

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

AMENDMENT NO. 1 TO

FORM 10-QSB/A

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

For the quarterly period ended June 30, 2003

OR

TRANSITION REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-27282

MANHATTAN PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

36-3898269

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer Identification No.)

787 Seventh Avenue, 48th Floor, New York, New York 10019  
(Address of principal executive offices)

(212) 554-4525

(Issuer's telephone number)

(Former Name, Former Address and Former Fiscal Year,  
if Changed Since Last Report)

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

As of March 11, 2004, there were 26,731,033 shares of the issuer's common stock, \$.01 par value, outstanding.

INTRODUCTORY NOTE

This Amendment No. 1 to the Quarterly Report on Form 10-QSB (the "10-QSB/A") for Manhattan Pharmaceuticals, Inc. (the "Company") for the quarter ended June 30, 2003, as filed with the Securities and Exchange Commission ("SEC") on August 14, 2003, is being filed solely for the purpose of amending Exhibit 10.1 thereto and correcting the exhibit index accordingly. The amendment to Exhibit 10.1 is based upon the SEC's review of the Company's confidentiality treatment request previously filed with respect to such exhibit.

This 10-QSB/A does not reflect events occurring after the filing of the original Form 10-QSB, or modify or update the disclosures therein in any way other than as required to reflect the amendment set forth above. The filing of this Form 10-QSB/A shall not be deemed an admission that the original filing, when made, included any untrue statement of a material fact or omitted to state a material fact necessary to make a statement not misleading.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Exhibit No.	Description
10.1	License Agreement dated April 4, 2003 between the Registrant and NovaDel Pharma, Inc.**
31.1	Certification of Chief Executive Officer.*

31.2 Certification of Chief Financial Officer.\*

32.1 Certifications of Chief Executive and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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\* As previously filed.

\*\* Filed herewith. Portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MANHATTAN PHARMACEUTICALS, INC.

Date: March 11, 2004

By: /s/ Leonard Firestone  
-----  
Leonard Firestone  
President and Chief Executive Officer

Date: March 11, 2004

By: /s/ Nicholas J. Rossettos  
-----  
Nicholas J. Rossettos  
Chief Financial Officer

EXHIBIT INDEX

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\* As previously filed.

\*\* Filed herewith. Portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[Portions herein identified by \*\*\* have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.]

#### LICENSE AND DEVELOPMENT AGREEMENT

THIS LICENSE AND DEVELOPMENT AGREEMENT (this "Agreement"), effective as of April 4, 2003 (the "Effective Date"), is entered into by and between NOVADEL PHARMA INC., a Delaware corporation ("NovaDel"), and MANHATTAN PHARMACEUTICALS, INC., a Delaware corporation (the "Licensee"). NovaDel and Licensee each may be referred to herein individually as a "Party," or collectively as the "Parties."

WHEREAS, NovaDel has certain proprietary rights and intellectual property (including to certain patents) with respect to lingual sprays for the metered delivery of pharmaceutical products (the "Technology"); and

WHEREAS, Licensee desires to obtain from NovaDel, and NovaDel desires to grant to Licensee, a license to develop and commercialize a pharmaceutical product containing propofol as active ingredient that will be administered using the Technology on the terms and conditions set forth herein; and

WHEREAS, Licensee desires that NovaDel provide, and NovaDel desires to provide, certain services in respect of the development of such pharmaceutical product containing propofol as active ingredient on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

#### ARTICLE 1 DEFINITIONS

For the purposes of this Agreement, the following words and phrases shall have the following meanings, unless otherwise specifically provided herein:

1.1 "AFFILIATE" shall mean, with respect to any Entity, any other Entity that directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Entity. For purposes of this Section 1.1 only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of an Entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of an Entity.

1.2 "APPLICABLE LAW" shall mean the applicable laws, rules, regulations, guidelines and requirements of the Regulatory Authorities, in the Territory.

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1.3 "COMBINATION PRODUCT" shall mean a combination pharmaceutical product containing one or more therapeutically active ingredients in addition to a Designated Compound.

1.4 "COMMERCIALY REASONABLE EFFORTS" shall mean, with respect to the development or commercialization of a Licensed Product, efforts and resources commonly used in the research-based pharmaceutical industry for a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability, and all other relevant factors. Commercially Reasonable Efforts shall be determined on a market-by-market basis for each Licensed Product without regard to the particular circumstances of a Party, including any other product opportunities of such Party.

1.5 "CONFIDENTIAL INFORMATION" shall have the meaning set

forth in Article 15.

1.6 "CONTROL" shall mean, with respect to any item of Information and Inventions, Patents or other intellectual property right, possession of the ability, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such item, Patent or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.7 "DESIGNATED COMPOUND" shall mean initially, propofol.

1.8 "DEVELOPMENT ACTIVITIES" shall mean the activities performed by the Parties under the Development Plan pursuant to Article 3.

1.9 "DEVELOPMENT BUDGET" shall have the meaning set forth in Section 3.3.

1.10 "DEVELOPMENT COMMITTEE" shall have the meaning set forth in Section 3.4.1.

1.11 "DEVELOPMENT PLAN" shall have the meaning set forth in Section 3.3.

1.12 "EFFECTIVE DATE" shall have the meaning set forth in the preamble.

1.13 "ENTITY" shall mean any individual, sole proprietorship, corporation, limited liability company, association, joint venture, partnership, limited partnership, limited liability partnership, trust, university, business, government or political subdivision thereof, including an agency, or any other organization that possesses independent legal standing.

1.14 "EXPLOIT" shall mean to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, improve, manufacture, have manufactured, store, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of a licensed product or process.

1.15 "EXPLOITATION" shall mean the making, having made, importation, use, sale, offering for sale of a licensed product or process, including the research, development,

registration, modification, improvement, manufacture, storage, optimization, import, export, transport, distribution, promotion, marketing, sale or other disposition of a licensed product or process.

1.16 "FDA" shall mean the United States Food and Drug Administration, or any successor agency responsible for the evaluation and approval of pharmaceutical products.

1.17 "FIRST COMMERCIAL SALE" shall mean the first sale for use or consumption by the general public of the Licensed Product in a country after Regulatory Approval (including pricing and reimbursement approval where applicable) for the marketing and sale of the Licensed Product has been obtained in such country.

1.18 "IMPROVEMENT" shall mean any modification, variation or revision to an apparatus, method, product or technology, or any discovery, technology, device, process or formulation related to an apparatus, method, product or technology, whether or not patented or patentable, including any enhancement in the manufacture or steps or processes thereof, ingredients, preparation, presentation, formulation, means of delivery, packaging or dosage of an apparatus, method, product or technology, any discovery or development of any new or expanded indications for an apparatus, method, product or technology, or any discovery or development that improves the stability, safety or efficacy of an apparatus, method, product or technology.

1.19 "IND" shall mean an investigational new drug application filed with the FDA for approval to commence human clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.

1.20 "INDEMNIFICATION CLAIM NOTICE" shall have the meaning set forth in Section 10.3.1.

1.21 "INDEMNIFIED PARTY" shall have the meaning set forth in Section 10.3.1.

1.22 "INFRINGEMENT SUIT" shall have the meaning set forth in Section 6.8.2.

1.23 "INFORMATION AND INVENTIONS" shall mean all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including pre-clinical and clinical trial results, manufacturing procedures and test procedures and techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all Improvements, whether to the foregoing or otherwise, and other discoveries, developments, inventions, and other intellectual property (whether or not confidential, proprietary, patented or patentable).

1.24 "KNOWLEDGE" shall mean the good faith understanding of the vice presidents, senior vice presidents, executive vice presidents, president or chief executive officer of the respective party of the facts and information then in their possession without any duty to conduct any investigation with respect to such facts and information.

1.25 "LICENSED PROCESS" shall mean the proprietary lingual spray technology for the delivery of pharmaceutical compounds through the mucosal membrane of the mouth using an aerosol or pump spray device that is under the Control of NovaDel as of the Effective Date and any Improvements thereto that are conceived and reduced to practice by NovaDel in the course of performing the Development Activities.

1.26 "LICENSED PRODUCT(S)" shall mean any dosage of pharmaceutical composition or preparation in finished form labeled and packaged for sale by prescription, over-the-counter or any other method for human applications that contains propofol delivered by means of the Licensed Process.

1.27 "LICENSED TECHNOLOGY" shall mean the NovaDel Patents, the NovaDel Know-How and the Drug Master File, collectively, but only with respect to the Exploitation of the Licensed Product.

1.28 "LICENSED TRADEMARK" shall mean those Trademarks set forth on Exhibit A attached hereto and such other Trademarks as may be designated by NovaDel in writing from time to time, and any registrations of the foregoing and pending applications relating thereto.

1.29 "LICENSEE" shall mean Manhattan Pharmaceuticals, Inc., a Delaware corporation.

1.30 "LOSSES" shall have the meaning set forth in Section 10.1.

1.31 "MAJOR MARKET COUNTRY" shall mean the United States of America and the European Union.

1.32 "NDA" shall mean a New Drug Application filed pursuant to the requirements of the FDA, as more fully defined in 21 C.F.R.ss.314.5 et seq., and any equivalent application required by any Regulatory Authority for the marketing, sale or use of the Licensed Product in the Territory.

1.33 "NET PROFITS" shall mean for any period, the gross amount invoiced by Licensee and its Affiliates for the sale of Licensed Product by Licensee or any of its Affiliates to Third Parties, less deductions for: (a) normal and customary trade, quantity and cash discounts and sales returns and allowances, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates, (ii) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors and (iv) chargebacks; (b) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced; (c) customs and excise duties and other duties related to the sales to the extent that such items are included in the gross amount invoiced; (d) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program; (e) sales and other taxes and duties directly related to the sale or delivery of the Licensed Product (but not including taxes assessed against the income derived from such sale); (f) distribution



expenses to the extent that such items are included in the gross amount invoiced; (g) any other similar and customary deductions that are consistent with United States generally accepted accounting principles, or in the case of non-United States sales, other applicable accounting standards; (h) insurance costs; (i) employee salaries and other consultant and employee compensation; (j) research and development costs; (k) manufacturing costs; (l) sales expenses (including sales commissions); (m) storage of Licensed Product; and (n) royalties payable to third parties. Any of the deductions listed above that involves a payment by Licensee or its Affiliates shall be taken as a deduction in the calendar quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers, uses or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes. For purposes of calculating Net Profits, sales between or among Licensee or its Affiliates shall be excluded from the computation of Net Profits, but sales by Licensee or its Affiliates to Third Parties shall be included in the computation of Net Profits.

1.34 "NET SALES" shall mean, for any period, the gross amount invoiced by Licensee and its Affiliates for the sale of Licensed Product by Licensee or any of its Affiliates to Third Parties, less deductions for chargebacks, billing errors, rejected goods, damaged goods and returns. Any of the deductions listed above that involves a payment by Licensee or its Affiliates shall be taken as a deduction in the calendar quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers, uses or dispositions for promotional, pre-clinical, clinical, regulatory or governmental purposes. For purposes of calculating Net Sales, sales between or among Licensee or its Affiliates shall be excluded from the computation of Net Sales, but sales by Licensee or its Affiliates to Third Parties shall be included in the computation of Net Sales.

1.35 "NOVADEL" shall have the meaning set forth in the preamble.

1.36 "NOVADEL KNOW-HOW" shall mean all Information and Inventions Controlled by NovaDel or an Affiliate of NovaDel as of the Effective Date or, from time to time, during the Term that (a) (i) are necessary for the use of the Licensed Process to Exploit the Licensed Product or (ii) relate to Improvements to the Licensed Product that are conceived and reduced to practice in the course of performing the Development Activities, and (b) are not generally known, but excluding any Information and Inventions to the extent claimed by any NovaDel Patents.

1.37 "NOVADEL PATENTS" shall mean the Patents that NovaDel Controls (a) as of the Effective Date that are listed on Exhibit A hereto and (b) from time to time during the Term that claim (i) the Licensed Process, or (b) any Improvements to the Licensed Product that are conceived and reduced to practice in the course of performing the Development Activities.

1.38 "PATENTS" shall mean (a) all patents and patent applications; (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications; and (c) any international equivalent of any of the foregoing.

1.39 "REGULATORY APPROVAL" shall mean any and all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Licensed Product in a country in the Territory, including (a) any approval of any Licensed Product (including any INDs, NDAs, and supplements or amendments thereto); (b) pre- and post-approval marketing authorizations for a Licensed Product (including any prerequisite manufacturing approval or authorization related thereto); (c) labeling approval for a Licensed Product; and (d) technical, medical and scientific licenses.

1.40 "REGULATORY AUTHORITY" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Licensed Technology or the Licensed Product in the Territory.

1.41 "REGULATORY DOCUMENTATION" shall mean all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), all supporting documents and all clinical studies and tests, relating to any Licensed Product, and all data contained in any of the foregoing, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.

1.42 "SECONDARY MARKET COUNTRIES" shall mean Japan, Canada, Australia and South Africa.

1.43 "SUBLICENSEE" shall mean any Third Party to which Licensee grants a sublicense pursuant to Section 2.5 under the licenses granted to Licensee by NovaDel under Section 2.1.

1.44 "SUBLICENSING FEES" shall mean all non-royalty consideration of any kind, including any fees, milestones or other payments (whether cash or non-cash (which shall be valued at fair market value)), received by Licensee or any of its Affiliates from any Sublicensee as a direct or indirect result of the grant by Licensee or any of its Affiliates to any Sublicensee of a license under, or the use by any such Sublicensee of, any of the Licensed Technology or Licensed Trademarks, in excess of the payments to be paid pursuant to sections 4.4 and 4.5.

1.45 "TECHNOLOGY" shall have the meaning set forth in the preamble.

1.46 "TERM" shall have the meaning set forth in Section 7.1.

1.47 "TERRITORY" shall mean the entire world.

1.48 "THIRD PARTY" shall mean any Entity other than NovaDel, Licensee and their respective Affiliates.

1.49 "THIRD PARTY CLAIM" shall have the meaning set forth in Section 10.3.2.

1.50 "TRADEMARK" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol.

1.51 "VALID CLAIM" shall mean, with respect to a particular country, a claim of a Patent in such country that (a) has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal, and (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country.

## ARTICLE 2 GRANT OF RIGHTS

### 2.1 LICENSE GRANTS TO LICENSEE.

2.1.1 Subject to Section 2.3 and the other terms and conditions of this Agreement, NovaDel hereby grants to Licensee and Licensee accepts, a non-transferable (except as provided in Article 12), sublicensable (only as provided in Section 2.5), royalty-bearing, worldwide, exclusive right and license under the Licensed Technology to Exploit the Licensed Product in the Territory, to the full end of the Term for which the Licensed Technology is licensed, unless sooner terminated as herein after provided.

2.1.2 Subject to Section 2.3 and the other terms and conditions of this Agreement, NovaDel hereby grants to Licensee and Licensee accepts, a non-transferable (except as provided in Article 13), sublicensable (only as provided in Section 2.4), royalty-bearing, non-exclusive right and license under the Licensed Trademarks for the sole purpose of using such Licensed Trademarks to market, distribute and sell the Licensed Product licensed under Section 2.1.1 in the Territory, to the full end of the Term for which the Licensed Product are licensed, unless sooner terminated as hereinafter provided.

2.2 LICENSE GRANT TO NOVADEL. Licensee hereby grants to NovaDel a limited, royalty-free, non-exclusive right and license in the Territory in and to the Licensed Technology to the extent necessary to perform its Development Activities under Article 3.

2.3 RETAINED RIGHTS. NovaDel retains all right, title and interest, including the right to grant licenses to Third Parties, in and to the Licensed Technology (other than for delivery of the Designated Compounds only as expressly provided in Section 2.1.1) and the Licensed Trademarks (other than for the Exploitation of Licensed Product only as expressly provided in Section 2.1.2). Licensee shall have no rights, express or implied, with respect to the Licensed Technology or the Licensed Trademarks, except as expressly set forth in Section 2.1, and Licensee covenants to NovaDel that none of Licensee, its Affiliates or Sublicensees shall use the Licensed Technology, directly or indirectly, for any purpose other than for administration of the Designated Compounds in connection with the Exploitation of Licensed Product, or the Licensed Trademarks, directly or indirectly, for any purpose other than the marketing, distribution and sale of Licensed Product hereunder. Licensee shall have no right to develop Combination Product under this Agreement. Notwithstanding anything in this Agreement to the

contrary, NovaDel does hereby retain the right to (a) enter into collaborations or other agreements with, and to grant licenses and other rights under the NovaDel Patents and NovaDel Know-How to Third Parties to Exploit products containing compounds other than the Designated Compounds and to use the Licensed Process in connection therewith, and (b) independently Exploit products containing compounds other than the Designated Compounds and to use the Licensed Process in connection therewith. Notwithstanding any other provision contained in this Agreement, NovaDel retains an irrevocable, non-exclusive, royalty-free right to use the Licensed Technology (including the Licensed Process) with respect to the Designated Compounds, for its internal, non-commercial research and development activities.

2.4 SUBLICENSES. Licensee shall have the right to grant sublicenses under the grants in Section 2.1 to Third Parties pursuant to a separate written agreement, subject to the following requirements and conditions:

2.4.1 Licensee must obtain NovaDel's prior written consent in respect of each such sublicense, such consent not to be unreasonably withheld, and any sublicense agreement must be fully consistent with the terms and conditions of this Agreement, including Articles 3.10, 5, 6, 10, 11, 13 and 16, and provide that Sublicensee will indemnify NovaDel and its Affiliates to the extent provided in Article 10.

2.4.2 Within five (5) days after execution or receipt thereof, as applicable, Licensee shall provide NovaDel with a full and complete copy of each sublicense granted here

2.4.3 .under and shall deliver copies of all reports (including relating to royalties and other payments) received by Licensee from such Sublicensees.

2.4.4 Termination of this Agreement by NovaDel pursuant to Section 8.3 with respect to Licensee shall not terminate any sublicense granted by Licensee pursuant to this Section 2.5 with respect to a Sublicensee, provided that (a) such Sublicensee is not in breach of any provision of this Agreement or the applicable sublicense agreement, (b) such Sublicensee shall perform all obligations of Licensee under this Agreement, (c) NovaDel shall have all rights with respect to any and all Sublicensees as it had hereunder with respect to Licensee prior to termination of this Agreement with respect to Licensee, (d) Licensee shall include in any sublicense a provision in which said Sublicensee acknowledges its obligations to NovaDel hereunder and the rights of NovaDel to terminate this Agreement with respect to any Sublicensee for breaches of this Agreement by such Sublicensee. The failure of Licensee to include in a sublicense the provisions referenced in clause (d) shall render the affected sublicense void ab initio.

### ARTICLE 3 DEVELOPMENT AND COMMERCIALIZATION ACTIVITIES

3.1 DEVELOPMENT AND COMMERCIALIZATION. Licensee shall have the sole right and obligation to develop and commercialize the Licensed Product in the Territory. NovaDel shall perform or cause to be performed, on behalf of Licensee, certain Development Activities in accordance with this Article 3. Except as set forth herein, Licensee shall be solely responsible

for all costs and expenses in connection with all development and commercialization activities, including the Development Activities performed by NovaDel on behalf of Licensee.

3.2 DEVELOPMENT ACTIVITIES. NovaDel shall not be required to commence any Development Activities until Licensee has paid at least twenty-five percent (25%) of the non-refundable License Fee described in Section 4.4.

3.2.1 GENERAL. Under the direction and supervision of the Development Committee, NovaDel and Licensee each shall perform, or cause to be performed, its respective Development Activities in accordance with the Development Plan and Development Budget. Notwithstanding the foregoing, the Parties acknowledge and agree that there can be no assurances that the objectives of the Development Activities can be achieved, or that they can be achieved in the manner or in the time set forth in the Development Plan. Although outcomes cannot be guaranteed, each Party shall use Commercially Reasonable Efforts to perform or cause to be performed its respective Development Activities in good scientific manner, and in material compliance with Applicable Law.

3.2.2 REPORTS. Within thirty (30) days after the end of each calendar quarter in which Development Activities are performed, each Party shall provide to the Development Committee a written progress report, which shall describe the Development Activities it has performed, or cause to be performed, during such calendar quarter, evaluate the work performed in relation to the goals of the Development Plan and in relation to the Development Budget, and provide such other information as may be required by the Development Plan or reasonably requested by the Development Committee with respect to the Development Activities.

3.3 DEVELOPMENT PLAN AND BUDGET. The development plan (the "Development Plan") and the development budget (the "Development Budget") for the Development Activities relating to propofol are attached hereto as Exhibit B and Exhibit C, respectively. The Development Committee shall review the Development Plans and the Development Budgets at least monthly and shall have the right to make such modifications or updates to the Development Plans or Development Budgets that it deems appropriate. The Parties acknowledge and agree that the amounts set forth in the Development Budgets are estimates and, given the unpredictability of the Development Activities, there can be no assurances that the Development Activities can be completed within the Development Budgets, provided, however, that the Parties agree to use their Commercially Reasonable Efforts to adhere to the Development Budgets.

#### 3.4 DEVELOPMENT COMMITTEE.

3.4.1 FORMATION AND AUTHORITY OF DEVELOPMENT COMMITTEE. NovaDel and Licensee shall establish a development committee (the "Development Committee"), which shall oversee the Development Activities performed by the Parties, review and approve the Development Budget and approve any changes to the Development Plan and Development Budget. Each Party shall appoint an equal number of representatives with the requisite experience and seniority to enable them to make decisions on behalf of the Parties with

respect to the Development Activities. From time to time, each Party may substitute its representatives on written notice to the other Party.

3.4.2 PROCEDURAL RULES OF DEVELOPMENT COMMITTEE. The Development Committee shall meet monthly, or as otherwise agreed to by the Parties. The Development Committee shall adopt such standing rules as shall be necessary for its work. A quorum of the Development Committee shall exist whenever there is present at a meeting at least one representative appointed by each Party. Members of the Development Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by the other participants. Representation by proxy shall not be allowed. The Development Committee shall take action by unanimous consent of NovaDel and Licensee, with each such Party having a single vote, irrespective of the number of representatives actually in attendance at a meeting, or by a written resolution signed by the designated representatives of each of NovaDel and Licensee.

3.4.3 DISPUTE RESOLUTION. If the Development Committee cannot, or does not, reach agreement on an issue, then either Party shall have the right to refer such issue to the Chief Executive Officers of the Parties who shall confer on the resolution of the issue. Any final decision mutually agreed to by the Chief Executive Officers of the Parties shall be in writing and shall be conclusive and binding on the Parties. If such officers are not able to agree on the resolution of an issue within twenty (20) days after such issue was first referred to them, either Party shall have the right to refer such dispute to arbitration pursuant to Article 9.

3.4.4 LIMITATIONS ON AUTHORITY OF DEVELOPMENT COMMITTEE. Each Party to this Agreement shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in the Development Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The Development Committee shall not have the power to amend or modify this Agreement, which may only be amended or modified as provided in Section 16.4.

3.5 REGULATORY APPROVALS. All INDs, NDAs and other filings, applications or requests pursuant to or in connection with the Regulatory Approvals required under the Development Plan shall be made in the name of Licensee or its designee, unless Applicable Law requires that a Regulatory Approval be solely or jointly in the name of NovaDel or its Affiliates, in which case NovaDel hereby assigns and shall cause its Affiliates to assign, as applicable, such Regulatory Approval to Licensee to the extent permitted by Applicable Law; provided, however, that NovaDel shall have a perpetual, irrevocable, worldwide right to use and reference the Regulatory Documentation with respect to the Licensed Product and any data included or referenced therein for all purposes. NovaDel, with prior notice to the Licensee, shall have the right to communicate with the Regulatory Authorities with regard to the Development Activities. Licensee agrees that the Drug Master File ("DMF") shall be owned by NovaDel, provided that Licensee shall have unlimited access to the DMF for purposes of any Regulatory Filings relating to each Licensed Product. Licensee agrees to request that the DMF be treated as confidential. NovaDel agrees to keep the Licensee reasonably informed as to the communications, if any, between NovaDel and the Regulatory Authorities.

3.6 REGULATORY RECORDS. NovaDel and Licensee each shall maintain, or cause to be maintained, records of its respective Development Activities in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of its respective Development Activities, and which shall be retained by such Party for at least five (5) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy any such records.

### 3.7 DEVELOPMENT EXPENSES.

3.7.1 LICENSEE'S OBLIGATION. In consideration of NovaDel's performance of its Development Activities, Licensee shall reimburse NovaDel for the reasonable and documented costs and expenses incurred by NovaDel in performing such activities in accordance with the Development Budget (as may be amended in accordance with Section 3.3). Licensee shall bear all costs and expenses incurred by or on behalf of Licensee in connection with the performance of its Development Activities.

3.7.2 INVOICES AND PAYMENTS. Within thirty (30) days after the end of each month in which Development Activities are performed, NovaDel shall invoice Licensee for any costs and expenses incurred by NovaDel or its Affiliates in such month. Each invoice shall be payable to NovaDel within thirty (30) days after receipt by Licensee of such invoice.

3.7.3 BOOKS AND RECORDS. Each party shall maintain complete and accurate books, records and accounts that, in reasonable detail, fairly reflect any reimbursable costs and expenses incurred by it or its Affiliates in performance of the Development Activities in conformity with Generally Accepted Accounting Principles ("GAAP"). Each party shall retain such books, records and accounts until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law. Each party shall have the right to have its certified public accountant, who shall be reasonably acceptable to NovaDel, audit the books and financial records of the other party and their respective Affiliates relating to its Development Activities during one or more calendar quarters; provided, however, that Licensee shall not have the right to audit a calendar quarter more than two (2) years after the end of such quarter, to conduct more than one such audit in any twelve-month period, or to audit any calendar quarter more than once; and provided further that each party shall bear the cost of such audit unless the audit reveals a variance of more than five percent (5%) from the reported results, in which case audited party shall bear the cost of the audit. The results of such accounting firm shall be final, absent manifest error.

3.8 COOPERATION. Each Party shall cooperate with any and all reasonable requests for assistance from the other Party with respect to the Development Activities, including by making its employees, consultants and other scientific staff available upon reasonable notice during normal business hours at their respective places of employment to consult with such other Party on issues arising in connection with the performance of such Development Activities.

3.9 DEVELOPMENT AND USE OF TRADEMARKS. Licensee shall have the sole right to determine the Trademarks to be used with respect to the Exploitation of the Licensed Product on a worldwide basis, provided that the product labeling and promotional materials disclose that the Licensed Product are delivered using the Licensed Process and include the Licensed Trademarks.

3.10 DILIGENCE OBLIGATIONS. Licensee shall use Commercially Reasonable Efforts to (a) develop and commercialize the Licensed Product in the entire Territory in accordance with the terms and conditions of this Agreement; (b) obtain Regulatory Approval(s) with respect to the Licensed Product in the Territory; and (c) thereafter diligently and aggressively Exploit the Licensed Product in the Territory to maximize sales. Licensee shall ensure that any Sublicense be terminable at the option of the Licensee in the event that a Sublicensee fails to maintain active, diligent marketing efforts for Licensed Product.

### 3.11 MANUFACTURING.

3.11.1 Subject to section 3.11.4, NovaDel shall manufacture and supply Licensee with Licensed Product on commercially reasonable terms for clinical development of the Licensed Product pursuant to a manufacturing agreement (the "Manufacturing Agreement") to be entered into following execution of this Agreement.

3.11.2 Subject to section 3.11.4, following receipt of Regulatory Approval, NovaDel shall manufacture and supply Licensee with Licensed Product on commercially reasonable terms pursuant to the Manufacturing Agreement.

3.11.3 NovaDel agrees that, at all times during the performance of the Development Activities, it will act in accordance with GMP and all applicable laws, rules and regulations.

3.11.4 The manufacturing agreement will provide among other things that in the event that Licensee enters into a Sublicense for a Licensed Product and such Sublicensee desires to obtain rights to manufacture such Licensed Product, then NovaDel will not unreasonably withhold its consent to transfer the manufacturing rights to such Sublicensee, provided that measures are incorporated into the sublicensing agreement to continue to safeguard the confidentiality of NovaDel Know-how and technology with respect to the Licensed Product as set forth in section 3.11.5

3.11.5 It is the intent of the Parties that NovaDel be the exclusive manufacturer of the Licensed Product pursuant to the terms of the Manufacturing Agreement; provided, however, that in the event that NovaDel is unable or unwilling to provide clinical or commercial supply of Licensed Product within a reasonable period of time upon commercially reasonable terms, then Licensee shall be entitled to seek alternate manufacturing source. In such event, Licensee shall use commercially reasonable efforts to ensure that any such alternate manufacturing source agree (a) to maintain in strictest confidence all information relating to the manufacture of the Licensed Product and the Licensed Technology, (b) not to file any intellectual property protection relating to inventions that may arise from the manufacture of the



Licensed Product and Licensed Technology, and (c) that any intellectual property that does arise out of the manufacture of the Licensed Product and Licensed Technology belong to NovaDel.

ARTICLE 4  
ROYALTIES AND OTHER CONSIDERATION

4.1 ROYALTIES. As partial consideration for the rights, privileges and licenses granted hereunder and the Development Activities performed by Licensor pursuant to Article 3, Licensee shall make the following payments to NovaDel:

4.1.1 Licensee shall pay to NovaDel royalties in an amount equal to the greater of (i) \*\*\* percent (\*\*\*) of worldwide aggregate Net Sales by Licensee or any Affiliate of Licensee of each Licensed Product during each calendar year and (ii) \*\*\* percent (\*\*\*) of worldwide aggregate Net Profit by Licensee or any Affiliate of Licensee of each Licensed Product during each calendar year.

4.1.2 Licensee shall pay to NovaDel (1) \*\*\* percent (\*\*\*) of all royalties received by Licensee or its Affiliate from sales by any Sublicensee of Licensed Product until such time as Licensee has recovered all of its out-of-pocket costs incurred directly in connection with the development and commercialization of the Licensed Product, and thereafter (2) \*\*\* percent (\*\*\*) of all royalties received by Licensee or its Affiliate from sales by any Sublicensee of Licensed Product;

4.1.3 Licensee shall pay to NovaDel (1) \*\*\* percent (\*\*\*) of all Sublicensing Fees until such time as Licensee has recovered all of its out-of-pocket costs incurred directly in connection with the development and commercialization of the Licensed Product, and thereafter (2) \*\*\* percent (\*\*\*) of all Sublicensing Fees.

4.2 ROYALTY TERM. Licensee's royalty obligations under Section 4.1 shall terminate, on a country-by-country basis, with respect to each Licensed Product upon the expiration date in such country of the last to expire of any issued NovaDel Patent that includes at least one Valid Claim covering the sale of such Licensed Product in such country. Upon termination of the royalty obligations under this Section 4.2 in a country, the license grants to Licensee in Section 2.1 shall be reduced in accordance with terms in Section 4.6.

4.3 ROYALTY PAYMENTS. Royalties under Section 4.1.1 and Other Income under 4.1.2(a) shall be payable to NovaDel on a quarterly basis, within forty-five (45) days after the end of each calendar quarter; provided, however, at the end of a calendar year Licensee shall determine the actual amounts owed to NovaDel under Section 4.1.2 and any additional amounts owed to NovaDel for the first three calendar quarters of such calendar year shall be paid with the royalty payment for the last calendar quarter of such calendar year, and provided further in the event that Licensee's payments for such calendar quarters exceed the actual royalties owed for such calendar quarters, Licensee shall have the right to offset such excess payments against the royalty payment for the last calendar quarter of such calendar year. Only one royalty payment will be due on Net Sales of the Licensed Product even though the manufacture, sale or use of such Licensed Product may be covered by more than one intellectual property right in a country.

4.4 LICENSEE FEE. Licensee shall pay to NovaDel \$500,000 as an up-front licensing fee for the Designated Compound, payable in cash as follows:

4.4.1 \$250,000 within 10 Business Days of the first date on which the Licensee has received an aggregate of \$5,000,000 through an equity financing or otherwise (including receipt of any milestone payments or other revenues); and

4.4.2 \$250,000 within 10 Business Days of the first date on which the Licensee has received an aggregate of \$10,000,000 through an equity financing or otherwise (including receipt of any milestone payments or other revenues).

4.5 MILESTONE PAYMENTS. Licensee shall also pay to NovaDel the following Milestone Payments:

4.5.1 \$1,000,000 within five (5) Business Days from the date on which the Company's first filed NDA is accepted for review by the FDA for a Licensed Product; and

4.5.2 \$1,000,000 within five (5) Business Days from the date on which the Company's first filed European Marketing Application for a Licensed Product in any country within the European Union is accepted for review by the appropriate Regulatory Authority; and

4.5.3 \$2,000,000 within five (5) Business Days from the date on which the Company's first filed NDA for a Licensed Product is approved by the FDA; and

4.5.4 \$2,000,000 within five (5) Business Days from the date on which the Company's first filed European Marketing Application for a Licensed Product in any country within the European Union is accepted for review by the appropriate Regulatory Authority; and

4.5.5 \$1,000,000 within five (5) Business Days from the date on which the application for commercial approval for the Licensed Product with the appropriate Regulatory Authority is approved in each Secondary Market Country

4.5.6 \$50,000 within five (5) Business Days from the date on which the Company's application for regulatory approval of a Licensed Product is approved by the appropriate Regulatory Authority in any country other than Major Market Countries or Secondary Market Countries.

4.6 REDUCTION OF PAYMENTS. In the event that, or from and after the date on which, (a) no Valid Claim of a NovaDel Patent covering a Licensed Product exists in a country and (b) no regulatory exclusivity with respect to such Licensed Product exists in such country (whether as a result of expiration of the exclusivity period or otherwise), (i) the milestone payments set forth in Section 4.5 with respect to such Licensed Product, if any, and (ii) the royalty rate payable to NovaDel by Licensee under Section 4.1 with respect to sales of such Licensed Product in such country, each shall be reduced by seventy-five percent (75%).

4.7 MODE OF PAYMENT. All payments to NovaDel under this Agreement shall be paid in United States Dollars to a bank account in the United States as NovaDel may reasonably designate. Any withholding taxes which Licensee, its Affiliates or any Sublicensee

shall be required by applicable law to withhold on remittance of the payments shall be deducted from such payment to NovaDel and remitted to the appropriate Regulatory Authority. Licensee shall furnish NovaDel with the original copies of all official receipts for such taxes. If any currency conversion shall be required in connection with the payments hereunder, such conversion shall be made by using the average of the exchange rates prevailing at Citibank, N.A. in New York, New York on the first business day of each month in the reporting period to which such payments relate.

4.8 NON-REFUNDABLE, NON-CREDITABLE. The amounts paid or payable under this Article 4 shall be non-refundable and non-creditable against any other amounts due NovaDel under this Agreement.

#### ARTICLE 5 REPORTS AND RECORDS

5.1 RECORD RETENTION. Licensee shall maintain (and shall ensure that its Affiliates and Sublicensees shall maintain) complete and accurate books, records and accounts that fairly reflect their respective Net Sales, Other Income and any milestones payable with respect to Licensed Product in sufficient detail to confirm the accuracy of any payments required hereunder and in accordance with GAAP, which books, records and accounts shall be retained by Licensee until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

5.2 AUDIT. NovaDel shall have the right to have an independent certified public accounting firm of nationally recognized standing, reasonably acceptable to Licensee, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of Licensee (and its Affiliates and Sublicensees) as may be reasonably necessary to verify the accuracy of such Net Sales, Milestone Payments or Sublicense Income for any calendar quarter ending not more than thirty-six (36) months prior to the date of such request; provided, however, that NovaDel shall not have the right to conduct more than one such audit in any twelve (12)-month period. The accounting firm shall disclose to each Party whether such Net Sales, Other Income or milestone payments are correct or incorrect and the specific details concerning any discrepancies. NovaDel shall bear the cost of such audit unless the audit reveals an under-reporting or underpayment in excess of the greater of one hundred thousand dollars (\$100,000) or two percent (2%) of royalties, Milestone Payments or Sublicense Income payable for such period, in which case Licensee shall bear the cost of the audit, rectify such underpayment and pay NovaDel applicable interest as required by Section 5.5. All payments required under this Section 5.2 shall be due within thirty (30) days of the date NovaDel provides Licensee notice of the payment due. The results of such accounting firm shall be final, absent manifest error.

5.3 REPORTS. Within thirty (30) days of the end of each quarter of each calendar year, Licensee shall deliver to NovaDel complete and accurate reports, giving such particulars of the business conducted by Licensee during the preceding quarter under this

Agreement as shall be pertinent to an accounting for royalties, milestone payments and Other Income hereunder. These shall include at least the following:

5.3.1 All Licensed Product used, leased or sold, by or for Licensee or its Affiliates.

5.3.2 Total amounts invoiced for Licensed Product used, leased or sold, by or for Licensee or its Affiliates.

5.3.3 Deductions applicable in computed "Net Sales" as defined in Section 1.33.

5.3.4 Total milestone payments due based on achievement of milestones.

5.3.5 Total Sublicensing Income owed by License from its Sublicensees.

5.3.6 Total royalties due based on Net Sales by or for Licensee or its Affiliates and Sublicensing Income owed by its Sublicensees, including any adjustments pursuant to Section 4.3.

5.3.7 Names and addresses of all Sublicensees and Affiliates of Licensee.

5.4 FINANCIAL STATEMENTS. Within one hundred twenty (120) days of the end of each fiscal year of Licensee, Licensee shall provide NovaDel with a copy of Licensee's audited financial statements for such year to NovaDel.

5.5 INTEREST. Amounts which are not paid when due and which are not the subject of a bona fide dispute shall accrue interest from the due date until paid, at a rate equal to the then prevailing prime rate of Citibank, N.A., plus six percent (6%), but in no event exceeding the amount permitted by applicable law.

5.6 CONFIDENTIALITY. Each report received by NovaDel shall be treated by NovaDel as if it were "Confidential Information" subject to the terms of Article 16.

ARTICLE 6  
PATENT AND TRADEMARK  
PROSECUTION AND MAINTENANCE

6.1 OWNERSHIP OF INFORMATION AND INVENTIONS. Subject to Section 6.2 and the license grants under Article 2, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all: (a) Information and Inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party (or its Affiliates or its Sublicensees (other than the other Party and its Affiliates)), whether or not patented or patentable, and any and all Patent and other intellectual property rights with respect thereto; and (b) other Information and Inventions, and Patent and other intellectual property rights that are Controlled (other than pursuant to the license grants set forth in Article 2) by such Party, its

Affiliates or Sublicensees (other than the other Party and its Affiliates). Subject to the license grants to Licensee under Article 2, as between the Parties, NovaDel shall own and retain all right, title and interest in and to all Licensed Technology.

6.2 OWNERSHIP OF THE LICENSED PROCESS. Subject to the license grants to Licensee under Article 2, as between the Parties, NovaDel shall own and retain all right, title and interest in and to the Licensed Process, including any and all Information and Inventions with respect to the Licensed Process (including any Improvements thereto) that are conceived, discovered, developed or otherwise made, by or on behalf of Licensee, its Affiliates or Sublicensees (other than NovaDel and its Affiliates), whether or not patented or patentable, and any and all Patent and other intellectual property rights with respect thereto. Licensee acknowledges and agrees that (a) the licenses granted to it pursuant to Section 2.1 permit Licensee to use the Licensed Process solely for the Exploitation of Licensed Product as provided in this Agreement, (b) Licensee has no right to use the Licensed Process or to discover, develop or otherwise make Improvements with respect to the Licensed Process under such grants, and (c) neither it, nor any of its Affiliates or Sublicensees, will engage, directly or indirectly, in activities designed to, or otherwise undertake or attempt, either on behalf of itself or another, to discover, develop or make any Information and Inventions that relate to the Licensed Process. Accordingly, Licensee shall promptly disclose to NovaDel in writing, the conception or reduction to practice, or the discovery, development or making of any such Information and Inventions that relate to the Licensed Process and shall, and does hereby, assign, and shall cause its Affiliates and Sublicensees to so assign, to NovaDel, without additional compensation, all of their respective rights, titles and interests in and to any such Information and Inventions.

6.3 OWNERSHIP OF JOINT TECHNOLOGY. Subject to Section 6.2 and the license grants under Article 2, the Parties shall each own an equal, undivided interest in and to any and all (a) Information and Inventions, conceived, discovered, developed or otherwise made, jointly by or on behalf of NovaDel (or its Affiliates or its sublicensees), on the one hand, and Licensee (or its Affiliates or Sublicensees), on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable; and (b) Patents (the "Joint Patents") and other intellectual property rights with respect thereto (collectively, the "Joint Technology"). Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, licensees and sublicensees to so disclose, the development, making, conception or reduction to practice of any Joint Technology.

6.4 OWNERSHIP OF LICENSED TRADEMARKS. Subject to the license grants under Article 2, as between the Parties, NovaDel shall own and retain all right, title and interest in and to the Licensed Trademarks. Licensee hereby acknowledges and affirms (a) that to the best of its knowledge, the Licensed Trademarks and the registrations thereof are valid and (b) that NovaDel or its Affiliates, as the case may be, are the owners of all right and title to and interest in the Licensed Trademarks and the registrations thereof, including any form or embodiment thereof, and the goodwill now and hereafter associated with the Licensed Trademarks. Licensee (on its own behalf and on behalf of its Affiliates) expressly disclaims any right or title to or interest in the Licensed Trademarks and the registrations thereof, except for the license granted in Section 2.1.2. Licensee hereby agrees and undertakes that it will not, and it will cause its Affiliates not to, contest or dispute the validity of, or the rights of NovaDel and its Affiliates, as the case may be, in and to, the Licensed Trademarks, or any part thereof, or the registrations thereof, nor

knowingly impair or endanger the validity of any of the foregoing. Licensee acknowledges that all use of the Licensed Trademarks by or on behalf of Licensee or its Affiliates shall inure to the benefit of NovaDel and its Affiliates. Upon termination of the license granted in Section 2.1.2, Licensee and its Affiliates shall not be entitled to any compensation for any increase in the value of the Licensed Trademarks or for any goodwill associated therewith. If so requested, Licensee shall, and shall cause its Affiliates to, assist NovaDel and its Affiliates to safeguard their full right, title and interest in and to the Licensed Trademarks and the registrations thereof.

6.5 UNITED STATES LAW. The determination of whether Information and Inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable United States law.

#### 6.6 PROSECUTION OF PATENTS AND TRADEMARKS.

6.6.1 PROSECUTION OF NOVADEL PATENTS AND TRADEMARKS. As between the Parties, NovaDel shall have the sole right, at its cost and expense, to obtain, prosecute and maintain throughout the world the NovaDel Patents and Licensed Trademarks; provided, however, that Licensee shall reimburse NovaDel for one hundred percent (100%) of the reasonable out-of-pocket costs incurred by NovaDel for filing, prosecuting and maintaining such NovaDel Patents to the extent that they claim or cover solely the Exploitation of the Licensed Product. Licensee shall, and shall cause its Affiliates and Sublicensees, as applicable, to, cooperate fully with NovaDel in the preparation, filing, prosecution, and maintenance of NovaDel's Patents. Such cooperation includes (a) promptly executing all papers and instruments and requiring employees to execute such papers and instruments as reasonable and appropriate so as to enable NovaDel to file, prosecute, and maintain its Patents in any country; and (b) promptly informing NovaDel of matters that may affect the preparation, filing, prosecution, or maintenance of any such Patents. NovaDel shall provide Licensee with drafts of all patent applications and other material submissions to and correspondence with any patent authorities to the extent such applications or submissions relate to the Licensed Technology (other than the Licensed Process), in sufficient time, but in any event not less than thirty (30) days prior to the date a reply is required by the relevant patent authorities, to allow for review and comment by Licensee. In addition, NovaDel shall provide Licensee with an opportunity to consult with NovaDel regarding the filing and contents of any such application, submission or correspondence. If Licensee provides to NovaDel comments with respect to any such application, submission or correspondence, to the extent such comments relate to any Licensed Technology (other than the Licensed Process), NovaDel agrees to reasonably consider such comments, it being understood that NovaDel retains the right to determine whether to comply with or incorporate such comments, if at all. If (x) NovaDel elects not to pursue the filing, prosecution or maintenance of a NovaDel Patent in a particular country, or to take any other action with respect to a NovaDel Patent in a particular country that is necessary or useful to establish or preserve rights with respect to the Licensed Product, and (y) such Patent does not claim or cover the Licensed Process, then NovaDel shall so notify Licensee promptly in writing and in good time to enable Licensee to meet any deadlines by which an action must be taken to establish or preserve any such rights in such NovaDel Patent in such country. Upon receipt of any such notice by NovaDel or if, at any time, NovaDel fails to initiate any such action within

thirty (30) days after a request by Licensee that it do so (and thereafter diligently pursue such action), Licensee shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such NovaDel Patent at its expense in such country. If Licensee elects to pursue such filing or registration, as the case may be, or continue such support, then Licensee shall notify NovaDel of such election and NovaDel shall, and shall cause its Affiliates to, (x) reasonably cooperate with Licensee in this regard, and (y) promptly grant to Licensee, without additional consideration, an exclusive, perpetual, irrevocable, royalty-free license in such country under such NovaDel Patent.

6.6.2 JOINT PATENTS. The Parties shall cooperate, and shall cause their respective Affiliates and Sublicensees, as applicable, to cooperate, with one another with respect to the filing, prosecution and maintenance of all Joint Patents, including by selecting outside counsel, reasonably acceptable to the Parties, to handle such filing, prosecution and maintenance. The Parties shall share equally in the expenses associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Joint Patents. If a Party elects not to pursue the filing, prosecution or maintenance of a Joint Patent in a particular country, or to take any other action with respect to Joint Technology in a particular country that is necessary or reasonably useful to establish or preserve rights thereto, then in each such case such Party shall so notify the other Party promptly in writing and in good time to enable such other Party to meet any deadlines by which an action must be taken to establish or preserve any such rights in such Joint Technology in such country. Upon receipt of each such notice by such other Party or if, at any time, such Party fails to initiate any such action within thirty (30) days after a request by such other Party that it do so (or thereafter diligently pursue such action), such other Party shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such Patent at its expense in such country. If such other Party elects to pursue such filing or registration, as the case may be, or continue such support, then such other Party shall notify such Party of such election and such Party shall, and shall cause its Affiliates, licensees and sublicensees, as applicable, to, (x) reasonably cooperate with such other Party in this regard, and (y) promptly release or assign to such other Party, without compensation, all right, title and interest in and to such Patent in such country.

#### 6.7 ENFORCEMENT OF PATENTS AND TRADEMARKS.

6.7.1 TECHNOLOGY AND TRADEMARKS OF NOVADEL. If either Party determines that any Technology or Trademark of NovaDel or any Joint Technology is being infringed by a Third Party's activities and that such infringement could affect the exercise by the Parties of their respective rights and obligations under this Agreement, it shall promptly notify such other Party in writing and provide such other Party with any evidence of such infringement that is reasonably available. Promptly after the receipt of such written notice, the Parties shall meet and discuss in good faith the removal of such infringement. NovaDel shall consider in good faith any comments from Licensee and shall keep Licensee reasonably informed of any steps taken to remove such infringement. NovaDel shall have the first right, but not the obligation, to remove such infringement at its sole cost and expense; provided, however, that Licensee shall reimburse NovaDel for one hundred percent (100%) of the reasonable out-of-pocket costs incurred by NovaDel with respect to the removal of any such infringement to the extent that such infringement adversely affects the Exploitation of the Licensed Product. In the

event that NovaDel fails within ninety (90) days following notice of such infringement, or earlier notifies Licensee in writing of its intent not, to take commercially appropriate steps to remove any infringement of any NovaDel Patent, Joint Patent or Licensed Trademark that is likely to have a material adverse effect on the sale of a Licensed Product, Licensee shall have the right to do so at Licensee's expense; provided, however, that if NovaDel has commenced negotiations with an alleged infringer for discontinuance of such infringement within such ninety (90) day period, NovaDel shall have an additional ninety (90) days to conclude its negotiations before Licensee may bring suit for such infringement, and provided further that Licensee shall not enter into any settlement or compromise with respect to any NovaDel Patent, Joint Patent or Licensed Trademark without NovaDel's prior consent, which consent shall not be unreasonably withheld. Each Party shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the enforcing Party to maintain the action. Any amounts recovered by a Party pursuant to this Section, whether by settlement or judgment, shall be used to reimburse the Parties for their reasonable costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), with any remainder being retained by the Party that brought the enforcement action; provided, however, that to the extent that any award is attributable to the loss of sales of Licensed Product, such amount shall be paid to Licensee and shall be treated as Net Sales on which royalties shall be due under Article 4.

#### 6.8 POTENTIAL THIRD PARTY RIGHTS.

6.8.1 THIRD-PARTY LICENSES. If (a) in the opinion of outside patent counsel to Licensee, Licensee, or any of its Affiliates or Sublicensees, cannot Exploit a Licensed Product in a country in the Territory without infringing one or more Patents that have issued to a Third Party in such country, or (b) as a result of any claim made against a Party, or any of its Affiliates or Sublicensees, alleging that the Exploitation of a Licensed Product infringes or misappropriates any Patent or any other intellectual property right of a Third Party in a country in the Territory, a judgment is entered by a court of competent jurisdiction from which no appeal is taken within the time permitted for appeal, such that Licensee cannot Exploit such Licensed Product in such country without infringing the Patent or other proprietary rights of such Third Party, then, in either case, Licensee shall have the first right, but not the obligation to negotiate and to obtain a license from such Third Party as necessary for the Exploitation of any Licensed Product hereunder in such country; provided, however, that NovaDel shall have the sole right to seek any such license with respect to the Licensed Process and shall use commercially reasonable efforts to obtain such a license in its own name from such Third Party in such country, under which NovaDel shall, to the extent permissible under such license, grant a sublicense to Licensee as necessary for Licensee, and any of its Affiliates and Sublicensees, to Exploit the Licensed Product as provided hereunder in such country. Licensee shall be solely responsible for one hundred percent (100%) of all royalty and other obligations with respect to the Exploitation of the Licensed Product; provided, however, that Licensee shall have the right to credit fifty percent (50%) any royalties paid by Licensee, its Affiliates or Sublicensees under such license with respect to such country against the royalty payments to be paid by Licensee to NovaDel with respect to the sale of the Licensed Product(s) under Section 4.1; provided, however, that no royalty payment when due, regardless of the amount or number of credits available to Licensee in accordance with this Agreement, shall be reduced by more than fifty



percent (50%) of the amounts otherwise owed pursuant to Section 4.1 in any calendar quarter. Credits not exhausted in any calendar quarter may be carried into future calendar quarters.

6.8.2 THIRD PARTY LITIGATION. In the event that a Third Party institutes a patent, trademark or other infringement suit (including any suit alleging the invalidity or unenforceability of the Patents of a Party or its Affiliates, or claiming confusion, deception or dilution of a Trademark) against either Party or its respective Affiliates, licensees or Sublicensees during the Term, alleging use of the Licensed Technology, Licensed Trademarks or any other activities hereunder, infringes one or more patent, trademark or other intellectual property rights held by such Third Party (an "Infringement Suit"), the Parties shall cooperate with one another in defending such suit. NovaDel shall have the first right to direct and control any Infringement Suit to the extent that it relates to the use of the Licensed Technology, the Licensed Trademarks or the Licensed Process; provided that Licensee shall bear one hundred percent (100%) of the costs and expenses associated with any such Infringement Suit to the extent that it relates to the Exploitation of the Licensed Product.

6.8.3 RETAINED RIGHTS. Nothing in this Section 6.8 shall prevent Licensee, at its own expense, from obtaining any license or other rights from Third Parties it deems appropriate in order to permit the full and unhindered exercise of its rights under this Agreement.

#### ARTICLE 7 TERM OF THE AGREEMENT

7.1 TERM. Unless otherwise terminated pursuant to Article 8, this Agreement shall enter into effect on the Effective Date and shall remain in full force and effect on a country-by-country basis until the later of (a) the expiration date of the last to expire of any issued NovaDel Patent that includes at least one Valid Claim and (b) the twentieth (20th) anniversary of the Effective Date.

#### ARTICLE 8 TERMINATION

8.1 TERMINATION UPON INSOLVENCY. If Licensee shall become bankrupt, or shall file a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee or of its assets, or if an involuntary petition for any of the foregoing shall be filed with respect to Licensee and not dismissed within sixty (60) days, or if the business of Licensee shall be placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of Licensee or otherwise, this Agreement shall automatically terminate.

8.2 TERMINATION FOR PAYMENT DEFAULT. Should Licensee fail to make payment to NovaDel of royalties or other amounts due in accordance with the terms of this Agreement, NovaDel shall have the right to terminate this Agreement within ten (10) days after giving said notice of termination unless Licensee shall pay to NovaDel, within the 10-day period, all such amounts due and payable. Upon the expiration of the 10-day period, if Licensee shall

not have paid all such amounts due and payable, the rights, privileges and licenses granted hereunder shall, at the option of NovaDel, immediately terminate. In the event a payment is the subject of a bona fide dispute between NovaDel and Licensee that is being pursued by a Party pursuant to the dispute resolution mechanism in Article 9, then Licensee shall make such payment, but shall provide NovaDel with written notice that such payment is being made subject to the outcome of such pending dispute resolution procedure and in the event such dispute is finally and conclusively resolved in favor of Licensee, NovaDel shall refund such payment to Licensee with interest calculated pursuant to Section 5.5 from the date of such payment.

8.3 TERMINATION FOR MATERIAL BREACH. Upon any material breach or default of this Agreement by either Party, other than as set forth in Sections 8.1 or 8.2 above, and subject to Section 2.4.3, the other Party shall have the right to terminate this Agreement and the rights, privileges and licenses granted hereunder upon giving thirty (30) days notice to the breaching Party. Such termination shall become effective upon the expiration of such thirty (30)-day period unless the breaching Party shall have cured any such breach or default prior to the expiration of such thirty (30) day period.

8.4 FAILURE TO OBTAIN FINANCING. Notwithstanding anything to the contrary herein, should Licensee fail to obtain financing in the amount of Five Million Dollars (US\$5,000,000) (the "Minimum Financing") by March 31, 2004, NovaDel shall have the right, which right shall continue until such time as Licensee obtains the Minimum Financing, but not the obligation, to immediately terminate this Agreement upon written notice to Licensee.

8.5 TERMINATION BY THE LICENSEE. The Licensee shall have the right at any time to terminate this Agreement in whole or as to any Licensed Product by giving 90 days notice thereof in writing to NovaDel.

8.6 SURVIVAL. Any expiration or termination of this Agreement shall not affect the rights and obligations of the Parties accrued prior to such expiration or termination. Without limiting the foregoing, Articles 4, 5, 6, 9, 10, 11, 14, 15 and 16 and Sections 8.6, 8.7, 8.8, 16.1, 16.7 and this 8.6 shall survive the termination or expiration of this Agreement for any reason.

8.7 WORK-IN-PROGRESS. Licensee and/or any Sublicensee thereof may, however, after the effective date of such termination and continuing for a period not to exceed six (6) months thereafter, sell all completed Licensed Product, and any Licensed Product in the process of manufacture at the time of such termination, and sell the same, provided that Licensee shall pay or cause to be paid to NovaDel the royalties thereon as required by Article 4 of this Agreement and shall submit the reports required by Article 5 hereof on the sales of Licensed Product.

#### 8.8 RETURN OF INFORMATION; ASSIGNMENT AND LICENSE.

8.8.1 Upon termination of this Agreement, Licensee shall, and shall cause its Affiliates and Sublicensees, as applicable, to return to NovaDel any and all data, files, records and other materials in its possession or control that relate to the Licensed Technology or contain or comprise NovaDel's Information and Inventions or other Confidential Information (except one copy of each that may be retained for archival purposes).

8.8.2 Upon the termination of this Agreement, Licensee (a) shall, and shall cause its Affiliates and, subject to Section 8.8.3, Sublicensees to, promptly disclose to NovaDel, in whatever form NovaDel may request, all Regulatory Documentation and all other Information and Inventions in the possession or Control of Licensee, its Affiliates or Sublicensees that relate to the Exploitation of such Licensed Product, (b) shall, and does hereby, assign, and shall cause its Affiliates and, subject to Section 8.8.3, Sublicensees to assign, to NovaDel, without additional compensation, all of their respective rights, titles and interests in and to any and all (i) patent, trademark, copyright or other intellectual property rights, (ii) Regulatory Documentation and all data included or referenced therein, and (iii) other Information and Inventions in the possession or Control of Licensee, its Affiliates or Sublicensees, in each case that relate to the Exploitation of such Licensed Product (the "Agreement-Related Assets") and are permitted to be assigned, and (c) to the extent that the Agreement-Related Assets may not be assigned, shall, and does hereby, grant, and shall cause its Affiliates and, subject to Section 8.8.3, Sublicensees to grant, to NovaDel, without additional compensation, a perpetual, irrevocable, royalty-free, exclusive, sublicenseable through multiple tiers of sublicensees, right and license to Exploit such Licensed Product in the Territory.

8.8.3 Notwithstanding anything contained in Section 8.8.1 or 8.8.2, in the event that any sublicense granted by Licensee survives pursuant to Section 2.4.3, the Sublicensee may retain (a) the information and materials identified in Section 8.8.1 that are rightfully in its possession and (b) Agreement-Related Assets, in each case until the termination of such sublicense, whereupon such Sublicensee shall return such materials to NovaDel,.

8.9 CUMULATIVE REMEDIES. The rights and remedies set forth in this Article 8 are cumulative and in addition to any other rights that may be available to the Parties.

8.10 NON-REFUNDABILITY OF MILESTONES AND DEVELOPMENT COSTS. Any and all Milestone Payments made to NovaDel by Licensee under Article 4.5 of this Agreement shall be non-refundable in the event of termination of this Agreement by either party under any of the provisions of Article 8 other than Article 8.5.

## ARTICLE 9 ARBITRATION

9.1 PROCEDURES. Any dispute arising from or relating to this Agreement shall be determined before a tribunal of three arbitrators in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association (the "AAA"). One arbitrator shall be selected by NovaDel, one arbitrator shall be selected by Licensee and the third arbitrator shall be selected by mutual agreement of the first two arbitrators or by the AAA, if the arbitrators appointed by the Parties are unable to select a third arbitrator within thirty (30) days.

9.2 PATENT DISPUTES. Any claim, dispute, or controversy concerning the validity, enforceability, or infringement of any patent contained in the NovaDel Patents licensed hereunder shall be resolved in any court having jurisdiction thereof. In the event that, in any arbitration proceeding, any issue shall arise concerning the validity, enforceability, or infringement of any patent contained in the NovaDel Patents licensed hereunder, the arbitrators

shall, to the extent possible, resolve all issues other than validity, enforceability, and infringement; in any event, the arbitrators shall not delay the arbitration proceeding for the purpose of obtaining or permitting either Party to obtain judicial resolution of such issues, unless an order staying the arbitration proceeding shall be entered by a court of competent jurisdiction. Neither Party shall raise any issue concerning the validity, enforceability, or infringement of any patent contained in the NovaDel Patents licensed hereunder, in any proceeding to enforce any arbitration award hereunder, or in any proceeding otherwise arising out of any such arbitration award.

9.3 COSTS. The costs of such arbitration shall be borne proportionate to the finding of fault as determined by the arbitration panel. Judgment on the arbitration award may be entered by any court of competent jurisdiction.

#### ARTICLE 10 INDEMNIFICATION AND INSURANCE

10.1 INDEMNIFICATION OF NOVADEL. Licensee shall defend, indemnify and hold NovaDel, its Affiliates, and their respective directors, officers, employees and agents harmless from and against all liability, demands, damages, including expenses or losses including death, personal injury, illness or property damage (collectively, "Losses") arising directly or indirectly out of any: (a) breach of this Agreement by Licensee, its Affiliates, Sublicensees or permitted assigns or transferees; (b) actual or asserted violations of Applicable Law by Licensee, its Affiliates, Sublicensees or permitted assignees or transferees; (c) use by Licensee, its Affiliates, Sublicensees or permitted assignees or transferees of the Licensed Technology or (d) Exploitation of the Licensed Product by Licensee, its Affiliates, Sublicensees or permitted assignees or transferees, except for those Losses for which NovaDel has an obligation to indemnify Licensee and its Affiliates pursuant to Section 10.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses and other than as a result of NovaDel's gross negligence, recklessness or willful misconduct.

10.2 INDEMNIFICATION OF LICENSEE. NovaDel shall defend, indemnify and hold Licensee, its Affiliates, and their respective directors, officers, employees and agents harmless from and against all Losses arising directly or indirectly out of any: (a) breach of this Agreement by NovaDel or its Affiliates; or (b) actual or asserted violations of Applicable Law by NovaDel or its Affiliates, except for those Losses for which Licensee has an obligation to indemnify NovaDel and its Affiliates pursuant to Section 10.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

#### 10.3 INDEMNIFICATION PROCEDURE.

10.3.1 NOTICE OF CLAIM. The indemnified Party shall give the indemnifying Party prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under Section 10.1 or Section 10.2, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount

of such Loss (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party").

10.3.2 THIRD PARTY CLAIMS. The obligations of an indemnifying Party under this Article 10 with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Sections 10.1 or 10.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:

(A) CONTROL OF DEFENSE. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by any indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party shall not be liable to the Indemnified Party or any other indemnified Party for any legal expenses subsequently incurred by such indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such Indemnified Party.

(B) RIGHT TO PARTICIPATE IN DEFENSE. Without limiting Section 10.3.2(a), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing or (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 10.3.2(a) (in which case the Indemnified Party shall control the defense).

(C) SETTLEMENT. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any

judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 10.3.2(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party.

(D) COOPERATION. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

(E) EXPENSES. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a calendar quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

#### 10.4 INSURANCE.

10.4.1 Prior to entering human clinical trials, Licensee shall have and maintain such type and amounts of liability insurance covering the manufacture, supply, use and sale of the Licensed Product as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and shall upon request provide NovaDel with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

10.4.2 At all times during the Development Activities, NovaDel shall have and maintain such type and amounts of liability insurance covering the manufacture, supply, use and sale of the Licensed Product as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and shall upon request provide the Licensee with

a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

ARTICLE 11  
REPRESENTATIONS AND WARRANTIES;  
LIMITATION OF LIABILITY

11.1 REPRESENTATIONS, WARRANTIES AND COVENANTS. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

11.1.1 DULY ORGANIZED. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as is contemplated to be conducted by this Agreement.

11.1.2 CORPORATE AUTHORITY. Such Party (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (b) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or in equity.

11.1.3 LITIGATION. Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.

11.1.4 CONSENTS, APPROVALS, ETC. All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

11.1.5 CONFLICTS. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation, bylaws, or any similar constitutive document of such Party, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

11.2 ADDITIONAL REPRESENTATIONS AND WARRANTIES OF NOVADEL.

11.2.1 NovaDel represents and warrants to Licensee that, to its Knowledge, as of the Effective Date, NovaDel is the owner or (sub)licensee (with the right to

grant sublicenses to Licensee as contemplated under this Agreement) of the NovaDel Patents, and has all right, title, and interest in and to the NovaDel Patents, including exclusive, absolute, irrevocable right, title and interest thereto, free and clear of all liens, charges, encumbrances or other restrictions or limitations of any kind whatsoever and to the NovaDel's knowledge and belief there are no licenses, options, restrictions, liens, rights of third parties, disputes, royalty obligations, proceedings or claims relating to, affecting, or limiting its rights or the rights of the Licensee under this Agreement with respect to, or which may lead to a claim of infringement or invalidity regarding, any part or all of the Licensed Technology and their use as contemplated in the underlying patent applications as presently drafted. The NovaDel Patents have not, as of the Effective Date, been held by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part.

11.2.2 To NovaDel's knowledge and belief there is no claim, pending or threatened, of infringement, interference or invalidity regarding, any part or all of the Licensed Technology and their use as contemplated in the underlying patent applications as presently drafted.

11.3 ADDITIONAL COVENANTS OF LICENSEE. Licensee on behalf of itself and its Affiliates agrees and covenants to the extent permitted by applicable law, never, in any country, region or jurisdiction in the Territory, to institute or prosecute any claim, action or suit at law or in equity seeking to have any claim in a NovaDel Patent declared invalid or unenforceable; provided, however, that nothing contained herein shall prohibit Licensee and its Affiliates and Sublicensees from either (a) asserting any and all defenses available to it, including assertions relating to the validity or enforceability of the NovaDel Patents, in any suit or proceeding brought against them alleging the infringement of any of the NovaDel Patents, or (b) asserting any and all defenses, evidence and arguments, including lack of patentability of the subject matter of a count or claim and lack of support for a count or claim, in any interference involving a patent or patent application owned by Licensee or its Affiliates or Sublicensees and a patent or patent application included within the definition of the NovaDel Patents. In its agreements with each of its Sublicensees, Licensee shall include provisions requiring a covenant, materially identical to that Licensee is making in this Section 11.3, on the part of the Sublicensee, and shall provide that NovaDel shall have march-in right to seek termination of such agreement in the event the Sublicensee breaches the covenant. NovaDel's right to seek termination of such agreement with the Sublicensee shall be subject to notice, cure and dispute resolutions provisions materially identical to the provision set forth in Section 7.2. Licensee and its Affiliates will take all reasonable action (including signing required documents) and offer full cooperation to allow NovaDel to exercise the march-in rights provided herein, to the extent permitted by law.

11.4 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 11.1 AND 11.2, NOVADEL MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, UNDER THIS AGREEMENT, AND NOVADEL SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO



THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES UNDER THIS AGREEMENT.

11.5 LIMITATION OF LIABILITY. NONE OF NOVADEL OR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (A) THE USE OF THE LICENSED TECHNOLOGY OR LICENSED TRADEMARKS OR (B) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT.

ARTICLE 12  
ASSIGNMENT

This Agreement and the rights and duties appertaining hereto may not be assigned by either party without first obtaining the written consent of the other which consent shall not be unreasonably withheld. Any such purported assignment, without the written consent of the other party, shall be null and of no effect. Notwithstanding the foregoing, the Company may assign this Agreement (i) to a purchaser, merging or consolidating corporation, or acquiror of substantially all of the Company's assets or business and/or pursuant to any reorganization qualifying under section 368 of the Internal Revenue Code of 1986 as amended, as may be in effect at such time, or (ii) to an Affiliate of the Company subject to the consent of the Licensors which consent shall not be unreasonably withheld.

ARTICLE 13

USE OF NAMES AND PUBLICATION

13.1 USE OF NAME. Nothing contained in this Agreement shall be construed as granting any right to Licensee, its Affiliates or Sublicensees to use in advertising, publicity, or other promotional activities the name of NovaDel or any of its units (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of NovaDel; provided, however, that NovaDel acknowledges and agrees that Licensee may use the names of NovaDel in various documents used by Licensee for capital raising and financing without such prior written consent to the limited extent that such use may be required by law, and provided further that all such uses shall be factually accurate and not misleading.

13.2 RELATIONSHIP OF THE PARTIES. Nothing herein shall be deemed to establish a relationship of principal and agent between NovaDel and Licensee, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as creating a partnership between NovaDel and Licensee, or as creating any other form of legal association or arrangement which would impose liability upon one Party for the act or failure to act of the other Party.

13.3 PUBLICATIONS. In the event that either party desires to publish or disclose, by written, oral or other presentation, Licensed Technology or any material information related

thereto, then such party shall notify the other in writing of its intention at least sixty (60) days prior to any speech, lecture or other oral presentation and at least sixty (60) days before any written or other publication or disclosure, and shall include with such notice a description of any proposed oral presentation or, with respect to any proposed written or other disclosure, a current draft of such proposed disclosure or abstract. NovaDel may request that Licensee, no later than thirty (30) days following the receipt of such notice, delay such presentation, publication or disclosure in order to enable NovaDel to file, or have filed on its behalf or jointly, as applicable, a patent application, copyright or other appropriate form of intellectual property protection related to the information to be disclosed or request that Licensee do so. Upon receipt of such request to delay such presentation, publication or disclosure, Licensee shall arrange for a delay of such presentation, publication or disclosure until such time as Licensee or NovaDel has filed, or had filed on its behalf, such patent application, copyright or other appropriate form of intellectual property protection in form and in substance reasonably satisfactory to NovaDel. If Licensee does not receive any such request from NovaDel to delay such presentation, publication or disclosure, Licensee may submit such material for presentation, publication or other form of disclosure. Notwithstanding the foregoing, in no event shall Licensee have any right to publish or disclose the Licensed Process or any information or data related thereto without the prior written consent of NovaDel, which consent NovaDel may withhold in its sole discretion.

ARTICLE 14  
PAYMENTS, NOTICES AND OTHER COMMUNICATIONS

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by telecopier (and promptly confirmed by personal delivery, registered or certified mail or overnight courier as provided herein), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to NovaDel to:

NovaDel Pharma Inc.  
31 State Highway 12  
NovaDel, NJ 08822  
Attention: President  
908.782.3431 (fax)

with a copy (not constituting notice) to:

Covington & Burling  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004  
Attention: John A. Hurvitz, Esq.  
202.662.6291 (fax)

If to Licensee to:

Manhattan Pharmaceuticals, Inc.  
787 Seventh Avenue, 48th Floor  
New York, NY 10019  
Attention: President  
212.554.4355 (fax)

with a copy (not constituting notice) to:

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given (a) when delivered, if personally delivered or sent by telecopier on a business day, (b) on the business day after dispatch, if sent by nationally-recognized overnight courier, and (c) on the third business day following the date of mailing, if sent by mail. It is understood and agreed that this Article 16 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

#### ARTICLE 15 CONFIDENTIALITY

15.1 DEFINITION. "Confidential Information" of a Party shall mean all information and know-how and any tangible embodiments thereof provided by or on behalf of such Party to the other Party either in connection with the discussions and negotiations pertaining to, or in the course of performing, this Agreement, including the terms of this Agreement; the Designated Compounds; data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For purposes of this Agreement, notwithstanding the Party that disclosed such information or know-how, all NovaDel Know-How and all Information and Inventions with respect to the Licensed Process shall be Confidential Information of NovaDel.

15.2 EXCLUSIONS. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information with respect to a receiving Party for purposes of this Agreement if such receiving party can affirmatively demonstrate through the production of written documentation that such information or know-how:

15.2.1 was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party;

15.2.2 was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party;

15.2.3 became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party through no fault of a Party other than the Party that Controls such information and know-how;

15.2.4 was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that Controls such information and know-how not to disclose such information or know-how to others; or

15.2.5 was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that Controls such information and know-how, except with respect to the NovaDel Know-How with respect to the Licensed Process, which shall be and remain Confidential Information of NovaDel.

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

15.3 DISCLOSURE AND USE RESTRICTION. Except as expressly provided herein, the Parties agree that during the Term of this Agreement, and for five (5) years thereafter, each Party and its Affiliates and sublicensees shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information of the other Party, its Affiliates or Sublicensees.

15.4 AUTHORIZED DISCLOSURE. Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

15.4.1 REQUIRED BY GOVERNMENTAL ORDER. Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that such Party shall first have given notice to such other Party and given such other Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

15.4.2 REQUIRED BY LAW. Otherwise required by law; provided, however, that the disclosing Party shall (a) provide the other Party with reasonable advance

notice of and an opportunity to comment on any such required disclosure, (b) if requested by such other Party, seek confidential treatment with respect to any such disclosure to the extent available, and (c) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment;

15.4.3 REQUIRED BY REGULATORY AUTHORITY. Made by such Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information; or

15.4.4 REQUIRED BY AGREEMENT. Made by such Party, in connection with the performance of this Agreement, to Affiliates, Sublicensees, research parties, employees, consultants, representatives or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 16.

15.5 PRESS RELEASES. Press releases or other similar public communication by either Party relating to this Agreement, shall be approved in advance by the other Party, which approval shall not be unreasonably withheld or delayed, except for those communications required by Applicable Law (which shall be provided to the other Party as soon as practicable after the release or communication thereof), disclosures of information for which consent has previously been obtained, and information of a similar nature to that which has been previously disclosed publicly with respect to this Agreement, each of which shall not require advance approval.

#### ARTICLE 16 MISCELLANEOUS PROVISIONS

16.1 GOVERNING LAW. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

16.2 REGISTRATION. If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee shall assume all legal obligations to do so and the costs in connection therewith.

16.3 TRADE REGULATIONS. Licensee shall observe all applicable United States and foreign laws with respect to the transfer of Licensed Product and related technical data to foreign countries, including the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations.

16.4 ENTIRE AGREEMENT. The Parties hereto acknowledge that this Agreement, including the Appendices and documents incorporated by reference, sets forth the entire agreement and understanding of the Parties hereto as to the subject matter hereof, and shall not be subject to any change of modification except by the execution of a written instrument subscribed to by the Parties hereto. This Agreement shall supersede all previous

communications, representations or understandings, either oral or written, between the Parties relating to the subject matter hereof.

16.5 SEVERABILITY. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision prohibited or unenforceable in any respect.

16.6 WAIVER. The failure of either 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.

16.7 EQUITABLE RELIEF. Each Party acknowledges and agrees that the restrictions set forth in Articles 6 and 16 of this Agreement are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of Article 6 and 16 may result in irreparable injury to such other Party. Each Party also acknowledges and agrees that in the event of a violation or threatened violation of any provision of Article 6 and 16, the other Party shall be entitled to seek preliminary and permanent injunctive relief, without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to such other Party. Nothing in this Section 16.7 is intended, or should be construed, to limit such other Party's right to preliminary and permanent injunctive relief or any other remedy for breach of any other provision of this Agreement.

16.8 FORCE MAJEURE. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is

necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for one-hundred and eighty (180) days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure, the non-performing Party may terminate this Agreement pursuant by written notice to the other Party.

16.9 CONSTRUCTION. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

16.10 FURTHER ASSURANCE. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

16.11 EXPENSES. Each of Licensee and NovaDel shall be responsible for their own expenses relating to the negotiation, execution and performance of this Agreement.

16.12 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.

16.13 BINDING. This Agreement shall not be binding upon the Parties until it has been signed below on behalf of each Party, in which event, it shall be effective as of the Effective Date.

IN WITNESS WHEREOF, the duly authorized officers of the Parties have executed this Agreement as of the dates set forth below their respective signatures.

NOVADEL PHARMA INC.

MANHATTAN PHARMACEUTICALS, INC.

By: /s/ Gary A. Shangold

By: /s/ Leonard Firestone

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Name: Gary A. Shangold

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Name: Leonard Firestone

Title: President and Chief Executive Officer

Title: President and Chief Executive Officer

Date: April 8, 2003

Date: April 4, 2003

[Pursuant to Item 601(b)(2) of Regulation S-K, the exhibits and schedules have been omitted from this agreement. The Registrant will furnish a copy of any omitted schedule or exhibit to the Commission upon request.]