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* Portions marked with a "*" have been omitted pursuant to a request for confidential treatment. Such portions have been filed separately with the SEC.

Execution Copy

13 September 2005

License Agreement

By And Between

Novartis International Pharmaceutical Ltd.

And

NexMed, Inc. and NexMed International Limited

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LICENSE AGREEMENT

This LICENSE AGREEMENT (this “**Agreement**”) is made as of this 13th day of September, 2005 (“**Effective Date**”), by and between Novartis International Pharmaceutical Ltd., a limited company organized and existing under the laws of Bermuda (“**Novartis**”) and NexMed, Inc., a corporation organized and existing under the laws of Nevada (“**NexMed, Inc.**”) and NexMed International Limited, a corporation organized and existing under the laws of the British Virgin Islands (“**NexMed International**”). Novartis and NexMed are each referred to individually as a “**Party**” and together as the “**Parties**”.

RECITALS

WHEREAS, NexMed owns or controls the NexMed Patent Rights and NexMed Know-How (each as defined below) relating to the NexMed Formulation (as defined below);

WHEREAS, Novartis wishes to obtain, and NexMed wishes to grant, rights to the NexMed Formulation; and

WHEREAS, Novartis will have the right to develop and commercialize the Product (as defined below) on a worldwide basis, subject to paying NexMed the royalty and milestone payments set out herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows.

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions.** Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

“**Accounting Standards**” means with respect to NexMed US GAAP (United States Generally Accepted Accounting Principles and with respect to Novartis the IFRS (International Financial Reporting Standards), both as generally and consistently applied throughout the Party’s organization.

“**Anti-Fungal Ingredient**” means any active ingredient that is used to treat fungal infection.

“**Affiliate**” means, in relation to a Party, any entity or person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “control” shall mean, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

“Alliance Manager” means the persons set out in Clause 3.1.

“Calendar Quarter” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

“Change of Control” means the announcement of any agreement or the consummation of any transaction of the following events: (a) any Third Party (or group of Third Parties acting in concert) becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the total voting power of the stock then outstanding of NexMed normally entitled to vote in elections of directors; (b) NexMed consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into NexMed, in either event pursuant to a transaction in which more than fifty percent (50%) of the total voting power of the stock outstanding of the surviving entity normally entitled to vote in elections of directors is not held by the parties holding at least fifty percent (50%) of the outstanding shares of NexMed preceding such consolidation or merger; (c) NexMed conveys, transfers or leases all or substantially all of its assets, or (d) any other arrangement whereby a third party controls or has the right to control the board of directors or equivalent governing body that has the ability to cause the direction of the management or policies of NexMed.

“Claims” means all demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) brought by a Third Party for losses, damages, legal costs and other expenses of any nature whatsoever and all costs and expenses incurred in connection therewith.

“Commercially Reasonable Efforts” means the expenditure of those efforts and resources used consistent with the usual practice of Novartis and its Affiliates in pursuing development or commercialization of its other similar pharmaceutical products with similar market potential and at a similar stage in development.

“Confidential Information” means all Know-How and other proprietary information and data of a financial, commercial or technical nature which the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement.

“DDAIP Patent Rights” means the NexMed Patent Rights set forth in Section 2 of Exhibit B covering the DDAIP Technology.

“DDAIP Technology” means the NexMed Technology relating to a novel permeation enhancing excipient.

“EMEA” means the European Medicines Agency (or any successor Agency thereto).

“Encumbrance” means any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal or security interest of any kind.

“First Commercial Sale” means, with respect to a Product, the first arm’s length sale to a Third Party for use or consumption of any such Product in a country.

“Fully Burdened Manufacturing Cost” shall have the meaning set out in Exhibit D.

“Generic Equivalent” means a pharmaceutical product with a formulation of an Anti-Fungal Ingredient with a similar qualitative composition and the same pharmaceutical form as the Product and which pharmaceutical product is approved by the relevant governmental authority, if applicable.

“IND” means an Investigational New Drug application in the US filed with the Food and Drug Administration (or any successor entity) (**“FDA”**) or the corresponding application for the investigation of the Product in any other country or group of countries, as defined in the applicable laws and regulations and filed with the Regulatory Authority of a given country or group of countries.

“Insolvency Event” means, in relation to either Party, any one of the following: (a) that Party becomes insolvent, (b) that Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings which are dismissed within sixty (60) days), (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party, (d) a resolution shall have been passed by that Party or that Party’s directors to make an application for an administration order or to appoint an administrator; or (e) that Party makes any general assignment, composition or arrangement with or for the benefit of all or some of that Party’s creditors or makes or suspends or threatens to suspend making payments to all or some of that Party’s creditors or the Party submits to any type of voluntary arrangement.

“Know-How” means all technical information, know-how and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to formulations, compositions, products or their manufacture, development, registration, use or marketing or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, relevant to the development, manufacture, use or sale of and/or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof.

“MAA” means an application for authorization to market the Product in any country or group of countries outside the United States, as defined in the applicable laws and regulations and filed with the Regulatory Authority of a given country or group of countries.

“Milestones” means the milestones relating to the Product as set out in Clause 7.2.

“Milestone Payments” means the payments due by Novartis to NexMed upon the achievement of the corresponding Milestones as set out in Clause 7.2.

“Nail-Infection Field” means the treatment, diagnosis or prevention of (i) any nail infection, including onychomycosis; and/or (ii) athletes foot.

“NDA” means a New Drug Application in the United States for authorization to market the Product, as defined in the applicable laws and regulations and filed with the FDA.

“Net Sales” means, with respect to any Product, the gross amount invoiced by or on behalf of Novartis or any Novartis Affiliate, licensee or sublicensee for that Product sold to Third Parties other than licensees or sublicensees in bona fide, arms-length transactions, less the following deductions, determined in accordance with Novartis’ standard accounting methods as generally and consistently applied by Novartis, to the extent included in the gross invoiced sales price of any Product or otherwise directly paid or incurred by Novartis, its Affiliates or distributors with respect to the sale of such Product:

- (i) normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of the Product;
- (ii) amounts repaid or credited by reasons of defects, rejection recalls, returns, rebates and allowances of goods or because of retroactive price reductions specifically identifiable to the Product;
- (iii) chargebacks and other amounts paid on sale or dispensing of such Product;
- (iv) amounts payable resulting from governmental (or agency thereof) mandated rebate programs;
- (v) Third-Party cash rebates and chargebacks related to sales of the Product, to the extent actually allowed;
- (vi) tariffs, duties, excise, sales, value-added and other taxes (other than taxes based on income);
- (vii) retroactive price reductions that are actually allowed or granted;
- (viii) cash discounts for timely payment;
- (ix) delayed ship order credits;
- (x) discounts pursuant to indigent patient programs and patient discount programs, including, without limitation, “Together Rx” and coupon discounts;
- (xi) all freight, postage and insurance included in the invoice price;
- (xii) amounts repaid or credited for uncollectible amounts on previously sold products; and
- (xiii) any other specifically identifiable amounts included in the Product’s gross invoice that should be credited for reasons substantially equivalent to those listed above;

all as determined in accordance with Novartis' usual and customary accounting methods, which are in accordance with international accounting standards (IAS) as consistently applied at Novartis. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties.

- (a) In the case of any sale or other disposal of a Product between or among Novartis and its Affiliates or sublicensees, for resale, Net Sales shall be calculated only on the value charged or invoiced on the first arm's-length sale thereafter to a Third Party;
- (b) In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Product is paid for, if paid for before shipment or invoice;
- (c) In the case of any sale or other disposal for value, such as barter or counter-trade, of any Product, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales shall be calculated on the value of the non-cash consideration received or the fair market price (if higher) of the Product in the country of sale or disposal; and
- (d) In the event the Product is sold in a finished dosage form containing the NexMed Formulation in combination with one or more other active ingredients (a "**Combination Product**"), the Net Sales of the Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product by the fraction, $A/(A+B)$ where A is the weighted (by sales volume) average sale price in a particular country of the Product when sold separately in finished form and B is the weighted average sale price in that country of the other product(s) sold separately in finished form. In the event that such average sale price cannot be determined for both the Product and the other product(s) in combination, Net Sales for purposes of determining royalty payments shall be agreed by the Parties based on the relative value contributed by each component, such agreement not to be unreasonably withheld.

"**NexMed**" means, subject to Clause 1.2(h), NexMed, Inc. and NexMed International jointly.

"**NexMed Formulation**" means a formulation of one or more Anti-Fungal Ingredients with the DDAIP Technology, including the formulation described in Exhibit A, as such may be modified and further developed by Novartis during the Term.

"**NexMed Know-How**" means the Know-How owned or controlled (including through a license with the right to sublicense to Novartis hereunder) by NexMed or its Affiliates as of the Effective Date or thereafter during the Term relating to the NexMed Formulation, the DDAIP Technology or the Products, their use, formulation, preparation or manufacture or that are reasonably necessary or useful for the research, development, manufacture, use, import or sale of the NexMed Formulation, the DDAIP Technology or the Products.

“NexMed Patent Rights” means the Patent Rights identified in Exhibit B and all other Patent Rights owned or controlled (including through a license with the right to sublicense to Novartis hereunder) by NexMed or its Affiliates as of the Effective Date or thereafter during the Term that claim the use, formulation, preparation, manufacture, research, development, import or sale of the NexMed Formulation, DDAIP Technology or the Products.

“NexMed Technology” means the NexMed Know-How and NexMed Patent Rights.

“Novartis Formulation” means any topical formulation of Terbinafine (other than the NexMed Formulation) developed by or on behalf of Novartis.

“Out-of-Pocket Expenses” means the direct project related expenses paid or payable to Third Parties (other than Affiliates) and specifically identifiable and incurred by the applicable Party, (a) in the case of NexMed, to perform the NexMed Studies for the NexMed Formulation and (b) in the case of Novartis, to develop the NexMed Formulation and the Product containing the NexMed Formulation under this Agreement; such expenses to have been recorded as income statement items in accordance with the applicable Party’s Accounting Standards and for the avoidance of doubt, not including pre-paid amounts, capital expenditures or travel expenses.

“Patent Countries” means the list of countries set forth in Exhibit E as such Exhibit may be updated and amended from time to time to reflect new countries in which there is a Valid Claim or to remove countries where there may no longer be a Valid Claim.

“Patent Milestone” means the payment of the issue fee for an allowed US Patent having a Valid Claim covering the NexMed Formulation, excluding claims included in the DDAIP Patent Rights.

“Patent Rights” means all patents and patent applications, including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions, registrations, and supplemental protection certificates and the like of any of the foregoing.

“Phase III Clinical Trial” means a pivotal clinical study of a Product in patients the protocol of which is designed to establish the efficacy and safety of such Product for the purpose of preparing and submitting a filing for NDA approval in the US or MAA approval in the EMEA.

“Phase III Completion Milestone” means the positive outcome of the first Phase III Clinical Trial for a Product based on the final study report for such trial and demonstrating a safety and efficacy profile sufficient to warrant preparation and filing of an NDA as determined by Novartis, such safety and efficacy profile to be provided to NexMed by Novartis prior to the initiation of the first Phase III Clinical Trial.

“Phase III 6 Month Milestone” means the positive outcome, as determined by Novartis, of a six (6) month analysis of the first Phase III Clinical Trial for a Product containing the NexMed Formulation and satisfying the criteria established by Novartis prior to commencement of such trial, such criteria to be provided to NexMed by Novartis prior to the initiation of such trial.

“Product” means a pharmaceutical product developed under this Agreement incorporating or comprising (a) the NexMed Formulation in finished dosage pharmaceutical form, including, in each case, all formulations and modes of administration thereof, the manufacture, sale or use of which (i) would, but for the license granted under this Agreement, infringe a Valid Claim of a NexMed Patent Right or (ii) embodies or incorporates NexMed Know-How, or (b) a Novartis Formulation in finished dosage pharmaceutical form.

“Regulatory Authority” means any governmental agency or authority responsible for granting Regulatory Approvals for Products, including the FDA, the EMEA, and any national or regional regulatory authorities.

“Regulatory Approval” means, with respect to a Product, any approval (including pricing approval), registration, license or authorization from a Regulatory Authority required for the manufacture, development, commercialization, sale, storage or transport of such Product. In the case of EMEA, Regulatory Approval must include pricing approval in at least three (3) of the five (5) major European countries of France, Germany, Italy, Spain and UK.

“Regulatory Dossier” means all files regarding the Regulatory Approvals, including correspondence, records, applications (including NDAs), supplements, annual reports, adverse event reports, to the extent related to the Product in the Territory.

“Royalty Payments” means the royalty due by Novartis to NexMed on Net Sales as set out in Clause 7.

“Royalty Term” means the term for payment of royalties as set forth in Clause 8.2.

“Sales & Royalty Report” means a written report or reports showing each of: (a) the Net Sales of each Product in each country in the world during the reporting period by Novartis and each Affiliate and sublicensee; (b) the number of Products sold in each country in the world during the reporting period by Novartis and each Affiliate and sublicensee, and if applicable, the average sale price during the reporting period for each Product in any Combination Product; (c) the Royalty Payments, in United States Dollars, which shall have accrued in respect of such sales and the basis of calculating the Royalty Payments; and (d) withholding taxes, if any, required by law to be deducted in respect of the transfer of the Royalty Payments to NexMed.

“Terbinafine” means terbinafine, and its esters, salts, racemates, and stereoisomers, including all possible combinations of stereoisomers in any desired ratio and including pure enantiomers.

“Terbinafine Field” means the treatment, diagnosis or prevention of diseases in all indications in humans and animals.

“Term” means the term as set forth in Clause 11.1.

“Territory” means worldwide.

“Third Party” means any entity or person other than a Party or an Affiliate of a Party.

“USD” or **“US\$”** means the lawful currency of the United States.

“Valid Claim” means a claim of an issued NexMed Patent Right, or a claim of a pending patent application or a supplementary protection certificate of a NexMed Patent Right, that has not expired or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period); provided however that such claim within a patent application has not been revoked, cancelled, withdrawn, held invalid or abandoned or been pending for more than five (5) years from the date of its first priority filing anywhere in the world; provided, however, that a claim of a pending application will only be considered a Valid Claim if its priority date is prior to the first anniversary of the Effective Date.

1.2 Interpretation. In this Agreement unless otherwise specified:

- (a) “includes” and “including” shall mean includes and including without limitation;
- (b) a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking;
- (c) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;
- (d) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;
- (e) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and attachments;
- (f) the headings in this Agreement are for information only and shall not be considered in the interpretation of this Agreement;
- (g) general words shall not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things; and

- (h) all references to “NexMed” and all rights and obligations of NexMed under this Agreement shall be joint unless expressly otherwise provided in this Agreement and shall be exercisable and enforceable by NexMed by NexMed, Inc. and NexMed International acting jointly and not separately provided that any notice or notification served upon NexMed, Inc. shall be deemed service on NexMed International and does not require signature by or notification to NexMed International to be a valid notice or notification under the terms of this Agreement.

2. LICENSE

- 2.1 **License Grant.** Subject to the terms and conditions of this Agreement, NexMed hereby grants to Novartis in the Territory for the Term an exclusive (even as to NexMed), worldwide, royalty-bearing, sub-licensable (subject to Section 2.2) license, under the NexMed Patent Rights and NexMed Know-How to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, offer for sale, sell, have sold and otherwise commercialize (a) the NexMed Formulation and Products containing the NexMed Formulation without Terbinafine in the Nail-Infection Field, (b) the NexMed Formulation and Products containing the NexMed Formulation with Terbinafine in the Terbinafine Field and (c) the Novartis Formulation and Products containing the Novartis Formulation in the Terbinafine Field. The foregoing license is exclusive to Novartis, and NexMed has no retained rights (and will not attempt to license any rights, directly or indirectly, to any Third Party) with respect to the exclusive rights to the NexMed Formulation, Products, the NexMed Patent Rights or NexMed Know-How outlined above; except for activities undertaken pursuant to the terms of this Agreement.
- 2.2 **Sublicense Rights.** Novartis may sublicense the rights granted to it by NexMed under this Agreement at any time, provided that Novartis gives NexMed a copy of any sublicense agreement (subject to any confidentiality obligations requiring Novartis to omit disclosure of certain confidential information). Novartis may exercise its rights and perform its obligations under this Agreement itself or through any of its Affiliates. In addition, Novartis may subcontract to Third Parties the performance of tasks and obligations with respect to the development and commercialization of the Product as Novartis deems appropriate. Novartis shall use Commercially Reasonable Efforts to ensure that each of its Affiliates to which it sublicenses its rights and sublicensees accepts and complies with all of the terms and conditions of this Agreement as if such Affiliates and sublicensees were a party to this Agreement and Novartis shall remain responsible for such Affiliates’ and sublicensees’ performance under this Agreement, provided, however, that, for purposes of Section 11.2 only, in no event shall the performance or non-performance by any sublicensee result in Novartis being deemed in material breach of this Agreement for so long as Novartis is using Commercially Reasonable Efforts to enforce the terms of such sublicense on its sublicensee.
- 2.3 **Right of First Negotiation.** NexMed shall notify Novartis within thirty (30) days of it determining to partner with a Third Party any opportunity to develop, have developed, make, have made, use, have used, import, have imported, offer for sale, sell, have sold or otherwise commercialize DDAIP Technology, the NexMed Formulation and Products containing the NexMed Formulation in the dermatologic or allergic fields. Should Novartis wish to pursue any such opportunity, it shall notify NexMed within thirty (30) days whereupon the Parties shall enter into exclusive good faith negotiations relating to such opportunity for a period of ninety (90) days. Nothing in this Clause 2.3 obliges either Party to enter into any such future agreement or agree upon any particular terms.

3. GOVERNANCE

- 3.1 **Alliance Managers.** Within thirty (30) days after the Effective Date, each Party will appoint (and notify the other Party of the identity of) a senior representative having a general understanding of pharmaceutical development and commercialization issues to act as its alliance manger under this Agreement (“**Alliance Manager**”). The Alliance Managers will serve as the contact point between the Parties and will be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration within and between the Parties. Each Party may replace its Alliance Manager on written notice to the other Party.
- 3.2 **Annual Update.** Within thirty (30) days of the end of the first calendar year following the Effective Date of this Agreement and each year thereafter during the Term, Novartis shall provide NexMed with a written summary of the development, commercialization and regulatory status of the Product.
- 3.3 **Change of Control.** In the event of a Change of Control of NexMed, Novartis may provide written notice to NexMed (or its successor entity) terminating the provisions included in this Clause 3 and upon such notice, Novartis will not be obligated under this Clause 3, or to disclose any Confidential Information to NexMed (including under Clause 5) for the remaining Term and Novartis may request the immediate return or destruction of Confidential Information already disclosed to NexMed, provided, however, that Novartis will still be obliged to provide the Sales & Royalty Report.

4. DISCLOSURE OF NEXMED KNOW-HOW & TECHNOLOGY TRANSFER

- 4.1 **Disclosure of NexMed Know-How.** Within thirty (30) days after the Effective Date, NexMed will disclose to Novartis or its designated Affiliate all NexMed Know-How (and any other data, information and documents known to NexMed relating to the NexMed Formulation or Products), which may be necessary or useful to Novartis to develop, manufacture, register, use or market the NexMed Formulation and Products and practice the licenses granted hereunder efficiently, including any study reports relating to the NexMed Formulation. As part of such disclosure, as soon as reasonably practicable, NexMed will disclose to Novartis all NexMed Know-How pertaining to the manufacture and development of the NexMed Formulation and the Product, including manufacturing batch records, development reports, analytical results, raw material and excipient sourcing information, quality audit findings and any other relevant technical information. NexMed shall also cooperate and assist Novartis in assigning any contract manufacturing agreements which NexMed may have entered into prior to the Effective Date with respect to the NexMed Formulation, which Novartis, in its sole discretion, deems useful or necessary to further its obligations under this Agreement.

4.2 Technology Transfer.

- (a) Within thirty (30) days after the Effective Date, NexMed shall, at its own cost, provide to Novartis all of the quantities of NexMed Formulation that it has in its possession as of the Effective Date. During the Term, NexMed will, at its own cost and expense, provide reasonable assistance to Novartis in connection with understanding and using the NexMed Know-How, including by providing information to assist Novartis in developing the Product and its related activities.
- (b) NexMed shall have a continuing obligation to disclose and provide promptly and effectively to Novartis such additional NexMed Know-How as is developed or obtained by NexMed or its Affiliates during the Term and which may be necessary or useful to Novartis to develop, manufacture, register, use or market the NexMed Formulation and Products and practice the licenses granted hereunder efficiently. Novartis and its Affiliates and sublicensees shall use such NexMed Know-How solely for the purposes of this Agreement and consistent with the licenses granted hereunder.

5. DEVELOPMENT

5.1 Development.

- (a) Subject to the terms and conditions of this Agreement, Novartis will be responsible for and shall itself or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to conduct, at its sole expense, the preclinical, clinical and other development of the NexMed Formulation or any Product as it determines appropriate in its sole discretion.
- (b) Notwithstanding the foregoing, Novartis agrees to complete the first Phase III Clinical Trial for a NexMed Formulation, subject to any safety concerns (as reasonably determined by Novartis) and/or any request or notification from any Regulatory Authority not to proceed.
- (c) Novartis acknowledges and agrees that prior to the Effective Date it has requested NexMed to initiate the pre-clinical trials set forth on Exhibit F ("NexMed Studies"). It is acknowledged and agreed by the Parties that, after the Effective Date, NexMed shall continue to conduct the NexMed Studies through completion and that Novartis shall grant NexMed the right to continue the NexMed Studies. On a monthly basis, NexMed shall supply Novartis with an invoice for NexMed's Out-of-Pocket Expenses incurred for conducting the NexMed Studies during such month and Novartis shall reimburse NexMed for such Out-of-Pocket Expenses within forty-five (45) days after receipt of such an invoice from NexMed. The total Out-of-Pocket Expenses reimbursed by Novartis shall not exceed US\$3.25 million without the prior written consent of Novartis. The data and results of the NexMed Studies shall be owned by Novartis (and NexMed hereby assigns its rights in such data and results to Novartis); provided, however, that Novartis shall permit NexMed access to and grant NexMed the right to reference and use, in association with any product (other than the Product), the data and results from the NexMed Studies set forth on Exhibit F.

5.2 **Novartis Formulation.** The Parties acknowledge that the NexMed Know-How may be valuable in development of any Product, whichever formulation is ultimately used for the Product. During the Term, Novartis may develop a Novartis Formulation as the formulation for development under this Agreement instead of a Product with the NexMed Formulation; provided that Novartis still completes the first Phase III Clinical Trial for a NexMed Formulation pursuant and subject to Clause 5.1(b). In such event, the obligations with respect to the development of the Product shall apply to the development of the Product containing such Novartis Formulation and Novartis shall pay to NexMed the payments required under Clause 7 for Products containing Novartis Formulations until this Agreement is terminated.

5.3 **Regulatory.**

- (a) Subject to the terms and conditions of this Agreement, Novartis will determine the regulatory plans and strategies for the Products. Novartis will file all regulatory filings with respect to the Products and will be responsible for obtaining and maintaining Regulatory Approvals throughout the Territory in the name of Novartis or its Affiliates or sublicensees.
- (b) NexMed shall fully cooperate with and provide assistance to Novartis in connection with filings to any Regulatory Authority relating to the NexMed Formulation or Products, including by executing any required documents, providing access to personnel and providing Novartis with copies of all reasonably required documentation.
- (c) To the extent requested by Novartis or as required, NexMed, subject to any Third Party confidentiality obligations, shall grant or cause to be granted to Novartis and its Affiliates or sublicensees assignments of, or cross-reference rights to, any relevant drug master files and other filings submitted by NexMed or its Affiliates with any Regulatory Authority with respect to the NexMed Formulation.
- (d) Notwithstanding the provisions of Clause 10, Novartis and its Affiliates shall have the right to disclose the existence of, and the results from, any clinical trials conducted under this Agreement in accordance with its standard policies. Nothing in this Clause 5.3(d) is intended to limit either Party's rights or obligations under Clause 15. Novartis acknowledges and agrees that NexMed has committed to presenting at the March 2006 American Academy of Dermatology Conference the results from NexMed's phase I clinical trials for the NexMed Formulation; provided that NexMed shall provide such presentation to Novartis pursuant to Clause 15.1 prior to such conference.

5.4 **Failure to File.** If Novartis chooses not to submit a filing for Regulatory Approval for the NexMed Formulation in any particular region of the Territory (i.e. Asia, Africa, Middle East), Novartis shall notify NexMed and the Parties shall discuss in good faith the filing strategy for such region and the possibility of allowing NexMed to pursue Regulatory Approval in such region. Nothing in this Clause 5.4 shall oblige either Party to agree to any particular filing strategy, including the grant of any rights to NexMed.

5.5 **Compliance.** Novartis agrees that in performing its development obligations (a) it shall comply with all applicable current international regulatory standards, laws, regulations and requirements, including cGMP, cGLP, cGCP and (b) it will not employ or use any person that has been debarred under Section 306(a) or 306(b) of the U.S. Federal Food, Drug and Cosmetic Act.

6. COMMERCIALIZATION

6.1 **Commercialization.** Subject to the terms and conditions of this Agreement, Novartis will be solely responsible for all aspects of worldwide commercialization of the Product(s), including planning and implementation. Novartis will undertake such activities at its sole expense. Novartis shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to commercialize, manufacture, market and sell Product(s). Notwithstanding the foregoing, Novartis' application of such Commercially Reasonable Efforts shall not require Novartis to commercialize a Product in any country or territory in which Novartis determines it is not commercially reasonable to do so for such Product. Subject to compliance with the foregoing, the commercialization and marketing of the Product shall be at Novartis' sole discretion.

6.2 **Manufacturing.** Subject to the terms and conditions of this Agreement, the manufacture and supply of the NexMed Formulation and Products under this Agreement shall be at sole discretion of Novartis.

6.3 Manufacturing Know-How and Assistance.

- (a) During the period from the Effective Date until the First Commercial Sale of the Product under this Agreement, upon the request of Novartis, NexMed shall fully cooperate with and provide assistance to Novartis or its designee, through documentation, consultation, training and face-to-face meetings, to enable Novartis or its designee in an efficient and timely manner to proceed with development and manufacturing of the NexMed Formulation and the Products and to obtain all appropriate Regulatory Approvals for manufacturing (including qualification by the applicable Regulatory Authority of manufacturing sites). Novartis shall reimburse NexMed for the reasonable out-of-pocket expenses incurred by NexMed in complying with such request, such expenses to be pre-approved in writing by Novartis.
- (b) During such period, NexMed shall make appropriate personnel available to assist Novartis or its designee at any time and from time to time as reasonably requested by Novartis, and shall provide the appropriate personnel of Novartis or its designee with access to the personnel and manufacturing and other operations of NexMed for such periods of time and in such manner as is reasonable in order to familiarize the personnel of Novartis or its designee with NexMed Know-How relating to the development and manufacture of the NexMed Formulation and the Products and the application of the same. At Novartis' request, such assistance shall also be furnished at the manufacturing facilities of Novartis or its designee. Novartis shall reimburse NexMed for the reasonable out-of-pocket expenses incurred by NexMed in complying with such request, such expenses to be pre-approved in writing by Novartis.

- 6.4 **Compliance.** Novartis agrees that in performing its commercialization, manufacturing, marketing and selling obligations it shall comply with all applicable current international regulatory standards, laws, regulations and requirements, including cGMP.

7. FINANCIAL PROVISIONS

- 7.1 **Upfront Payment.** Novartis shall pay to NexMed a one-time, non-refundable, non-creditable upfront payment of four million USD (US\$4,000,000) promptly following receipt by Novartis of an invoice in the form of Exhibit C from NexMed on or after the Effective Date.
- 7.2 **Milestone Payments.** In consideration of the granting of the licenses and rights to Novartis hereunder, after the achievement of each of the following Milestones with respect to the first Product, NexMed shall invoice and Novartis shall make the corresponding one-time, non-refundable, non-creditable Milestone Payment.

- (a) Milestones:

Milestone	Milestone Payment (USD)
Patent	
Patent Milestone	\$2 million
Clinical Milestones (subject to sub-clause (b) below)	
Phase III 6 Month Milestone	\$3 million
Phase III Completion Milestone	\$6 million
Regulatory Milestones	
NDA Submission	\$7 million
Submission for MAA Regulatory Approval by the EMEA	\$3 million
NDA Regulatory Approval	\$14 million
MAA Regulatory Approval by the EMEA	\$8 million
MAA Regulatory Approval in Japan	\$4 million

- (b) Unless and until the Patent Milestone is achieved, the Milestone Payments due by Novartis to NexMed for the achievement of the Clinical Milestones shall be fifty percent (50%) of the amounts set out above. In the event that the Patent Milestone is achieved after the achievement of a Clinical Milestone, the remaining fifty percent (50%) of the Milestone Payment for the applicable Clinical Milestone not previously paid shall be invoiced and paid with the Milestone Payment for the Patent Milestone. For clarity, if the Patent Milestone is achieved before a Clinical Milestone is achieved, then the Milestone Payment for such Clinical Milestone shall be the full amount set out above.
- (c) For the avoidance of doubt: (i) each Milestone Payment shall be payable only on the first occurrence of the Milestone; (ii) none of the Milestone Payments shall be payable more than once; (iii) should the Product be replaced by another Product, no additional Milestone Payments shall be due for Milestones completed by the previous Product; and (iv) following achievement of NDA Submission Milestone the Phase III Completion Milestone shall be deemed achieved (if not previously achieved) and where the Product which is the subject of the NDA Submission incorporates the NexMed Formulation the Phase III 6 Month Milestone shall also be deemed achieved (if not previously achieved). In addition, no Milestone Payments will be due for the development and commercialization of Products for any additional indications.

7.3 **Royalty Payments.** Subject to the provisions of this Clause 7, in consideration of the granting of the licenses and rights to Novartis hereunder, Novartis will make royalty payments for the Royalty Term as set forth in Clause 8.2 to NexMed on Net Sales of Products including the NexMed Formulation at the applicable rates set forth below. For the avoidance of doubt, royalties shall be payable only once with respect to the same unit of Product. Multiple prescription forms of the same Anti-Fungal Ingredient in the same mode, but with different dosages shall be deemed the same Product for the purposes of aggregating annual Net Sales.

Annual Net Sales of each Product	Royalty Rate
*	*
*	*
*	*
*	*

For example, if Net Sales of a Product in a calendar year are \$*, the royalty on such Net Sales shall be equal to *% of \$*, *% of \$* and *% of \$*.

7.4 **Know-How Royalty.** Subject to the provisions of this Clause 7 and notwithstanding Clause 7.3, in any country in which the sale of a Product including the NexMed Formulation will not infringe a Valid Claim, Novartis shall pay a royalty equal to fifty percent (50%) (“**Know-How Royalty**”) of the royalties set forth above in Clause 7.3 on the Net Sales in such country for the Royalty Term as set out in Clause 8.2. For the avoidance of doubt, a royalty on Net Sales of a Product in a particular country may be payable under either Clause 7.3 or Clause 7.4 but not both at the same time.

- 7.5 **Royalty Payable on Novartis Formulation.** Subject to the provisions of this Clause 7, Novartis shall pay NexMed a royalty on Net Sales of Product including the Novartis Formulation (a) in the Patent Countries at the royalty rates set forth above in Clause 7.3 or (b) outside the Patent Countries at the Know-How Royalty set forth in Clause 7.4.
- 7.6 **Loss of Market Exclusivity.** In the event that the Net Sales of a Product in any country in any calendar year are reduced below a level of eighty percent (80%) as compared with the Net Sales of such Product in the preceding calendar year in such country and such reduction is due to the marketing or sale of a Generic Equivalent by Third Parties in such country, as measured in the local currency, and which Generic Equivalent sales are evidenced by independent market data (where available), such as that published by IMS, then the royalty rates applicable to Net Sales of such Product in such country thereafter for the remainder of the Royalty Term shall (a) be reduced by fifty percent (50%) if there is a Valid Claim covering the sale of the Product in such country (or in the Patent Countries with respect to Products containing the Novartis Formulation) or (b) cease to be owed by Novartis if there is not a Valid Claim covering the sale of the Product in such country (or outside the Patent Countries with respect to Products containing the Novartis Formulation).
- 7.7 **Third Party Obligations.**
- (a) Scope. If Novartis reasonably determines that it must acquire rights to intellectual property owned by a Third Party to exercise the licenses to the NexMed Patent Rights or NexMed Know-How, Novartis shall have the right to acquire such rights through a license with such Third Party or otherwise and to deduct from the Royalty Payments due to NexMed the amounts paid (including milestone payments, royalties or other license fees) by Novartis to such Third Party. Novartis shall provide NexMed with written notice of such belief and allow NexMed to provide its input regarding the acquisition of such rights.
 - (b) Reductions. Notwithstanding the foregoing, nothing contained in Clause 7.7(a) shall reduce the Royalty Payments otherwise due to NexMed by more than fifty percent (50%) for any given year. Any amount that Novartis is entitled to deduct that is reduced by this limitation on the deduction shall be carried forward and Novartis may deduct such amount from subsequent Royalty Payments due to NexMed until the full amount that Novartis was entitled to deduct is deducted.
 - (c) NexMed shall remain responsible for the payment of royalty obligations, if any, due to Third Parties under any NexMed Patent Rights or NexMed Know-How which has been licensed to NexMed and is sublicensed to Novartis under this Agreement. All such payments shall be made promptly by NexMed in accordance with the terms of its license agreement.

- 7.8 **Cost of Goods.** In the event that the Fully Burdened Manufacturing Costs for the Product (including any required devices or delivery methods) exceed twenty percent (20%) of the Net Sales on an aggregated worldwide basis, the royalty payable for the Product shall be reduced by fifteen percent (15%) of the amount that would otherwise be payable under this Agreement. In calculating Fully Burdened Manufacturing Costs, Novartis agrees and acknowledges that no amounts may be both deducted from Net Sales and included in Fully Burdened Manufacturing Costs.

8. REPORTS AND PAYMENT TERMS

8.1 Payment Terms.

- (a) Novartis will notify NexMed of the achievement of each Milestone as soon as reasonably practicable (and at least within thirty (30)) days after its achievement. After receipt of notice of the achievement of a Milestone, NexMed shall submit an invoice to Novartis substantially in the form of Exhibit C with respect to the corresponding Milestone Payment. Novartis shall make the Milestone Payment within thirty (30) days after receipt of the invoice.
- (b) Within thirty (30) days after each Calendar Quarter during the Term following the First Commercial Sale of a Product, Novartis will provide to NexMed the Sales & Royalty Report. If NexMed has no comments on such report, NexMed shall submit an invoice to Novartis substantially in the form of Exhibit C with respect to the Royalty Payment. If NexMed has comments on such report, NexMed shall submit an invoice to Novartis for any undisputed amounts substantially in the form of Exhibit C with respect to the undisputed portion of the Royalty Payment. Novartis shall pay the amount invoiced pursuant to this Clause 8.1(b) within thirty (30) days after receipt of invoice.

- 8.2 **Royalty Term.** Royalties will be payable on a Product-by-Product and country-by-country basis until the later of (a) the expiration of the last to expire Valid Claim covering the Product or its sale or the use for which the Product is being sold in such country and (b) ten (10) years after the First Commercial Sale of such Product in such country ("**Royalty Term**"). Following the Royalty Term on a Product-by-Product and country-by-country basis, Novartis' licenses with respect to such Product shall continue in effect, but become fully paid-up, royalty-free, transferable, perpetual and irrevocable.
- 8.3 **Currency.** All payments under this Agreement shall be payable in US dollars. When conversion of payments from any foreign currency is required to be undertaken by Novartis, such conversion shall be made using Novartis' then-current standard exchange rate methodology as applied in its external reporting.
- 8.4 **Taxes.** Any payments made by Novartis to NexMed under this Agreement shall be reduced by the amount required to be paid or withheld pursuant to any applicable law. Any such withholding taxes required by law to be paid or withheld shall be an expense of NexMed. Novartis, as applicable, shall submit to NexMed reasonable proof of payment of the withholding taxes, together with an accounting of the calculations of such taxes, within thirty (30) days after such withholding taxes are remitted to the proper authority. The Parties will cooperate reasonably in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable law in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment.

8.5 Records and Audit Rights.

- (a) Novartis shall keep complete, true and accurate books and records in accordance with its Accounting Standards in relation to the Fully Burdened Manufacturing Cost, where used to reduce the Royalty Payments pursuant to Clause 7.8, Net Sales and Royalty Payments under this Agreement. Novartis will keep such books and records for at least three (3) years following the Calendar Quarter to which they pertain.
- (b) NexMed shall have the right for a period of three (3) years after receiving any Sales & Royalty Report to appoint an internationally-recognized independent accounting firm (which is reasonably acceptable to Novartis) (the “**Auditor**”) to inspect the relevant records of Novartis to verify such reports, statements, records or books of accounts, as applicable. Before beginning its audit, the Auditor shall execute an undertaking acceptable to Novartis by which the Auditor shall keep confidential all information reviewed during such audit. The Auditor shall have the right to disclose to NexMed its conclusions regarding any payments owed under this Agreement.
- (c) Novartis and its Affiliates shall make their records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from NexMed, solely to verify the accuracy of the Sales & Royalty Reports and the calculation of Fully Burdened Manufacturing Costs, solely in the event such are used to reduce the Royalty Payments pursuant to Clause 7.8. Such inspection right shall not be exercised more than once in any calendar year and not more frequently than once with respect to records covering any specific period of time. NexMed agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or if disclosure is required by law, regulation or judicial order (which such disclosure shall be governed by the provision of Clause 10.3(b)).
- (d) NexMed shall pay for such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that in the event there is any upward adjustment in aggregate amounts payable for any year shown by such audit of more than five percent (5%) of the amount paid, Novartis shall pay for such audit.

8.6 Invoicing and Payment.

- (a) Each Party shall provide to the other Party an invoice for all amounts due to it under this Agreement substantially in the form set out in Exhibit C. Except as otherwise set forth in this Agreement, payments on such invoices shall be made within sixty (60) days of the Party's receipt of the applicable invoice.
- (b) Payments to each Party shall be made by electronic wire transfer of immediately available funds to the account of the Party, as designated in writing to the other Party.

9. INTELLECTUAL PROPERTY RIGHTS

9.1 **Ownership of Inventions.** All inventions arising from the Parties' activities under this Agreement, including any patent applications and patents covering such inventions (collectively, "**Inventions**"), made after the Effective Date solely or jointly by employees of either Party under this Agreement shall be owned by Novartis.

9.2 Patent Prosecution.

- (a) NexMed will be responsible for filing, prosecuting and maintaining the NexMed Patent Rights through an outside law firm reasonably acceptable to Novartis. Novartis shall reimburse NexMed, within thirty (30) days after receipt of an invoice from NexMed, for all costs and expenses incurred by or on behalf of NexMed in the filing, prosecution and maintenance of the NexMed Patent Rights other than the DDAIP Patent Rights, as set out in Section 1 of Exhibit B. Novartis will be responsible for filing, prosecuting and maintaining its Patent Rights. NexMed will be responsible for filing, prosecuting and maintaining the DDAIP Patent Rights at its own cost and expense.
- (b) NexMed will keep Novartis informed of the status of the NexMed Patent Rights being prosecuted by it and will provide to Novartis copies of substantive documentation submitted to, or received from, the patent offices in connection therewith. NexMed shall allow for review and consultation with Novartis before NexMed makes a submission to any patent office which could materially affect the scope or validity of the patent coverage that may result. Novartis shall offer its comments promptly.
- (c) NexMed will notify Novartis of any decision not to file applications for, or to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any NexMed Patent Rights on a country-by-country basis. NexMed will provide such notice at least thirty (30) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Patent Right. In such event and at Novartis' request, NexMed will assign all its right, title and interest in and to such NexMed Patent Rights other than the DDAIP Patent Rights to Novartis, subject to any Third Party rights existing as of the Effective Date, Novartis shall have the right, at its sole discretion and expense, to file or to continue prosecution or maintenance of such NexMed Patent Rights.

9.3 Patent Infringement.

- (a) Each Party will promptly notify (and at least within ten (10) business days) the other of any infringement by a Third Party of any of the NexMed Patent Rights or NexMed Know-How in the Terbinafine Field of which it becomes aware, including any “patent certification” filed by a Third Party FDA application which references the foregoing and of any declaratory judgment or similar action alleging the invalidity, unenforceability or non-infringement of any of the NexMed Patent Rights (collectively “**Third Party Infringement**”).
- (b) Novartis will have the first right to bring and control any such action in connection with the Third Party Infringement of any Patent Rights relating to (i) the NexMed Technology (excluding the DDAIP Technology) in the Terbinafine Field and (ii) the DDAIP Technology in the Nail-Infection Field or, if relating to a Product containing Terbinafine in the Terbinafine Field, as it reasonably determines appropriate. NexMed shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. At the request of Novartis, NexMed shall provide reasonable assistance to Novartis in connection therewith, including by executing any required documents and joining as a party to the action if required. In connection with any such proceeding, Novartis shall not enter into any settlement admitting the invalidity of, or otherwise impairing NexMed’s rights in, the NexMed Patent Rights without the prior written consent of NexMed (not to be unreasonably withheld or delayed). Any recoveries resulting from such an action brought by Novartis relating to a claim of Third Party Infringement (after payment of each Party’s costs and expenses) will be deemed Net Sales.
- (c) If Novartis fails to bring an action or proceeding with respect to, or to terminate, the Third Party Infringement prior to the earlier of (i) one hundred eighty (180) days following the notice of alleged infringement or (ii) ten (10) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, (except if Novartis notifies NexMed in writing prior to ten (10) days before the time limit for the filing of any such action that Novartis intends to file an action before the time limit), NexMed shall have the right to bring and control any such action in connection with the Third Party Infringement at its own expense and by counsel of its own choice, and Novartis shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Any recoveries resulting from such an action relating to a claim of Third Party Infringement brought by NexMed after Novartis’ failure to bring such an action or to terminate such Third Party Infringement (after payment of each Party’s costs and expenses) will be divided equally between the Parties.

9.4 **Trademarks.** Novartis shall have the sole right to brand the Products using Novartis related trademarks and any other trademarks and trade names it determines appropriate for the Product, which may vary by country or within a country (“**Product Trademarks**”). Novartis shall own all rights in the Product Trademarks and will register and maintain any such Product Trademarks as it determines reasonably necessary.

9.5 Drug Price Competition and Patent Term Restoration Act.

- (a) The Parties agree to cooperate in an effort to avoid loss of any NexMed Patent Rights which may otherwise be available to the Parties hereto under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States, including by executing any documents as may be reasonably required. In particular, the Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country and region where applicable to the NexMed Patent Rights. NexMed shall provide all reasonable assistance to Novartis, including permitting Novartis to proceed with applications for such in the name of NexMed, if so required.
- (b) NexMed shall provide any required relevant patent information to Novartis so that Novartis may determine, if applicable, which of NexMed Patent Rights it will attempt to extend.
- (c) NexMed shall provide reasonable assistance to Novartis, including by executing any required documents and providing any relevant patent information to Novartis, so that Novartis, as NDA or MAA applicant, may inform the FDA or other Regulatory Authority.

10. CONFIDENTIALITY

- 10.1 **Duty of Confidence.** All Confidential Information disclosed by a Party or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use the Confidential Information for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Each Party shall hold as confidential such Confidential Information of the other Party and its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information, but in no event less than reasonable care. A recipient Party may only disclose Confidential Information of the other Party to employees, agents, contractors, consultants and advisers of the Party and its Affiliates and sublicensees and to Third Parties to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such persons and entities are bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.
- 10.2 **Exceptions.** The mutual obligations under this Clause shall not apply to any information to the extent that such information:
 - (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;

- (b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party;
- (c) is disclosed to the recipient Party or an Affiliate by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates; or
- (d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without reference to the Confidential Information disclosed by the disclosing Party or its Affiliates under this Agreement.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the recipient Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the recipient Party unless the combination and its principles are in the public domain or in the possession of the recipient Party.

10.3 Authorized Disclosures.

- (a) In addition to disclosures allowed under Clause 10.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is necessary in the following instances: (i) filing or prosecuting Patent Rights as permitted by this Agreement; (ii) regulatory filings for Products such Party has a license or right to develop hereunder; and (iii) prosecuting or defending litigation as permitted by this Agreement. In addition, Novartis and its Affiliates and sublicensees may disclose Confidential Information of NexMed to Third Parties as may be necessary or useful in connection with the development and commercialization of the Product as contemplated by this Agreement, including in connection with subcontracting transactions.
- (b) In the event the recipient Party is required to disclose Confidential Information of the disclosing Party by law or in connection with bona fide legal process (including pursuant to any court order or governmental regulation), such disclosure shall not be a breach of this Agreement; provided that the recipient Party (i) informs the disclosing Party as soon as reasonably practicable of the required disclosure, (ii) limits the disclosure to the required purpose, and (iii) at the disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure.

11. TERM AND TERMINATION

- 11.1 **Term.** The term of this Agreement will commence upon the Effective Date and continue until the expiration of the royalty obligations of Novartis ("**Term**"), unless earlier terminated as permitted by this Agreement.

11.2 Termination for Breach or Insolvency.

- (a) If either Novartis or NexMed are in material breach of any material obligation hereunder, the non-breaching Party may give written notice to the breaching Party specifying the claimed particulars of such breach, and in the event such material breach is not cured within sixty (60) days after such notice, in addition to any other damages or remedies available to the non-breaching party, the non-breaching Party shall have the right thereafter to terminate this Agreement immediately by giving written notice to the breaching Party to such effect; provided, however, that if such breach is capable of being cured but cannot be cured within such sixty (60) day period and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable in the circumstances to cure such breach. Any termination by any Party under this Clause and the effects of termination provided herein shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party.
- (b) Either NexMed or Novartis may terminate this Agreement without notice if an Insolvency Event occurs in relation to the other Party. In any event when a Party first becomes aware of the likely occurrence of any Insolvency Event in regard to that Party, it shall promptly so notify the other Party in sufficient time to give the other Party sufficient notice to protect its interests under this Agreement.

11.3 Termination by Novartis. Novartis may terminate this Agreement in its sole discretion at any time during the term hereof in its entirety, or on a country-by-country basis without cause (a) on not less than ninety (90) days prior written notice to NexMed if such termination occurs prior to launch of such Product in such country, or (b) on not less than one hundred eighty (180) days prior written notice to NexMed if such termination occurs after the launch of such Product in such country, in which case Novartis' obligation to perform any further work under this Agreement shall cease in such country as of the date of such notice; provided that in no event shall Novartis have the right to terminate this Agreement pursuant to this Clause 11.3 unless and until Novartis has completed the first Phase III Clinical Trial for the NexMed Formulation, subject to Clause 5.1.

11.4 Termination for NexMed Formulation and Novartis Formulation Failure. In the event that Novartis is commercializing a topical pharmaceutical product for the treatment, prevention or diagnosis of onychomycosis and is not also commercializing a NexMed Formulation or the Novartis Formulation due to failure to meet clinical trial endpoints or pre-clinical criteria established by Novartis, the Parties shall discuss in good faith Novartis' development efforts with respect to the NexMed Formulation or the Novartis Formulation. In such event, if NexMed is not reasonably satisfied that Novartis is using Commercially Reasonable Efforts to develop and commercialize another NexMed Formulation, NexMed shall have the right to terminate this Agreement.

12. EFFECT OF TERMINATION

- 12.1 Upon termination of this Agreement by Novartis pursuant to Clause 11.2(a), the licenses granted by NexMed to Novartis will remain in full force and effect in accordance with their respective terms, provided, however, that the Milestone Payments and Royalty Payments payable by Novartis shall be reduced to 50% of the amount that would be payable under the terms of this Agreement during its term and Novartis shall have the right to prosecute, maintain and defend the NexMed Patent Rights other than the DDAIP Patent Rights.
- 12.2 Upon termination of this Agreement by NexMed pursuant to Clause 11.2 or Clause 11.4 or by Novartis pursuant to Clause 11.3 and solely in relation to the NexMed Formulation, save in relation to Clause 12.2(f), and subject to Clause 12.3(a) :
- (a) Assignments. Novartis will promptly (and in each case within sixty (60) days of receipt of NexMed's request) and at NexMed's cost, save in the event of termination by NexMed pursuant to Clause 11.2:
- (i) upon NexMed's request, assign to NexMed all of Novartis' right, title and interest in and to any agreements between Novartis and Third Parties that are freely assignable by Novartis and that relate solely to the development, manufacture or commercialization of the NexMed Formulation and the corresponding Product;
- (ii) assign to NexMed, to the extent freely assignable by Novartis, the management and continued performance of any clinical trials for the NexMed Formulation and the corresponding Product ongoing as of the effective date of such termination;
- (iii) transfer to NexMed all of Novartis' right, title and interest in and to any and all clinical and regulatory data and information, including the Regulatory Dossier, generated by or on behalf of Novartis, regulatory filings and Regulatory Approvals relating solely to the NexMed Formulation and the corresponding Product;
- (iv) to the extent that any agreement or other asset described in this Clause 12.2(a) is not assignable by Novartis or does not relate solely to NexMed Formulation and the corresponding Product, then such agreement or other asset will not be assigned, and upon the request of NexMed, Novartis will take such reasonable 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 Novartis has the right and ability to do so solely for NexMed's continued development and/or commercialization of the relevant NexMed Formulation and corresponding Product; and
- (v) provide copies of any other books, records, documents and instruments to the extent related to the technical aspects of the NexMed Formulation and the corresponding Product and to the extent necessary for NexMed to continue the development and commercialization of the corresponding Product.

(b) Manufacturing Activities. Novartis will:

(i) upon NexMed's request, use Commercially Reasonable Efforts to supply NexMed with (A) the clinical materials for the NexMed Formulation it has on hand at the time of termination within a period of twelve (12) months if this Agreement is terminated prior to First Commercial Sale of the Product or (B) commercial quantities of NexMed Formulation and the corresponding Product for a period of eighteen (18) months if this Agreement is terminated after First Commercial Sale of the corresponding Product; provided, however, that NexMed will reimburse Novartis for the Fully Burdened Manufacturing Costs with respect to the NexMed Formulation and the corresponding Product; and

(ii) to the extent it is reasonably able to provide and subject to any Third Party restrictions, transfer the completed manufacturing process (together with any unique mold or tooling used solely in connection therewith that do not incorporate any trademarks or logos of Novartis) for the NexMed Formulation and the corresponding Product to NexMed or its designee upon NexMed's request and at its cost and expense, and cooperate with NexMed to effect the transition of such manufacturing responsibilities.

(c) License Grant. Novartis agrees to grant and hereby grants to NexMed, effective only upon such termination of this Agreement, a worldwide, exclusive, royalty-free right and license, with the right to sublicense and authorize the grant of further sublicenses, under any intellectual property (excluding the Patent Rights of Novartis as set out in sub-clause (g) below) owned or controlled (with the right to sublicense to NexMed) by Novartis and developed under this Agreement relating solely to the NexMed Formulation and the corresponding Product solely for the purposes of developing and commercializing the Product comprising the NexMed Formulation being developed under this Agreement; provided, however, that NexMed will be responsible for any payments associated with the grant of any license pursuant to the preceding sentence (including, without limitation, any royalty or other payment obligations to an upstream licensor of any such Patents Rights).

(d) Disclosure and Delivery. Novartis will provide to NexMed any Know-How owned or controlled (with the right to sublicense to NexMed) by Novartis developed under this Agreement, to the extent then used in connection with the manufacture, commercialization or development of the NexMed Formulation and the corresponding Product solely for the purposes of developing and commercializing the Product comprising the NexMed Formulation being developed under this Agreement; such transfer shall be effected by the delivery of documents, to the extent such Know-How is embodied in documents, and to the extent that such Know-How is not fully embodied in documents, Novartis shall make its employees and agents who have knowledge of such Know-How in addition to that embodied in documents available to NexMed for interviews, demonstrations and training to effect such transfer for a reasonable amount of time (not to exceed 200 person hours).

- (e) Disposition of Inventory. NexMed shall have the option, exercisable within thirty (30) days following the effective date of such termination, to purchase any inventory of the NexMed Formulation and the corresponding Product affected by such termination at Novartis' Fully Burdened Manufacturing Costs therefor (unless Novartis determines that it is appropriate for it to destroy such inventory). NexMed may exercise such option by written notice to Novartis during such thirty (30)-day period. Upon such exercise, the Parties will establish mutually agreeable payment and delivery terms for the sale of such inventory. If NexMed does not exercise such option during such thirty (30)-day period, or if NexMed provides Novartis with written notice of its intention not to exercise such option, then Novartis and its Affiliates and sublicensees will be entitled, during the period ending on the last day of the sixth (6th) full month following the effective date of such termination, to sell any inventory of the NexMed Formulation and the corresponding Product affected by such termination that remain on hand as of the effective date of the termination, so long as Novartis pays to NexMed the Royalty Payments, in accordance with the terms and conditions set forth in this Agreement.
- (f) Know-How License Grant. NexMed agrees to grant and hereby grants to Novartis, effective upon such termination of this Agreement, a worldwide, non-exclusive, royalty-free right and license, with the right to sublicense and authorize the grant of further sublicenses, under the NexMed Know-How solely for the purposes of developing and commercializing the Novartis Formulation and the corresponding Product.
- (g) Patent License. Novartis will grant NexMed a right exercisable within sixty (60) days of termination to negotiate in good faith a royalty bearing license to any Patent Rights of Novartis reasonably required for the development and commercialization of the NexMed Formulation and corresponding Product at commercially reasonable terms agreed upon by the Parties (such rate not to exceed the Royalty Payments under Clause 7).

12.3 Upon termination of this Agreement by Novartis pursuant to Clause 11.3:

- (a) Pre-Launch. (i) Novartis shall within sixty (60) days deliver a report to NexMed outlining the status of development of the Product and within one hundred eighty (180) days a report setting forth the total of the Out-of-Pocket Expenses incurred by Novartis. NexMed shall within sixty (60) days of delivery of both reports notify Novartis in writing if it wishes to receive the support and assistance set forth in Clauses 12.2 (a)-(e) inclusive and in the event NexMed so elects the provisions of Clauses 12.2(a)-(e) shall apply forthwith; (ii) in the event that NexMed elects to receive such support and assistance, Novartis shall provide such support and assistance to NexMed and NexMed shall pay Novartis a royalty of one and a half percent (1.5%) on net sales of Product invoiced by or on behalf of NexMed and any NexMed Affiliate, licensee or sublicensee for the Product, where net sales and payment terms shall have an equivalent meaning to the definition of Net Sales and payment terms in this Agreement in relation to Novartis until such time as the total amount of such royalties equals the Novartis Out-of-Pocket Expenses.

- (b) Post-Launch. In consideration of the provisions of Clauses 12.1 (a)-(e), NexMed shall pay Novartis a royalty of three percent (3%) on net sales of Product invoiced by or on behalf of NexMed and any NexMed Affiliate, licensee or sublicensee for the Product, where net sales and payment terms shall have an equivalent meaning to the definition of Net Sales and payment terms in this Agreement in relation to Novartis.

12.4 Upon termination of this Agreement by NexMed pursuant to Clause 11.2 or 11.4:

- (a) Pre-Launch. No royalty shall be payable by NexMed to Novartis on net sales of Product.
- (b) Post-Launch. In consideration of the provisions of Clauses 12.1 (a)-(e), NexMed shall pay Novartis a royalty of one and a half percent (1.5%) on net sales of Product invoiced by or on behalf of NexMed and any NexMed Affiliate, licensee or sublicensee for the Product, where net sales and payment terms shall have an equivalent meaning to the definition of Net Sales and payment terms in this Agreement in relation to Novartis.

12.5 **Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the obligations pursuant to the following Clauses; 9 (Intellectual Property Rights), 12.1 (Effect of Termination), 12.2, 12.3 and 12.4 (Effect of Termination), 12.5 (Survival), 13.1 (Representations and Warranties by Each Party), 13.2 (Representations and Warranties by NexMed), 13.5 (No Other Warranties), 14 (Indemnification), 15 (Publications and Publicity), 16.4 (Governing Law), 16.5 (Dispute Resolution), 16.8 (Relationship of the Parties), 16.7 (Waivers and Amendments), 16.10 (Notices), 16.15 (Expenses), and any other provision of this Agreement which is expressly or by implication intended to come into or continue in force on or after termination shall survive expiration or termination of this Agreement. The provisions of Clause 10 (Confidentiality) shall survive the termination or expiration of this Agreement for a period of ten (10) years.

13. REPRESENTATIONS AND WARRANTIES

13.1 **Representations and Warranties by Each Party.** Each Party represents and warrants to the other that:

- (a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
- (b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

- (c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity); and
- (d) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not
 - (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party, or (iii) violate any law.

13.2 **Representations and Warranties by NexMed.** NexMed represents and warrants, as of the Effective Date, to Novartis that:

- (a) Exhibit B sets forth a complete and accurate list of all NexMed Patent Rights in existence as of the Effective Date;
- (b) NexMed is the sole and exclusive owner of all of the NexMed Patent Rights free from Encumbrances and is listed in the records of the appropriate governmental agencies as the sole and exclusive owner of record for each registration, grant and application included in the NexMed Patent Rights;
- (c) NexMed has the right to grant to Novartis the licenses under the NexMed Patent Rights and NexMed Know-How that it purports to grant hereunder;
- (d) NexMed has the right to use and disclose and to enable Novartis to use and disclose (in each case under appropriate conditions of confidentiality) the NexMed Know-How free from Encumbrances;
- (e) to the knowledge of NexMed, the issued patents in the NexMed Patent Rights are valid and enforceable without any claims, challenges, oppositions, interference or other proceedings pending or threatened and NexMed has filed and prosecuted the patent applications within the NexMed Patent Rights in good faith and complied with all duties of disclosure with respect thereto;
- (f) to the knowledge of NexMed, NexMed has not committed any act, or omitted to commit any act, that may cause the NexMed Patent Rights to expire prematurely or be declared invalid or unenforceable;
- (g) all application, registration, maintenance and renewal fees in respect of the NexMed Patent Rights as of the Effective Date have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining the NexMed Patent Rights;

- (h) NexMed has not granted and will not grant during the Term, any Third Party, including any academic organization or agency, any right to the NexMed Technology which is inconsistent with the rights granted under this Agreement;
- (i) to the knowledge of NexMed, the development, manufacture, use and sale of the NexMed Formulation do not infringe the Patent Rights or misappropriate the Know-How of any Third Party, nor has NexMed received any written notice alleging such infringement or misappropriation;
- (j) NexMed has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating any NexMed Technology, nor have any proceedings been threatened by NexMed, nor does NexMed know of any valid basis for any such proceeding;
- (k) NexMed has taken all reasonable precautions to preserve the confidentiality of the NexMed Know-How;
- (l) NexMed has obtained from all individuals who participated in any respect in the invention or authorship of any NexMed Technology effective assignments of all ownership rights of such individuals in such NexMed Technology, either pursuant to written agreement or by operation of law; and
- (m) No officer or employee of NexMed is subject to any agreement with any other Third Party which requires such officer or employee to assign any interest in any NexMed Technology to any Third Party.

13.3 **Covenants of NexMed.** NexMed covenants and agrees that (a) it shall continue to own or possess all its rights, title and interest in and to the NexMed Patent Rights and the NexMed Know-How related to the Products and/or NexMed Formulation free and clear of all Encumbrances (other than this Agreement); (b) it will not grant any interest in the NexMed Patent Rights or NexMed Know-How which is inconsistent with the terms and conditions of this Agreement; and (c) NexMed has complied with and will continue to comply during the Term in all material respects, with all laws and regulations applicable to all activities relating to any of the NexMed Formulation and/or Products including without limitation, manufacturing and development activities related to the same.

13.4 **Covenants of Novartis.** Novartis covenants and agrees that it has complied with and will continue to comply during the Term in all material respects, with all laws and regulations applicable to all activities relating to any of the Products including without limitation, manufacturing and development activities related to the same.

13.5 **No Other Warranties.** Except as expressly stated in this Clause 13, (a) no representation, condition or warranty whatsoever is made or given by or on behalf of Novartis or NexMed and (b) all other conditions and warranties whether arising by operation of law or otherwise are hereby expressly excluded, including any conditions and warranties of merchantability, fitness for a particular purpose or non-infringement.

14. INDEMNIFICATION AND LIABILITY

14.1 **Indemnification by NexMed.** NexMed shall indemnify and hold Novartis and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns, harmless from and against any Claims against Novartis or any of the foregoing persons arising or resulting from:

- (a) NexMed's actions in connection with the development or commercialization of the NexMed Formulation and/or Products prior to or after the Effective Date or following termination in whole or in part of this Agreement and the reversion of the applicable rights hereunder to NexMed in accordance with Clause 12;
- (b) the negligence or willful misconduct of NexMed; or
- (c) the breach of any of the covenants, warranties and representations made by NexMed to Novartis under this Agreement.

NexMed shall only be obliged to so indemnify and hold Novartis harmless to the extent that such Claims do not arise from the breach, negligence or willful misconduct of Novartis.

14.2 **Indemnification by Novartis.** Novartis shall indemnify and hold NexMed and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns, harmless from and against any Claims against NexMed or any of the foregoing persons arising or resulting from:

- (a) the manufacture, handling, packaging, storage, sale or other disposition of any of the NexMed Formulation, Novartis Formulation and/or Products by or on behalf of Novartis, its Affiliates or sublicensees during the Term;
- (b) the negligence or willful misconduct of Novartis; or
- (c) the breach of any of the warranties and representations made by Novartis to NexMed under this Agreement.

Novartis shall only be obliged to so indemnify and hold NexMed harmless to the extent that such Claims do not arise from the breach, negligence or willful misconduct of NexMed.

14.3 **Indemnification Procedure.**

- (a) A Party hereto or any of its Affiliates seeking indemnification hereunder ("**Indemnified Party**") shall notify the other Party ("**Indemnifying Party**") in writing reasonably promptly after the assertion against the Indemnified Party of any claim or allegation by a Third Party ("**Third Party Claim**") in respect of which the Indemnified Party intends to base a claim for indemnification hereunder, but the failure or delay to notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Third Party Claim is adversely affected thereby.

- (b) Subject to the provisions of sub-Clauses (d) and (e) below, the Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the notice from the Indemnified Party of any Third Party Claim to assume the defense and handling of such Third Party Claim, at the Indemnifying Party's sole expense, in which case the provisions of sub-Clause (c) below shall govern.
- (c) The Indemnifying Party shall select counsel reasonably acceptable to the Indemnified Party in connection with conducting the defense and handling of such Third Party Claim, and the Indemnifying Party shall defend or handle the same in consultation with the Indemnified Party, and shall keep the Indemnified Party timely apprised of the status of such Third Party Claim. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to a settlement of any Third Party Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder. The Indemnified Party shall cooperate with the Indemnifying Party and shall be entitled to participate in the defense and handling of such Third Party Claim with its own counsel and at its own expense. Notwithstanding the foregoing, in the event the Indemnifying Party fails to conduct the defense and handling of any Third Party Claim in good faith after having assumed such, then the provisions of sub-Clause (e) below shall govern.
- (d) If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the notice from the Indemnified Party of any Third Party Claim, of the Indemnifying Party's election to assume the defense and handling of such Third Party Claim, the provisions of sub-Clause (e) below shall govern.
- (e) The Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Third Party Claim and defend or handle such Third Party Claim in such manner as it may deem appropriate, provided, however, that the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Third Party Claim and shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party defends or handles such Third Party Claim, the Indemnifying Party shall cooperate with the Indemnified Party and shall be entitled to participate in the defense and handling of such Third Party Claim with its own counsel and at its own expense.

- 14.4 **Mitigation of Loss.** Each Indemnified Party and any applicable Affiliate will take all such reasonable steps and action as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims under this Clause. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.
- 14.5 **Special, Indirect and Other Losses.** IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A THIRD-PARTY CLAIM.
- 14.6 **No Exclusion.** No Party excludes any liability for death or personal injury caused by its negligence or that of its employees, agents or sub-contractors.

15. PUBLICATIONS AND PUBLICITY

- 15.1 **Publications.** Any proposed oral public disclosures or written publications of NexMed relating to a Product and/or NexMed Formulation shall require the written consent of Novartis prior to their release; provided, that the foregoing shall not apply to information which is in the public domain or any public disclosures required by law or governmental regulation or by the rules of any recognized stock exchange.
- 15.2 **Publicity.** Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the existence of this Agreement, the terms hereof or the Parties' relationship under this Agreement without the prior written consent of the other Party; provided however, that neither Party will be prevented from complying with any duty of disclosure it may have pursuant to law or governmental regulation or pursuant to the rules of any recognized stock exchange and Novartis may issue press releases and other public statements as it deems appropriate in connection with the development and commercialization of Products under this Agreement. In the event of a disclosure required by law, governmental regulation or the rules of any recognized stock exchange, the Parties shall coordinate with each other with respect to the timing, form and content of such required disclosure and, if so requested by the other Party, the Party subject to such obligation shall use commercially reasonable efforts to obtain an order protecting to the maximum extent possible the confidentiality of such provisions of this Agreement as reasonably requested by the other Party. If the Parties are unable to agree on the form or content of any required disclosure, such disclosure shall be limited to the minimum required as determined by the disclosing Party in consultation with its legal counsel.

16. GENERAL PROVISIONS

- 16.1 **Assignment.** Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that (a) either Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (b) either Party may assign this Agreement in its entirety to a successor to all or a significant part of its business, which shall include a merger partner or the acquirer of the assets of all or a significant part of its business, subject to Novartis' rights under Clause 3.3 with respect to a Change of Control of NexMed. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee shall by written undertaking to the other Party assume all obligations of its assignor under this Agreement. Any attempted assignment in contravention of the foregoing shall be void.

- 16.2 **Extension to Affiliates.** Each Party shall have the right to extend the rights and immunities granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and immunities. The Party extending the rights and immunities granted hereunder shall remain primarily liable for any acts or omissions of its Affiliates.
- 16.3 **Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.
- 16.4 **Governing Law and Jurisdiction.** This Agreement shall be governed by and construed under the laws of New York, without giving effect to the conflicts of laws provision thereof. Subject to Clause 16.5, any dispute arising out of or relating to this Agreement shall be subject to the exclusive jurisdiction of the courts located in New York, New York.
- 16.5 **Dispute Resolution.** In the event of a dispute under this Agreement, the Parties will refer the dispute to the Alliance Managers for discussion and resolution. If the Alliance Managers are unable to resolve such a dispute within thirty (30) days of the dispute being referred to them, either Party may require that the Parties forward the matter to the Chief Executive Officer of NexMed and the Head of Pharma Development of Novartis Pharma AG (or a designee with similar authority to resolve such dispute), who shall attempt in good faith to resolve such dispute. If they cannot resolve such dispute within thirty (30) days of the matter being referred to them, then either Party may pursue any remedy or rights it may have.
- 16.6 **Force Majeure.** Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder if such delay or nonperformance is caused by strike, stoppage of labor, lockout or other labor trouble, fire, flood, accident, war, act of terrorism, act of God or of the government of any country or of any local government, or by cause unavoidable or beyond the control of any Party hereto. In such event, the Party affected will use commercially reasonable efforts to resume performance of its obligations.

- 16.7 **Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.
- 16.8 **Relationship of the Parties.** Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between NexMed and Novartis, or to constitute one as the agent of the other. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.
- 16.9 **Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.
- 16.10 **Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (receipt requested), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by notice):

If to NexMed:

NexMed, Inc.
350 Corporate Boulevard
Robbinsville, NJ 08691
Attn: Chief Executive Officer
Fax: 609-208-1622

with a copy to:

Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
Attn: Steven M. Cohen
Fax: 609-919-6701

If to Novartis:

Novartis International Pharmaceutical Ltd.
“Hurst Holme”, 12 Trott Road
P.O. Box HM 2899
Hamilton, HM LX
Bermuda
Attn: Board of Directors
Fax: 1-441-296-5083

with a copy to:

Novartis Pharma AG
Lichtstrasse 35
Post Office Box 4002
Basel, Switzerland
Attn: Legal Department
Fax: 41-61-324-7399

and

Novartis Pharma AG
Lichtstrasse 35
Post Office Box 4002
Basel, Switzerland
Attn: Head, Business Development and Licensing

- 16.11 **Further Assurances.** Novartis and NexMed hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.
- 16.12 **Compliance with Law.** Each Party shall perform its obligations under this Agreement in accordance with all applicable laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable law.
- 16.13 **No Third Party Beneficiary Rights.** The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights to any Third Party, except as otherwise expressly provided in Clause 14 (Indemnification). Except as expressly provided in Clause 14 (Indemnification), no person who is not a Party to this Agreement (including any employee, officer, agent, representative or subcontractor of either Party) shall have the right to enforce any term of this Agreement which expressly or by implication confers a benefit on that person without the express prior agreement in writing of the Parties.

- 16.14 **English Language.** This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.
- 16.15 **Expenses.** Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.
- 16.16 **Entire Agreement.** This Agreement, together with its Exhibits, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter. In the event of any conflict between a substantive provision of this Agreement and any Exhibit hereto, the substantive provisions of this Agreement shall prevail.
- 16.17 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives, as of the Effective Date.

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.**NEXMED, INC.**By: /s/_____By: /s/ Joseph Mo_____

Name: _____

Name: Joseph Mo_____

Title: _____

Title: President & CEO_____By: /s/_____By: /s/ Kenneth F. Anderson_____

Name: _____

Name: Kenneth F. Anderson_____

Title: _____

Title: V.P., Commercial Development_____**NEXMED INTERNATIONAL LIMITED**By: /s/ Joseph Mo_____Name: Joseph Mo_____Title: Managing Director_____By: /s/ Kenneth F. Anderson_____Name: Kenneth F. Anderson_____Title: V.P., Commercial Development_____

EXHIBIT A

NEXMED FORMULATION

*** The information contained in this exhibit has been omitted pursuant to a request for confidential treatment. Such portions have been filed separately with the SEC. ***

EXHIBIT B**NEXMED PATENT RIGHTS****Section 1**

<u>Case No. / Title / Inventor(s)</u>	<u>Country</u>	<u>Appln. No./Series No.</u>	<u>Filed</u>	<u>Patent No.</u>	<u>Granted</u>	<u>Status</u>
NMD-130 Antifungal Nail Coat and Method of Use (Kepka, Mo, Wang, Lu, Pfister)	U.S.	10/514,190	11/10/04			Pending
	PCT (all countries)	PCT/US2004/00861803/22/04				Pending
NMD-147 Antifungal Nail Coat and Method of Use (C-I-P of Appln. No. 10/514,190, which is U.S. National Phase of PCT/US2004/008618 and claiming priority of Provisional Application No. 60/456,684 (Kepka, Mo, Wang, Lu, Pfister)	U.S.					In Preparation

Section 2 - DDAIP Patent Rights

<u>Case No. / Title / Inventor(s)</u>	<u>Country</u>	<u>Appln. No./Series No.</u>	<u>Filed</u>	<u>Patent No.</u>	<u>Granted</u>	<u>Status</u>
NMD-107	U.S.	09/314,571	5/19/99	6,118,020	09/12/00	Granted
Crystalline Salts of Dodecyl	Australia	50232/00	05/18/00			Allowed
2-(N,N-Dimethylamino)-Propionate	Brazil	0006133-6	05/18/00			Pending
(Büyüktimkin)	Canada	2,338,139	05/18/00			Pending
	China	00800913.9	05/18/00			Pending
	China (Div. 1)					Authorized
	Europe	00932524.2	05/18/00	1097126	08/04/04	Granted
	(Albania, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Monaco, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland)					
	Europe (Div. 1)	04006144.2	03/15/04			Pending
	(Albania, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Monaco, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland)					
	Hong Kong	01108398.0	11/29/01			Pending
	Hungary	P 02 02090	05/18/00			Pending
	India	2000/00670	05/18/00			Pending
	Israel	140569	05/18/00			Pending
	Japan	2000-618227	05/18/00			Pending
	South Korea	10-2001-7000789	05/18/00			Pending
	Mexico	1000669	05/18/00	(224294)	(11/19/04)	Allowed
	South Africa	2001/0142	05/18/00	2001/0142	03/27/02	Granted
	Taiwan	89109133	05/12/00			Pending
Biodegradable Absorption Enhancers (Wong et al.)	U.S.	201,029	06/1/88	4,980,378	12/25/90	Granted
Biodegradable Absorption Enhancers (Wong et al.)	U.S.	566,758	08/14/90	5,082,866	01/21/92	Granted

EXHIBIT C**SAMPLE INVOICE****Sender's Logo****INVOICE**

Street
Town, Country
Phone and Fax Nr.

INVOICE DATE:
_____ **200**__

INVOICE No.: XXXX

Bill To:

Novartis International Pharmaceutical Ltd.
"Hurst Holme", 12 Trott Road
Att. Mr. Emil Bock / Ms. Wendy Wiseman
P.O. Box HM 2899
Hamilton, HM LX
Bermuda
And via fax to no. +1 441 296 5083

For:

Product X Royalties 1st Quarter 2006
(or Milestone for event Y)

DESCRIPTION	AMOUNT (USD)
Product X royalties January - March 200_ calculated based on Novartis provided sales & royalty report (see attached worksheet)	US\$ 000'000.00

(Or milestone payment for event Y, according to paragraph XY of agreement ZZZZ dated)

Novartis Contract Code

Please specify the event for which the invoice is due

Please remit by wire transfer within 60 days to:

Receiving Bank -
Swift Code -
ABA Number -
Credit Account -
Beneficiary -

TOTAL 000'000,00

If you have any questions concerning this invoice, contact
or e-mail to

VAT -Reg. No. XXXXXXXXXX (if applicable)

EXHIBIT D**FULLY BURDENED MANUFACTURING COSTS**

“Fully Burdened Manufacturing Costs” mean the sum total of: Total Product Costs plus Variance Costs plus Inventory Re-/ Devaluation Costs plus Non-Product Related Production Costs plus Warehousing and Distribution Costs plus Write-Offs plus Third Party Royalties.

“Total Product Costs” mean the total of the Material Costs and Processing Costs.

“Material Costs” mean the costs of raw materials and intermediates needed for the manufacturing process and costs of packaging material for these raw materials and intermediates.

“Processing Costs” mean the total amount of costs related to the direct labor, equipment, production area overhead, quality assurance, material handling overhead, general factory overhead, utilities and ecology.

Material and Processing Costs are to be established on a regular, standard basis. In this standard setting process all relevant costs as mentioned above are determined.

Costs of equipment shall be based on a planned utilization of equipment. Idle capacity costs are not to be included in processing costs. Costs of equipment are costs of depreciation or rent of the building accommodating that equipment plus repair and maintenance for the building, and costs for equipment depreciation, and other equipment costs such as costs for repair and maintenance. The building costs shall be allocated to the equipment using an appropriate key such as space occupied by the equipment.

Production area overhead costs are costs for personnel which typically embraces a controlling and supervisory function, costs of indirect space such as costs for a break room, costs of in-process control, costs of microbiological monitoring of production environment, costs of training of process personnel, costs for utilities and ecology, costs for auxiliary and consumables, costs of shop floor control systems, costs for cleaning of production buildings, and costs of working clothes.

Quality assurance costs include costs of identifying and analyzing the raw materials and intermediates needed for the manufacturing process, costs of finished product control, costs of production support, costs of cleaning validation, costs of EDP for the QA/QC department, costs of microbiology department, costs of laboratory infrastructure, costs of quality systems support and compliance, costs of overheads within the QA/QC department.

Materials handling overhead costs are costs for warehousing and internal transportation of raw material and semi-finished goods, costs of quality control of raw and packaging material, costs of the purchasing department.

General factory overhead (GFO hereafter) costs shall mean costs of plant and production management, costs for ensuring sufficient levels of safety, health and environment such as fire brigade, medical services, documentation for transportation of hazardous goods. Other GFO costs include costs for the scheduling of production, costs of the maintenance of the bills of materials, costs for the technical support, expenses of the plant administration and general services, costs of IT for non-dedicated IT systems such as SAP.

Utility costs are costs associated with the consumption of supportive media such as electricity, water, nitrogen, steam, and air.

Ecology costs are costs associated with the deposition of solid or liquid waste, purification of effluent water, and purification of waste air.

“Variance Costs” mean the costs include deviations from the standard costs used to determine the total Product Costs attributable to the product.

“Inventory Re/Devaluation Costs” mean the gain or loss as a result of the inventory value adjustment due to changes in the standard costs.

“Non-Product Related Production Costs” mean the technical operations corporate headquarter overhead costs, non product allocated QA costs, validation costs, directly expensed IT project costs, and other costs that cannot be attributed to specific products.

“Warehousing & Distribution Costs” mean the deduction of a fixed percentage (1-2%) for distribution and warehousing expenses.

“Write-Offs” mean the costs of products that cannot be used (for example, due to expiration of shelf-life, spoilage in the production process or transportation mishaps).

“Third Party Royalties” mean any royalties or other payments due by Novartis to third parties related to the manufacture, supply, sale, import or use of the product (other than any deducted from royalties pursuant to Clause 7.7).

EXHIBIT E**PATENT COUNTRIES**

The Patent Countries, as of the Effective Date, are set out below:

Algeria	Australia
Brazil	Canada
China	Colombia
Croatia	Ecuador
Egypt	Iceland
India	Indonesia
Israel	Philippines
Japan	Korea (South)
Morocco	Mexico
Norway	New Zealand
Poland	Russia
Singapore	South Africa
Tunisia	United Arab Emirates
USA	

Europe via European Patent Office (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Luxembourg, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and all EPO extension states)

EXHIBIT F

NEXMED STUDIES

Two (2) year dermal carcinogenicity study of DDAIP in mice

Two (2) year dermal carcinogenicity study of terbinafine HCL NexMed Formulation