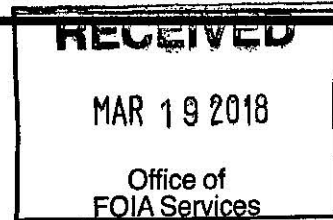


18-03288-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Saturday, March 17, 2018 11:40 AM
To: foiapa
Subject: FOIA Request



I would like to request access to Exhibit 10.31 to the 12/31/07 10-K, filed by NexMed, Inc. (now called Apricus Biosciences, Inc.) on 3/12/2008. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

April 9, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr.
Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03288-E

Dear Mr. Edwards:

This letter is in response to your request, dated March 17, 2018 and received in this office on March 19, 2018, for access to Exhibit 10.31 to the December 31, 2007 10-K, filed by NexMed, Inc. (now called Apricus Biosciences, Inc.) on March 12, 2008.

The search for responsive records has resulted in the retrieval of 32 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed in the processing of this request. If you have any questions, please contact me at osbornes@sec.gov or (202) 551-8371. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in cursive script that reads "Sonja Osborne".

Sonja Osborne
FOIA Lead Research Specialist

Enclosure

LICENSE AGREEMENT

This License Agreement (this “**Agreement**”) is made effective as of November 1, 2007 (the “**Effective Date**”) by and between NexMed Inc., a Nevada corporation (“**NexMed**”), and Warner Chilcott Company, Inc., a Puerto Rico corporation (“**Warner**”). NexMed and Warner are each hereinafter referred to individually as a “**Party**” and together as the “**Parties**.”

WHEREAS, NexMed Controls (as that term is hereafter defined) certain proprietary patent, know-how and technology rights related to a pharmaceutical formulation containing alprostadil for the treatment of erectile dysfunction; and

WHEREAS, Warner desires to obtain a license from NexMed to develop and commercialize the Licensed Products (as hereafter defined); and

WHEREAS, NexMed desires to grant such license to Warner on the terms and subject to the conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Section 1 shall have the meanings specified.

1.1. “**Affiliate**” shall mean any corporation, firm, limited liability company, partnership or other entity that controls or is controlled by or is under common control with a Party to this Agreement. For purposes of this Section 1.1, “control” means ownership, directly or indirectly through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a person or entity controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or otherwise has the ability to direct the affairs or operations of such person.

1.2. “**API**” shall mean alprostadil.

1.3. “**Approval**” shall mean, with respect to any Licensed Product, approval from the FDA (as hereafter defined) for the marketing, use and sale of the Licensed Product in the Territory.

1.4. “**Commercially Reasonable Efforts**” means, with respect to a Party, efforts and resources comparable to those undertaken by pharmaceutical companies of similar size and scope as such Party, as applicable, to pursue intellectual property protection for, Develop, manufacture, market, sell and distribute a pharmaceutical product owned by it or to which it has rights, which is of similar overall market potential at a similar stage in its product lifecycle,

taking into account, inter alia, the competitiveness of the marketplace, the proprietary position of the product, the profitability of the product and other relevant factors.

1.5. “**Confidential Information**” shall mean with respect to a Party all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical materials, assays, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by such Party, or has otherwise become known to such Party, or to which rights have been assigned or licensed to such Party, as well as any other information and materials that are deemed confidential or proprietary to or by such Party (including, without limitation, all information and materials of such Party’s customers and any other Third Party and their consultants), in each case that are disclosed by such Party to the receiving Party, whether orally, visually, in writing or by way of any other media, that if disclosed in tangible form is marked “confidential,” or if disclosure is not in tangible form, the disclosing Party has notified the receiving Party at the time of disclosure that such disclosure is confidential and summarized such disclosure in writing, marking the summary “confidential” and submitting it to the receiving Party (or, if applicable, to such of the receiving Party’s Affiliates or sublicensees to whom disclosure has been made) within thirty (30) days of the disclosure. Confidential Information shall not include any such information, data or materials to the extent that the receiving Party can demonstrate that such information, (a) as of the date of disclosure is known to the receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to the receiving Party or its Affiliates; (b) as of the date of disclosure is, or subsequently becomes, publicly known, through no fault or omission of the receiving Party or its Affiliates; (c) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the disclosing Party; or (d) is independently developed by or for the receiving Party or its Affiliates without reference to or reliance upon any Confidential Information of the disclosing Party.

1.6. “**Contract Year**” shall mean each successive period of four consecutive calendar quarters, with the first such Contract Year beginning on the first day of the first full calendar quarter that begins after the Effective Date.

1.7. “**Control**” or “**Controlled**” shall mean with respect to any Technology or Patent Rights (as such terms are defined hereunder), the ownership of the intellectual property rights in and to such Technology or Patent Rights, or the possession by a Party of rights under such Technology or Patent Rights sufficient to permit it to grant licenses or sublicenses to such Technology or Patent Rights as provided for herein, in each case without violating the terms of any legally binding agreements between such Party and any Third Party.

1.8. “**Development**” or “**Develop**” means, with respect to a Licensed Product, all clinical and other development activities undertaken to obtain Approval of such Licensed Product in accordance with this Agreement. When used as a verb, “Developing” means to engage in Development and “Developed” shall have a corresponding meaning.

1.9. “**Divided Patent Rights**” shall mean the Patent Rights set forth on Exhibit B hereto and any Licensed Patent Rights other than the Undivided Patent Rights.

1.10. “**FDA**” shall mean the United States Food and Drug Administration and any successor agency or authority thereto.

1.11. “**Field**” shall mean the topical treatment of erectile dysfunction.

1.12. “**First Commercial Sale**” shall mean the date of the first arm’s length transaction, transfer or disposition for value to a Third Party of a Licensed Product by or on behalf of Warner or any Affiliate or Sublicensee of Warner.

1.13. “**Generic Product**” shall mean any Third Party product that contains the API, is identical to the Licensed Product in strength, dosage form and route of administration, is bioequivalent to the Licensed Product and is approved by the FDA as an AB-rated equivalent (as defined in the 27nd edition of Approved Drug Products with Therapeutic Equivalence Evaluations issued by the United States Department of Health and Human Services) to the Licensed Product.

1.14. “**Licensed Know-How**” shall mean any Technology (as hereafter defined) that is Controlled by NexMed as of the Effective Date or at any time thereafter that is necessary or useful for Warner to Develop, have Developed, make, have made, use, have used, sell, distribute for sale, have distributed for sale, offer for sale, have sold, import or have imported the Licensed Products and any NexMed Improvements.

1.15. “**Licensed Patent Rights**” shall mean any Patents Rights under the Control of NexMed as of the Effective Date, or at any time thereafter, that cover Licensed Product or any NexMed Improvements.

1.16. “**Licensed Product**” shall mean any form or dosage of a pharmaceutical product for use in the Field that contains the API as an active ingredient.

1.17. “**NDA**” shall mean a new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time), or supplement thereto, filed with the FDA, seeking regulatory approval to market and sell any Licensed Product in the Territory in the Field.

1.18. “**Net Sales**” shall mean the gross invoiced sales price for all Licensed Products sold by Warner, its Affiliates or Sublicensees to Third Parties throughout the Territory during a reporting period, less the following amounts actually incurred or paid by Warner or its Affiliates or Sublicensees during such reporting period with respect to sales of Licensed Products: (a) allowances for normal and customary trade, quantity and cash discounts, rebates, chargebacks; (b) fees, reimbursements or similar payments or adjustments granted or paid to wholesalers or other distributors, buying groups, healthcare insurance carriers or other similar persons; (c) transportation, shipping, customs duties, insurance and postage charges included in the billing amount, if paid by Warner, any Warner Affiliate or any Sublicensee; (d) credits or allowances actually granted for damaged goods, recalls, returns or rejections (including, but not limited to, wholesaler, distributor and retailer returns) of Licensed Products or for retroactive price reductions; (e) any payment, allowance or credit to any governmental entity, including Federal or state Medicaid, Medicare or similar program; (f) actual write-offs for bad debts and (g) sales, use, excise, value-added and other taxes (other than income taxes) or governmental charges included in the billing amount, in each case, determined in accordance with United States generally accepted accounting principles (“**GAAP**”).

If any Licensed Products are sold to Third Parties in transactions that are not at arm's length between the buyer and seller, or for consideration other than cash, then the gross amount to be included in the calculation of Net Sales for such sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length, which amount shall be determined, whenever possible, by reference to the average selling price of the relevant Licensed Product in arm's-length transactions at the time of sale. If Warner or its Affiliates or Sublicensees sell Licensed Products to a Third Party who also purchases other products or services from Warner or its Affiliates or Sublicensees, Warner shall not, and shall require its Affiliates and Sublicensees not to, (i) bundle or include any Licensed Product as part of any incentive programs, chargebacks, disease management programs or similar programs based on multiple product offerings or (ii) discount or price any Licensed Product, in the case of either of the foregoing clauses (i) or (ii), such that the applicable rebate, discount, other form of reimbursement for, or the price of, such Licensed Product in such arrangement is inconsistent with the rebate, discount, or other form of reimbursement for, or price of, such Licensed Product when sold separately to such Third Party from any such other products or services sold to such Third Party.

1.19. **"NexMed Improvement"** shall mean any change in the formulation, ingredients, preparation, presentation, means of delivery, dosage, package of, manufacture, or any new or expanded uses of the Licensed Product in the Field developed during the term of this Agreement by or on behalf of NexMed.

1.20. **"OTC Product"** shall mean a Licensed Product for sale over-the-counter.

1.21. **"Patent Rights"** shall mean all rights arising under patents or patent applications (including any patents issuing therefrom), as well as any substitutions, continuations, continuations-in-part, divisionals and all reissues, renewals, reexaminations, extensions, supplementary protection certificates, confirmations, revalidations, registrations or patents of addition in connection with any of the foregoing.

1.22. **"Pre-Notification Room Temperature Formulation Development Activities"** shall mean all Development activities conducted by NexMed during the period from the Effective Date until the Room Temperature Formulation Notification Date with respect to the Room Temperature Formulation.

1.23. **"Refrigerated Formulation"** shall mean a formulation of the Licensed Product that is manufactured, distributed, stored and sold under refrigeration.

1.24. **"Refrigerated Formulation NDA"** shall mean an NDA with respect to the Refrigerated Formulation.

1.25. **"Room Temperature Formulation"** shall mean a formulation of the Licensed Product that is manufactured, distributed, stored and sold at room temperature.

1.26. **"Room Temperature Formulation NDA"** shall mean an NDA with respect to the Room Temperature Formulation.

1.27. “**Sublicense**” shall mean each sublicense agreement entered into by Warner pursuant to Section 2.2 with respect to a Licensed Product.

1.28. “**Sublicensee**” shall mean any Third Party or Affiliate of Warner to whom Warner grants a Sublicense of the rights granted to Warner under this Agreement, as provided under Section 2.2.

1.29. “**Technology**” shall mean and include, whether or not patentable, any and all proprietary ideas, inventions, discoveries, Confidential Information, biologic materials, data, results, formulae, designs, specifications, methods, processes, formulations, techniques, ideas, know-how, technical information (including, without limitation, structural and functional information), process information, pre-clinical information, clinical information, and any and all proprietary biological, chemical, pharmacological, toxicological, pre-clinical, clinical, assay, control and manufacturing data and materials.

1.30. “**Term**” shall have the meaning set forth in Section 9 hereof.

1.31. “**Territory**” shall mean the United States of America, including its possessions and territories.

1.32. “**Third Party**” shall mean any person or entity other than Warner, NexMed and their respective Affiliates.

1.33. “**Undivided Patent Rights**” shall mean the Patent Rights set forth on Exhibit C hereto and any Licensed Patent Rights that relate solely to the Licensed Products.

1.34. “**Valid Claim**” shall mean a claim that has been allowed or is contained in an issued patent or pending patent application, which claim has not lapsed, been canceled, or become abandoned and which claim has not been declared invalid or unenforceable by an unappealable decision of a court of competent jurisdiction.

1.35. “**Warner Improvement**” shall mean any change in the formulation, ingredients, preparation, presentation, means of delivery, dosage, package of, manufacture, or any new or expanded uses of the Licensed Product in the Field developed during the term of this Agreement by or on behalf of Warner.

2. GRANT OF RIGHTS

2.1. **License to Warner.** Subject to the terms and conditions of this Agreement, NexMed grants to Warner an exclusive (even as to NexMed and its Affiliates but subject to Section 2.5) license under the Licensed Know-How and Licensed Patent Rights to Develop, have Developed, make, have made, use, have used, sell, distribute for sale, have distributed for sale, offer for sale, have sold, import or have imported Licensed Products in the Field in the Territory.

2.2. **License to NexMed.** Warner hereby grants to NexMed a fully paid-up, exclusive license under any Warner Improvements and Joint Inventions to develop, manufacture, use, sell,

offer for sale and import products including Licensed Products (i) outside the Territory and (ii) inside the Territory outside the Field, including the right to grant sublicenses.

2.3. **Right to Sublicense.** Warner shall have the right to grant sublicenses under the exclusive license granted pursuant to Section 2.1 to an Affiliate of Warner. In the event Warner intends to grant to a Third Party a sublicense of the rights granted hereunder, it shall provide written notice to NexMed of its intention to appoint or designate a sublicensee, including a reasonably detailed description of the scope and nature of such sublicense. In connection with the grant of any permitted sublicense hereunder, Warner shall ensure that each of its Affiliates and Sublicensees accepts and complies with all of the terms and conditions of this Agreement as if such Affiliates or Sublicensees were a party to this Agreement and Warner shall guarantee and remain obligated for the performance (or failure of performance) of any Affiliate or Sublicensee hereunder, including by way of example only and not limitation, for the payment to NexMed of its milestone and royalty obligations as described in Section 5 hereof.

2.4. **Non-Compete.** During the Term, except as contemplated by this Agreement, neither Party nor their respective Affiliates, directly or indirectly or with or through a Third Party, shall develop, make, use, promote, distribute or sell a pharmaceutical product in the Field in the Territory.

2.5. **Retained Rights and License to NexMed.** Except as expressly provided hereunder, NexMed reserves all other rights in and to the Licensed Know-How and Licensed Patent Rights. Warner hereby grants NexMed a non-exclusive, worldwide, royalty-free license under the Licensed know-How and Licensed Patent Rights solely to the extent necessary to allow NexMed to fulfill its obligations to Develop, manufacture and supply Licensed Products under this Agreement.

2.6. **Right of Reference.** Each Party and its Affiliates will, upon reasonable request, provide the other Party with a right of reference to any filings with the FDA related to the Licensed Product including, but not limited to, drug master files.

2.7. **OTC Product.** If at any time during the Term the JSC determines in good faith that it is reasonably likely that an OTC Product could be (i) manufactured under a commercially viable manufacturing process and (ii) sold in compliance with applicable law then Warner shall notify NexMed within ninety (90) days of such determination if it intends to Develop and commercialize such OTC Product (such notice, the “**OTC Commercialization Notice**”). Following delivery of the OTC Commercialization Notice, Warner shall use Commercially Reasonable Efforts to Develop and commercialize the OTC Product as promptly as practicable. Notwithstanding the foregoing, if Warner fails to provide the OTC Commercialization Notice within the period described in this Section 2.7, the rights granted to Warner to Develop and commercialize the OTC Product in the Field and in the Territory under this Agreement shall revert to NexMed and NexMed shall thereafter have the unencumbered right to grant one or more Third Parties the right to develop and commercialize the OTC Product.

3. **DEVELOPMENT, REGULATORY APPROVAL AND COMMERCIALIZATION OF LICENSED PRODUCTS.**

3.1. **Regulatory Approval for Refrigerated Formulation NDA.** NexMed will use Commercially Reasonable Efforts to obtain Approval of the Refrigerated Formulation NDA as promptly as practicable following the Effective Date. In the event the Parties determine that additional Development is required following submission of the Refrigerated Formulation NDA to the FDA in order to obtain Approval of such submission, such Development shall be conducted by NexMed at the direction of the JSC (as hereafter defined) in accordance with Section 3.2 and Warner shall reimburse NexMed for all costs and expenses (other than any FDA filing fees with respect to the Refrigerated Formulation NDA) relating to such Development, including any amounts paid to a contract research organization engaged by NexMed to perform such Development. Warner shall determine the nature and extent of any improvements, upgrades, personnel changes or other modifications that are necessary to enable the NexMed manufacturing facility to receive all required approvals relating to the FDA pre-approval inspection (the “**PAI**”) conducted in connection with obtaining Approval of the Refrigerated Formulation NDA (collectively, the “**PAI Upgrades**”). Warner shall use Commercially Reasonable Efforts to timely conduct such PAI Upgrades in advance of the PAI and NexMed shall provide reasonable assistance and cooperation to facilitate the PAI Upgrades. Warner shall bear the cost of the PAI Upgrades.

3.2. **Development.**

3.2.1. **JSC.** All Development (other than that Pre-Notification Room Temperature Formulation Development Activities) with respect to the Licensed Products shall be conducted at the direction of a joint steering committee (the “**JSC**”) that shall be established by the Parties as promptly as practicable after the Effective Date. The JSC shall (i) oversee all Development in connection with obtaining Approval of the Refrigerated Formulation NDA and (ii) in the event Warner determines to proceed with the Development of the Room Temperature Formulation in accordance with Section 3.2.3, prepare a Development plan with respect to the Room Temperature Formulation and oversee the Development thereof and the preparation and filing of the Room Temperature Formulation NDA. The JSC shall consist of six (6) members, three (3) nominated by each Party. Each Party may designate a substitute for a member nominated by it, who is unable to be present at a meeting. Meetings of the JSC shall be held on a quarterly basis, or at such other interval as may be agreed between the Parties. The JSC will be chaired by one of the Warner designated representatives (the “**Chair**”). Meetings shall be held alternately at the offices of Warner or NexMed. The JSC may be convened, polled or consulted from time to time by means of telecommunication or correspondence. The meetings of the JSC shall be documented in written minutes to be approved by both Parties. Each Party shall bear its own costs for participation in the JSC. At each JSC meeting the NexMed representatives shall provide an update with respect to all material aspects of any ongoing Development and regulatory filings. If there is a material change with respect to such updates after any such meeting, NexMed will promptly notify Warner thereof.

3.2.2. **JSC Decisions.** The JSC members shall use reasonable efforts to reach agreement on any and all matters. In the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by the JSC, then the Chair of the JSC shall have the right to make the final decision on such matter, but shall only exercise such right in good faith after full consideration of the positions of both Parties; provided, however, that NexMed shall not be required to provide resources or expertise beyond its reasonable capabilities,

notwithstanding the fact that Warner is required to reimburse NexMed for such Development costs and expenses.

3.2.3. **Room Temperature Formulation.**

3.2.3.1. NexMed shall provide Warner with reasonably detailed summaries of all Pre-Notification Room Temperature Formulation Development Activities at such times as Warner shall reasonably request.

3.2.3.2. In the event Warner determines, in its sole discretion, to proceed with the Development and commercialization of the Room Temperature Formulation, Warner shall notify NexMed in writing (such notice, the “**Room Temperature Formulation Development Notice**”) on or prior to the date that is 30 days following Approval of the Refrigerated Formulation NDA (such date, the “**Room Temperature Formulation Notification Date**”). Thereafter, the Parties shall promptly enter into good faith discussions in order to determine mutually acceptable product labeling with respect to the Room Temperature Formulation NDA. Following receipt of the Room Temperature Formulation Development Notice, NexMed shall provide Warner with reasonably detailed documentation of all expenses incurred by NexMed relating to Pre-Notification Room Temperature Formulation Development Activities and Warner shall promptly reimburse NexMed for all costs and expenses relating to such Development, including any amounts paid to a contract research organization engaged by NexMed to perform such Development. Following receipt of the Room Temperature Formulation Development Notice (i) all Development thereafter conducted with respect to the Room Temperature Formulation shall be conducted by NexMed at the direction of the JSC in accordance with Section 3.2 and Warner shall reimburse NexMed for (A) all costs and expenses relating to such Development, including any amounts paid to a contract research organization engaged by NexMed to perform such Development and (B) any filing fees paid to the FDA with respect to the Room Temperature Formulation NDA and (ii) at the direction of the JSC in accordance with Section 3.2, NexMed will use commercially reasonable efforts to prepare, submit and obtain Approval of a Room Temperature Formulation NDA that reflects the labeling agreed by the Parties, as promptly as practicable. For the avoidance of doubt, it is understood that Warner shall only be responsible to reimburse NexMed for Pre-Notification Room Temperature Formulation Development Activities if Warner delivers the Room Temperature Formulation Development Notice and in no instance shall Warner be responsible to reimburse NexMed for Development conducted prior to the Effective Date. The Party manufacturing the Room Temperature Formulation shall be responsible for payment to the FDA of any annual fees on establishments under the Prescription Drug User Fee Act (“**PDUFA**”) with respect to such Party’s manufacturing facility for so long as such Party manufactures the Room Temperature Formulation.

3.3. **FDA Meetings and Submissions.** NexMed shall own all regulatory filings and Approvals for all Licensed Products in the Territory and NexMed shall be responsible for and shall control the regulatory strategy and interactions with regulatory authorities for all Licensed Products in the Territory and shall be the designated point of contact with such regulatory authorities, it being understood that NexMed shall consult with Warner with respect to such strategy and interactions and will consider in good faith any Warner recommendations relating thereto. Warner shall be entitled to participate in all meetings and discussions with the FDA

relating to the Licensed Products. Prior to submitting any correspondence or other information relating to the Licensed Products to the FDA (an “**FDA Submission**”), NexMed shall (i) provide Warner with a copy of the FDA Submission and (ii) in the case of a material FDA Submission, provide Warner with a reasonable opportunity to review such FDA Submission and NexMed shall consider and discuss in good faith any comments or proposed changes to such submission by Warner. NexMed shall be responsible for pursuing, compiling and submitting all regulatory documents, and for interacting with the FDA. Nexmed shall be responsible for all product renewal fees payable to the FDA with respect to any Licensed Product under PDUFA.

3.4. **Commercialization.**

3.4.1. **Responsibility.** From and after the Effective Date, Warner, subject to the terms and conditions of this Agreement, shall be fully responsible for and shall have full control and authority over the commercialization of Licensed Products in the Field in the Territory, including without limitation, (a) subject to Section 4.2.2, all activities relating to manufacture and supply of all Licensed Products, and (b) all marketing, promotion, sales and distribution activities relating to any Licensed Product.

3.4.2. **Diligence.** Warner will exercise Commercially Reasonable Efforts to commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, Warner shall be deemed to have satisfied its obligations under this Section 3.4.2 so long as it is exercising Commercially Reasonable Efforts to commercialize the Refrigerated Formulation, the Room Temperature Formulation or the OTC Product.

3.4.3. **Warner Responsibilities.** In addition to and without limiting, defining or otherwise qualifying the standards of conduct set forth elsewhere in this Agreement, Warner shall:

3.4.3.1. launch the Licensed Product within six (6) months following receipt of Approval of the Licensed Product in the Territory;

3.4.3.2. perform pre-commercialization analysis, planning, market preparation, and related marketing activities for the Territory;

3.4.3.3. conduct phase IV clinical trials and marketing studies as Warner deems necessary or useful for commercialization of Licensed Product;

3.4.3.4. conduct the commercialization of Licensed Product in compliance in all material respects with all requirements of applicable laws; and

3.4.3.5. consult with and keep NexMed and the JSC informed, through regular, periodic written reports, in accordance with Section 3.4.5.

3.4.4. **Commercialization Expenses.** Warner shall be responsible and pay for one hundred percent (100%) of all costs and expenses incurred in connection with the distribution, marketing, sale or other commercialization of the Licensed Product in the Territory.

3.4.5. **Updates and Reports.** In addition to royalty information reports to be provided by Warner pursuant to Section 5.5 hereof, no later than sixty (60) days prior to the expected date of Approval of each Licensed Product, Warner shall provide NexMed a preliminary written commercialization plan and budget for such Licensed Product for review and comment by NexMed (each, a “**Commercialization Plan**”). Warner shall consider all of NexMed’s comments in good faith. Each Commercialization Plan shall be developed by Warner in good faith in accordance with usual pharmaceutical industry practices and, at a minimum, shall contain: (a) a quarterly Net Sales forecast (dollars and units) and associated pricing and market share assumptions for at least the four (4) consecutive calendar quarters after the forecasted First Commercial Sale of such Licensed Product; (b) the out-of-pocket expense budgets for promotional activities including but not limited to advertising and public relations and any other relevant promotional activities; and (c) a description of the sales force efforts, including the number, type and allocation of pharmaceutical sales representatives beginning with pre-launch activities through and including the 4th quarter of the Net Sales forecast. Warner shall amend and update each Commercialization Plan annually after the first such plan is prepared for each Licensed Product and shall promptly provide a copy of such updated Commercialization Plan to NexMed. Warner shall provide NexMed with oral updates as reasonably requested by NexMed with respect to any Commercialization Plan. All such Commercialization Plans and updates shall be considered Confidential Information of Warner, subject to the terms of Section 6 hereof.

3.4.6. **Pharmacovigilance.** Warner shall be responsible for all processing of information related to any adverse events, including, without limitation, any information regarding such adverse events that is received from a Third Party with respect to Licensed Product in the Territory. As soon as reasonably practicable following the date of this Agreement, the pharmacovigilance departments of each of NexMed and Warner shall meet and determine the approach to be taken for the collection, review, assessment, tracking and filing of information related to adverse events associated with Licensed Product, consistent with the provisions of this Section 3.4.6. Such approach shall be documented in a separate and appropriate written pharmacovigilance agreement between each of NexMed and Warner. Each Party agrees to share relevant information it receives (either directly or indirectly) with the other Party in a timely manner so as to allow each Party to comply with its responsibility to report pharmacovigilance information.

4. **LICENSED PRODUCT MANUFACTURE AND SUPPLY**

4.1. **Licensed Product Manufacture by Warner.** Subject to Section 4.2, Warner shall have the sole obligation and responsibility for the manufacture of the Licensed Products for commercial sale during the Term.

4.2. **Option for Licensed Product Manufacture by NexMed.** In the event Warner notifies NexMed that it desires NexMed to manufacture the Refrigerated Formulation, the Parties shall promptly negotiate in good faith and execute the necessary manufacturing and supply agreement (the “**Manufacturing Agreement**”); provided that it is understood that in the event the parties agree to enter into the Manufacturing Agreement, Warner shall retain responsibility for the manufacture and supply of Licensed Product until such time as NexMed is able to qualify and validate a facility for the manufacture of Licensed Product for the Territory. The

Manufacturing Agreement shall provide that NexMed shall be exclusively responsible for the manufacture of and supply to Warner, and Warner shall exclusively purchase from NexMed, all requirements of the Refrigerated Formulation for a period of three years commencing on the date of Approval of the Refrigerated Formulation NDA (the “**Manufacturing Term**”), it being understood that the Manufacturing Agreement shall also provide that NexMed shall manufacture quantities of the Refrigerated Formulation necessary to adequately supply the trade in anticipation of the commercial launch of the Refrigerated Formulation. Warner shall be responsible for the cost of any initial plant and equipment improvements with respect to NexMed’s manufacturing facility that are necessary to enable NexMed to meet its supply obligations under the Manufacturing Agreement (the “**Manufacturing Improvements**”), it being understood that the Manufacturing Improvements shall not include personnel and Warner shall have no obligation with respect to costs associated with personnel. Warner shall be responsible for determining the Manufacturing Improvements that are necessary and a process for conducting such improvements. Warner will oversee the implementation of the Manufacturing Improvements and NexMed shall reasonably cooperate to allow such improvements to be completed in a timely manner. The price for the Refrigerated Formulation supplied to Warner under the Manufacturing Agreement shall be NexMed’s fully-loaded cost of supply with respect to such Refrigerated Formulation. The Party manufacturing the Refrigerated Formulation shall be responsible for payment to the FDA of any annual fees on establishments under PDUFA with respect to such Party’s manufacturing facility for so long as such Party manufactures the Refrigerated Formulation.

4.3. **Transfer of Manufacturing Know-How**

4.3.1. Upon the reasonable request of Warner, for a period of time from the Effective Date until twelve (12) months after Approval, NexMed shall provide to Warner the assistance of NexMed’s employees and access to NexMed’s other internal resources to provide Warner with a reasonable level of technical assistance and consultation with respect to the transfer from NexMed to Warner, or any Third Party manufacturer designated by Warner of the manufacture of the Refrigerated Formulation. After such initial twelve (12) month period, Warner shall pay NexMed \$600 per day per full time equivalent for the provision of such assistance.

4.3.2. Upon the reasonable request of Warner, for a period of time from the Effective Date until twelve (12) months after Approval, NexMed shall provide to Warner the assistance of NexMed’s employees and access to NexMed’s other internal resources to provide Warner with a reasonable level of technical assistance and consultation with respect to the transfer to Warner of any expertise or know-how that NexMed has developed relating to the manufacture of Room Temperature Formulation. After such initial twelve (12) month period, Warner shall pay NexMed \$600 per day per full time equivalent for the provision of such assistance.

5. **PAYMENTS AND ROYALTIES.**

5.1. **Upfront License Fee.** In consideration of the grant of the licenses described in Section 2 hereof, Warner hereby shall pay NexMed on the Effective Date a nonrefundable, non-creditable license fee in the amount of Five Hundred Thousand Dollars (\$500,000.00 US).

5.2. **Milestone Payments.** Additionally, Warner shall pay to NexMed the following amounts:

5.2.1. If Warner determines, in its sole discretion, to proceed with the commercialization of the Refrigerated Formulation following Warner's receipt of all (i) FDA comments received by NexMed in connection with a ninety-day conference with the FDA per 21 C.F.R. 314.102(c) with respect to the Refrigerated Formulation NDA (the "**Ninety Day Conference Comments**") or (ii) material FDA comments provided to NexMed in connection with the process of obtaining Approval of the Refrigerated Formulation NDA if such ninety-day conference does not occur, then Warner shall provide notice of such determination within 45 days following the receipt of such comments, together with a milestone payment in the amount of Two Million Five Hundred Thousand Dollars (\$2,500,000 US). For the avoidance of doubt, if the Ninety Day Conference Comments do not provide, in Warner's reasonable judgement, a reasonable basis for evaluating the likelihood of Approval of the Refrigerated Formulation NDA in a form that will allow for the launch of a commercially viable product then such 45 day period shall commence upon receipt of all material FDA comments with respect to the Refrigerated Formulation.

5.2.2. If the Licensed Product labeling reflected in the Refrigerated Formulation NDA as approved by the FDA is materially consistent with the labeling set forth in Exhibit A hereto and, in Warner's reasonable determination, will allow it to launch a commercially viable Licensed Product, Warner shall provide notice of such determination to NexMed within 30 days following Approval of the Refrigerated Formulation NDA, together with a milestone payment in the amount of Two Million Dollars (US \$2,000,000 US). For the avoidance of doubt, the First Commercial Sale by Warner of the Refrigerated Formulation shall require the payment of the milestone set forth in this Section 5.2.2 regardless of the final labeling approved by the FDA.

5.2.3. If the FDA approves a Room Temperature Formulation NDA which reflects labeling that is materially consistent with the labeling agreed by the Parties in accordance with Section 3.2.3.2, then Warner shall pay NexMed a milestone payment in the amount of Two Million Dollars (\$2,000,000 US) within 30 days of such Approval. For the avoidance of doubt, the First Commercial Sale by Warner of the Room Temperature Formulation shall require the payment of the milestone set forth in this Section 5.2.3 regardless of the final labeling approved by the FDA.

5.2.4. Within 30 days after the date of the First Commercial Sale of a Licensed Product, Warner shall pay NexMed a milestone payment in the amount of Six Million Dollars (\$6,000,000 US). For the avoidance of doubt, the payment hereunder shall be payable only once irrespective of whether Warner engages in the commercial sale of the Refrigerated Formulation, the Room Temperature Formulation and/or the OTC Product.

5.3. **Royalty Rates; Payment.**

5.3.1. **Royalty Payment.** In further consideration of the grant of the licenses by NexMed hereunder, and subject to the other terms of this Agreement, commencing on the date of the First Commercial Sale of a Licensed Product and continuing until the last to expire Valid Claim included in the Licensed Patent Rights covering such Licensed Product:

5.3.1.1. with respect to Net Sales of Licensed Product during the period from the date of the First Commercial Sale of the Licensed Product until the end of the first full calendar year thereafter ("**Year 1**"), Warner shall pay to NexMed a royalty payment equal to (i) 8% of the first \$150 million of Net Sales, (ii) 13% of Net Sales in excess of \$150 million and up to \$300 million and (iii) 20% of Net Sales in excess of \$300;

5.3.1.2. with respect to Net Sales of Licensed Product during the 12 month period following Year 1 ("**Year 2**"), Warner shall pay to NexMed a royalty payment equal to (i) 9% of the first \$150 million of Net Sales, (ii) 13% of Net Sales in excess of \$150 million and up to \$300 million and (iii) 20% of Net Sales in excess of \$300 million; and

5.3.1.3. with respect to Net Sales of Licensed Product during the 12 month period following Year 2 ("**Year 3**") and thereafter until the expiration of the Term, Warner shall pay to NexMed a royalty payment equal to (i) 10% of the first \$150 million of Net Sales, (ii) 13% of Net Sales in excess of \$150 million and up to \$300 million and (iii) 20% of Net Sales in excess of \$300 million.

5.3.2. **Generic Competition.** The royalties payable by Warner, its Affiliates and Sublicensees under Section 5.3.1 shall be reduced by fifty percent (50%) for any period during which one or more Generic Products that have received Approval in the Field are sold by one or more Third Parties in the Territory during the Term provided there is a reduction in the market share of the Licensed Product in the Territory of at least twenty percent (20%), as measured by unit sales (as determined by IMS International, or if such data is not available, a reliable source of data as reasonably agreed by the Parties) from the calendar quarter immediately prior to such first Generic Product sale. Notwithstanding anything in this Section to the contrary, no adjustment for Generic Product competition will be due in the event Warner, its Affiliates and Sublicensees fail to use Commercially Reasonable Efforts to promote and market Licensed Product.

5.4. **Payment.** All payments to be made by Warner hereunder shall be made in United States Dollars by wire transfer of immediately available funds to such United States bank account as shall be designated by NexMed. Late payments shall bear interest at the rate of 1% of the outstanding balance per month as prorated, or the maximum amount permitted by law, whichever is less.

5.5. **Sales Reports and Royalty Payments.** After the First Commercial Sale of a Licensed Product and during the Term, Warner shall furnish to NexMed a written report, within thirty (30) days after the end of each calendar quarter (or portion thereof, if this Agreement terminates during a calendar quarter), showing the amount of royalty payments due for the immediately preceding calendar quarter (or portion thereof). Royalty payments for each calendar quarter shall be due at the same time as such written reports. Each written report shall contain the following information:

5.5.1. the gross sales and quantity of each Licensed Product sold by Warner, its Affiliates, and Sublicensees in the preceding calendar quarter;

5.5.2. the calculation of Net Sales from such gross sales; and

5.5.3. the royalties payable in United States Dollars which shall have accrued hereunder in respect of such Net Sales.

If no royalty payment is due for any royalty period hereunder, Warner shall so report.

5.6. **Tax Withholding; Restrictions on Payment.** All payments hereunder shall be made free and clear of any taxes, duties, levies, fees or charges, except for withholding taxes (to the extent mandated by applicable law). Warner shall make any applicable withholding payments due on behalf of NexMed and shall provide NexMed upon request with such written documentation regarding any such payment as is available to Warner.

5.7. **Sales Record Audit.** Warner shall keep, and shall cause each of its Affiliates, and Sublicensees, if any, to keep, full and accurate books of accounting in accordance with GAAP as may be reasonably necessary for the purpose of calculating the royalties payable to NexMed. Such books of accounting (including, without limitation, those of Warner's Affiliates, and Sublicensees, if any) shall be kept at their principal place of business and, with all necessary supporting data, shall during all reasonable times for the three (3) years next following the end of the calendar year to which each shall pertain, be open for inspection at reasonable times upon written notice by NexMed, no more than once per year, by a nationally recognized independent certified accountant selected by NexMed (reasonably acceptable to Warner), for the purpose of verifying royalty statements for compliance with this Agreement. Such accountant must have agreed in writing to maintain all information learned in confidence, except as necessary to disclose to NexMed such compliance or noncompliance by Warner. The results of each inspection, if any, shall be binding on both Parties. NexMed shall pay for such inspections, except that in the event there is any upward adjustment in aggregate royalties payable for the period of such inspection of more than five percent (5%) of the amount actually paid to NexMed, Warner shall pay for the reasonable out-of-pocket costs of such audit. Any underpayments shall be paid by Warner within thirty (30) days of notification of the results of such inspection plus interest as calculated in accordance with Section 5.4. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods or, if no such amounts become payable within ninety (90) days after notification of such results, shall be refunded.

5.8. **Minimum Royalties.** If at any time after the completion of Year 3 Warner fails to generate at least \$25 million of Net Sales in each of two consecutive Contract Years (the "**Net Sales Minimums**"), upon the written request of NexMed, the Parties shall enter into a co-promotion agreement on commercially reasonable terms with respect to the Licensed Products pursuant to which NexMed will have the right to co-promote the Licensed Products. Notwithstanding the foregoing, if Warner, in its sole discretion, makes a payment to NexMed within thirty (30) days of receipt of such request equal to difference between (i) the amount of the royalty that NexMed would have received under Section 5.3.1.3 if Warner had generated \$25 million of Net Sales in each of such two consecutive Contract Years and (ii) the amount of the royalty actually paid to NexMed with respect to such periods, then NexMed shall have no co-promotion rights hereunder as a result of Warner's failure to meet such Net Sales Minimums.

6. TREATMENT OF CONFIDENTIAL INFORMATION

6.1. **Confidentiality Obligations.** Each of NexMed and Warner agree that during the Term and for ten (10) years thereafter, it will keep confidential, and will cause its employees, consultants, Affiliates, agents, subcontractors, and Sublicensees to keep confidential, all Confidential Information of the other Party. Neither NexMed nor Warner nor any of their employees, consultants, Affiliates, agents, subcontractors, or Sublicensees shall use Confidential Information of the other Party for any purpose whatsoever other than exercising any rights granted to it or reserved by it hereunder. Without limiting the foregoing, each Party may disclose information to the extent such disclosure is reasonably necessary to (a) file and prosecute patent applications and/or maintain patents which are filed or prosecuted in accordance with the provisions of this Agreement, or (b) file, prosecute or defend litigation in accordance with the provisions of this Agreement or (c) comply with applicable laws, regulations or court orders; provided, however, that if a Party is required to make any such disclosure of the other Party's Confidential Information in connection with any of the foregoing, it will give reasonable advance notice to the other Party of such disclosure requirement and will use reasonable efforts to assist such other Party in efforts to secure confidential treatment of such information required to be disclosed.

6.2. **Limited Disclosure and Use.** NexMed and Warner each agree that any disclosure of the other Party's Confidential Information to any of its employees, consultants, Affiliates, agents, subcontractors, or sublicensees shall be made only if and to the extent necessary to carry out its rights and responsibilities under this Agreement, shall be limited to the maximum extent possible consistent with such rights and responsibilities, and shall only be made to the extent any such persons are bound by confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement. NexMed and Warner each further agree not to disclose or transfer the other Party's Confidential Information to any Third Parties under any circumstance without the prior written approval from the other Party, except as otherwise required by law, and except as otherwise expressly permitted by this Agreement. Each Party shall take such action, and shall cause its employees, consultants, Affiliates, agents, subcontractors, and sublicensees to take such action, to preserve the confidentiality of each other Party's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information. In connection with the termination of this Agreement, upon the request of the other Party, each Party will return all the Confidential Information disclosed or transferred to it by the other Party pursuant to this Agreement, including all copies and extracts of documents and all manifestations of Confidential Information in any form, within sixty (60) days of such request; provided however, that a Party may retain (a) any Confidential Information of the other Party relating to any license which expressly survives such termination and (b) one (1) copy of all other Confidential Information in inactive archives solely for the purpose of maintaining a record of information and materials deemed to be Confidential Information hereunder.

6.3. **Publicity.** Neither Party may publicly disclose the existence or terms or any other matter of fact regarding this Agreement without the prior written consent of the other Party; provided, however, that either Party may make such a disclosure (a) to the extent required by law or by the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded, or (b) to any

actual or prospective sublicensees, investors, lenders, other financing sources, acquirors, or companies being acquired by such Party who are obligated to keep such information confidential. The Party desiring to make any such public announcement or disclosure shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release and shall provide the other Party with a written copy thereof. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including, without limitation, requests for confidential treatment of proprietary information of either Party included in such disclosure.

7. **PROVISIONS CONCERNING THE FILING, PROSECUTION AND MAINTENANCE OF LICENSED PATENT RIGHTS**

7.1. **Ownership of Inventions.**

7.1.1. **Sole Inventions.** Subject to Section 7.1.3, each Party shall exclusively own all inventions conceived by such Party, its employees, agents and consultants during the Term without the use in any material respect of any Technology owned by the other Party (“**Sole Inventions**”). Sole Inventions conceived solely by NexMed, its employees, agents and consultants are referred to herein as “**NexMed Sole Inventions**”. Sole Inventions conceived solely by Warner, its employees, agents and consultants are referred to herein as “**Warner Sole Inventions.**”

7.1.2. **Joint Inventions.** Subject to Section 7.1.3, the Parties shall jointly own all inventions (a) conceived or first reduced to practice jointly by or on behalf of both Warner (or any of its Affiliates) and NexMed (or any of its Affiliates) or (b) conceived or first reduced to practice by or on behalf of one Party or any of its Affiliates as a result of its use in any material respect of the Technology of the other Party, on the basis of each Party having an undivided interest in the whole (collectively “**Joint Inventions**”).

7.1.3. **Permeation Inventions.** Notwithstanding Section 7.1.1 or Section 7.2.2, in the event a Joint Invention is a discovery, invention, improvement or new use of permeation enhancing excipient technology (a “**Permeation Invention**”), such Permeation Invention shall be the sole and exclusive property of NexMed, and Warner agrees to assign, and hereby does assign, its entire right, title and interest in and to such Permeation Invention to NexMed. Thereafter, all assigned Permeation Inventions shall be part of the “Licensed Know-How” under this Agreement.

7.1.4. **Inventorship.** For purposes of determining whether an invention is a NexMed Sole Invention, a Warner Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws.

7.2. **Cooperation.** Warner agrees to cooperate with all reasonable requests of NexMed in the filing and prosecution of the Licensed Patent Rights.

7.3. **Patent Filing, Prosecution and Maintenance.** Subject to the other terms of this Section 7, NexMed, at its cost, shall use Commercially Reasonable Efforts to diligently prepare, file, prosecute, and maintain, the Licensed Patent Rights in the Territory. NexMed shall timely

provide to Warner, prior to filing, any patent applications or filings with respect to the Licensed Patent Rights in the Territory and shall consider in good faith any comments by Warner thereon. NexMed will keep Warner informed of the status of filing, prosecution and maintenance of all Licensed Patent Rights in the Territory and shall provide Warner with copies of all material documents relating thereto. NexMed also shall promptly notify Warner in the event it determines to abandon or permit the expiration of any Patent Rights included in the Licensed Patent Rights in the Territory (other than any expiration of the natural life of such Patent Right(s)), which notice shall, to the extent practical, be delivered no less than thirty (30) days prior to such action or inaction, in order to permit Warner, in Warner's reasonable judgment and at Warner's cost and expense, to prosecute or maintain such Licensed Patent Right(s), provided, however, that any such action does not violate the terms of any judgment, settlement, compromise or other resolution binding upon NexMed.

7.4. **Notice of Infringement.** If, during the Term, either Party learns of any actual, alleged or threatened infringement by a Third Party of any Licensed Patent Rights in the Territory, such Party shall notify the other Party within fifteen (15) days of becoming aware of such infringement and shall provide such other Party with available evidence of such infringement.

7.5. **Infringement of Licensed Patent Rights.** NexMed shall have the first right (but not the obligation), at its own expense and with legal counsel of its own choice, to bring suit (or take other appropriate legal action) against any actual, alleged or threatened infringement of the Divided Patent Rights in the Territory. Warner shall have the first right (but not the obligation), at its own expense and with legal counsel of its own choice, to bring suit (or take other appropriate legal action) against any actual, alleged or threatened infringement of the Undivided Patent Rights in the Territory. Each Party shall have the right, at its own expense, to be represented in any such action brought by the other by counsel of such Party's own choice; provided, however, that under no circumstances shall the foregoing affect the right of the other Party to control the suit as described in this Section 7.5. Notwithstanding the foregoing, neither Party shall settle, compromise or otherwise resolve any such suit that (i) in the case of a settlement by NexMed, materially restricts or waives rights under the Licensed Patent Rights granted to Warner hereunder and (ii) in the case of a settlement by Warner, materially restricts or waives any rights under the Licensed Patents, in each case without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. If the Party having the first right to bring suit does not file any action or proceeding against any such infringement within thirty days after the earliest of notice under Section 7.4, or a written request from the other to take action with respect to such infringement, then other Party shall have the right (but not the obligation), at its own expense, to bring suit (or take other appropriate legal action) against such actual, alleged or threatened infringement, with legal counsel of its own choice, but shall not be permitted to settle, compromise or otherwise resolve any such suit without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Any damages, monetary awards or other amounts recovered by a Party, whether by judgment or settlement, pursuant to any suit, proceeding or other legal action taken under this Section 7.5, shall be applied as follows:

7.5.1. first, to reimburse the Parties for their respective out-of-pocket costs and expenses (including reasonable attorneys' fees and costs) incurred in prosecuting such enforcement action; and

7.5.2. second, any remaining balance that (i) represents compensation for lost sales, royalty or profits, or any other damages as result of impairment of Warner's rights hereunder resulting from the infringement (collectively, "**Infringement Damages**"), shall be retained by or paid to Warner; provided, such Infringement Damages shall be deemed Net Sales and subject to royalty payments as set forth in Section 5.3.1 and (ii) represents punitive and exemplary damages shall be shared equally by Warner and NexMed.

If a Party brings any such action or proceeding hereunder, the other Party agrees to be joined as Party plaintiff if necessary to prosecute such action or proceeding, and to give the Party bringing such action or proceeding reasonable assistance and authority to file and prosecute the suit; provided, however, that neither Party shall be required to transfer any right, title or interest in or to any property to the other Party or any Third Party to confer standing on a Party hereunder.

7.6. **Defense of Claims.** In the event that any action, suit or proceeding is brought against NexMed or Warner or any Affiliate or Sublicensee of either Party alleging the infringement of the Technology or intellectual property rights of a Third Party by reason of the development, manufacture, use, sale, importation or offer for sale of a Licensed Product in the Territory (a "**Third Party Action**") then Warner shall have the first right to defend itself and NexMed in such Third Party Action. In such case, NexMed shall have the right to be represented by independent counsel at NexMed's own expense. If either Warner refuses to accept control of the defense of a Claim by a Third Party for which it has the first right to control defense hereunder within thirty (30) days after receiving or giving notice thereof, then the other NexMed shall have the right to defend against such Third Party Action. The Parties and their respective Affiliates shall cooperate with each other in the defense of any Third Party Action. The Parties will give each other prompt written notice of the commencement of any Third Party Action and will furnish each other a copy of each communication relating to the alleged infringement. Warner shall not compromise, settle or otherwise dispose of any Third Party Action without NexMed's advice and prior consent if such compromise, settlement or other disposition would impair the use of such Technology or Patent Rights, provided that such consent shall not be unreasonably withheld. The Parties shall each be responsible for fifty percent (50%) of the amount of any settlement, judgment or legal expenses arising out of such Third Party Action.

8. **REPRESENTATIONS AND WARRANTIES**

8.1. **NexMed Representations.** NexMed represents and warrants to Warner that:

8.1.1. the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate NexMed corporate action;

8.1.2. this Agreement is a legal and valid obligation binding upon NexMed and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by NexMed does not conflict with any agreement, instrument or understanding to which NexMed is a Party or by which it is bound;

8.1.3. To the knowledge of NexMed, NexMed has not provided to Warner any written information concerning the Licensed Know-How which is materially inaccurate or misleading and has not failed to provide to Warner any written information in its possession or under its Control which is materially inconsistent with the written information provided to Warner by NexMed as of the Effective Date;

8.1.4. NexMed is the owner of the Licensed Patent Rights and Licensed Know-How and has the requisite rights to grant to Warner the licenses granted herein to Warner, and, to the knowledge of NexMed, no right or license of any Third Party is required to permit NexMed to perform its obligations under this Agreement in accordance with the terms of this Agreement;

8.1.5. to the knowledge of NexMed no Third Party patent, patent application or other intellectual property rights would be infringed by practicing any process or method or by making, using or selling any composition which is claimed or disclosed in the Licensed Patent Rights, or which constitutes Licensed Know-How;

8.1.6. there is no litigation pending or, to the knowledge of NexMed, threatened, against NexMed with respect to the Licensed Patent Rights existing as of the Effective Date; and

8.1.7. NexMed is not aware of any infringement or misappropriation by a Third Party of the Licensed Patent Rights or Licensed Know-How.

8.2. **Warner Representations.** Warner represents and warrants to NexMed that:

8.2.1. the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Warner corporate action; and

8.2.2. this Agreement is a legal and valid obligation binding upon Warner and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by Warner does not conflict with any agreement, instrument or understanding to which Warner is a Party of or by which it is bound.

8.3. **No Warranties.** Except as expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, AND EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, ALL SUCH WARRANTIES ARE HEREBY DISCLAIMED, INCLUDING, WITHOUT LIMITATION, WARRANTIES ARISING BY COURSE OF DEALING, PERFORMANCE, CUSTOM OR USAGE IN THE TRADE, AND IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

8.4. **Indemnification.**

8.4.1. **Warner Indemnity.** Warner shall indemnify, defend and hold harmless NexMed, its Affiliates and their respective directors, officers, employees, stockholders and agents and their respective successors, heirs and assigns (the “**NexMed Indemnitees**”) from and against any liability, damage, loss or expense (including reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon such NexMed Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including, without limitation, product liability matters, to the extent arising (i) as a consequence of a breach by Warner of its representations, warranties, covenants or agreements, hereunder or (ii) out of the manufacture, sale or use by any person of any Licensed Product manufactured or sold by Warner or any Affiliate or Sublicensee under this Agreement, in each case, except to the extent of NexMed’s responsibility therefore under Section 8.4.2, or arising from the negligence or willful misconduct of NexMed.

8.4.2. **NexMed Indemnity.** NexMed shall indemnify, defend and hold harmless Warner, its Affiliates and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (the “**Warner Indemnitees**”), from and against any liability, damage, loss or expense (including reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon such Warner Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, arising as a result of (i) a breach by NexMed of its representations, warranties, covenants or agreements hereunder, in each case, except to the extent of Warner’s responsibility therefore under Section 8.4.1, or arising from the negligence or willful misconduct of Warner or (ii) the manufacture by NexMed of any Licensed Product.

8.4.3. **Indemnification Procedures.** In the event that any Indemnatee is seeking indemnification under Section 8.4 above from a Party (the “**Indemnifying Party**”), the other Party shall notify the Indemnifying Party of such claim with respect to such Indemnatee as soon as reasonably practicable after the Indemnatee receives notice of the claim, and the Party (on behalf of itself and such Indemnatee) shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The indemnification obligations under Section 8 shall not apply to any harm suffered as a direct result of any delay in notice to the Indemnifying Party hereunder or to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld or delayed unreasonably. The Indemnatee, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by Section 8.4.

8.5. **LIMITATION OF LIABILITY.**

8.5.1. EXCEPT FOR EACH PARTY’S OBLIGATION OF INDEMNITY UNDER SECTION 8.4, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY LOST PROFITS OR FOR ANY INDIRECT, EXEMPLARY, SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, EXCEPT FOR A BREACH OF EITHER PARTY’S

OBLIGATIONS WITH RESPECT TO SECTION 6 (“TREATMENT OF CONFIDENTIAL INFORMATION”).

8.5.2. THE LIMITATIONS OF LIABILITY CONTAINED IN THIS AGREEMENT ARE A FUNDAMENTAL PART OF THE BASIS OF EACH PARTY’S BARGAIN HEREUNDER, AND NEITHER PARTY WOULD ENTER INTO THIS AGREEMENT ABSENT SUCH LIMITATION OF LIABILITY.

8.6. **Insurance.** Each Party will obtain and maintain, during the term of this Agreement, at its own cost and expense, with reputable and financially sound insurance carriers, comprehensive commercial general liability insurance, product liability insurance, to cover such Party’s indemnification obligations hereunder, or self-insurance, in amounts consistent with such Party’s normal business practices. Each Party will name the other Party as an additional insured on each such insurance policy. Each such policy or self-insurance shall be in types and amount that are reasonable and customary in the pharmaceutical industry for companies engaged in similar business and operations and amounts that meet all contractual requirements of each Party’s vendors, distributors or other contractors. Maintenance of such insurance coverage will not relieve a Party of any responsibility under this Agreement for Losses in excess of such insurance limits or otherwise. Each Party will provide the other Party, upon reasonable request, with a certificate from the insurer(s) evidencing such insurance coverage.

9. TERM AND TERMINATION

9.1. **Term; Expiration.** Unless earlier terminated as provided herein, the term of this Agreement (“**Term**”) shall commence on the Effective Date and continue until expiration of the last to expire of the Licensed Patent Rights. Upon the expiration of the last payment obligation to NexMed hereunder (other than a termination for cause), Warner shall have a fully paid-up, irrevocable and sublicensable (subject to the terms of Section 2.2) license in the Territory and the Field under the Licensed Know-How to make, have made, use, have used, sell, distribute for sale, have distributed for sale, offer for sale, have sold, import or have imported Licensed Products in the Territory.

9.2. **Termination by NexMed.**

9.2.1. **Insolvency.** NexMed shall have the right to terminate this Agreement with respect to any or all licenses granted to Warner pursuant to Section 2 of this Agreement, at NexMed’s sole discretion, upon delivery of written notice to Warner upon the filing by Warner in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction of a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of Warner or its assets, or if Warner is served with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by Warner of an assignment of substantially all of its assets for the benefit of its creditors.

9.2.2. **Material Breach.** NexMed shall have the right to terminate this Agreement with respect to any or all licenses granted to Warner pursuant to Section 2 of this

Agreement by giving thirty (30) days written notice to Warner in the event of any breach by Warner of any material terms and conditions of this Agreement, provided that such breach has not been cured within sixty (60) days after written notice thereof is given by NexMed to Warner specifying the nature of the alleged breach.

9.2.3. **Termination for Convenience.** NexMed may terminate this Agreement upon delivery of written notice to Warner if Warner (i) has not delivered the Room Temperature Formulation Development Notice and (ii)(A) the 45 day period set forth in Section 5.2.1 has expired and Warner has not made a payment to NexMed thereunder or (B) the 30 day period set forth in Section 5.2.2 has expired and Warner has not made a payment to NexMed thereunder.

9.2.4. **Patent Challenge.** NexMed will be permitted to terminate this Agreement by written notice effective upon receipt if Warner or its Affiliates directly, or indirectly through assistance granted to a Third Party, commence any interference or opposition proceeding, challenge the validity or enforceability of (other than in defense of an action for infringement of a Patent Controlled by Warner), or oppose any extension of or the grant of a supplementary protection certificate with respect to, any Licensed Patent Right (each such action, a "**Patent Challenge**"). Warner will include provisions in all agreements granting sublicenses of Warner's rights hereunder providing that if the Sublicensee or its Affiliates undertake a Patent Challenge with respect to any NexMed Patent under which the sublicensee is sublicensed, Warner will be permitted to terminate such sublicense agreement. If a sublicensee of Warner (or an Affiliate of such sublicensee) undertakes a Patent Challenge of any such Licensed Patent Right under which such Sublicensee is sublicensed, then Warner upon receipt of notice from NexMed of such Patent Challenge will terminate the applicable sublicense agreement. If Warner fails to so terminate such sublicense agreement, NexMed may terminate Warner's right to sublicense and any sublicenses previously granted to such sublicensee shall automatically terminate. In connection with such sublicense termination, Warner shall cooperate with NexMed's reasonable requests to cause such a terminated sublicensee to discontinue activities with respect to the Licensed Product.

9.3. **Termination by Warner.**

9.3.1. **Insolvency.** Warner shall have the right to terminate this Agreement at Warner's sole discretion, upon delivery of written notice to NexMed upon the filing by NexMed in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction of a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of NexMed or its assets, or if NexMed is served with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by NexMed of an assignment of substantially all of its assets for the benefit of its creditors.

9.3.2. **Material Breach.** In addition, Warner may terminate this Agreement by giving thirty (30) days written notice to NexMed in the event of any breach by NexMed of any material terms and conditions of this Agreement, provided that such breach has not been cured within sixty days (60) days after written notice thereof is given by Warner to NexMed specifying the nature of the alleged breach.

9.3.3. **Termination for Convenience.** Warner may terminate this Agreement upon delivery of written notice to NexMed following:

9.3.3.1. receipt of (i) Ninety Day Conference Comments sufficient to commence the 45 day period under Section 5.2.1 hereof or (ii) all material FDA comments provided to NexMed in connection with the process of obtaining Approval of the Refrigerated Formulation NDA if such Ninety Day Comments are not received; provided Warner delivers such notice within forty five (45) days of receipt of such comments;

9.3.3.2. receipt of Approval of the Refrigerated Formulation NDA, if such NDA, as approved, (i) contains labeling that is not materially consistent with the labeling set forth in Exhibit A or (ii) in Warner's reasonable determination, will not allow it to launch a commercially viable Licensed Product; provided Warner delivers such notice within thirty (30) days of receipt of such Approval; or

9.3.3.3. receipt of Approval of the Room Temperature Formulation Supplement, if such NDA, as approved, contains labeling that is not materially consistent with the labeling agreed by the Parties in accordance with Section 3.2.3.2; provided Warner delivers such notice within thirty (30) days of receipt of such Approval.

For the avoidance of doubt, if Warner exercises its termination right under this Section 9.3.3 it shall have no obligation to make any milestone payment with respect to the milestone event resulting in such termination.

9.4. **Effect of Termination.** Upon termination of this Agreement or any right or license pursuant to Sections 9.2 or 9.3, the rights and obligations of the Parties hereunder, and all licenses granted to Warner hereunder shall immediately cease.

9.4.1. **Payments.** Subject to Section 9.3.3, all amounts due or payable to NexMed prior to the effective date of termination shall remain due and payable, but (except as otherwise expressly provided herein) no additional amounts shall be payable.

9.4.2. **Inventory.** Should Warner have any inventory of any Licensed Product approved and allocated for commercial sale prior to termination other than upon the occurrence of a material breach by NexMed pursuant to Section 9.3.2, Warner shall have twelve (12) months thereafter in which to dispose of such inventory (subject to the payment to NexMed of any royalties due hereunder thereon). In the event that, at the end of such twelve-month period, Warner has unsold inventory of Licensed Product remaining, Warner shall offer to sell such Licensed Products to NexMed at Warner's fully loaded manufacturing cost (but NexMed shall be under no obligation to purchase same unless it agrees to do so in writing at such time). If NexMed terminates this Agreement pursuant to Section 9.2.1 or 9.2.2, Warner and its Affiliates and Sublicensees shall immediately cease all sales of Licensed Product.

9.4.3. **Assignments.** Warner will promptly (and in each case within sixty (60) days of receipt of NexMed's request) and at no cost to NexMed:

9.4.3.1. following any termination of this Agreement other than a termination under Section 9.3.1 or 9.3.2:

9.4.3.1.1. upon NexMed's request, assign to NexMed all of Warner's right, title and interest in and to any agreements between Warner and Third Parties that are freely assignable by Warner and that relate to the commercialization of Licensed Product;

9.4.3.1.2. Warner, if in Warner's name or possession, agrees to transfer and assign, and hereby does transfer and assign, to NexMed all of Warner's right, title and interest in and to any and all regulatory filings, regulatory dossiers and Approvals (including the NDA and any foreign equivalents thereto) for Licensed Product;

9.4.3.1.3. assign to NexMed all of Warner's right, title and interest in and to any trademarks utilized by Warner in connection with the commercialization of Licensed Product (other than any Warner housemarks or logos) (including any goodwill associated therewith), any registrations and design patents for any of the foregoing and any Internet domain name registrations for such trademarks and slogans, all to the extent solely related to Licensed Product;

9.4.3.1.4. to the extent that any agreement or other asset described in this Section 9.4.3 is not assignable by Warner or does not relate solely to Licensed Product, then such agreement or other asset will not be assigned, and upon the request of NexMed, Warner will take such steps as may be necessary to allow NexMed to obtain and to enjoy the benefits of such agreement or other asset in the form of a license or other right to the extent Warner has the right and ability to do so; and

9.4.3.1.5. provide copies of any other books, records, documents and instruments to the extent related to Licensed Product.

9.4.3.2. following any termination of this Agreement under Section 9.3.1 or 9.3.2, Warner (i) if in Warner's name or possession, agrees to transfer and assign, and hereby does transfer and assign, to NexMed all of Warner's right, title and interest in and to any and all regulatory filings, regulatory dossiers and Approvals (including the NDA and any foreign equivalents thereto) for Licensed Product and (ii) will promptly assign to NexMed all of Warner's right, title and interest in and to any trademarks utilized by Warner in connection with the commercialization of Licensed Product (other than any Warner housemarks or logos) (including any goodwill associated therewith), any registrations and design patents for any of the foregoing and any Internet domain name registrations for such trademarks and slogans, all to the extent solely related to Licensed Product.

9.4.4. **Manufacturing.** To the extent Warner is then manufacturing Licensed Product, Warner will, upon NexMed's request, supply NexMed with quantities of Licensed Product for the shorter of (i) the period until NexMed or its designee is able to resume manufacturing Licensed Product or (ii) twelve (12) months from the effective date of such termination; provided, however, that NexMed will reimburse Warner for Warner's cost of goods, it being understood that in the case of a termination under Section 9.3.1 or 9.3.2 Warner shall have no obligation to supply NexMed with Licensed Product.

9.4.5. **Sublicensees.** Except for a termination for cause by NexMed arising as a result of a breach by a Sublicensee of the terms, conditions and limitations set forth herein, upon

any termination of this Agreement where Warner has designated a non-Affiliate as a Sublicensee as permitted hereunder, such Sublicensee shall be permitted to exercise the rights granted under such Sublicense on the same terms and conditions under which such rights and licenses were granted to such Sublicensee, provided that such Sublicensee (i) is in material compliance with the Sublicense terms; (ii) agrees in writing to be bound by the terms, conditions and limitations relating to the Licensed Patent Rights, Licensed Know-How, Licensed Compounds and Confidential Information as set forth hereunder; and (iii) agrees, to further evidence the continuation of the licenses granted under this Agreement and the Sublicense, execute a document having the same text and meaning as the Sublicense in favor of NexMed but does not include obligations upon NexMed that exceed the obligations of NexMed under this Agreement.

9.5. **Remedies.** Except as otherwise expressly set forth in this Agreement, the termination provisions of this Section 9 are in addition to any other relief and remedies available to either Party at law.

9.6. **Surviving Provisions.** Notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in Sections 5.5, 5.6, 5.7, 8.4, 8.5, 9.4, 11.3 and Articles 1 and 6, as well as any rights or obligations otherwise accrued hereunder (including any accrued payment obligations), shall survive the expiration or termination of the Term for any reason. Without limiting the generality of the foregoing and subject to Section 9.3.3, Warner shall have no obligation to make any milestone or royalty payment to NexMed that has not accrued prior to the effective date of any termination of this Agreement, but shall remain liable for all such payment obligations accruing prior to the effective date of such termination.

10. **Jurisdiction.** The Parties agree that any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the transactions contemplated hereby shall be brought in the United States District Court for the District of New Jersey or any New Jersey State court, so long as one of such courts shall have subject matter jurisdiction over such suit, action or proceeding, and that any cause of action arising out of this Agreement shall be deemed to have arisen from a transaction of business in the State of New Jersey, and each of the parties hereby irrevocably consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. Process in any such suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any such court.

11. MISCELLANEOUS

11.1. **Notification.** All notices, requests and other communications hereunder shall be in writing, shall be addressed to the receiving Party's address set forth below or to such other address as a Party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) made by facsimile transmission (to be followed with written confirmation by the delivering Party), (iii) sent by private courier service providing evidence of receipt, or (iv) sent by registered or certified mail, return receipt requested, postage prepaid. The addresses and other contact information for the Parties are as follows:

If to NexMed:	NexMed, Inc. 89 Twin Rivers Drive East Windsor, NJ 08520 Attn: Chief Financial Officer Fax: (609) 426-9116
With a copy to:	Morgan, Lewis & Bockius LLP 502 Carnegie Center Princeton, New Jersey 08540 Attn: Steven M. Cohen Fax: (609) 919-6701
If to Warner:	Warner Chilcott Company, Inc. PO Box 1005 Fajardo, Puerto Rico 00738 Attn: Director, Business Management Fax: (787) 863 5355
With a copy to:	Warner Chilcott (US), Inc. 100 Enterprise Drive Rockaway, New Jersey 07866 Attn: General Counsel Fax: (973) 442-3310

All notices, requests and other communications hereunder shall be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving Party at the address of such Party set forth above, (ii) if made by facsimile transmission, at the time that receipt thereof has been acknowledged by the recipient, (iii) if sent by private courier, on the day such notice is delivered to the recipient, or (iv) if sent by registered or certified mail, on the fifth (5th) business day following the day such mailing is made.

11.2. **Language.** This Agreement has been prepared in the English language and the English language shall control its interpretation.

11.3. **Governing Law.** This Agreement will be construed, interpreted and applied in accordance with the laws of the State of New Jersey, excluding its body of law controlling conflicts of law.

11.4. **Entire Agreement.** This Agreement is the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements between the Parties with respect to the subject matter hereof. No modification shall be effective unless in writing with specific reference to this Agreement and signed by the Parties.

11.5. **Waiver.** The terms or conditions of this Agreement may be waived only by a written instrument executed by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term shall be deemed as a continuing waiver of such condition or term or of another condition or term.

11.6. **Headings.** Section and subsection headings are inserted for convenience of reference only and do not form part of this Agreement.

11.7. **Assignment.** This Agreement shall not be assignable by either Party to any third party without the written consent of the other Party hereto; except either party may assign this Agreement, without such consent, to (i) an Affiliate or (ii) an entity that acquires all or substantially all of the capital stock, business or assets of the Party to which this Agreement pertains, (whether by merger, reorganization, acquisition, sale or otherwise) and agrees in writing to be bound by the terms and conditions of this Agreement. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 11.7 shall be void. The terms and conditions of this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the Parties.

11.8. **Force Majeure.** Except for obligations of payment arising hereunder, neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of such Party. In event of such force majeure, the Party affected thereby shall use commercially reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

11.9. **Construction.** The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement. Neither Party shall challenge the validity or enforceability of the terms, conditions, obligations and covenants hereunder.

11.10. **Severability.** If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the Term hereof, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby provided that a Party's rights under this Agreement are not materially affected. The Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid, illegal or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

11.11. **Status.** Nothing in this Agreement is intended or shall be deemed to constitute a partner, agency, employer-employee, or joint venture relationship between the Parties.

11.12. **Section 365(n)**. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to “intellectual property” as defined in Section 101 of such Code.

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

11.14. **Counterparts**. This Agreement may be executed simultaneously in one or more counterparts (including by facsimile), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representative.

NEXMED INC.

WARNER CHILCOTT COMPANY, INC.

By: _____

By:_____

Name: Vivian H. Liu

Name: Max Torres

Title: Chief Executive Officer

Title: Senior Director

Exhibit A – Refrigerated Formulation Labeling

In connection with the Approval of the labeling with respect to the Refrigerated Formulation NDA, the FDA shall not require any material adverse revisions to the labeling set forth in the Refrigerated Formulation NDA submitted to the FDA prior to the Effective Date. The initial dose of the Refrigerated Formulation set forth in the Dosage and Administration section of such labeling as approved by the FDA shall be 300 mcg and such labeling shall not require or suggest that a physician titrate from a 200 mcg dose.

In connection with the Approval of the Refrigerated Formulation NDA, the FDA shall not require the implementation of a Risk Evaluation and Mitigation Strategy (REMS) or distribution restrictions

Exhibit B – Divided Patents

DIVIDED – Compositions, Penetration Enhancers and Applicators					
	<u>Patent No.</u>	<u>Appln. No.</u>	<u>Filed</u>	<u>Granted</u>	<u>Title</u>
	4,980,378	07/201,029	June 1, 1988	December 25, 1990	Biodegradable Absorption Enhancers
	5,082,866	07/566,758	August 14, 1990	January 21, 1992	Biodegradable Absorption Enhancers
NMD-102	6,046,244	08/964,509	November 5, 1997	April 4, 2000	Topical Compositions For Prostaglandin E ₁ Delivery
NMD-107	6,118,020	09/314,571	May 19, 1999	September 12, 2000	Crystalline Salts Of Dodecyl 2-(N, N-Dimethylamino)-Propionate
NMD-110	6,224,573	09/232,360	January 15, 1999	May 1, 2001	Medicament Dispenser
NMD-113	6,414,028	09/542,668	April 4, 2000	July 2, 2002	Topical Compositions Containing Prostaglandin E ₁
NMD-121	7,105,571	10/236,485	September 6, 2002	September 12, 2006	Prostaglandin Compositions And Methods Of Treatment For Male Erectile Dysfunction [Claims to compositions]
NMD-125	6,841,574	10/336,481	January 3, 2003	January 11, 2005	Topical Stabilized Prostaglandin E Compound Dosage Forms

Exhibit C – Undivided Patents

UNDIVIDED – Methods of Treating Erectile Dysfunction and Suitable Applicator plus Medicament					
	<u>Patent No.</u>	<u>Serial No.</u>	<u>Filed</u>	<u>Granted</u>	<u>Title</u>
NMD-118	6,323,241	09/480,738	January 10, 2000	November 27, 2001	Prostaglandin Compositions And Methods Of Treatment For Male Erectile Dysfunction [Claims to Methods of Treatment]
NMD-123	6,693,135	09/947,617	September 6, 2001	February 17, 2004	Prostaglandin Compositions And Methods Of Treatment For Male Erectile Dysfunction [Claims to Applicator and Medicament]