of any stock exchange or similar self-governing body) If a Party decides to make an announcement or disclosure it believes to be required by law or regulation with respect to this Agreement or the subject matter hereof, it will give the other Party such notice as is reasonably practicable and the Parties will work together in good faith to attempt to agree on the content of the disclosure; provided, however, that if such announcement or disclosure is required to be made immediately pursuant to any applicable law or regulation, then no such agreement will be required, and provided further that the Party deciding to make such an announcement shall have the final decision making authority with respect to the form, content and timing of such disclosure.

11.3 Required Disclosure. The receiving Party will be entitled to disclose Confidential Information where such disclosure is reasonably necessary to enforce its rights pursuant to this Agreement or where demand for such disclosure is made on the receiving Party pursuant to: (i) a valid order of a court or other governmental body or (ii) any other applicable law or regulation; provided that if the receiving Party intends to make such disclosure or receives such demand, the receiving Party will give the disclosing Party prompt notice of such fact to enable the disclosing Party to seek a protective order or other appropriate remedy concerning any such disclosure. The receiving Party will fully co-operate with the disclosing Party at the disclosing Party's expense in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving Party will make such disclosure only to the extent that such disclosure is legally required.

11.4 Use of Council's Name. LICENSEE will not use or refer to Council's name, in writing or otherwise, except (1) with the approval of Council in accordance with the following sentence of this clause, (ii) by disseminating informational materials furnished by Council or (iii) in order to comply with any requirement of the FDA or any other requirement of applicable law. Prior to each proposed use of Council's name (other than pursuant to clause (ii) above), LICENSEE will submit to Council a sample of such proposed use. Not later than the tenth Business Day (the "Notice Deadline") after the date of its receipt of such sample, Council will notify LICENSEE in writing (the "Use Notice") whether it approves such proposed use, which approval will not be unreasonably withheld. If Council does not deliver the Use Notice on or before the Notice Deadline, Council will be deemed to have approved such use. When using Council's name in any promotional and other materials or public information generated by LICENSEE relating to the Licensed Product, LICENSEE will credit Council for its role in inventing and developing the Licensed Product.

## **XII. TERM AND TERMINATION**

12.1 Term. The "Term" of this Agreement will commence on, and this Agreement will remain in full force and effect from, the Effective Date and will continue until the later of (a) the expiration of the last-to-expire of the Council Patent Rights in the Territory, or (b) the date following such expiration that follows a continuous period of six (6) months during which LICENSEE or any of its Affiliates or sublicensees have made no commercial sales of Licensed Product in the Territory, unless earlier terminated as specified in this Article XII.

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12.2 Termination by Council.

12.2.1 Subject to this Section 12.2.1, Council may terminate this Agreement upon written notice as follows:

- (a) in the event of a material breach by LICENSEE of this Agreement (other than a failure to pay an undisputed material amount or a disputed material amount due under Section 3.1.1 or 3.1.2).
- (b) if LICENSEE shall have failed to pay an undisputed material amount, or
- (c) if LICENSEE shall have failed to pay a disputed material amount due under Section 3.1.1 or 3.1.2 within seven (7) days of the date payment was due, immediately upon expiration of the foregoing seven (7) day period;

provided that in the case of 12.2.1(a) and 12.2.1(b) above, LICENSEE has received written notice from Council of such breach, specifying in reasonable detail the particulars of the alleged breach, and such breach in the case of (a) above, if curable, has not been cured within sixty (60) calendar days of the date of notice or such longer period as may reasonably be required to cure such breach, or in the case of (b) above within seven (7) Business Days, after the date of the relevant notice.

12.2.2 Notwithstanding the foregoing Section 12.2.1:

- (a) other than with respect to a disputed material payment amount, if LICENSEE in good faith disputes a purported material breach referred to in 12.2.1(a), or the failure to cure or remedy such material breach and elects by written notice to Council within seven (7) Business Days after notice to LICENSEE of such breach to resolve the dispute in accordance with the dispute resolution provisions in Section 14.3, then Council may not terminate this Agreement until the date on which it has been, determined under Section 14.3 that LICENSEE is in material breach of this Agreement;
- (b) if LICENSEE elects by written notice given within seven (7) Business Days of the payment date therefore to resolve a dispute regarding a material payment due under Section 3.1.1 or 3.1.2 pursuant to Section 14.3 and has made payment of such disputed amount to Council within such seven (7) Business Day period as provided above, then Council may not terminate this Agreement on account of failure to make such payment and LICENSEE will be entitled to recover from Council all or such portion of such payment as may be determined to be owing to it pursuant to Section 14.3; and
- (c) for a disputed material payment amount, either Party may submit such dispute to an audit procedure as set forth in Section 3.2.4 upon written notice to the other Party, with the Party whose position in the applicable dispute is farthest away from what the auditors determine to bear the costs of such audit, and any such dispute so resolved shall not be subject to further dispute resolution pursuant to Section 14.3.

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12.2.3 If Council terminates this Agreement pursuant to Section 12.2.1, the License granted to LICENSEE and any permitted sublicensees, and any other rights granted by Council hereunder (including any license to any trademarks), will automatically terminate and the following obligations will apply (the "Program Transfer Provisions"):

(a) LICENSEE and all permitted sublicensees whose sublicenses are terminated will promptly provide to Council complete documentation of all clinical data and all regulatory data, in each case regarding the Licensed Product and generated by or on behalf of LICENSEE and solely to the extent owned or Controlled by LICENSEE.

(b) LICENSEE and all permitted sublicensees whose sublicenses are terminated will promptly provide to Council reasonably detailed disclosure of all Program Improvements and any other know-how or information other than the Program Improvements set forth in Section 12.2.2(a) and that are Controlled by LICENSEE or its Affiliates.

(c) Where any Third Party rights have been obtained by LICENSEE, or any permitted sublicensee whose sublicense is terminated, for purposes of the Program, LICENSEE and all such permitted sublicensees will use all reasonable efforts to promptly assign (or failing assignment, to sublicense) to Council or its designee such Third Party rights.

(d) LICENSEE and all permitted sublicensees whose sublicenses are terminated will transfer to Council or its designee the ownership of all regulatory submissions and filings related to the Licensed Product that are owned or Controlled by LICENSEE or such sublicensees, including the NDA for the Licensed Product.

(e) LICENSEE and all permitted sublicensees whose sublicenses are terminated will promptly transfer to Council or its designee, at LICENSEE's expense, any inventory and supplies of Licensed Product and any other inventories or supplies obtained by LICENSEE or its Affiliates for purposes of the Program, and will grant to Council or its designee a fully-paid-up license to use any LICENSEE trademarks on such inventory and supplies on customary terms solely for the purpose of selling such remaining inventory and supplies.

(f) LICENSEE and all permitted sublicensees whose sublicenses are terminated will make personnel (as well as the personnel of its Affiliates) reasonably available to Council or its designee to effect an orderly transition to Council or its designee of the information and rights contemplated above in this Section 12.2.2 for a period of up to ninety (90) days following the effective date of termination.

(g) The exclusivity provisions of Section 10.2.1 as applied to LICENSEE and all permitted sublicensees whose sublicenses provided for Commercialization of the Licensed Product and are terminated will survive such termination for the lesser of (i) a period of three (3) years following the effective date of such termination, or (ii) the remainder of the Exclusivity Term.

### 12.3 Termination by LICENSEE

12.3.1 LICENSEE may terminate this Agreement upon written notice to Council (a) for any reason, upon one-hundred eighty (180) days' written notice to Council, (b) in the event of a material breach by Council or its Affiliates of this Agreement, provided that Council has received written notice from LICENSEE of such breach, specifying in reasonable detail the particulars of the alleged breach, such breach is continuing for sixty (60) calendar days after such notice and such breach has not been cured within such sixty (60) day period (except that, in the event such breach is curable but may not reasonably be cured in sixty (60) calendar days, then such cure period will be extended for an additional period during which Council is making good faith attempts to cure such breach); (c) immediately in the event (i) that Council becomes insolvent or is unable to pay its debts when due; (ii) Council files a petition in bankruptcy, reorganization or similar proceeding, or, if such a petition is filed against Council, such petition is not dismissed within ninety (90) days; (iii) Council discontinues its business; or (iv) a receiver is appointed or there is an assignment for the benefit of Council's creditors, and (d) on fifteen (15) days written notice following the NDA Response Date if the FDA indicates that the Licensed Product does not qualify as employing an NCE that is entitled to five years regulatory exclusivity in the United States.

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12.3.2 If LICENSEE terminates this Agreement pursuant to Section 12.3.1(a), the Program Transfer Provisions will apply.

(a) For the avoidance of doubt, upon LICENSEE's termination of this Agreement pursuant to Section 12.3.1(a), LICENSEE's rights included in the relevant licenses granted by Council to LICENSEE under this Agreement will immediately and automatically revert to Council; provided, however, that LICENSEE will have ninety (90) days from LICENSEE's termination of the Agreement to complete the sale of any Licensed Product then in inventory, subject to payment of royalties and milestone payments pursuant to Article III.

12.3.3 If LICENSEE terminates the Agreement pursuant to Section 12.3.1(b) or (c), then (i) Council's License grant to LICENSEE will convert to an irrevocable exclusive License, with the right to sublicense, and will survive termination, and (ii) the obligations of the Parties under Article III will also survive such termination.

12.4 Automatic Termination. This Agreement will terminate automatically, without notice or opportunity to cure, upon the occurrence of any of the following events:

12.4.1 LICENSEE being authorized (whether by its board of directors or such other Person having authority to direct LICENSEE) to commence or institute any bankruptcy, receivership, insolvency, reorganization or other similar proceedings under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code (as may be amended, the "Bankruptcy Code") or under any similar laws or statutes of the United States or any state thereof or of any jurisdiction (whether or not in the United States) having authority or jurisdiction over the assets of LICENSEE or in which LICENSEE may operate or have assets;

12.4.2 the commencement or institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against LICENSEE under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the Bankruptcy Code or under any similar laws or statutes of the United States or any state thereof or of any jurisdiction (whether or not in the United States) having authority or jurisdiction over the assets of LICENSEE or in which LICENSEE may operate or have assets; and

12.4.3 the appointment of a receiver, trustee, or similar party with respect to any material asset of LICENSEE.

12.5 Rights and Duties Upon Termination or Expiration. Upon the termination or expiration of this Agreement, each Party will have the right to retain all payments from the other Party properly made pursuant to this Agreement, and each Party will pay to the other all sums accrued hereunder which are then due.

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### **XIII. INDEMNIFICATION AND LIMITATION OF LIABILITY**

13.1 In order to allocate between themselves the responsibility for claims arising out of this Agreement, and except as otherwise specifically provided for herein, from and after the Effective Date, the parties will indemnify each other as provided in this Article XIII.

13.1.1 **Indemnification Obligations of LICENSEE.** From and after the Effective Date, LICENSEE will defend, indemnify and hold Council, its Affiliates, and each of their respective officers, directors, agents, employees and shareholders (collectively, "**Council Indemnitees**"), harmless from and against any and all Damages which Council Indemnitees may incur or suffer, or with which any of them may be faced arising out of or in connection with:

- (a) The development or Commercialization of the Licensed Product (including with respect to product liability, death, personal injury, pregnancy, or otherwise);
- (b) The breach by LICENSEE of this Agreement including any breach of its representations, warranties, covenants or obligations under this Agreement;
- (c) LICENSEE's violation of any applicable Laws; and
- (d) LICENSEE's willful misconduct; and
- (e) Any suit against Council related directly or indirectly to the Licensed Product and brought by any investor or holder of equity or other interest in, or lender to, LICENSEE or any sublicensee hereunder;

provided, however, that, in each such case, LICENSEE will not be liable hereunder to the extent such Damages arise from the willful misconduct of, or a violation of any applicable laws by or from the breach of the provisions of this Agreement by Council, its Affiliates, agents, employees or contractors.

13.1.2 **Indemnification Obligations of Council.** From and after the Effective Date, Council will defend, indemnify and hold LICENSEE, its Affiliates, and each of their respective officers, directors, agents, employees, shareholders or members (collectively, "**LICENSEE Indemnitees**") harmless from and against any and all Damages which LICENSEE Indemnitees may incur, or suffer, or with which any of them may be faced arising out of:

- (a) The breach by Council of this Agreement including any breach of its representations, warranties, covenants or obligations under this Agreement;
- (b) Council's violation of any applicable Laws;
- (c) Claims made by subjects in the Council-sponsored clinical trials to the extent they make a claim based on their participation in those trials;
- (d) Claims made by Watson Pharma Inc. and/or its successor in interest with respect to the Watson License or by WomanCare Global Trading CIC and/or its successor in interest with respect to the WCG Agreement; and
- (e) Council's willful misconduct;

provided, however, that, in each such case, Council will not be liable hereunder to the extent such Damages arise from willful misconduct of, or a violation of any applicable laws or from the breach of the provisions of this Agreement LICENSEE, its Affiliates, agents, employees or contractors.

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13.2 Conditions of Indemnification of Third-Party Claims. The obligations and liabilities of an indemnifying Party under Section 13.1 and hereof with respect to Damages resulting from Claims made by Third Parties will be subject to the following terms and conditions:

13.2.1 Promptly after the delivery of a notice seeking indemnification in respect of a Claim and subject to Section 13.2.3, the indemnifying Party may elect, by written notice to the indemnified Party, to undertake the defense thereof, at the sole cost and expense of the indemnifying Party, provided that an indemnified Party's failure or delay to provide notice to the indemnifying party will not constitute a waiver of the indemnifying Party's indemnification obligations unless, and then only to the extent that, an indemnifying Party is actually and damaged thereby. If the indemnifying Party chooses to defend any Claim, the indemnified Party will cooperate with all reasonable requests of the indemnifying Party and will make available to the indemnifying Party any books, records or other documents within its control that are necessary or appropriate for such defense.

13.2.2 In the event that the indemnifying Party, within a reasonable time after receipt of a notice seeking indemnification, does not so elect to defend such Claim, the indemnified Party will have the right (upon further notice to the indemnifying Party) to undertake the defense, compromise or settlement of such Claim for the account of the indemnifying Party, subject to the right of the indemnifying Party to assume the defense of such Claim pursuant to the terms of Section 13.2.1 at any time prior to settlement, compromise or final determination thereof, provided, that the indemnifying Party reimburses in full all costs of the indemnified Party (including reasonable attorney's fees and expenses) incurred by it in connection with such defense prior to such assumption.

13.2.3 Notwithstanding anything in this Section 13.2 to the contrary, if the indemnifying Party assumes the defense of any Claim, any indemnified Party will be entitled to participate in the defense, compromise or settlement of such Claim with counsel of its own choice at its own expense.

13.3 Insurance. In addition to its duty to indemnify, beginning on the date of the first commercial sale of a Licensed Product and during the Term and for a period of [\*\*\*], LICENSEE will, at its expense, maintain with insurers rated A-7 or higher by A.M. Best a comprehensive general liability insurance policy or policies, including coverage exclusively for the Licensed Product for product liability of least [\*\*\*], provided that LICENSEE will, on no less than an annual basis have the applicable policies reviewed by a reputable licensed insurance broker in the applicable market with reference to Licensed Product sales in the prior period, projected sales and other relevant factors to determine an appropriate level of insurance for the Licensed Product, will increase the foregoing exclusive coverage as so advised by such broker, and will promptly notify the Council in writing regarding any such increased coverage. Such insurance policy or policies will name Council as an additional insured and will provide that at least 30 days' prior written notice of cancellation or material change in coverage under such policy or policies will be given to Council. LICENSEE will furnish copies of such policy or policies to Council as promptly as reasonably practicable after the Effective Date, and will provide documentation evidencing that such policy or a similar policy is in force each year during the Term.

13.4 Settlements. No Person who has undertaken to defend a Claim under Sections 13.2.1 or 13.2.2 will, without written consent of all indemnified Parties, settle or compromise any Claim or consent to entry of any judgment, provided, however, that such consent will not be required if such settlement, compromise or judgment (i) includes as an unconditional term thereof the release by the claimant or the plaintiff of all indemnified Parties from all liability arising from events which allegedly gave rise to such Claim and (ii) contains no restriction, limitation or prohibition of any kind on the manner in which any indemnified Party conducts its business. Any payment made by a Party to settle a Claim against it without obtaining consent of the indemnifying Party will be at its own cost and expense. Notwithstanding the foregoing, the indemnifying Party will be liable under this Article XIII for any settlement effected without its consent if the indemnifying Party has refused to acknowledge liability for indemnification hereunder and/or declines to defend the indemnified Party in any such Claim, action or proceeding and it is determined that the indemnifying Party was liable to the indemnified Party for indemnification related to such settlement.



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13.5 Disclaimer of Consequential Damages. IN NO EVENT WILL EITHER COUNCIL OR LICENSEE BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL, OR PUNITIVE DAMAGES ARISING UNDER OR AS A RESULT OF THIS AGREEMENT (OR THE TERMINATION HEREOF) INCLUDING, BUT NOT LIMITED TO, THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES, OR ON ACCOUNT OF EXPENSES, INVESTMENTS, OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF LICENSEE OR COUNCIL OR OTHERWISE, EXCEPT TO THE EXTENT ANY SUCH DAMAGES RESULT FROM SUCH OTHER PARTY'S BREACH OF ARTICLE XI HEREOF, WILLFUL MISCONDUCT OR ARE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM.

#### XIV. MISCELLANEOUS

##### 14.1 Certain Events.

(a) It is the intention of LICENSEE and Council that LICENSEE's rights under this Agreement will remain in place if Council files a petition in bankruptcy, is adjudicated as bankrupt or files a petition or otherwise seeks relief under any bankruptcy, insolvency or reorganization statute or proceeding, or a petition in bankruptcy is filed against it or is not dismissed within 60 days, or it becomes insolvent or makes an assignment for the benefit of creditors or a custodian, receiver or trustee is appointed for it or a substantial portion of its business or assets or it admits in writing its inability to pay its debts as they become due (each a "Bankruptcy Event"). It is the intention of LICENSEE and Council that LICENSEE's exclusive rights and licenses to Commercialize and market the Licensed Product in the Territory continue, without impairment, if and after any Bankruptcy Event. All rights and licenses granted under this Agreement by Council to LICENSEE are, and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses or other rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code. Council and LICENSEE agree that LICENSEE, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

14.2 Governing Law. For all matters other than the scope and validity of patents, this Agreement will be deemed to have been made in the State of New York and its form, execution, validity, construction and effect will be determined in accordance with the laws of the State of New York, without giving effect to the principles of conflicts of law thereof and the Parties agree to the personal jurisdiction of and venue in any federal court located in the Southern District of New York or state court located in New York County, New York. The application of the United Nations Convention for Contracts for the International Sales of Goods is hereby expressly excluded.

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14.3 Dispute Resolution. If a dispute arises between the Parties under or with respect to this Agreement (a “Dispute”), it will first be submitted to the respective chief executive officers of the Parties for resolution by good-faith negotiation. Any Dispute not resolved by such good-faith negotiation after thirty (30) days from the first notification by one Party to the other Party of the existence of such Dispute may be submitted thereafter by one or both Parties to Arbitration in accordance with this Section 14.3. Any Dispute not settled by negotiation between the Parties will be finally resolved by, arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (“AAA”) then in effect (the “Rules”), except as modified herein. The place of arbitration will be New York, New York. If the amount in controversy is \$4 million or less (including all claims and counterclaims) there will be one (1) neutral and impartial arbitrator who will be agreed upon by the Parties within twenty (20) days of receipt by respondent of a copy of the demand for arbitration. If the amount in controversy is more than \$4 million (including all claims and counterclaims) there will be three (3) neutral and impartial arbitrators, of whom each Party will appoint one (1) within thirty (30) days of the receipt by the respondent of the demand for arbitration. The two (2) arbitrators so appointed will select the chair of the arbitral tribunal within thirty (30) days of the appointment of the second arbitrator. If any arbitrator is not appointed within the time limit provided herein, such arbitrator will be appointed by the AAA in accordance with the listing, striking, and ranking procedures in the Rules. Any arbitrator appointed by the AAA will be a retired judge or a practicing attorney with no less than fifteen (15) years of experience with commercial cases and an experienced arbitrator, who will if practicable, have substantial experience with transactions or disputes related to the field of pharmaceuticals and/or, if applicable, intellectual property. In rendering an award, the arbitral tribunal will be required to follow the laws of the state of New York. The arbitral tribunal is not empowered to award damages in excess of compensatory damages, and each party hereby irrevocably waives any right to recover punitive, exemplary, multiple or similar damages with respect to any Dispute. Any arbitration proceedings, decision, or award rendered hereunder and the validity, effect, and interpretation of this arbitration provision will be governed by the Federal Arbitration Act, 9 U.S.C. §1 et seq. The award will be in writing and will state the findings of fact and conclusions of law on which it is based. The award will be final and binding upon the Parties and will be the sole and exclusive remedy between the Parties regarding any claims, counterclaims, issues, or accounting presented to the arbitrator(s). Judgment upon the award may be entered in any court having jurisdiction. Any costs or fees (including attorneys’ fees and expenses) incident to enforcing the award will be charged against the Party resisting such enforcement. By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment, or other order in aid of arbitration proceedings and the enforcement of any award. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitral tribunal will have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of a Party to respect the arbitral tribunal’s orders to that effect. The Parties hereby submit to the exclusive jurisdiction of the federal and state courts located in New York County, New York, for the purpose of an order to compel arbitration, for preliminary relief in aid of arbitration, or for a preliminary injunction to maintain the status quo or prevent irreparable harm prior to the appointment of the arbitrators, and to the non-exclusive jurisdiction of such courts for the enforcement of any award issued hereunder. The Parties hereby agree to accept service of process pursuant to the notice provisions of this Agreement.

14.4 Assignment and Binding Effect.

14.4.1 This Agreement may not be assigned, by operation of law or otherwise, by either Party without the prior written consent of the other, such consent not to be unreasonably withheld; provided, however, that either party may assign this Agreement without the prior written consent of the other Party: (a) to any Affiliate of such Party, or (b) in connection with the sale of all or substantially all of the assets of such Party (whether by sale of assets, sale of stock or merger).

14.4.2 No assignment under this Section 14.4 will be effective unless the intended assignee executes and delivers to the Party which is not the assignor a writing whereby the assignee expressly undertakes to perform and comply with all of its assignor’s obligations hereunder. Notwithstanding such undertaking, such assignor will continue to be primarily liable for such assignee’s performance hereof and compliance herewith.

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14.4.3 Any assignment in violation of this Section 14.4 will be void and of no effect.

14.4.4 This Agreement, and the rights and duties of the Parties therein contained, will be binding upon, and will inure to the benefit of, the Parties and their respective legal representatives, successors and permitted assigns.

14.5 Independent Contractor Status. The relationship of the Parties hereto is that of independent contractors. Nothing in this Agreement will be construed to constitute, create, give effect or otherwise imply a joint venture, agency, partnership or other formal business organization or any employer/employee relationship of any kind between the Parties.

14.6 Notices. All notices, requests and other communications required or permitted to be given hereunder or with respect hereto will be in writing, and may be given by (i) personal service, (ii) registered first-class United States mail, postage prepaid, return receipt requested, or (iii) overnight delivery service, charges prepaid, and in each case addressed to the other Party at the address for such Party as set forth below, and will be effective upon receipt in the case of clauses (i) or (iii) above, and five days after mailing in the case of clause (ii) above.

If to LICENSEE:

Therapeutics MD, Inc.  
6800 Broken Sound Parkway, NW  
3<sup>rd</sup> Floor  
Boca Raton, FL 33487  
Attention: Legal Department

With a copy to:

King & Spalding LLP  
101 Second Street  
Suite 2300  
San Francisco, CA 94105  
Attention: Stephen Abreu

If to Council:

Population Council  
One Dag Hammarskjold Plaza  
New York, NY 10017  
Attention: General Counsel

The address of either Party set forth above may be changed from time to time by written notice in the manner prescribed herein from the Party requesting the change.

14.7 Waivers. The waiver by either Party of a default or a breach of any provision of this Agreement by the other Party will not operate or be construed to operate as a waiver of any subsequent default or breach. The continued performance by either Party with knowledge of the existence of a default or breach will not operate or be construed to operate as a waiver of any default or breach. Any waiver by a Party of a particular provision or right will be in writing, will be as to a particular matter and, if applicable, for a particular period of time and will be signed by such Party.

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14.8 Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof, superseding all prior agreements and negotiations, and may be modified only by written agreement executed by both Parties.

14.9 Severability. If any provision in this Agreement is deemed to be, or becomes, invalid, illegal, void or unenforceable under applicable laws, then: (i) it will be deleted and the validity, legality and enforceability of the remaining provisions of this Agreement will not be impaired or affected in any way, and (ii) the Parties will use Commercially Reasonable Efforts to substitute for the invalid, illegal or unenforceable provision a valid, legal and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

14.10 Counterparts. This Agreement may be executed in more than one counterpart, each of which will be deemed to be an original but all of which taken together will be deemed a single instrument. A facsimile transmission of the signed Agreement will be legal and binding on both Parties.

14.11 Force Majeure. Neither Party to this Agreement will be liable for failure or delay in the performance of any of its obligations hereunder (other than the failure to pay monies owed), if such failure or delay is due to acts of God, earthquakes, fires, strikes, acts of war (whether declared or not), civil unrest, or intervention of any governmental authority, but any such delay or failure will be remedied by such Party as soon as practicable after the removal of the cause of such failure or delay. Upon the occurrence of an event of force majeure, the Party failing or delaying performance will promptly notify the other Party in writing, setting forth the nature of the occurrence, its expected duration and how such Party's performance is affected. If any event of force majeure lasts for more than ninety (90) days, the Party failing or delaying performance will use its all reasonable efforts to mitigate any Damages suffered by the other Party as a result of the failure or delay. A force majeure event that lasts longer than one-hundred eighty (180) days will give the Party not failing in or delaying performance the option, in its sole discretion, to terminate this Agreement for material breach.

14.12 Interest on Late Payments. If any Party fails to pay in full on or before the date due any royalty, fee or other amount that is required to be paid to the other Party under this Agreement, the paying Party will also pay to the other Party (or its designee), on demand, interest compounded daily on any such amount beginning thirty (30) days after such due date at an annual rate equal to the lowest prime rate as published by The Wall Street Journal (or, if The Wall Street Journal is not then published, such other financial periodical of general circulation in the United States) on or nearest to such due date plus two percent (2%) to be assessed from the date payment of the amount in question first became due.

14.13 Cumulative Remedies. Unless expressly set forth in this Agreement, all rights and remedies of the Parties, including all rights to payment, rights of termination, rights to injunctive relief, and other rights provided under this Agreement, will be cumulative and in addition to all other remedies provided for in this Agreement, in law, and in equity.

14.14 Amendment. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by both Parties that specifically refers to this Agreement.

14.15 Headings and References. All section headings contained in this Agreement are for convenience of reference only and will not affect the meaning or interpretation of this Agreement.

14.16 No Strict Construction. This Agreement has been prepared jointly and will not be strictly construed against either Party.

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14.17 Survival. Upon expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement will cease, except as specifically provided in this Agreement to the contrary, including the rights and obligations in the following sections which will survive termination: Article I, Section 3.2.3(a) (solely with respect to reporting of Net Sales that occur prior to such termination), Section 3.2.4 (solely with respect to reporting of Net Sales that occur prior to such termination), Section 3.3 (solely with respect to reporting of Net Sales that occur prior to such termination), Section 6.1, Article XI (for the time periods described therein), Section 12.2.2 (solely for the time periods necessary to perform the activities described therein), Section 12.2.3 (solely for the time periods necessary to perform the activities described therein), Section 12.3.3, Section 12.5, Section 13.1, Section 13.2, Section 13.4, Section 13.5, and Article XIV.

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IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

THE POPULATION COUNCIL, INC.

THERAPEUTICSMD, INC.

By: /s/ Julia Buntine

By: /s/ Dan Cartwright

Name: Julia Buntine

Name: Dan Cartwright

Title: President

Title: CFO

[SIGNATURE PAGE TO LICENSE AGREEMENT]

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**EXHIBIT A**

**Council Patent Rights**

<b>Country Code</b>	<b>COUNTRY</b>	<b>Application No</b>	<b>Patent Number</b>	<b>Status</b>
US	United States	[***]	[***]	[***]

[\*\*\*]

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CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [\*\*\*]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

**SCHEDULE 4.2.2(a),**

1. A clinical drug-drug interaction study to evaluate the effects of strong CYP3A induction and inhibition on the pharmacokinetics of SA and EE from the SA/EE contraceptive vaginal system (CVS).
  2. An open-label pharmacokinetic study to evaluate the effects of tampons on the pharmacokinetics of SA and EE from the SA/EE CVS.
  3. Study to characterize the in vivo release rate.
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**SCHEDULE 4.2.2(b),**

A controlled, non-interventional, long term cohort study that follows a series of cohorts comprising new users of your ring [Segesterone Acetate (SA) and Ethinyl Estradiol (EE) contraceptive vaginal system], new users of other ring contraceptives, new users of any intrauterine system, and new users of combined oral contraceptives containing other progestins. The primary objective of the study is to assess the risk for venous thromboembolism (VTE) of short term and long-term use of your product in a study population representative of actual users of the product in the United States and other countries where your ring is prescribed.

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Schedule 2.3.1(a)

API Supply Agreement

[\*\*\*]

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Schedule 2.3.1(b)

Letter Agreement

[\*\*\*]

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Schedule 2.3.3

- ANNOVERA™
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Schedule 5.4.1

Outreach Plan

At least once per Quarter following Launch of the licensed Product and ending upon the first commercial sale of a Generic Equivalent in the Territory: LICENSEE will:

1. [\*\*\*]
  2. [\*\*\*]
  3. [\*\*\*]
  4. [\*\*\*]
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