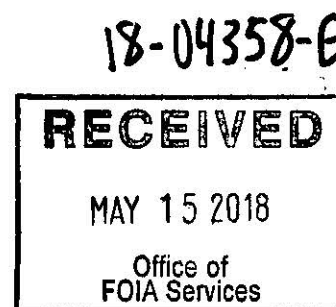




FOIA / PA Officer John Livornese
U.S. Securities & Exchange Commission
FOIA Office
100 F Street NE, Mail Stop 5100
Washington, DC 20549



May 15, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231, 110 Stat. 3048, copies of the following agreements, based on the **CT Order File No. 000-23776 - CF# 22170**.

Exhibit 10.10 to Form 10-Q filed on 05/15/2008 by DARA BioSciences, Inc.
Exhibit Title: Exclusive License Agreement
CIK: 919745

Exhibit 10.11 to Form 10-Q filed on 05/15/2008 by DARA BioSciences, Inc.
Exhibit Title: Exclusive License Agreement
CIK: 919745

Exhibit 10.12 to Form 10-Q filed on 05/15/2008 by DARA BioSciences, Inc.
Exhibit Title: Exclusive License Agreement
CIK: 919745

Sectilis will pay up to \$183 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos
Research Assistant
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814



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

Office of FOIA Services

June 27, 2018

Ms. Stella Vasconcellos
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04358-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on May 15, 2018, for Exhibits 10.10, 10.11, and 10.12 to Form 10-Q filed on May 15, 2008 by DARA BioSciences, Inc.

The search for responsive records has resulted in the retrieval of the enclosed records that may be responsive to your request.

If you have any questions, please contact me at jacksonw@sec.gov or (202) 551-8312. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Jeffery Ovall as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in cursive script that reads "Warren E. Jackson".

Warren E. Jackson
FOIA Research Specialist

Enclosures

EXCLUSIVE LICENSE AGREEMENT

This Agreement is made effective the 22nd day of December 2006 (the "Effective Date"), by and between Nuada, LLC, a North Carolina limited liability company having an address at 406 Blackwell Street, Suite 200, Durham, NC 27701 ("Nuada"), and DARA BioSciences, Inc., a Delaware corporation having an address at 4505 Falls of Neuse Road, Suite 125, Raleigh, NC 27609 ("DARA"). Nuada and DARA may be referred to herein individually as a "Party" or together, as the "Parties".

In consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows.

I. Definitions.

For the purpose of this Agreement, the following definitions shall apply.

"Affiliate" means any Person that, directly or indirectly, controls, is controlled by or is under common control with a Party for so long as such control exists. For purposes of this definition, the term "control" means the decision-making authority as to such Person, through ownership of equity, membership interests or contract. Such control will be presumed to exist where a Person owns more than fifty percent (50%) of the equity entitled to vote regarding composition of the board of directors or other body entitled to direct the affairs of the entity.

"API" means therapeutically active pharmaceutical ingredient.

"Combination Product" means any Product that is a pharmaceutical preparation for human use incorporating two or more APIs, at least one of which is not a Licensed API.

"Control" means, with respect to any Licensed Patent or Licensed Know-How, possession of the right, 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 Licensed Patent or Licensed Know-How as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

"Exploitation" means to make, have made, import, use, sell, offer for sale, or otherwise dispose of, including any and all discovery, research, development, registration, modification, enhancement, improvement, manufacture, storage, formulation, exportation, transportation, distribution, promotion and marketing activities related thereto.

"First Commercial Sale" means the first shipment of commercial quantities of any Product sold to a Third Party by a Party, its Affiliate or Sublicensee in any country after receipt of Marketing Authorization Approval for such Product in such country. Sales for test marketing, sampling and promotional uses, clinical trial or research purposes, compassionate uses, or to an Affiliate or Sublicensee for resale will not be considered to constitute a First Commercial Sale.

"Governmental Authority" means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, (ii) a federal, state, provincial, county, city or other political subdivision thereof, or (iii) any supranational body, including but not limited to, the United States Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products.

"Laws" means all laws, statutes, rules, regulations (including but not limited to, current Good Manufacturing Practice regulations as specified in 21 C.F.R. §§ 210 and 211; Investigational New Drug Application regulations at 21 C.F.R. § 312; NDA regulations at 21 C.F.R. § 314; relevant provisions of the Federal Food, Drug and Cosmetic Act, and other laws and regulations enforced by the FDA), ordinances and other pronouncements having the binding effect of law of any Governmental Authority.

"Licensed API" means an API which is the subject of Valid Claims in the Licensed Patents.

"Licensed Know-How" means all inventions, discoveries, improvements, information, formulations, methods, processes, materials, data, drawings, sketches, designs, testing and test results, records and Regulatory Documentation relating to the Licensed Patents.

"Licensed Patents" means those patents and patent applications listed on Exhibit A attached hereto, including United States provisional applications and foreign priority applications and any continuations, continuations-in-part, divisionals, registrations, confirmations, revalidations, reissues, Patent Cooperation Treaty (PCT) applications, utility models, design patents, petty patents as well as all related extensions, restorations of terms and/or reissues and foreign counterparts of the foregoing (including extensions granted under the US Drug Price Competition and Patent Term Restoration Act 1984 and the EC Supplementary Protection Certificate Regulation (Council Regulation (EEC) No. 1768/92), any legislation, amending, replacing or implementing the foregoing, and any similar or equivalent extension under any applicable Law), and all other intellectual property related to the application or patent including supplementary protection certificates or any other such right; in each case, to the extent the same has not been held, by a court or Governmental Authority of competent jurisdiction, to be invalid or unenforceable in a decision from which no appeal can be taken.

"Marketing Authorization Approval" means all approvals, licenses, registrations or authorizations required by or from a Governmental Authority for sale and marketing of a product in its jurisdiction, including any applicable pricing, final labeling and reimbursement approvals of such Governmental Authority.

"Net Sales" means the total gross amounts invoiced for sales of a Product by DARA or any of its Affiliates or Sublicensees less, to the extent included in the gross invoice amount, the following: (a) reasonable and customary trade, quantity, or cash discounts, rebates, retroactive price reductions, credits, or other allowances actually allowed or granted from the billed amount and taken; (b) tariffs, duties, and sales, customs, excise, use, value added, consumption, or similar taxes (provided that, to the extent any of the foregoing paid with respect to the sale of a Product are recovered by DARA, such amounts shall be included in Net Sales during the calendar quarter in which they are recovered); (c) allowances, rebates, credits and refunds for returned, damaged, recalled, or defective products; and (d) shipping, freight, and insurance costs.

A "sale" will include any transfer or other disposition for consideration, and Net Sales will include the fair market value of all consideration received by DARA, its Affiliates or Sublicensees in respect of any sale of a Product, whether such consideration is in cash payment, in kind, set off or in any other form, subject to the deductions in (a) through (d) above; provided, however, that sales of Products for clinical trials, test marketing, promotional purposes, sampling purposes, or research purposes, or compassionate uses shall not constitute Net Sales for purposes of this Agreement; provided further, however, that, notwithstanding the foregoing, any such sales for clinical trials made following Market Authorization Approval for a Product in a manner and at a price substantially equivalent to those of such Product when sold for purely commercial purposes (e.g. sale at full price for use in Phase IV clinical studies) shall not be excluded from Net Sales. Amounts received by DARA or its Affiliates or Sublicensees for the sale of Products among DARA and its Affiliates and Sublicensees for resale shall not be included in the computation of Net Sales hereunder.

"Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, joint venture, proprietorship or other *de jure* entity organized under the Laws of any jurisdiction.

"Phase I Clinical Trial(s)" means, with respect to the United States, the first phase of human clinical trials, typically including clinical trials conducted in relatively small numbers of healthy volunteers or patients with the condition to obtain information on, typically, a Product's safety, tolerability, pharmacological activity, pharmacokinetics, drug metabolism and mechanism of action, as more fully defined in 21 C.F.R. § 312.21(a), as may be amended, and, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

"Phase II Clinical Trial(s)" means, with respect to the United States, well-controlled clinical trials in human subjects, including clinical trials conducted in patients with the condition, and typically designed to evaluate clinical activity (including but not limited to, pertinent pharmacodynamic effects or biomarker responses) and safety for a Product for one or more indications, as well as to obtain an indication of the dosage regimen required, as more fully defined in 21 C.F.R. § 312.21(b), as may be amended, and, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

"Phase III Clinical Trial(s)" means, with respect to the United States, large-scale, pivotal, clinical trials conducted in a sufficient number of human patients whose primary objective is typically to obtain a definitive evaluation of the therapeutic efficacy and safety of a Product in patients for the particular indication in question that is needed to evaluate the overall risk-benefit profile of such Product and to provide an adequate basis for obtaining requisite regulatory approval(s) and product labeling, as more fully defined in 21 C.F.R. § 312.21(c), as may be amended, and, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

"Product" means a product, the manufacture, use, sale, offer for sale, or import of which would, but for the licenses granted hereunder, infringe a Valid Claim of a Licensed Patent or that incorporates Licensed Know-How.

"Regulatory Authority" shall mean any applicable Government Authorities regulating or otherwise exercising authority with respect to the Exploitation of a Product.

"Sublicensee" shall mean any sublicensee of DARA or an Affiliate thereof with respect to any of the rights granted under this Agreement.

"Third Party" means a Person who is not a Party or an Affiliate of a Party.

"Term" means the period from the Effective Date until termination in accordance with Section 7 of this Agreement or, if later, the later of (i) expiration or termination of the last Valid Claim of a patent right within the Licensed Patents or (ii) the twentieth (20th) anniversary of this Agreement.

"Valid Claim" means any claim pending in a patent application or in an unexpired patent that has not been held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through reissue or disclaimer.

2. Grant.

2.1 License. Subject to the terms of this Agreement, effective as of the Effective Date, Nuada grants to DARA a worldwide exclusive license, with rights of sublicense, under the Licensed Patents to Exploit Products and a worldwide nonexclusive license, with rights of sublicense under the Licensed Know-How to Exploit Products.

2.2 Sublicenses. DARA may grant sublicenses to Third Parties and its Affiliates with respect to the rights licensed hereunder without Nuada's prior written consent, provided that such sublicenses are consistent with the relevant terms of this Agreement.

3. Diligence.

3.1 Within 180 days of the Effective Date, DARA shall provide to Nuada a copy of DARA's initial plan for the Exploitation of Products, which is subject to change or update at any time by DARA in its sole discretion.

3.2 DARA shall, during the Term, use commercially reasonable efforts to diligently pursue the Exploitation of at least one Product under the licenses granted hereunder. The activities of DARA's Affiliates and their Sublicensees shall be deemed the activities of DARA for purposes of satisfying this Section 3.2.

3.3 DARA shall, during the Term, submit annual progress reports to Nuada for each year within 90 days after the end of such year. The progress reports will discuss in reasonable

detail the progress and results, as well as ongoing plans, with respect to the Exploitation of the Products. Nuada shall also have the right to meet with DARA's senior business, scientific and technical personnel to discuss such information at a mutually acceptable time and place.

4. Consideration. In consideration for the license of the Licensed Patents and the Licensed Know-How hereunder, DARA agrees to pay Nuada the following amounts.

4.1 License Fee. DARA shall pay Nuada **[\$10,000]** on the Effective Date.

4.2 Milestone Fees. DARA shall pay the amounts detailed below within 120 days of the achievement of the corresponding milestones.

<u>Milestone</u>	<u>Milestone Fee</u>
The dosing of the first patient in the first Phase I Clinical Trial conducted by or on behalf of DARA or its Affiliates or Sublicensees with respect to a Product.	\$ [100,000]
The receipt of final results of the first Phase II Clinical Trial conducted by or on behalf of DARA or its Affiliates or Sublicensees with respect to a Product, which results would permit the commencement of a Phase III Clinical Trial.	\$ [350,000]
The receipt of final results of the first Phase III Clinical Trial conducted by or on behalf of DARA or its Affiliates or Sublicensees with respect to a Product, which results would permit the submission of a new drug application to the Federal Drug Administration.	\$ [1,000,000]
Marketing Authorization Approval in the first Major Market (defined below) for the sale of a Product.	\$ [4,000,000]
Marketing Authorization Approval in the second Major Market for the sale of a Product.	\$ [500,000]

"Major Market" shall mean any of the United States, Japan or any country that is a member of the European Union.

Each milestone payment above shall only be made once under this Agreement upon the initial accomplishment of the relevant milestone by the first Product to achieve it, regardless of the number of Products or indications with respect thereto satisfying such milestone.

4.3 Running Royalties.

4.3.1 DARA shall pay Nuada, within 45 days following the end of each calendar quarter, (i) **[two and one-half percent (2.5%)]** of Net Sales of all Products in countries in

which there is a Valid Claim of a Patent claiming the use, sale, or manufacture of Products, until the aggregate of such Net Sales in all countries equals [\$400,000,000], after which the royalty rate on any subsequent Net Sales in excess of [\$400,000,000] in the same calendar year will increase to [three percent (3.0%)], and (ii) [one-half percent (0.5%)] of Net Sales of all Products in countries in which there is not a Valid Claim of a Patent claiming the use, sale, or manufacture of such Products.

4.3.2 Notwithstanding anything to the contrary in this Agreement, all royalties payable under this Section 4.3 shall be paid on a country-by-country basis from the date of First Commercial Sale of a Product in a particular country.

4.4 Duration of Royalty Payments. All royalty obligations under this Agreement with respect to a particular Product shall expire at the end of the Term. Upon the expiration of all royalty obligations under this Agreement, the licenses granted to DARA by Nuada under this Agreement will become non-exclusive, perpetual, irrevocable, fully-paid, and royalty-free.

4.5 Bundling. In the event that a Product is included as a "bundle" of products or services, DARA may discount Net Sales of such Product for purposes of calculating royalties due under this Agreement by no more than the average percentage discount of all products subject to reimbursement by managed health care organizations, health insurers, and government agencies in a manner similar to that of the Product ("Comparable Products") in a particular "bundle," calculated as $[1 - (A/B)] \times 100$, where "A" equals the total discounted price of the portion of a particular "bundle" consisting of such products, and "B" equals the sum of the undiscounted bona fide list prices of each unit of every such product in such "bundle". DARA will provide to Nuada, to the extent reasonably available or ascertainable, documentation establishing such average discount with respect to each "bundle". If DARA cannot so establish the average discount of a "bundle," Net Sales for the "bundled" Product will be based on (i) the median selling price of the Product alone during the applicable calendar quarter, if the Product is sold in a non-"bundled" form during such calendar quarter, or, if such Product is not sold in a non-"bundled" form during such calendar quarter, (ii) the undiscounted list price of the Product in the "bundle". If a Product in a "bundle" is not sold separately, and/or no bona fide list price exists for such Product or the other Comparable Products included in the "bundle," then the Parties will negotiate in good faith, based on a commercially reasonable determination of the relative values and/or imputed prices of the "bundled" product's constituent products and Product, and imputed discounts provided with respect thereto, an alternative determination of Net Sales with respect to the Product included in such "bundled" product consistent with the intent of this Section 4.5.

4.6 Combination Products. In the event a Product is sold which is a Combination Product, for purposes of determining payments due under Section 4.3, Net Sales of Combination Products shall be calculated by multiplying the Net Sales of the Combination Product by the fraction $A/(A+B)$, in which A is the Gross Selling Price (as defined below) of the Product when such Product is sold in substantial quantities containing a Licensed API as the sole API during the applicable accounting period in which the Net Sales of the Product were calculated, and B is the Gross Selling Price of products incorporating solely the other APIs contained in the Combination Product sold separately in substantial quantities during the applicable accounting

period. In the event that no separate sale of either the Product containing a Licensed API as the sole API or products incorporating solely the other APIs of the Combination Product are made during the accounting period in which the Net Sales were calculated, or if the Gross Selling Price for a product solely incorporating a particular API cannot be determined for the applicable accounting period, Net Sales allocable to the Product and Combination Product shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on a reasonably equitable method of determining same that takes into account variations in potency, the relative contribution of each API in the Combination Product, and relative value to the end user of each API. For purposes of this Section, "Gross Selling Price" shall mean the gross price at which a product incorporating such API as the sole API is sold to a Third Party, before discounts, deductions, credits, taxes or allowances.

4.7 Third Party Royalties. In the event that:

(a) a Product is deemed by a final, unappealable decision of a court of competent jurisdiction to infringe a claim of a patent(s) owned or controlled by a Third Party in any given country and such infringement is directly related to the manufacture, use, practice, or sale of the Licensed Patents, and DARA, an Affiliate thereof, or any Sublicensee licenses such patent(s) in settlement of such claims ("Infringement License"), or

(b) DARA, an Affiliate thereof, or any Sublicensee determines, in its reasonable discretion, including (1) consultation with its patent counsel and (2) the provision to Nuada of a reasonable opportunity to discuss such determination, that it is commercially, reasonably necessary to obtain a license to practice any Third Party's rights in any given country in order to avoid, with respect to the Exploitation of a Product, (i) infringement or misappropriation of such Third Party's rights or (ii) infringement- or misappropriation-related litigation with respect to such Third Party rights, provided that, in either case, such possible infringement or misappropriation is directly related to the manufacture, use, practice, or sale of the Licensed Patents (such license, a "Necessary License"), and, provided further, that DARA or its Affiliate or any Sublicensee provides Nuada a reasonable opportunity to discuss and evaluate the necessity of such license,

then DARA may deduct up to one hundred percent (100%) of any fees, milestones or royalties paid by DARA, an Affiliate thereof, or any Sublicensee to Third Parties for Infringement Licenses and Necessary Licenses (or such amounts paid by DARA, an Affiliate thereof, or any Sublicensee in settlement of any related infringement action) from the amounts otherwise due but not yet paid to Nuada pursuant to Sections 4.2 and 4.3 hereof; provided, however, that, notwithstanding the foregoing, (i) the total amount due to Nuada under this Agreement with respect to any particular calendar quarter shall not be reduced by more than fifty percent (50%) as a result of any adjustments under this Section 4.7 and (ii) any amounts not deducted in a calendar quarter as a result of the application of (a) and/or (b) above shall be carried forward for deduction in the subsequent calendar quarter(s), subject to such fifty percent (50%) limitation in each case.

4.8 Compulsory Licenses. Should a compulsory license be granted to a Third Party under the applicable Laws of any country under the Licensed Patents, or with respect to

Products, DARA shall notify Nuada, including any material information concerning such compulsory license, prior to the grant of such compulsory license and the running royalty rate payable hereunder for sales of Products in such country will be adjusted, if necessary, to match any lower royalty rate granted to such Third Party for such country with respect to the sales of such Products, provided that during such periods such Third Parties sell or offer for sale under the compulsory license articles that compete with the Products then marketed and sold by DARA, its Affiliates, or Sublicensees in that country.

4.9 Tax Withholding. In addition, in the event any of the payments made by DARA pursuant to this Section 4 become subject to withholding taxes under the Laws of any jurisdiction, such amounts payable to Nuada shall be reduced by the amount of taxes deducted and withheld, and DARA shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Nuada an official tax certificate or other evidence of such tax obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Nuada to claim such payment of taxes. Any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, Nuada. DARA will provide Nuada with reasonable assistance, as requested by Nuada, at Nuada's expense, to enable Nuada to recover such taxes as permitted by Law.

4.10 Net Sales Report. Within 45 days following the end of each calendar quarter following the First Commercial Sale, DARA will submit to Nuada a written report setting forth Net Sales (including the detailed computation thereof) on a country-by-country basis and Product-by-Product basis during such calendar quarter and calendar year-to-date, total royalty and milestone payments due to Nuada, relevant sales and pricing data in support of royalties paid on Product sold as a "bundle" and Combination Products, and relevant information as necessary to support any reduction in royalties paid resulting from the application of Section 4 hereof.

4.11 Payment Terms. All sums due to Nuada will be payable in United States dollars. Except as otherwise set forth herein with respect to royalties and milestones, all other payments due hereunder will be paid within thirty (30) days following receipt of an invoice requesting such payment.

4.12 Financial Records: Audits. DARA will keep at its corporate headquarters, accurate and complete records of milestones achieved and Net Sales reasonably sufficient to determine the amounts due to Nuada under this Agreement. Such records will be retained by DARA for at least the three (3) calendar years following the end of the calendar year during which such Net Sales or milestones were achieved. During normal business hours and with reasonable advance written notice to DARA, such records will be made available for inspection, copying, review and audit, at the request of Nuada, by an independent certified public accountant appointed by Nuada and reasonably acceptable to DARA for the purpose of verifying the accuracy of accounting reports and payments pursuant to this Agreement. Such auditor will be required to enter into a confidentiality agreement with DARA prior to performing the audit. The final report of the auditor, including methodology and supporting documentation, will be transmitted to both Parties. Such audits may not be performed by Nuada more than once per calendar year. All costs and expenses incurred in performing any such audit will be paid by

Nuada unless the audit discloses at least a five percent (5%) shortfall in payments made with respect to the audited time period(s), in which case DARA will bear the costs and expenses of the audit. Nuada will be entitled to recover any shortfall in payments as determined by such audit.

5. Certain Warranties.

5.1 Mutual Representations and Warranties. DARA and Nuada each represents and warrants to the other, with respect to itself and not the other Party, as of the Effective Date that:

(a) Such Party (i) is a company duly organized, validly existing and in good standing under the Laws of its jurisdiction of organization; (ii) has the requisite power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; and (iii) has obtained all necessary licenses, permits, consents, or approvals from or by, and has made all necessary notices to, all Governmental Authorities having jurisdiction over such Party, required for entering into and performing this Agreement;

(b) The execution, delivery and performance of this Agreement by such Party (i) are within the corporate or limited liability company power of such Party; (ii) have been duly authorized by all necessary or proper corporate or limited liability company action; (iii) do not conflict with any provision of the organizational documents of such Party; (iv) do not, to such Party's knowledge, violate any Law or any order or decree of any court or Governmental Authority; and (v) do not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, loan, agreement or other instrument to which such Party is a party, or by which such Party is bound; and

(c) This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

5.2 Nuada Representations and Warranties. Nuada hereby represents, warrants and covenants that:

(a) Nuada Controls all of the rights, title and interest in and to the Licensed Patents and Licensed Know-How as necessary to enter into and grant the licenses contemplated by this Agreement;

(b) Nuada does not have any present knowledge from which it would reasonably conclude that the Licensed Patents are invalid or that the Exploitation of any technology claimed therein would infringe patent rights of Third Parties;

(c) Nuada has not omitted to furnish DARA with any material information requested by DARA, or intentionally concealed from DARA, any material information in its possession concerning the Licensed Patents, the Licensed Know-How, or the subject matter of the transactions contemplated by this Agreement which would be material to DARA's decision to enter into this Agreement and to undertake the commitments and obligations set forth herein;

(d) Neither Nuada nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any Person obtaining any interest in, or that would give to any Person any right to assert any claim in or with respect to, any rights granted to DARA under this Agreement or anticipated to be the subject of the licenses contemplated hereby;

(e) Nuada has not, and during the Term of the Agreement will not, grant any right to any Third Party relating to the Licensed Patents or the Licensed Know-How that conflicts with the rights or obligations of DARA hereunder;

(f) During the Term, Nuada shall not, without the prior written consent of DARA, encumber the Licensed Patents or the Licensed Know-How with liens, mortgages, security interests or another similar interest that would give the holder the right to convert the interest into ownership, unless the encumbrance is expressly subject to DARA's rights under this Agreement and the license agreements contemplated hereby;

(g) Nuada has furnished, or will furnish promptly after the Effective Date, to DARA all tangible manifestations of the Licensed Know-How which Nuada Controls as of the Effective Date;

(h) Nuada has taken reasonable measures, using its good faith business judgment, to protect the confidentiality of the Licensed Know-How; and

(i) With respect to the Licensed Patents:

(1) No Licensed Patent is the subject of any pending interference, opposition, cancellation or other protest proceeding;

(2) Nuada has no knowledge of any claim pending, threatened or previously made in writing alleging infringement or misappropriation by Nuada of any patent, trade secret or other intellectual property right of any Third Party; and

(3) Nuada is not aware of any Third Party activities which would constitute misappropriation or infringement of any of the Licensed Patents.

5.3 Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS SECTION 5, NEITHER PARTY MAKES AND EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES AND RENOUNCES ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ALL WARRANTIES ARISING FROM ANY COURSE OF DEALING OR PERFORMANCE OR USAGE OF TRADE.

6. Patents.

6.1 Prosecution and Maintenance of Patents. DARA shall, as between the Parties, bear the cost of all future patent expenses associated with the preparation, filing, prosecuting, issuance, and maintenance of patents and patent applications included in the Licensed Patents following the Effective Date. The Parties acknowledge and agree that the foregoing obligation shall include, but not be limited to, the costs and expenses associated with the Licensed Patents due in December for filings in Australia, Canada, India, Japan, the United States and the European Union. Such filings, prosecution, and maintenance shall be by counsel of DARA's choosing, under the primary control and direction of DARA, and shall be in the name of Nuada. DARA shall keep Nuada advised as to such filing, prosecution, issuance, and maintenance by forwarding to Nuada copies of all material official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating thereto. Nuada shall have the right to comment and advise DARA as to the conduct of such filing, prosecution, and maintenance, provided, however, that DARA shall have the right to make the final decisions for all matters associated with such filing, prosecution, and maintenance. In the event that DARA elects not to maintain or prosecute any patent or patent application within the Licensed Patents, (i) DARA shall give Nuada sixty (60) days prior written notice of such election and (ii) Nuada will thereafter have the right, but not the obligation, upon written notice to DARA during such sixty (60) day period, at Nuada's sole expense, to prosecute and/or maintain such patents or patent applications, in light of the commercial interests of both parties, in the name of Nuada.

6.2 Indemnification.

6.2.1 Indemnification Claims. If (a) a claim is brought by a Third Party alleging patent infringement by DARA, its Affiliates, or their Sublicensees with respect to the development, manufacture, use, sale, offer for sale or importation of Products, (b) a civil action is brought by a Third Party arising out of or relating to the practice of the Licensed Patents, or (c) any Third Party challenges the validity of any claims of any Licensed Patent, each Party will give prompt written notice to the other Party of such claim (collectively, an "Indemnification Claim"). DARA will, at its sole cost and expense, (i) defend such Indemnification Claim, (ii) assume all costs, expenses, damages and other obligations for payments incurred in connection with such Indemnification Claim, and (iii) indemnify and hold harmless Nuada and its managers, members, Affiliates, successors and assigns from and against any and all damages, losses, liabilities and costs relating to or arising out of such Indemnification Claim. DARA shall be free to enter into a settlement, consent judgment, or other voluntary disposition of such Indemnification Claim, provided that any settlement, consent judgment or other voluntary disposition of such Indemnification shall (x) contain a full and unconditional release of Nuada and its managers, members, Affiliates, successors and assigns, (y) not subject Nuada to any liability or obligation and (z) not admit fault or wrongdoing on the part of Nuada. Nuada agrees to cooperate with DARA, at DARA's expense, in any reasonable manner deemed by DARA to be necessary in defending any such Indemnification Claim. DARA shall reimburse Nuada for any reasonable out of pocket expenses incurred in providing such assistance. Any recovery or damages received by DARA in any action or settlement under this Section 6.2.1 with respect to the rights licensed under this Agreement shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses incurred in connection with such action, and the

remainder shall be deemed Net Sales subject to royalties under Section 4.3. Notwithstanding the foregoing, either Party, at its expense, shall have the right to be represented by counsel of its choice in any such proceeding controlled by the other Party.

6.2.2 Infringement of Patents. In the event that DARA or Nuada becomes aware of actual or threatened infringement of any Licensed Patent during the Term, that Party will promptly notify the other Party in writing, which notice shall include any known material details concerning such infringement or misappropriation. With respect to any alleged actual or threatened infringement of the Licensed Patents, DARA shall have the first and primary right, but not the obligation, to, in its sole discretion, to initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, on its behalf or in Nuada's name, if necessary, with respect to such alleged infringement or misappropriation. If, within twelve (12) months of the notice above, DARA (i) shall have been unsuccessful in persuading the alleged infringer or misappropriator to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement or misappropriation action, or (iii) has not entered into settlement discussions with respect to such infringement or misappropriation, or if DARA notifies Nuada that it has decided not to undertake any of the foregoing against any such alleged infringer or misappropriator, then Nuada shall then have the right, but not the obligation, to bring suit to enforce the Licensed Patents, or to seek relief with respect to such misappropriation, at its own expense. In any such litigation brought by DARA, DARA shall have the right to, if and as reasonably necessary or useful in such action, use and sue in Nuada's name, and Nuada shall cooperate reasonably, as requested by DARA and at DARA's expense (which expense shall be reasonable and documented). The Party pursuing or controlling any action against an alleged infringer or misappropriator pursuant to the foregoing (the "Controlling Party") shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action, provided, however, that (i) the Controlling Party shall consult with the other Party (the "Secondary Party") prior to entering into any settlement thereof and (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) materially limits the scope, validity, or enforceability of any Licensed Patent (if Nuada is the Secondary Party), (2) subjects the Secondary Party to any non-indemnified liability or obligation, or (3) admits fault or wrongdoing on the part of Secondary Party, must be approved in writing by Secondary Party, such approval not to be unreasonably withheld. Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within ten (10) business days of any request for such approval by the Controlling Party, provided that (i) in the event Secondary Party wishes to deny such approval, such notice shall include a written description of Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (ii) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such ten (10) business day period. Any recovery or damages received by the Controlling Party with respect to the infringement or misappropriation of DARA's rights under the Licensed Patents shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses incurred in connection with such action, and the remainder shall be deemed Net Sales and subject to the payment of royalties to Nuada under Section 4.3 above. Notwithstanding the foregoing, the Secondary Party, at its expense, shall have the right to be represented by counsel of its choice in any such proceeding.

6.3 Assistance. For purposes of this Section 6, the Party not bringing suit or defending any suit will, at the expense of the other Party, execute such legal papers or take such actions necessary for the prosecution or defense of such suit as may be reasonably requested by the Party bringing suit or defending any suit.

7. Term and Termination.

7.1 Term. Unless otherwise mutually agreed to by the Parties or earlier terminated as provided herein, this Agreement will commence on the Effective Date and will end upon expiration of the Term. Except in the event of termination under Section 7.2, the licenses granted by Nuada to DARA pursuant to Section 2 will be considered fully-paid and will become perpetual, irrevocable, and non-exclusive upon expiration of the Term.

7.2 Termination for Material Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event that the other Party materially breaches in the performance of its obligations under this Agreement; provided that, if such breach can be cured, the breaching Party will have thirty (30) days after receipt of written notice thereof from the non-breaching Party to cure such breach. Any such termination will become effective at the end of such 30-day period unless the breaching Party has cured any such breach prior to the expiration of such 30-day period. Notwithstanding the foregoing, in the event of a breach by DARA of the provisions of Section 3.2, such breach shall be considered to be a material breach for purposes of this Section 7.2, and DARA's right to cure any such breach shall be limited only to its first breach of Section 3.2, and DARA shall not have the right to cure any subsequent breach of the provisions of Section 3.2.

7.3 Effects of Termination.

7.3.1 Effect of Termination for Material Breach.

(a) Material Breach by DARA. In the event this Agreement is terminated by Nuada pursuant to Section 7.2 for material breach by DARA, all licenses granted by Nuada to DARA or its Affiliates under this Agreement will terminate, subject to Section 7.3.2, provided that, notwithstanding the foregoing, DARA and its Affiliates shall have the privilege, subject to the payment of royalties as required under Section 4, of (i) completing the manufacture of any Products in the process of manufacture as of the effective date of such termination (the "Termination Date"), (ii) selling such Products and all finished Products in DARA's or its Affiliates' possession or under their control as of the Termination Date for a period of one year following the Termination Date upon commercially reasonable conditions, and (iii) completing performance of all contracts entered into with Third Parties prior to the Termination Date for the marketing, sale, or manufacture of Products for a period of one year following the Termination Date.

(b) Material Breach by Nuada. In the event this Agreement is terminated by DARA pursuant to Section 7.2 for material breach by Nuada all licenses granted by Nuada to DARA or its Affiliates under this Agreement prior to termination will survive, subject to DARA's continued obligation to pay milestones and royalties to Nuada hereunder.

7.3.2 Sublicenses. If this Agreement is terminated by Nuada for DARA's breach, pursuant to Section 7.2, all sublicenses granted to Third Parties regarding the intellectual property rights licensed to DARA by Nuada hereunder prior to such termination shall survive and be automatically assigned to, and enforceable by, Nuada upon such termination, subject to the payment of any future amounts due thereunder to Nuada, in order to permit such Sublicensees' continued quiet enjoyment of their rights thereunder in accordance with the terms thereof; provided, however, that such assignment shall not subject Nuada to any obligations or liabilities in excess of those imposed by this Agreement.

7.4 Accrued Rights; Surviving Obligations. Except as provided elsewhere, termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration will not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement, including but not limited to, definitions, rights to payment, and Sections 6.2, 6.3, 7, 8, 9, and 10 and will not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination or expiration.

8. Confidential Information.

8.1 Definition. "Confidential Information" means confidential or proprietary information, data or know-how, whether provided in written, oral, visual or other form, provided by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with this Agreement, including but not limited to, the terms of this Agreement and information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products. Confidential Information will not include any such information that: (i) is already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure (as evidenced by written records of the Receiving Party); (ii) is or becomes generally available to the public other than through any act or omission of the Receiving Party; (iii) is disclosed to the Receiving Party without obligation of confidentiality by a Third Party who had the legal right to disclose such information; or (iv) is independently discovered or developed by or on behalf of the Receiving Party without the use or benefit of the Confidential Information of the Disclosing Party (as evidenced by written records of the Receiving Party).

8.2 Confidentiality. The Receiving Party will keep in confidence all Confidential Information of the Disclosing Party with the same degree of care it employs to maintain the confidentiality of its own Confidential Information, but no less than a reasonable degree of care. The Receiving Party will not use such Confidential Information for any purpose other than in performance of or exercise of its rights under this Agreement or disclose the same to any other Person other than to such of its employees, agent, or subcontractors who have a need to know such Confidential Information to implement the terms of or exercise of its rights under this Agreement. A Receiving Party will advise any employee, agent or subcontractor who receives Confidential Information of such obligations, and the Receiving Party will ensure that all such agents, employees and subcontractors comply with such obligations as if they had been a Party

hereto. The Receiving Party will be liable for breach of this Section 8 by any of its employees, agents or subcontractors. Notwithstanding the foregoing, nothing in this Section 8 shall limit or preclude DARA's use or disclosure of Nuada's Confidential Information in its reasonable efforts to Exploit the Licensed Patents.

8.3 Permitted Disclosure and Use. The Receiving Party will have the right to disclose Confidential Information if, in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is required by Law or the rules of any stock exchange, provided that, to the extent reasonably practicable, the Receiving Party gives adequate prior notice of such disclosure to the Disclosing Party to permit the Disclosing Party to intervene and to request protective orders or other confidential treatment. The Receiving Party will cooperate reasonably with any such efforts by the Disclosing Party.

8.4 Confidentiality of this Agreement. The terms of this Agreement will be deemed Confidential Information of each Party. Either Party may disclose the terms of this Agreement (i) if, in the opinion of its counsel, such disclosure is required by Law, provided that such Party will seek appropriate confidentiality of those portions of the Agreement for which confidential treatment or a protective order is typically permitted by the relevant Governmental Authority or (ii) as necessary in connection with any financing, merger, strategic partnership, or other similar transaction, subject to the execution of confidentiality agreement with the Third Party.

8.5 Return. Upon termination of this Agreement, the Receiving Party will return or destroy all documents or other media containing Confidential Information of the Disclosing Party.

8.6 Remedies. Money damages will not be an adequate remedy if this Section 8 is breached and, therefore, either Party may, in addition to any other legal or equitable remedies, seek an injunction or other equitable relief against such breach or threatened breach without the necessity of posting any bond or surety.

8.7 Survival. This Section 8 will survive the expiration or termination of this Agreement for a period of ten (10) years.

9. Indemnification; Limitation of Liability.

9.1 Indemnification by DARA. Subject to Sections 9.3 and 9.4, DARA will defend, indemnify and hold harmless Nuada and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all actions, suits, proceedings, hearings, investigations, charges, complaints, claims, demands, injunctions, judgments, orders, decrees, rulings, damages, dues, penalties, fines, costs, amounts paid in settlement, liabilities, obligations, losses, taxes, liens, diminutions in value, costs, expenses and fees (including reasonable attorneys' fees and expenses, and the costs of investigation incurred in defending against or settling any such matter and any amounts paid in settlement thereof) (collectively, "Losses") arising out of claims made by Third Parties, to the extent arising out of (i) DARA's negligence or willful misconduct in performing any of its obligations or exercising its rights under this Agreement, (ii) breach by DARA of any of its representations, warranties, covenants,

or agreements under this Agreement or (iii) the Exploitation of Products by DARA, its Affiliates, agents, subcontractors or Sublicensees, except to the extent resulting from the negligence or willful misconduct, breach of this Agreement, or failure to comply with applicable Laws by Nuada or its Affiliates, sublicensees, officers, directors, employees, contractors, agents, other representatives, successors, or assigns.

9.2 Indemnification by Nuada. Subject to Sections 9.3 and 9.4, Nuada will defend, indemnify and hold harmless DARA and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Losses arising out of claims made by Third Parties, to the extent arising out of (i) Nuada's negligence or willful misconduct in performing any of its obligations or exercising its rights under this Agreement or (ii) breach by Nuada of any of its representations, warranties, covenants or agreements under this Agreement, except to the extent resulting from the negligence or willful misconduct, breach of this Agreement, or failure to comply with applicable Laws by DARA or its Affiliates, sublicensees, officers, directors, employees, contractors, agents, other representatives, successors, or assigns.

9.3 Procedure for Indemnification. A Party which intends to seek indemnification under this Section 9 (such Party hereinafter referred to as the "Indemnitee") for a Loss in respect to a Claim by a Third Party ("Third Party Claim"), will promptly give written notice thereof to the Party from whom indemnification is sought (such other Party hereinafter referred to as the "Indemnitor") within a reasonable period of time after the assertion of such Third Party Claim; provided, however, that the failure to provide written notice of such Third Party Claim within a reasonable period of time will not relieve Indemnitor of any of its obligations hereunder, except to the extent that Indemnitor is materially prejudiced by such failure. Indemnitor may assume the complete control of the defense, compromise or settlement of any Third Party Claim (provided that any settlement of any Third Party Claim that (i) subjects Indemnitee to any non-indemnified liability or (ii) admits fault or wrongdoing on the part of Indemnitee will require the prior written consent of such Indemnitee, provided such consent will not be unreasonably withheld), including, at its own expense, employment of legal counsel, and at any time thereafter Indemnitor will be entitled to exercise, on behalf of Indemnitee, any rights which may mitigate the extent or amount of such Third Party Claim; provided, however, that if Indemnitor will have exercised its right to assume control of such Third Party Claim, Indemnitee (i) may, in its sole discretion and at its own expense, employ legal counsel to represent it (in addition to the legal counsel employed by Indemnitor) in any such matter; (ii) will, at Indemnitor's own expense, make available to Indemnitor those employees, officers, contractors, and directors of Indemnitee whose assistance, testimony or presence is necessary or appropriate to assist Indemnitor in evaluating and in defending any such Third Party Claim; provided, however, that any such access will be conducted in such a manner as not to interfere unreasonably with the operations of the businesses of Indemnitee; and (iii) will otherwise fully cooperate with Indemnitor and its legal counsel in the investigation and defense of such Third Party Claim.

9.4 Consequential Damages. EXCEPT WITH RESPECT TO BREACHES OF SECTION 8, BREACHES OF THE LICENSES GRANTED HEREUNDER, OR CLAIMS FOR PATENT INFRINGEMENT, IN NO EVENT WILL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, TREBLE

OR CONSEQUENTIAL DAMAGES INCLUDING LOST PROFITS, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY; PROVIDED, HOWEVER, THAT, NOTWITHSTANDING THE FOREGOING, THIS LIMITATION WILL NOT LIMIT THE INDEMNIFICATION OBLIGATION OF SUCH PARTY IN RESPECT OF THIRD PARTY LOSSES UNDER THE PROVISIONS OF THIS SECTION 9.

9.5 Setoffs. If DARA shall be entitled to be indemnified for Losses in accordance with this Section 9 or, as determined by a court of competent jurisdiction, suffers damages as a result of a breach of this Agreement by Nuada, the parties hereby agree that DARA shall set off the amount of such Losses or damages (subject to the limitations of Section 9.4) from existing or future amounts, if any, owed to Nuada pursuant to this Agreement, and nothing in this Agreement shall be construed to require or permit DARA to seek indemnification from Nuada or other legal relief prior to offsetting any such Losses or damages from amounts owed to Nuada hereunder.

10. Miscellaneous.

10.1 Public Announcements. Except as may be expressly permitted under this Section 10.1 or required by applicable Laws or the rules of any stock exchange, neither Party will make any public announcement of any information regarding this Agreement without the prior written approval of the other Party, which approval will not be unreasonably withheld, conditioned, or delayed, provided that, notwithstanding the foregoing, DARA shall have the right to identify Nuada as the licensor and to disclose the terms of this Agreement to actual or prospective investors, strategic partners, investment bankers, acquirors, acquisition targets, and regulatory authorities, in connection with its financing, regulatory, licensing, development, stockholder relations, and other business activities or that it may deem to be required in any prospectus, offering memorandum, or other document or filing prepared in connection with its compliance obligations under applicable securities Law or other applicable Law or regulation.

10.2 Relationship of the Parties. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party to this Agreement in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without such Party's approval. For all purposes, DARA's legal relationship under this Agreement to Nuada will be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement will be construed to establish a relationship of partners or joint venturers between the Parties.

10.3 Expenses. The fees and expenses of both DARA and Nuada incurred in connection with the negotiation, preparation and execution of this Agreement shall be paid as follows: (a) DARA shall pay the first \$8,000 of such fees and expenses, whether incurred by DARA or Nuada, (b) Nuada shall pay the next \$4,000, whether incurred by DARA or Nuada, and (c) any such amounts in excess of \$12,000 shall be paid one-half by DARA and one-half by Nuada.

10.4 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable

control of the Party affected or any of its Affiliates, and which could not with the exercise of due diligence have been avoided ("Force Majeure Event"), including but not limited to, fire, accident, strike, riot, civil commotion, act of God, inability to obtain raw materials, delay or errors by shipping companies or change in law, will not excuse such Party from the performance of its obligations or duties under this Agreement, but will merely suspend such performance during the Force Majeure Event. The Party subject to a Force Majeure Event will promptly notify the other Party of the occurrence and particulars of such Force Majeure Event and will provide the other Party, from time to time, with its estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected will use commercially reasonable efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty will promptly recommence. The Party subject to the Force Majeure Event will not be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 10.4.

10.5 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of North Carolina, excluding that body of law known as choice of law, and shall be binding upon the parties hereto in the United States and worldwide. All disputes with respect to this Agreement shall be brought and heard either in the North Carolina state courts located in Wake County, North Carolina, or the federal district court for the Eastern District of North Carolina located in Raleigh, North Carolina. The parties to this Agreement each consent to the in personam jurisdiction and venue of such courts. The parties agree that service of process upon them in any such action may be made if delivered in person, by courier service, by telegram, by telefacsimile or by first class mail, and shall be deemed effectively given upon receipt.

10.6 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided that either Party may assign this Agreement without such consent to any of its Affiliates or to a successor to all or substantially all of the assets or business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or other similar transaction. Any assignment in violation of this provision is void and without effect. This Agreement will be binding upon and inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

10.7 Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing, in English, and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

Nuada:

Nuada, LLC
c/o Intersouth Partners
406 Blackwell Street, Suite 200
Durham, NC 27701
Attn: Bob Bell
Facsimile: (919) 493-6649

DARA:

DARA BioSciences, Inc.
4505 Falls of Neuse Road, Suite 125
Raleigh, NC 27609
Attn: Richard A. Franco, Sr.
Facsimile: (919) 861-0239

or to such other address as the addressee will have last furnished in writing in accord with this provision. Any such communication shall be deemed given (a) when delivered, if personally delivered or sent by facsimile on a business day, (b) on the second business day after dispatch, if sent by an internationally recognized overnight courier, and (c) upon receipt, if sent in any other manner.

10.8 Severability. If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, that provision will be limited or eliminated to the minimum extent necessary so that this Agreement will otherwise remain in full force and effect and enforceable.

10.9 Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

10.10 Waiver. No waiver of any term or condition of this Agreement will be effective unless set forth in a written instrument that explicitly refers to this Agreement that is duly executed by or on behalf of the waiving Party. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, will be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any prior, concurrent or future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

10.11 Entire Agreement. This Agreement (including the appendices and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties, whether written or oral, including but not limited, to all proposals, negotiations, conversations, letters of intent, memoranda of understanding or discussions, between Parties relating to the subject matter of this Agreement and all past dealing or industry custom.

10.12 Modification. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and the clause to be modified, which amendment is signed by duly authorized representatives of DARA and Nuada.

10.13 Counterparts. This Agreement may be executed in any two counterparts, each of which, when executed, will be deemed to be an original and both of which together will constitute one and the same document.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have duly executed this Exclusive License Agreement on the dates indicated below.

NUADA, LLC

By: /s/ Robert M. Bell

Name: Robert Bell

Title: Manager

DARA BIOSCIENCES, INC.

By: /s/ Richard A. Franco

Name: RICHARD A. FRANCO

Title: PRESIDENT

EXHIBIT A

LICENSED PATENTS

<u>Title:</u>	<u>Status</u>	<u>Serial Number</u>	<u>Filing Date</u>	<u>Inventors</u>
Peptidase Inhibitors	Pending	PCT/US2005/025837	July 21, 2005	Royalty, Susan

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this "Agreement") is made effective as of July 1st, 2004 (the "Effective Date") by and between Kirin Brewery Company, Limited, a Japanese corporation with a principal place of business at 10-1 Shinkawa 2-chome, Chuo-ku, Tokyo 104-8288 Japan (hereinafter "Kirin"), and Dara Therapeutics, Inc., a Delaware corporation with a place of business at 1234 Airport Road, Suite #105, Destin, FL 32541 (hereinafter "Dara"). Each of Kirin and Dara may be referred to hereinafter as a "Party" and together as the "Parties."

WHEREAS, Kirin is the owner of or otherwise controls certain proprietary patents and technology relating to or otherwise useful in the production of Licensed Product (defined below); and

WHEREAS, Dara desires to obtain the exclusive right from Kirin to develop and commercialize Licensed Product in the Licensed Field (defined below) using such patents and technology; and

WHEREAS, Dara intends to conduct clinical trials of Licensed Product in the Licensed Field and requires sufficient supply of Drug Product (defined below) therefor; and

WHEREAS, Kirin desires to grant such rights and to supply, or assist in the supply by NCI of, Drug Substance (defined below) to Dara on the terms and conditions of this Agreement.

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

1. DEFINITIONS

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

1.1 "**Adverse Event**" shall mean any untoward medical occurrence in a patient or subject who is administered a Licensed Product, whether or not considered related to a Licensed Product, including, without limitation, any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Licensed Product.

1.2 "**Affiliate**" shall mean any corporation, firm, limited liability company, partnership or other entity that directly controls or is controlled by or is under common control with a Party to this Agreement. "Control" for purposes of this Section 1.2 means ownership, directly or indirectly through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, status as a

general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity.

1.3 "**BLA**" shall mean a biologics license application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) filed with the FDA seeking Regulatory Approval to market and sell any Licensed Product in the United States for a particular indication within the Licensed Field.

1.4 "**Confidential Information**" shall mean (a) with respect to a Party (the "Receiving Party"), any and all information (including all Licensed Technology, to the extent not publicly disclosed in connection with the development or marketing of Licensed Product), which is disclosed by the other Party (the "Disclosing Party") to the Receiving Party hereunder or to any of its employees, consultants, Affiliates, licensees or Sublicensees, at any time and from time to time during the Term, except to the extent that the information described in this Section 1.4, as shown by competent written documentation, (i) as of the date of disclosure is known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to such Party or its Affiliates; (ii) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (iii) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (iv) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party. "Confidential Information" shall include, without limitation, information relating to scientific, technical and economic information, business or research strategies, know-how, trade secrets, results of testing, and material embodiments thereof.

1.5 "**Control**" or "**Controlled**" shall mean, with respect to any data, results, information, inventions, know-how, formulas, trade secrets, techniques, methods, procedures, development, material or compositions of matter of any type or kind, whether or not patentable, or any intellectual property right, possession of the ability, whether by ownership or license, to assign, grant a license, sublicense, immunities or other rights as provided for herein to such item or under such right without violating the terms of any agreement or other arrangement with any Third Party.

1.6 "**CTA**" shall have the meaning set forth in Schedule B attached hereto.

1.7 "**Derivatives**" shall mean the specific structures possessing a SAN backbone described in allowed composition of matter claims of the Licensed Patent Rights.

1.8 "**Dara Inventions**" shall mean any pre-clinical and clinical data, invention or discovery relating to the manufacture or use of Licensed Product created, identified, developed, conceived or reduced to practice solely by employees of or consultants to Dara, during the Term.

1.9 "**Development**" and "**Develop**" shall mean, with respect to any Licensed Product, all activities with respect to such Licensed Product relating to research and development in connection with seeking, obtaining and/or maintaining any Regulatory Approval for such

Licensed Product in the Licensed Field in the Territory, including without limitation, all pre-clinical research and development activities, all human clinical studies, all activities relating to developing the ability to manufacture any Licensed Product or any component thereof (including, without limitation, process development work), and all other activities relating to seeking, obtaining and/or maintaining any Regulatory Approvals from the FDA and/or any Foreign Regulatory Authority.

1.10 "**Disclosing Party**" shall have the meaning set forth in Section 1.4 hereof.

1.11 "**Drug Approval Application**" shall mean any application for Regulatory Approval (including pricing and reimbursement approvals) required prior to any commercial sale or use of a Licensed Product in any country or jurisdiction in the Territory, including, without limitation, (a) any BLA or NDA filed with the FDA, and (b) any equivalent application filed with any Foreign Regulatory Authority for Regulatory Approval (including pricing and reimbursement approvals) required prior to any commercial sale or use of a Licensed Product in any country or jurisdiction in the Territory.

1.12 "**Drug Product**" shall mean formulated Drug Substance suitable for use in human clinical trials.

1.13 "**Drug Substance**" shall mean bulk active KRN5500.

1.14 "**FDA**" shall mean the United States Food and Drug Administration and any successor agency or authority thereto.

1.15 "**First Commercial Sale**" shall mean, on a country-by-country basis, the date of the first arm's length transaction, transfer or disposition for value to a Third Party of a Licensed Product by or on behalf of Dara or any Affiliate or Sublicensee in such country.

1.16 "**Foreign Regulatory Authority**" shall mean any applicable supranational, national, federal, state or local regulatory agency, department, bureau or other governmental entity of any country or jurisdiction in the Territory (other than the FDA in the United States), having responsibility in such country or jurisdiction for any Regulatory Approvals of any kind in such country or jurisdiction, and any successor agency or authority thereto.

1.17 "**IND**" shall mean an investigational new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) filed or to be filed with the FDA with regard to any Licensed Product or the equivalent application to perform clinical trials filed or to be filed with any Foreign Regulation Authority.

1.18 "**Intermediates of KRN5500**" shall mean SAN and TDG set forth in Section 1.32 and 1.36 hereof.

1.19 "**Know-how**" shall mean any and all inventions, improvements, discoveries, claims, formulae, processed, technologies and know-how (including Confidential Information) that generated, owned or Controlled by Kirin at any time before or during the term of this Agreement relating to, derived from or useful for the manufacture or use of the Licensed Product, including, without limitation, synthesis, preparation, recovery and purification process and techniques, control methods and assays, chemical data and specifications.

1.20 "**KRN5500**" shall mean 6-[2-Deoxy-4-[(2E, 4E) tetradecadienoyl]glycyl]amino-L-glycero-β-L-mannoheptopyranosyl]amino-9H-purine; NSC number: NSC 650426.

1.21 "**Licensed Field**" shall mean the treatment of pain and central and peripheral nervous system conditions or diseases.

1.22 "**Licensed Patent Rights**" shall mean any of the patents and patent applications listed on Schedule A attached hereto, any patents or patent applications claiming Know-how, and any divisional, continuation, continuation-in-part, reissue, re-examination, renewal, revalidation, registration or extension or substitute thereof, or any patent issuing therefrom or any supplementary protection certificates, patents of addition or any foreign counterparts related thereto.

1.23 "**Licensed Product**" shall mean any product (including without limitation KRN5500 and analogs and derivatives thereof) the manufacture, use or sale of which would, absent the license granted to Dara hereunder, infringe any Valid Claim included in the Licensed Patent Rights.

1.24 "**Licensed Technology**" shall mean and include the Technology listed on Schedule B attached hereto and all other Technology Controlled by Kirin as of the Effective Date or during the Term, whether or not patentable, that is (i) related to any Valid Claim or is necessary or useful for the practice of the license granted to Dara hereunder or (ii) necessary or useful for manufacturing KRN5500 and/or Licensed Product.

1.25 "**NCI**" shall mean the National Cancer Institute.

1.26 "**NDA**" shall mean a new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) filed with the FDA seeking Regulatory Approval to market and sell any Licensed Product in the United States for a particular indication within the Licensed Field.

1.27 "**Net Sales**" shall mean the gross invoiced sales price for all Licensed Product sold by Dara, its Affiliates or Sublicensees to Third Parties throughout the Territory during each calendar quarter, less the following amounts incurred or paid by Dara or its Affiliates or Sublicensees during such calendar quarter with respect to sales of Licensed Product regardless of the calendar quarter in which such sales were made:

(a) trade, cash and quantity discounts or rebates actually allowed or taken, including discounts or rebates to governmental or managed care organizations;

(b) credits or allowances actually given or made for rejection of, and for uncollectible amounts on, or return of previously sold Licensed Product (including Medicare and similar types of rebates);

(c) any charges for insurance, freight, and other transportation costs directly related to the delivery of Licensed Product to the extent included in the gross invoiced sales price;

(d) any tax, tariff, duty or governmental charge levied on the sales, transfer, transportation or delivery of a Licensed Product (including any tax such as a value added or similar tax or government charge) borne by the seller thereof, other than franchise or income tax of any kind whatsoever; and

(e) any import or export duties or their equivalent borne by the seller.

"Net Sales" shall not include sales or transfers between Dara and its Affiliates or Sublicensees, unless the Licensed Product is consumed by the Affiliate or Sublicensee. In the event that a Licensed Product under this Agreement is sold in combination with another active ingredient or component, then "Net Sales," for purposes of determining royalty payments on the combination, shall be calculated using one of the following methods:

- (i) By multiplying the Net Sales of the combination by the fraction $A/A+B$, where A is the gross selling price, during the royalty paying period in question, of the Licensed Product sold separately in similar quantities in the same country, and B is the gross selling price, during the royalty period in question, of the other active ingredients or components sold separately in similar quantities in the same country; or
- (ii) In the event that no such separate sales are made of the Licensed Product or any of the active ingredients or components in such combination package in similar quantities in the same country during the royalty paying period in question, Net Sales, for the purposes of determining royalty payments shall be calculated using the above formula where A is the reasonably estimated commercial value of the Licensed Product sold separately in similar quantities in the same country and B is the reasonably estimated commercial value of the other active ingredients or components sold separately in similar quantities in the same country. Any such estimates shall be determined using criteria to be mutually agreed upon by the Parties. Such estimates shall be reported to Kirin with the reports to be provided pursuant to Section 4.5.1 hereof.

1.28 "**Phase II Clinical Trial**" shall mean a clinical investigation (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) conducted to evaluate the effectiveness of a License Product for a particular indication within the Licensed Field in patients with the disease or indication under study.

1.29 "**Post Phase II Meeting**" shall mean a meeting between Dara and the FDA following completion of a Phase II Clinical Trial to test the safety and efficacy of a Licensed Product for a particular indication in the Licensed Field as a result of which Dara is authorized to proceed with a phase III clinical trial or to file a Drug Approval Application.

1.30 "**Receiving Party**" shall have the meaning set forth in Section 1.4 hereof.

1.31 "**Regulatory Approval**" shall mean any and all approvals (including pricing and reimbursement approvals), product and establishment licenses, registrations or authorizations of any kind of the FDA or any Foreign Regulatory Authority necessary for the development, pre-clinical and/or human clinical testing, manufacture, quality testing, supply, use, storage, importation, export, transport, marketing and sale of a Licensed Product (or any component thereof) for use in the Licensed Field in any country or other jurisdiction in the Territory. "Regulatory Approval" shall include, without limitation, any Drug Approval Application

1.32 "**SAN**" shall mean Spicamycinaminonucleoside—6-amino-[L-mannoheptopyranosyl]amino-9H-purine.

1.33 "**Sublicense**" shall mean an agreement with a Third Party to whom Dara grants a sublicense of some or all of the rights granted to Dara pursuant to Section 2.1 hereof.

1.34 "**Sublicensee**" shall mean a Third Party to whom Dara grants a Sublicense.

1.35 "**Sublicense Royalty**" shall have the meaning set forth in Section 4.3.2 hereof.

1.36 "**TDG**" shall mean Tetradecadienoylglycine.

1.37 "**Technology**" shall mean and include any and all unpatented proprietary ideas, inventions, discoveries, Confidential Information, biologic materials, data, results, formulae, designs, specifications, methods, processes, formulations, techniques, ideas, know-how, technical information (including, without limitation, structural and functional information), process information, pre-clinical information, clinical information, and any and all proprietary biological, chemical, pharmacological, toxicological, pre-clinical, clinical, assay, control and manufacturing data and materials.

1.38 "**Term**" shall have the meaning set forth in Section 8.1 hereof.

1.39 "**Territory**" shall mean all countries and jurisdictions of the world except Australia, New Zealand and all countries in Asia.

1.40 "**Third Party**" shall mean any person or entity other than Dara, Kirin and their respective Affiliates.

1.41 "**Third Party Payments**" shall have the meaning set forth in Section 4.3.4 hereof.

1.42 **“Valid Claim”** shall mean a claim of any issued unexpired patent within the Licensed Patent Rights that has not been held unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been rendered unenforceable through disclaimer or otherwise or which has not been lost through an interference proceeding.

2. GRANT OF RIGHTS

2.1 License to Dara.

2.1.1 **Grant of License.** Kirin hereby grants to Dara an exclusive, royalty-bearing license, including the right to grant sublicenses in accordance with Section 2.1.3 below, under the Licensed Patent Rights, Licensed Technology and Know-how to research, Develop, have Developed, manufacture, have manufactured, use, have used, sell, offer for sale, have sold, import, have imported, export and have exported, Licensed Product in the Territory, for any and all uses within the Licensed Field, subject to the terms and conditions of this Agreement.

2.1.2 **NCI Consents.** The grant of the license in Section 2.1.1 above with respect to any Licensed Technology owned by NCI is subject to Dara obtaining any required consent or agreement from NCI. Kirin will cooperate with Dara to obtain such consent or agreement, but Kirin does not guaranty that NCI will give such consent or agreement.

2.1.3 **Right to Sublicense.** Dara shall have the right to grant sublicenses to all or any portion of its rights under the license granted pursuant to Section 2.1.1 above to any Third Party; provided, however, that Kirin shall be notified of any and all executed Sublicenses.

2.2 Dara Inventions

2.2.1 **Ownership.** Dara shall solely own all right, title and interest in the Dara Inventions.

2.2.2 **Option.** Dara hereby offers to Kirin an exclusive option, on a country-by-country basis (each, an “Option”), for an exclusive royalty-free license (each, an “Extra-Territorial License”), with the right to grant sublicenses, under the Dara Inventions and/or any patent application or patent Controlled by Dara that claims the Dara Inventions to develop, manufacture, have manufactured, use, have used, sell, offer for sale, have sold, import, have imported, export and have exported, Licensed Product in the Licensed Field, for any country outside the Territory during the Term. Kirin shall exercise the Option by providing written notice to Dara during the Term of its intent to exercise such Option, provided, however, at any time during the Term, Dara may provide notice to Kirin that it intends to grant to a Third Party an Extra-Territorial License in a country or countries in which no Option has been exercised, which notice shall contain the terms to be offered to such Third Party. Kirin shall have sixty (60) days (the “Option Period”) following receipt of such notice to exercise the Option and enter into good faith negotiations with Dara. If Kirin provides written notice of its intent not to exercise the Option or upon expiration of the Option Period, Dara shall have the right to grant such Extra-Territorial license to any Third Party on the terms provided in the notice without any further obligation to Kirin with regard thereto.

3. DEVELOPMENT AND COMMERCIALIZATION OF LICENSED PRODUCT; SUPPLY AND MANUFACTURE OF KRN5500.

3.1 Commercialization.

3.1.1 Responsibility. On and after the Effective Date, Dara shall have full control and authority over all Development and commercialization of Licensed Product in the Licensed Field in the Territory including, without limitation, (a) all activities relating to manufacture and supply of all Licensed Product (including all required process development and scale up work with respect thereto), (b) all marketing, promotion, sales, distribution, import and export activities relating to any Licensed Product, and (c) all activities relating to any regulatory filings, registrations, applications and Regulatory Approvals relating to any of the foregoing. Dara shall own all data, results and all other information arising from any such activities under this Agreement, including without limitation, all regulatory filings, registrations, applications and Regulatory Approvals relating to Licensed Product including, without limitation, any INDs and any Drug Approval Applications, and all of the foregoing information, documentation and materials shall be considered Confidential Information and Technology solely owned by Dara. All activities relating to Development and commercialization under this Agreement shall be undertaken at Dara's sole cost and expense, except as otherwise expressly provided in this Agreement.

3.1.2 Diligence. Dara will exercise commercially reasonable efforts and diligence in developing and commercializing Licensed Product in the Licensed Field in the Territory, such reasonable efforts and diligence to be in accordance with the efforts and resources Dara would use for a product candidate owned by it or to which it has rights, which is of similar market potential as the applicable Licensed Product, taking into account the competitiveness of the marketplace, the proprietary position of the Licensed Product, the relative potential safety and efficacy of the Licensed Product, the cost of goods and availability of capacity to manufacture and supply the Licensed Product at commercial scale, the profitability of the applicable Licensed Product, and other relevant factors including, without limitation, technical, legal, scientific or medical factors.

3.2 Updates and Reports.

3.2.1 Updates and Reports. Dara shall provide Kirin with brief written reports no less frequently than annually during the Term (commencing with the first anniversary of the Effective Date) summarizing (i) Dara's material efforts to develop and commercialize all Licensed Product hereunder and (ii) any Dara Invention made during the period since the last such report. In addition, Dara shall provide Kirin with prompt written notice of the occurrence of the First Commercial Sale of any Licensed Product.

3.2.2 Adverse Events. Upon execution of a disclosure agreement between Dara and NCI, Dara may reference NCI's clinical data of Licensed Product including but not limited to Adverse Events and Serious Adverse Events Reports, pharmacokinetic and pharmacodynamic data, and relevant correspondence with the FDA. Kirin will provide

reasonable assistance as is reasonably requested by Dara. Additionally, subject to Kirin's exercise of an Option pursuant to Section 2.2.2 hereof, the Parties agree to provide each other with Adverse Event information and product complaint information relating to the relevant Licensed Product as compiled and prepared by each Party in the normal course of business in connection with the Development and commercialization of the relevant Licensed Patent Rights, within time frames consistent with reporting obligations under applicable laws and regulations.

3.2.3 All reports, updates, Adverse Event, product complaint and other information provided by one Party to the other Party under this Agreement (including under this Section 3), shall be considered Confidential Information of the disclosing Party, subject to the terms of Section 5.

3.3 KRN5500 Supply.

3.3.1 Supply of KRN5500. Within fourteen (14) days of Dara's written request, Kirin will provide 200g of Drug Substance from Lot SK032 (the "Lot SK032 Material"). Dara agrees to retest, at Dara's sole expense, the stability of the Lot SK032 Material at Midwest Research Institute ("MRI"), or another subcontractor of Dara's choosing, prior to use in clinical trials. If, in Dara's sole discretion, the Lot SK032 Material meets release specifications and is suitable for use in clinical trials, Dara may choose to use the Lot SK032 Material to manufacture Drug Product at Ben Venue Laboratories, or another subcontractor of Dara's choosing. In parallel, Dara will use commercially reasonable efforts to obtain 25g of Drug Substance from Lot SK030 (the "Lot SK030 Material") from the NCI. Dara agrees to retest the stability of any Lot SK030 Material received from NCI at MRI, or another subcontractor of Dara's choosing, prior to use in clinical trials, at Dara's sole expense. Pursuant to the CTA, Kirin has granted consent to the NCI to supply Drug Product and Drug Substance to Dara. Kirin agrees to help facilitate this supply process, if reasonably required. If, in Dara's sole discretion, the Lot SK030 Material meets release specifications and is suitable for use in clinical trials, Dara may choose to use the Lot SK030 Material to manufacture Drug Product at Ben Venue Laboratories or another subcontractor of Dara's choosing. If Dara judges any Lot SK032 Material or Lot SK030, for any reason, to be unacceptable for use in clinical trials or if there is insufficient quantities of Lot SK032 Material or Lot SK030 Material to complete the clinical trials undertaken by Dara, Kirin grants Dara the right to manufacture additional quantities of Drug Substance from Kirin's stockpile of raw materials and intermediates stored at Starks Associates, Inc. or elsewhere.

3.3.2 Spicamycin and Derivatives Supply. Within thirty (30) days of Dara's written request, Kirin shall supply, at no charge, reasonable quantities of SAN and TDG currently in Kirin's inventory in order to facilitate Dara's medicinal chemistry initiative to synthesize new Spicamycin analogues and Derivatives.

3.3.3 Nothing herein shall preclude Dara from making its own arrangements for the manufacture and supply of Drug Product, Drug Substance, intermediates for KRN5500, SAN, TDG, Spicamycin or any Derivatives on its own or with Third Parties. Dara hereby agrees that it shall use KRN5500 in compliance with all applicable federal, state and local laws.

3.4 Technology Transfer.

3.4.1 With fourteen (14) days of the Effective Date, Kirin shall provide to Dara all Know-how and process information Controlled by Kirin for manufacturing Drug Product from Drug Substance.

3.4.2 Within thirty (30) days of completion of a Phase II Clinical Trial, the results of which are sufficiently satisfactory to Dara to justify conducting Phase III trials, Kirin shall provide to Dara a reasonable quantity of viable cell line from working and master cell banks previously used to produce Spicamycin and shall provide to Dara all Technology Controlled by Kirin as of such date that is necessary for or useful in the manufacture of Drug Substance.

3.4.3 At such times during the Term as Dara shall request, Kirin shall also provide technical assistance as is reasonably requested by Dara, or its Sublicensees, in order to manufacture Drug Product and Drug Substance as contemplated under this Agreement. After completion of a Phase II Clinical Trial, the results of which are sufficiently satisfactory to Dara to justify conducting phase III clinical trials, Kirin's assistance shall include reasonably requested visits by qualified representatives of Kirin, to Dara's or its Sublicensees' manufacturing facilities for the purpose of validating Drug Product and/or Drug Substance manufacturing process conducted at such facilities.

3.5 **Commercial Supply.** At the request of Dara, the Parties will negotiate in good faith a commercial supply agreement; provided, however, neither Party shall be obligated to enter into it.

4. PAYMENTS AND ROYALTIES

4.1 **Upfront Fee.** In consideration of the grant of the license by Kirin hereunder, Dara hereby agrees to pay Kirin an upfront license fee in the amount of **[One Hundred Thousand Dollars (\$100,000)]** payable within thirty (30) days of execution of this Agreement, which payment shall be nonrefundable and noncreditable.

4.2 Milestone Payments.

4.2.1 **Payment.** In consideration of inclusion of access to Kirin's pre-clinical and clinical data, Kirin's provision of Know-how, Kirin's supply of Drug Substance, and the grant of the license by Kirin hereunder and subject to the other terms and conditions of this Agreement, Dara shall make the following nonrefundable, noncreditable payments to Kirin within thirty (30) days of the first occurrence of each of the following events by Dara or an Affiliate or Sublicensee:

<u>Milestone</u>	<u>Payment</u>
Submission to, and acceptance by, the applicable regulatory authority (after any required waiting period) of an IND (or foreign equivalent) for a Licensed Product	\$ [100,000]
Post Phase II Meeting	\$ [100,000]

It is hereby acknowledged and agreed that any milestone payment shall be made only once, with respect to the first achievement of the relevant milestone for the first Licensed Product, regardless of how many times such milestones are achieved by Licensed Product and regardless of how many times a particular Licensed Product achieves such milestones.

4.3 Payment of Royalties

4.3.1 Royalty Payments In further consideration of the grant of the license by Kirin hereunder, and subject to the other terms of this Agreement (including the remainder of this Section 4.3), commencing on the date of the First Commercial Sale of any Licensed Product and for the remainder of the Term, Dara shall pay to Kirin a royalty equal to **[four percent (4%)]** of Net Sales of any Licensed Product sold by Dara or its Affiliates in the Territory.

4.3.2 Sublicense Royalties. In addition to all other fees set forth above, and subject to the other terms of this Agreement (including the remainder of this Section 4.3), Dara shall pay to Kirin an amount equal to **[the lesser of the following ("Sublicense Royalties") determined on a quarterly basis: (i) twenty-five percent (25%) of all royalty payments received by Dara based on sales of Licensed Product in the Licensed Field in the Territory by Sublicensees, but not less than an amount equal to two percent (2%) of Sublicensee Net Sales, or (ii) four percent (4%) of all Sublicensee Net Sales.]**

4.3.3 One Royalty. Only one royalty, calculated at the highest applicable royalty rate under this Section 4.3, shall be payable to Kirin hereunder for each sale of a Licensed Product.

4.3.4 Third Party Royalty Offset. If in any period in which royalties or Sublicense Royalties are due, Dara, its Affiliates or Sublicensees actually make royalty payments to one or more Third Parties ("Third Party Payments") as consideration for a license to any patent application or issued patent claiming the Development, manufacture, use, sale, import, or export of Licensed Product, then Dara shall have the right to reduce the royalties or Sublicense Royalties, as the case may be, otherwise due to Kirin pursuant to this Section 4.3 for such Licensed Product by **[fifty percent (50%)]** of the full amount of such Third Party Payments during the same period. Notwithstanding the foregoing, such reductions shall in no event reduce such royalties or Sublicense Royalties, as the case may be, for such Licensed Product in any such country to less than **[fifty percent (50%)]** of the rates otherwise specified in this Section 4.3. In no event shall any reduction pursuant to this Section 4.3.4 be available with regard to royalties due for a license from The General Hospital Corporation under its intellectual property rights in Patent Application No. PCT US0129371, Publication No. WO02-24146 and in U.S. Patent No. 5,905,069.

4.4 Payment Terms

4.4.1 Payment of Royalties. Dara shall deliver to Kirin a written report on any royalty or Sublicense Royalty, within forty-five (45) days from the end of each quarter in such payment accrues, specifying: the gross sales (if available) and Net Sales in the applicable

currency; the applicable royalty rate under this Agreement; the royalties payable in each currency, including an accounting of deductions taken in the calculation of Net Sales and any applicable calculation pursuant to Section 4.3.4 hereof; the applicable exchange rate to convert from each country's currency to United States Dollars under this Section 4.4. For purposes of determining when a sale of any Licensed Product occurs under this Agreement, royalties shall accrue on the date of the invoice to the purchaser of the Licensed Product. Dara shall make any royalty or Sublicense Royalty payments owed to Kirin hereunder in arrears, within sixty (60) days from the end of each quarter in which such payment accrues.

4.4.2 Overdue Royalties. Subject to the other terms of this Agreement, royalties not paid within the time period set forth in this Section 4 shall bear interest at a rate of **[one percent (1%)]** per month from the due date until paid in full.

4.4.3 Accounting. All payments hereunder shall be made in United States dollars by wire transfer of immediately available funds in accordance with the wiring instructions furnished by Kirin in writing. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in *The Wall Street Journal*) on the last business day of the calendar quarter for which the royalties are paid. If *The Wall Street Journal* ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States as the Parties reasonably agree. Dara shall deduct any taxes that it is obligated to pay and/or withhold on the payments due under this Agreement and pay them to the proper authorities as required by applicable laws. Therefore, it is agreed and understood that any amount to be paid under the terms of this Agreement is net of any such tax. Dara shall maintain official receipts of payment of any such taxes and forward these receipts to Kirin within sixty (60) days and shall provide reasonable assistance to Kirin in obtaining any credit or refund of such taxes.

4.5 Records Retention; Review.

4.5.1 Records. Commencing as of the date of the First Commercial Sale of the first Licensed Product, Dara and its Affiliates and Sublicensees shall keep for at least three (3) years from the end of the calendar year to which they pertain complete and accurate records of sales by Dara, its Affiliates or Sublicensees, as the case may be, of each Licensed Product, in sufficient detail to allow the accuracy of the payments hereunder to be confirmed.

4.5.2 Review. Subject to the other terms of this Section 4.5.2, at the request of Kirin (which shall not be made more frequently than once per calendar year during the Term), upon at least thirty (30) days' prior written notice from Kirin, and at the expense of Kirin (except as otherwise provided herein), Dara shall permit an independent certified public accountant reasonably selected by Kirin and reasonably acceptable to Dara to inspect (during regular business hours) the relevant records required to be maintained by Dara under this Section 4.5 for the then-preceding three (3) years for purposes of verifying Dara's royalty calculations. In every case the accountant must have previously entered into a confidentiality agreement with Dara, or with Kirin and naming Dara as a third party beneficiary thereof, substantially similar to the provisions of Section 5 and limiting the disclosure and use of such information by such accountant to authorized representatives of the Parties and the purposes germane to this Section 4.5. No other information shall be shared. Results of any such review

shall be binding on both Parties absent manifest error. Kirin agrees to treat the results of any such accountant's review of Dara's records under this Section 4.5 as Confidential Information of Dara subject to the terms of Section 5 hereof. If any review reveals a deficiency in the calculation of royalties resulting from any underpayment by Dara, Dara shall promptly pay Kirin the amount remaining to be paid, and if such underpayment is by ten percent (10%) or more, Dara shall pay the reasonable out-of-pocket costs and expenses of the review.

4.5.3 Other Parties. Dara shall include in any agreement with its Affiliates or Sublicensees record retention and record review terms substantially similar to those in Section 4.5.2 above. Subject to the other terms of such agreement, at the request of Kirin (which shall not be made more frequently than once per calendar year during the Term), upon at least thirty (30) days' prior written notice from Kirin, and at the expense of Kirin, Dara shall inspect or have a Third Party inspect, such Affiliate's or Sublicensee's records.

5. TREATMENT OF CONFIDENTIAL INFORMATION

5.1 Confidential Obligations. Kirin and Dara each recognize that the other Party's Confidential Information constitutes highly valuable and proprietary confidential information. Kirin and Dara each agree that during the Term and for five (5) years thereafter, it will keep confidential, and will cause its employees, consultants, Affiliates and Sublicensees to keep confidential, all Confidential Information of the other Party. Neither Kirin nor Dara nor any of their respective employees, consultants, Affiliates or Sublicensees shall use Confidential Information of the other Party for any purpose whatsoever other than exercising any rights granted to it or reserved by it hereunder. Without limiting the foregoing, each Party may disclose information to the extent such disclosure is reasonably necessary in (i) filing and prosecuting patent applications and maintaining patents which are filed in accordance with the provisions of this Agreement, (ii) granting Sublicenses permitted hereunder, (iii) filing, prosecuting or defending litigation in accordance with the provisions of this Agreement or (iv) complying with applicable laws, regulations or court orders; provided, however, that if a Party is required to make any such disclosure of the other Party's Confidential Information other than to a Third Party that agrees in writing to maintain the confidentiality of such Confidential Information, it will give reasonable advance notice to the other Party of such disclosure requirement and will use reasonable efforts to assist such other Party in efforts to secure confidential treatment of such information required to be disclosed. Confidential Information of Kirin shall include, without limitation, "INFORMATION" as defined in that certain Confidentiality Agreement between the Parties dated September 26, 2002.

5.2 Limited Disclosure and Use. Kirin and Dara each agree that any disclosure of the other Party's Confidential Information to any officer, employee, consultant or agent of the other Party or any of its Affiliates or Sublicensees shall be made only if and to the extent necessary to carry out its rights and responsibilities under this Agreement, shall be limited to the maximum extent possible consistent with such rights and responsibilities and shall only be made to persons who are bound by written confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement. Kirin and Dara each further agree not to disclose or transfer the other Party's Confidential Information to any Third Parties under any circumstance without the prior written approval from the other Party (such approval not to be unreasonably withheld),

except either Party may without such approval disclose Confidential Information of the other Party to: (i) a Sublicensee or prospective Sublicensee solely in connection with the exercise of such Party's rights under this Agreement, or a Third Party in connection with an actual or potential investment, loan, financing, merger or acquisition transaction with such Party; provided, that such Sublicensee, prospective Sublicensee or Third Party has undertaken in writing an obligation of confidentiality with respect to the Confidential Information substantially similar to that provided herein, (ii) as otherwise required by law, or (iii) as otherwise expressly permitted by this Agreement. Each Party shall take such action, and shall cause its Affiliates or Sublicensees to take such action, to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information, and in no event, less than reasonable care. Each Party, upon the request of the other Party, will return all the Confidential Information disclosed or transferred to it by the other Party pursuant to this Agreement, including all copies and extracts of documents and all manifestations in whatever form, within sixty (60) days of the request or, if earlier, the termination or expiration of this Agreement; provided however, that a Party may retain Confidential Information of the other Party relating to any license or right to use Licensed Technology which survives such termination and one copy of all other Confidential Information may be retained in inactive archives solely for the purpose of establishing the contents thereof.

6. PROVISIONS CONCERNING THE FILING, PROSECUTION AND MAINTENANCE OF PATENT RIGHTS

6.1 **Patent Maintenance.** Subject to the other terms of this Section 6.1, Kirin shall be responsible for preparing, filing and maintaining, at its sole cost, expense and discretion all Licensed Patent Rights. Kirin will keep Dara reasonably informed of the status of all such filings and maintenance, including, without limitation, (A) by providing Dara with copies of all communications received from or filed in patent office(s) with respect to such filings, and (B) by providing Dara, a reasonable time prior to taking or failing to take any action that would affect the scope or validity of any such filing (including the substantially narrowing, cancellation or abandonment of any claim(s) without retaining the right to pursue such subject matter in a separate application, or the failure to file or perfect the filing of any claim(s) in any country), with prior written notice of such proposed action or inaction so that Dara has a reasonable opportunity to review and comment. If Kirin fails to undertake the filing(s) of any patent submission with respect to any claim under the Licensed Patent Rights, then not less than ninety (90) days prior to the last date for making the applicable filing or submission to preserve rights under such patent, Dara may undertake such filing(s) at its own expense, in Kirin's name.

6.2 **Notice of Infringement.** If, during the Term, either Party learns of any actual, alleged or threatened infringement by a Third Party of any Licensed Patent Rights in the Licensed Field in the Territory, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement.

6.3 **Infringement of Patent Rights.** In the event of an actual, alleged or threatened infringement by a Third Party of any Licensed Patent Rights, the Parties shall mutually agree on the action to be taken to stop such infringement; provided, however, Kirin shall have the first right (but not the obligation), at its own expense and with legal counsel of its own choice, to bring suit (or take other appropriate legal action) against any actual, alleged or

threatened infringement of the Licensed Patent Rights in the Licensed Field. If Kirin does not file any action or proceeding against such infringement within six (6) months after the later of (i) Kirin's notice to Dara under Section 6.2 above, (ii) Dara's notice to Kirin under Section 6.2 above, or (iii) a written request from Dara to take action with respect to such infringement, then the Parties shall in good faith and in a timely manner discuss the appropriate legal action to stop such infringement, but if the Parties do not agree on another course of action, Dara shall, subject to Kirin's approval, which approval shall not be unreasonably withheld, have the right (but not the obligation), at its own expense, to bring suit (or take other appropriate legal action) against such actual, alleged or threatened infringement, with legal counsel of its own choice, but shall not be permitted to settle any such suit without the prior consent of Kirin, which consent shall not be unreasonably withheld. Any damages, monetary awards or other amounts recovered, whether by judgment or settlement, pursuant to any suit, proceeding or other legal action taken under this Section 6.3, shall applied as follows:

- (a) First, to reimburse the Parties for their respective costs and expenses (including reasonable attorneys' fees and costs) incurred in prosecuting such enforcement action;
- (b) Second, to Dara in reimbursement for lost sales (net of royalties) associated with Licensed Product and to Kirin in reimbursement for lost royalties owing hereunder based on such lost sales;
- (c) Third, any amounts remaining shall be allocated as follows: (a) if Kirin is the Party bringing such suit or proceeding or taking such other legal action, one hundred percent (100%) to Kirin, (b) if Dara is the Party bringing such suit or proceeding or taking such other legal action, one hundred percent (100%) to Dara, and (c) if the suit is brought jointly, fifty percent (50%) to each Party.

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

7. REPRESENTATIONS AND WARRANTIES

7.1 Kirin Representations. Kirin represents and warrants to Dara that:

- (a) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Kirin corporate action;
- (b) this Agreement is a legal and valid obligation binding upon Kirin and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by the Parties does not conflict with any agreement, instrument or understanding to which Kirin is a party or by which it is bound;

(c) Kirin has the full right and legal capacity to grant the rights to Dara pursuant to Section 2 above without violating the rights of any Third Party;

(d) Kirin is the sole owner or exclusive licensee of the Licensed Technology other than Licensed Technology identified as belonging to NCI;

(e) the Licensed Patents are the only patent applications or patents Controlled by Kirin that claim Licensed Product or the use thereof;

(f) Kirin is not aware of any Third Party patent, patent application or other intellectual property rights that would be infringed (i) by practicing any process or method or by making, using or selling any composition which is claimed or disclosed in, or which constitutes, Licensed Technology, or (ii) by making, using, offering for sale, selling or importing Licensed Product; and

(g) Kirin is not aware of any actual or threatened infringement by any Third Party of the Licensed Patents in the Licensed Field.

7.2 Dara Representations. Dara represents and warrants to Kirin that:

(a) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Dara corporate action; and

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

7.3 No Warranties.

Nothing in this Agreement is or shall be construed as:

(a) a warranty or representation by either Party as to the validity or scope of any patent application or patent licensed hereunder;

(b) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted pursuant to this Agreement is or will be free from infringement of patents, copyrights, and other rights of Third Parties.

7.4 Disclaimer. Except as expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR OF NON-INFRINGEMENT OF ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OF THIRD PARTIES, OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.

8. TERM AND TERMINATION

8.1 Term; Expiration. The term of this Agreement ("Term") shall commence upon the Effective Date and shall continue, unless terminated earlier pursuant to this Section 8, until the later of (a) the last to expire Valid Claim or (b) seven (7) years from the date of the First Commercial Sale of the first Licensed Product. Upon the expiration of the Term of this Agreement, Dara shall have a fully paid-up, irrevocable, freely transferable and sublicensable license under the Licensed Patent Rights and Licensed Technology, to Develop, have Developed, make, have made, use, have used, sell, have sold, offer for sale, import and have imported any and all Licensed Product for any and all uses in the Licensed Field, in the Territory.

8.2 Termination for Breach. Subject to the other terms of this Agreement, this Agreement and the rights and options granted herein may be terminated by either Party upon any material breach by the other Party of any material obligation or condition, effective ninety (90) days after giving written notice to the breaching Party of such termination, which notice shall describe such breach in reasonable detail. The foregoing notwithstanding, if such default or breach is cured or remedied or shown to be non-existent within the aforesaid ninety (90) day period, the notice shall be automatically withdrawn and of no effect. However, prior to giving any notice for breach, the Parties shall first attempt to resolve any disputes as to the existence of any breach as set forth in Section 9 hereof.

8.3 Effects of Termination.

8.3.1 Termination by Kirin. Upon any termination of this Agreement by Kirin under Section 8.2 above, as of the effective date of such termination, all relevant licenses and sublicenses granted by Kirin to Dara hereunder shall terminate automatically. Notwithstanding the foregoing, (a) no such termination of this Agreement shall be construed as a termination of any valid Sublicense hereunder, and thereafter each such Sublicensee shall be considered a direct licensee of Kirin, provided that (i) such Sublicensee is then in full compliance with all terms and conditions of its sublicense, and (ii) such Sublicensee agrees in writing to assume all applicable obligations of Dara under this Agreement, and (b) Dara and its Affiliates and Sublicensees shall have the right, for six (6) months or such longer time period (if any) on which the Parties mutually agree in writing, to sell or otherwise dispose of all Licensed Product then on hand, with royalties to be paid to Kirin on all Net Sales of such Licensed Product as provided for in this Agreement.

8.4 Remedies. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Section 8 are in addition to any other relief and remedies available to either Party at law.

8.5 Surviving Provisions. Notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in Sections 1, 5, 7, 8.3, 8.5, 9, and 10.3 as well as any rights or obligations otherwise accrued hereunder (including any accrued payment obligations), shall survive the expiration or termination of the Term. Without limiting the generality of the foregoing, Dara shall have no obligation to make any milestone or royalty payment to Kirin that has not accrued prior to the effective date of any termination of this Agreement, but shall remain liable for all such payment obligations accruing prior to the effective date of such termination.

9. DISPUTES

9.1 The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the Term that relates to either Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by written notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated senior officials are as follows:

For Dara: Chief Executive Officer

For Kirin: Vice President, Planning Department, Pharmaceutical Division

In the event the designated senior officials are not able to resolve such dispute within the thirty (30) day period, either Party may invoke the provisions of Section 9.2.

9.2 Any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement, or the performance by either Party of its obligations under this Agreement (other than bona fide Third Party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a Party), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be held in London, England in accordance with the then-prevailing Rules of Conciliation and Arbitration of the International Chamber of Commerce by a panel of three arbitrators appointed in accordance with such rules. The method and manner of discovery in any such arbitration proceeding shall be governed by the laws of England. The arbitrators shall have the authority to grant injunctions and/or specific performance and to allocate between the Parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.

10. MISCELLANEOUS

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

If to Kirin:	Katsuhiko Asano, Ph.D. Managing Executive Officer President of Pharmaceutical Division Kirin Brewery Company, Limited 26-1, Jingumae 6-chome, Shibuya-ku, Tokyo 150-8011 Japan Phone: +81-3-5485-6207 Fax: +81-3-3499-6152
If to Dara:	Dara Therapeutics, Inc. 1234 Airport Road, Suite #105 Destin, FL 32541 U.S.A. Phone: 850-650-1010 Fax: 850-650-2213
With a copy to:	Jeffrey M. Wiesen, Esq. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center Boston, MA 02111 U.S.A. Phone: (617) 542-6000 Fax: (671) 542-2241

All notices, requests and other communications hereunder shall be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving Party at the address of such Party set forth above, (ii) if made by telecopy or facsimile transmission, at the time that receipt thereof has been acknowledged by electronic confirmation or otherwise, (iii) if sent by private courier, on the third (3rd) business day following the day such notice is delivered to the courier service, or (iv) if sent by registered or certified mail, on the fifth (5th) business day following the day such mailing is made.

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

10.3 **Governing Law.** This Agreement will be construed, interpreted and applied in accordance with the laws of England (excluding its body of law controlling conflicts of law).

10.4 **Limitations.** Except as set forth elsewhere in this Agreement, neither Party grants to the other Party any right or license to any of its intellectual property.

10.5 **Entire Agreement.** This is the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements between the Parties with respect to the subject matter hereof including, without limitation, that certain Confidentiality Agreement between the Parties dated September 26, 2002. No modification shall be effective unless in writing with specific reference to this Agreement and signed by the Parties.

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

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

10.8 **Assignment.** Neither this Agreement nor any right or obligation hereunder may be assigned, delegated or otherwise transferred, in whole or part, by either Party without the prior express written consent of the other; provided, however, that either Party may, without the written consent of the other, assign this Agreement and its rights and delegate its obligations hereunder to its Affiliates, or in connection with the transfer or sale of all or substantially all of such Party's assets or business related to this Agreement, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 10.8 shall be void. The terms and conditions of this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the Parties.

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

10.10 **Construction.** The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

10.11 **Severability.** If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the Term hereof, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby. The Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in

order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid, illegal or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

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

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

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

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

DARA THERAPEUTICS, INC.

KIRIN BREWERY COMPANY, LIMITED

By: /s/ Steve Gorlin

By: /s/ Katsuhiko Asano

Name: Steve Gorlin

Name: Katsuhiko Asano, Ph.D.

Title: Chairman of the Board of Directors

Title: Managing Executive Officer
President of Pharmaceutical Division

Schedule A

Licensed Patent Rights

<u>Patent or Patent Application</u>	<u>Jurisdiction</u>	<u>Issue Date or Filing Date</u>
US Patent No. 5631238	United States	May 20, 1997
US Patent No. 5461036	United States	October 24, 1995

Schedule B

Licensed Technology

1. Technology and information developed under the AGREEMENT BETWEEN THE DIVISION OF CANCER TREATMENT DIAGNOSIS AND CENTERS, NATIONAL CANCER INSTITUTE AND KIRIN BREWERY COMPANY LIMITED FOR THE CLINICAL DEVELOPMENT OF KRN5500, dated January 17, 1996 and amended on November 8, 2002 (the "CTA").
2. Kirin's Drug Master File
3. Kirin's non-audited reports of clinical trials of KRN5500 in Japan for Dara's own use
4. Kirin's pre-clinical data on KRN5500, including acute, subchronic and chronic toxicity studies
5. Other pre-clinical data of Kirin that Kirin agrees is needed in Dara's IND
6. NCI's IND
7. NCI's clinical data, including but not limited adverse event and serious adverse event reports, pharmacokinetic and pharmacodynamic data and relevant correspondence with the FDA

EXHIBIT 10.12

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (the "Agreement") is entered into as of October 8, 2007 (the "Effective Date") by and between BAYER PHARMACEUTICALS CORPORATION, a Delaware corporation with offices located at 400 Morgan Lane, West Haven, CT 06516 ("Licensor"), and DARA BIOSCIENCES, INC., a Delaware corporation with its offices located at 4505 Falls of Neuse Road, Suite 125, Raleigh, NC 27609 ("Licensee"). Licensor and Licensee may be referred to herein individually as a "Party" or collectively, as the "Parties."

RECITALS

WHEREAS, Licensor owns certain intellectual property rights concerning PPAR α , PPAR γ , or PPAR δ compounds that may be potential pharmaceutical product opportunities;

WHEREAS, Licensee wishes to license such rights in order to research, develop and commercialize such successful pharmaceutical products; and

WHEREAS, the Parties desire to enter into an agreement granting Licensee the right to exploit such intellectual property rights on the terms described herein.

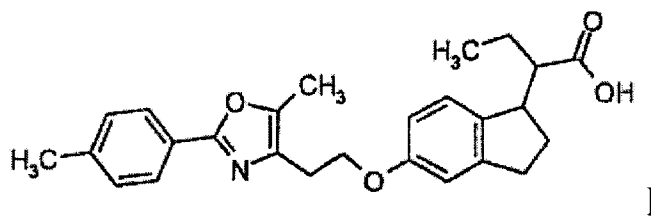
Now, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows;

1. DEFINITIONS

1.1 "Affiliate" means a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with a Party. For the purposes of this Section 1.1, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.2 "API" means active pharmaceutical ingredient.

1.3 "Bay 62-9069" means [2-(5-{2-[5-methyl-2-(4-methylphenyl)-1,3-oxazol-4-yl]ethoxy}-2,3-dihydro-1H-inden-1-yl)butanoic acid, represented by the following formula:



1.4 "Development Candidate" means (i) Bay 62-9069 or (ii) any other compound that (a) is covered, or the manufacture or use of which is covered, by a Valid Claim of any Licensed Patent and (b) consistently demonstrates EC₅₀ values greater than 5 micromolar with respect to

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PPAR_α, PPAR_γ, and PPAR_δ in a PPAR Assay performed consistent with generally-accepted scientific and industry standards. Any compound other than Bay 62-9069 that consistently demonstrates EC₅₀ values less than or equal to 5 micromolar with respect to any one (or more) of PPAR_α, PPAR_γ, or PPAR_δ in a PPAR Assay shall be excluded from the definition of Development Candidate.

1.5 "Combination Product" means a pharmaceutical product containing both (i) an API of a Licensed Product which is a subject of this Agreement and (ii) one or more other active ingredients or delivery systems for which rights are not included in the license granted under this Agreement but, with respect to the items in (ii), which may each or collectively form the basis for a separate product.

1.6 "Commence" or "Commencement," when used to describe a Phase 2 Trial or Phase 3 Trial, or any other human clinical trial of a Licensed Product, means the first dosing of the first patient for such trial.

1.7 "Commercialization" means all activities that are undertaken after Regulatory Approval of a particular Licensed Product and that relate to the commercial marketing and sale of such Licensed Product, including but not limited to prelaunch activities, advertising, marketing, promotion, distribution, and/or sales.

1.8 "Confidential Information" means all Information, and other information and materials, received by either Party from the other Party pursuant to this Agreement that: (i) is designated as confidential at the time of disclosure or promptly thereafter; (ii) under the circumstances surrounding disclosure should be treated as confidential by the receiving Party, or (iii) by reason of its nature would be treated as confidential by a reasonable receiving party, which would include, without limitation, trade secrets.

1.9 "Control" means, with respect to any intellectual property right, that a Party owns or has a license to such item or right, and has the ability to grant a license or sublicense in or to such right as set forth herein without violating the terms of any agreement or other arrangement with any Third Party.

1.10 "Develop" or "Development" means, with respect to a Licensed Product, engaging in preclinical, clinical, and other product development activities, which may include but is not limited to research, pre-clinical, clinical and regulatory activities directed towards obtaining Regulatory Approval of a Licensed Product in the Territory.

1.11 "Diabetes Product" means a Licensed Product developed and intended for the treatment of type 2 diabetes, as evidenced in Regulatory Filings made with respect to such Licensed Product.

1.12 "Diligent Efforts" means the carrying out of obligations or tasks in a manner consistent with the efforts a Party devotes to research, development or marketing of a pharmaceutical product or products of similar market potential, profit potential or strategic value resulting from its own research efforts, taking into account technical and regulatory factors, target product profiles, product labeling, past performance, costs, economic return, the regulatory

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environment and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing, and subject to and in consideration of, in each case, the resources available to such Party and within such Party's organization for such efforts.

1.13 "DMF" means a drug master file, as provided for in 21 CFR § 314.420 or similar submission to or file maintained with the FDA or other Governmental Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

1.14 "FDA" means the United States Food and Drug Administration, or any successor federal agency thereto.

1.15 "Field" means all uses and applications.

1.16 "First Commercial Sale" means the first sale of any Licensed Product sold to a Third Party by Licensee, its Affiliate or a sublicensee of either of the foregoing for human therapeutic or prophylactic use after receipt of Regulatory Approval for such Licensed Product. A sale for clinical trial, research, development, test marketing, sampling, promotional, or compassionate use purposes for which compensation is not received, or compensation is less than or equal to Licensee's cost of manufacturing or procuring such Licensed Product, will not be considered a First Commercial Sale.

1.17 "Governmental Authority" means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision.

1.18 "Improvements" means any improvements, enhancements, or modifications of any Licensed Products or other technology claimed in the Licensed Patents, or which would be useful or necessary in the manufacture, use, or sale of Licensed Products, which come under the Control of Licensor or its Affiliates during the Term.

1.19 "IND" means an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any equivalent agency or government authority outside of the United States (including any supra-national agency such as in the European Union) necessary to Commence human clinical trials in such jurisdiction, and including all regulations at 21 CFR § 312 et. seq., and equivalent foreign regulations.

1.20 "Information" means information, results and data of any type whatsoever, including without limitation, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and patent and other legal information or descriptions.

1.21 "Know-How" means any non-public, proprietary Information and other data, instructions, processes, methods, formulae, techniques, compositions, materials, expert opinions and information, including without limitation, biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data and information. Know-How does not include any rights under Patents.

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1.22 "Licensed Product" means a product the use, sale, or manufacture of which would be the subject of a Valid Claim pursuant to this Agreement

1.23 "Licensed Know-How" means all Know-How Controlled by Licensor or its Affiliates as of the Effective Date, or which is developed or acquired by and Controlled by Licensor or its Affiliates during the term of this Agreement, including but not limited to any Know-How related to Improvements, that is necessary or useful for the research, development, manufacture, importation, use or sale of Licensed Products.

1.24 "Licensed Patents" means (i) the patents and patent applications listed on Schedule 1.24, (ii) any Patents related or claiming priority thereto, and, to the extent Controlled by Licensor or its Affiliates as of the Effective Date or coming under the Control of Licensor or its Affiliates following the Effective Date, (iii) any Patents claiming Improvements and other Patents necessary or useful for the research, development, manufacture, importation, use or sale of Licensed Products.

1.25 "Licensed Technology" means Licensed Patents and Licensed Know-How.

1.26 "Major Market" means the United States of America, Germany, Japan, the United Kingdom, Italy, France, or Spain.

1.27 "Net Sales" means

(a) with respect to a Licensed Product (subject to subsections (b) and (c) below), the amount received by a Party or its Affiliate or a Third Party sublicensee for sales of such Licensed Product to Third Parties in countries where such Licensed Product is covered by a Valid Claim, excluding (i) reasonable returns, allowances, refunds, and rebates actually paid, granted or accrued, (ii) trade, quantity, cash, and other discounts and any other reasonable adjustments actually allowed or granted, including, but not limited to, those granted on account of price adjustments (including retroactive price adjustments), billing errors, rejected goods, damaged or defective goods, or recalls, (iii) chargebacks, rebates, reimbursements or similar payments or adjustments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers or other institutions, pharmacy benefit management companies, health maintenance organizations or other health care organizations, or any governmental or regulatory authority or agency (including their purchasers and/or reimbursers), (iv) adjustments arising from consumer discount programs, (v) customs or excise duties, tariffs, sales, consumption, value added, and other taxes (except income taxes) or similar payments related to particular sales or shipments of Licensed Products, and (vi) freight, handling, and insurance, provided that the exclusion for (vi) shall be limited to no greater than one and one-half percent (1.5%) of gross sales; and

(i) in the case of Combination Products, if Licensee and/or its Affiliate and/or any Third Party sublicensee of either of the foregoing separately sells in such country during such year when it sells such Combination Product both (1) one or more Licensed Products containing Licensed API(s) as their sole API(s) and (2) products containing the other API(s) or delivery system(s) that are also contained in such Combination Product but not covered by the Licensed Patents, the Net Sales attributable to such Combination Product during such year

shall be calculated by multiplying the Net Sales (as originally defined above) of the Combination Product by the fraction $A/(A+B)$, where A is the average sale price of the corresponding Licensed Product(s) containing a Licensed API as its(their) sole API and B is the average sale price of the other product(s) or system(s) sold separately in finished form, so that A+B is the average sale price of all the product(s) and, if applicable, the delivery system(s) together, as the case may be. In the event that any such average sale price(s) cannot be determined, Net Sales for the purposes of determining royalty payments with respect to such Combination Product shall be commercially reasonable and determined by good faith negotiation between Licensee and Licensor consistent with the ratio referenced above.

(b) in the case of discounts on "bundles" of products or services which include Licensed Products (such "bundles" including but not limited to (i) contingent arrangements involving drugs that share the same NDC (whether the same or different package sizes), drugs with different NDCs, or drugs and other products or services, (ii) circumstances in which a discount is conditioned on the achievement of some other performance requirement for the Licensed Product or other product or service (e.g. achievement of market share or placement on a formulary tier), or (iii) otherwise where the resulting price concessions or discounts are greater than those which would have been available had the bundled products or services been purchased separately or outside the bundled arrangement), Licensee may with notice to Licensor discount the bona fide list price of a Licensed Product by the average percentage discount of all products or services of Licensee and/or its Affiliates or Third Party sublicensee in a particular "bundle", calculated as follows:

$$\begin{array}{l} \text{Average percentage} \\ \text{discount on a} \\ \text{particular "bundle"} \end{array} = [1 - (X/Y)] \times 100$$

where X equals the total discounted price of a particular "bundle" of products or services, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product or service in such "bundle". Licensee shall provide Licensor documentation reasonably supporting such average discount with respect to each "bundle." If a Licensed Product in a "bundle" is not sold separately, and no bona fide list price exists for such Licensed Product, Licensee and Licensor shall negotiate in good faith a reasonable imputed list price for such Licensed Product and Net Sales with respect thereto shall be based on such imputed list price.

Notwithstanding anything herein to the contrary, the transfer of a Licensed Product to an Affiliate, sublicensee, or other Third Party, at no cost or for a price that is not materially in excess of Licensee's cost of manufacturing or procuring such Licensed Product, (i) in connection with the research, development or testing of a Licensed Product, (ii) for purposes of distribution as promotional samples or resale, or (iii) for indigent or similar public support or compassionate use programs shall not, in any case, be considered a sale of a Licensed Product under this Agreement.

1.28 "Carcinogenicity Studies" means, with respect to a Licensed Product, two year carcinogenicity studies performed in rats (and mice if requested by the FDA or other Regulatory Authority) as outlined in ICH guidelines S1A, S1B and S1C.

1.29 “Original Jurisdiction” means (i) the State of Connecticut in the United States, in the case of Bayer, and (ii) the State of North Carolina in the United States, in the case of Dara.

1.30 “PPAR” means peroxisome proliferator activated-receptor protein.

1.31 “PPAR Assay” means the assay described on Schedule 1.31.

1.32 “Patents” means all rights under patents and patent applications, any and all patents issuing therefrom (including utility, model and design patents and certificates of invention), together with any and all substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations-in-part, re-examinations, and renewals of any of the foregoing, all domestic and foreign counterparts of any of the foregoing and patents issuing therefrom, and all improvements, supplements, modifications, corrections, or additions with respect to any of the foregoing.

1.33 “Phase 2 Trial” means a clinical trial of a Licensed Product on patients, including possibly pharmacokinetic studies, the principal purpose of which is to make a preliminary determination that such Licensed Product is safe for its intended use and to obtain sufficient information about such Licensed Product’s efficacy to permit the design of further clinical trials, and generally consistent with 21 CFR § 312.21(b).

1.34 “Phase 3 Trial” means a clinical trial that provides for a pivotal human clinical trial of a Licensed Product, which trial is designed to: (a) establish that a Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) support Regulatory Approval of such Licensed Product; and (d) generally consistent with 21 CFR § 312.21(c).

1.35 “Regulatory Approval” means any and all approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, clearances, or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or, in Licensee’s reasonable judgment, sale of a Licensed Product for human therapeutic use in a particular jurisdiction.

1.36 “Regulatory Authority” means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of pharmaceutical products in a particular jurisdiction, including, without limitation, the FDA, and where applicable any ethics committee or any equivalent review board.

1.37 “Regulatory Filing” means, with respect to the United States, a New Drug Application, Biologic License Application, or Investigational New Drug application, any foreign counterparts or equivalents thereof, any DMFs, and any other filings or submissions required by Regulatory Authorities relating to the Development or Commercialization of any Licensed Product, including any supporting documentation, correspondence, meeting minutes, amendments, or supplements with respect to any of the foregoing.

1.38 “Royalty Term” means, on a country-by-country and Licensed Product-by-Licensed Product basis, the term commencing on the First Commercial Sale of a Licensed Product and continuing until the latest of (i) the tenth (10th) anniversary of such First Commercial Sale, (ii) expiration of the last to expire Valid Claim covering the manufacture, use or sale of a Licensed Product in the country where such Licensed Product is sold, or (iii) the expiration or termination of any Patent Term Extensions (as defined in Section 5.5 below).

1.39 “Secondary Indication” means a second therapeutic indication for a Licensed Product, previously the subject of a Regulatory Approval for a different indication, for which a supplemental NDA is submitted (or intended to be submitted).

1.40 “Secondary Product” means any Licensed Product other than a Diabetes Product (i.e. a Licensed Product not developed or intended for the treatment of type 2 diabetes).

1.41 “Successful Completion” means:

(a) with respect to Carcinogenicity Studies of a particular Licensed Product, (i) the observation of tumors at AUC (Area Under the Curve) exposures greater than 10-fold of the maximum recommended human dose (MRHD) exposure of such Licensed Product and (ii) FDA or EMEA approval to Commence a Phase 3 Trial of such Licensed Product with a treatment duration of greater than six (6) months; and

(b) with respect to a Phase 2 Trial of a certain Licensed Product, FDA approval to Commence a Phase 3 Trial of such Licensed Product

1.42 “Term” has the meaning assigned to it in Section 8.1.

1.43 “Territory” means worldwide.

1.44 “Third Party” means any entity other than (a) Licensor, (b) Licensee or (c) an Affiliate of either of them.

1.45 “Valid Claim” means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent within the Licensed Patents that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted by Licensor in writing to be invalid or unenforceable or of a scope not covering Licensed Products through reissue, disclaimer or otherwise, provided that if a particular claim has not issued within five (5) years of its initial filing, it shall not be considered a Valid Claim for purposes of this Agreement, notwithstanding the foregoing definition.

2. LICENSES AND RELATED RIGHTS

2.1 License to Licensee. Licensor, on behalf of itself and its successors and assigns, hereby grants to Licensee and its Affiliates an exclusive license, with the right to sublicense as set forth in Section 2.2, under the Licensed Technology to make, have made, use, sell, offer for sale and import Licensed Products in the Field in the Territory, provided that the foregoing license shall not include any rights to make, have made, use, sell, offer for sale and import any product(s) incorporating any Development Candidate as an API.

2.2 Sublicensing. Licensee and its Affiliates shall have the right to sublicense their rights under Section 2.1 to one or more Third Parties upon prior written approval by Bayer, such approval not to be (i) unreasonably withheld, delayed, or conditioned or (ii) conditioned on the payment of any additional consideration to Bayer or amendment of any economic terms of this Agreement in favor of Bayer. Licensee shall provide Licensor a written copy of any proposed sublicense for Bayer's review and approval, provided that Licensee may redact any portions of such sublicenses (or amendments) disclosing sublicensees' proprietary information, technology, or research, development, or commercialization plans as reasonably necessary to comply with any confidentiality obligations to such sublicensee. Bayer shall provide Licensee notice of its approval or denial of a sublicense within ten (10) business days of any request for such approval by Licensee, provided that (i) in the event Bayer wishes to deny such approval, such notice shall include a written description of Bayer's reasonable objections to the proposed sublicense, and (ii) Bayer shall be deemed to have approved such sublicense in the event it fails to provide such notice within such ten (10) business day period. Each sublicense shall be consistent with the terms and conditions of this Agreement. For purposes of this Agreement, a Third Party to whom Licensee or its Affiliate grants exclusive rights to market one or more Licensed Products in a given territory shall be deemed a "sublicensee" of Licensee hereunder for such territory.

2.2A Right of First Negotiation. Prior to Licensee's first entering into material negotiations concerning a sublicense of Licensee's rights hereunder to any Third Party for purposes of enabling such Third Party to Commercialize any Licensed Product(s), Licensee shall provide Licensor written notice of its intent to pursue such a sublicense and Licensor shall have the right, if it provides written notice to Licensee within thirty (30) days of such notice, to exclusively negotiate with Licensee for period of sixty (60) days following its notice to Licensee within the aforementioned initial thirty (30) day period, during which negotiations both parties shall exercise commercially reasonable good faith efforts to reach an agreement concerning Licensor's Commercialization of Licensed Product(s). If (i) the parties do not conclude such an agreement within such sixty (60) day period or (ii) Licensor does not provide written notice to Licensee indicating its intention to exercise such right of negotiation within the thirty (30) day period described above, Licensee shall have no further obligation to Licensor under this Section 2.2A. Further, once Licensee has complied with this Section 2.2A once under this Agreement, Licensee shall have no further obligations under this Section 2.2A and shall be free to sublicense any or all of its rights under this Agreement without providing any further or future right to negotiation for the benefit of Licensor.

2.3 Bankruptcy. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. The Parties agree that a Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against the licensing Party (such Party, the "Involved Party") under the U.S. Bankruptcy Code, the other Party (such Party, the "Noninvolved Party") shall be

entitled to a complete duplicate of or complete access to (as such Noninvolved Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, provided the Noninvolved Party continues to fulfill its payment or royalty obligations as specified herein in full. Such intellectual property and all embodiments thereof shall be promptly delivered to the Noninvolved Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefore by the Noninvolved Party, unless the Involved Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Involved Party upon written request therefor by the Noninvolved Party. The foregoing is without prejudice to any rights the Noninvolved Party may have arising under the U.S. Bankruptcy Code or other applicable law.

2.4 Disclosure of Information. Upon execution of this Agreement and thereafter during the term hereof, Licensor shall disclose to Licensee, in confidence under the terms of Section 7 hereof, all relevant Information as shall become available to it relating to Licensed Technology and Licensed Products. If and as requested by Licensee, Licensor will use reasonable efforts to disclose to Licensee or any Regulatory Authority (including but not limited to the FDA and EMEA) all relevant Information in its possession required for Licensee to register for sale or obtain approval for sale of each Licensed Product.

2.5 Improvements. Licensor shall promptly inform Licensee in detail and in writing of any Improvements.

3. FINANCIAL TERMS

3.1 Upfront Payment. Licensee shall pay Licensor [\$600,000] within thirty (30) days of the Effective Date.

3.2 Royalty Payments. Licensee shall pay to Licensor the following royalty payments, subject to adjustment as described in Sections 3.3 and 3.4, based on Net Sales of Licensed Products in the Territory by Licensee, its Affiliates, and their Third Party sublicensees:

(a) Eleven percent (11%) of Net Sales for the first \$250,000,000 of aggregate worldwide Net Sales in a particular calendar year;

(b) Twelve percent (12%) of Net Sales of aggregate worldwide Net Sales in excess of \$250,000,000 but less than \$750,000,000 in a particular calendar year;

(c) Thirteen percent (13%) of Net Sales for all aggregate worldwide Net Sales in excess of \$750,000,000 (seven hundred and fifty thousand dollars) but less than \$1,000,000,000 (one billion dollars) in a particular calendar year; and

(d) Fourteen percent (14%) of Net Sales for all aggregate worldwide Net Sales in excess of \$1,000,000,000 (one billion dollars) in a particular calendar year.]

[As an example of the royalty calculation contemplated by this Section 3.2, if aggregate worldwide Net Sales in a particular calendar year total \$1,600,000,000, and there are no adjustments to royalties pursuant to Section 3.3 or 3.4, Licensee shall owe Licensor]

[$\$204,000,000$ under this Section 3.2 for such calendar year ($11\% \times \$250,000,000 = \$27,500,000$; 12% of $\$500,000,000 = \$60,000,000$; $13\% \times \$250,000,000 = \$32,500,000$; and 14% of $\$600,000,000 = \$84,000,000$; $\$27,500,000 + \$60,000,000 + \$32,500,000 + \$84,000,000 = \$204,000,000$)]. No multiple royalties shall be payable because the manufacture, use, or sale of any Licensed Product is, or shall be, covered by more than one Valid Claim contained in the Licensed Patents. A royalty shall be payable under this Section 3.2 only once with respect to any particular Licensed Product.

3.3 Third Party Royalties. In the event that (a) a Licensed Product is deemed by a final, unappealable decision of a court of competent jurisdiction to infringe a claim of a patent(s) owned or controlled by a Third Party in any given country of the Territory, and Licensee, an Affiliate thereof, or any sublicensee thereof licenses such patent(s) in settlement of such claims, or to avoid future such claims, (b) Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing determines that it is commercially, reasonably necessary or advisable to pay royalties to a Third Party to obtain a license to practice any Third Party's rights in order to manufacture, use, Commercialize or Develop a Licensed Product in any given country of the Territory, or (c) it would be necessary to obtain a license to practice any Third Party's rights that could improve, enhance, or modify a Licensed Product in any given country of the Territory, as determined by Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing, then Licensee may deduct an amount equal to fifty percent (50%) of any fees, milestones or royalties due to such Third Parties for such rights (or such amounts paid by Licensee, its Affiliate, or any sublicensee of either of the foregoing in settlement of any infringement action) (collectively, all of the foregoing, "Third Party Royalties") from the any amounts due Licensor hereunder.

3.4 Compulsory Licenses. Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the applicable laws of any country in the Territory under the Licensed Patents, the Party receiving notice thereof or otherwise becoming aware thereof shall promptly notify the other Party thereof, including any material information concerning such compulsory license, and the royalty rate payable hereunder for sales of Licensed Products in such country will be adjusted to match any lower royalty rate granted to such Third Party for such country with respect to the sales of such Licensed Products, subject to any adjustments pursuant to Section 3.3 above.

3.5 Milestone Payments. Licensee shall pay Licensor the following amounts within ninety (90) days of Licensee, an Affiliate, or any sublicensee of either of the foregoing achieving the indicated milestone:

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<u>MILESTONE</u>	<u>PAYMENT DUE</u>
Approval by the appropriate Regulatory Authority of an IND filed by or on behalf of Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing with respect to a Diabetes Product.....	\$ [500,000]
Approval by the appropriate Regulatory Authority of an IND filed by or on behalf of Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing with respect to a Secondary Product (or a Diabetes Product for a Secondary Indication)	\$ [250,000]
Successful Completion of Carcinogenicity Studies for a Diabetes Product conducted by or on behalf of Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing.....	\$ [2,000,000]
Successful Completion of Carcinogenicity Studies for a Secondary Product conducted by or on behalf of Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing.....	\$ [1,000,000]
Successful Completion of a Phase 2 Trial concerning a Diabetes Product conducted by or on behalf of Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing	\$ [1,000,000]
Successful Completion of a Phase 2 Trial concerning a Secondary Product (or a Diabetes Product for a Secondary Indication) conducted by or on behalf of Licensee, an Affiliate thereof, or any sublicensee of either of the foregoing.....	\$ [500,000]
Regulatory Approval of a Diabetes Product in a Major Market for the benefit of Licensee, an Affiliate thereof, or a sublicensee of either of the foregoing	\$ [2,000,000]
Regulatory Approval of a Secondary Product (or a Diabetes Product for a Secondary Indication) in a Major Market for the benefit of Licensee, an Affiliate thereof, or a sublicensee of either of the foregoing.....	\$ [1,000,000]
120th day following First Commercial Sale in a Major Market of a Diabetes Product by or on behalf of Licensee, an Affiliate thereof, or a sublicensee of either of the foregoing.....	\$ [5,000,000]
120 th day following First Commercial Sale in a Major Market of a Secondary Product (or a Diabetes Product for a Secondary Indication) by or on behalf of Licensee, an Affiliate thereof, or a sublicensee of either of the foregoing.....	\$ [2,500,000]

The first Diabetes Product is subject to the Diabetes Product milestones set forth above. In the event the first Diabetes Product fails to achieve Regulatory Approval, Licensee may develop a second replacement Diabetes Product being obligated to pay only those milestone payments described above not already paid to Licensor with respect to the first Diabetes Product. Thus, milestone payments for the first successful Diabetes Product shall not exceed **[ten and one-half million (\$10.5M)]**, regardless of how many Diabetes Products are evaluated. A "successful" product means, for purposes of this Section 3.5, Regulatory Approval in a Major Market.

As described above, a Secondary Indication for the first successful Licensed Product shall be considered a Secondary Product for purposes of the milestone payments described above and shall be paid at **[one half]** the original milestones established above with respect to the Diabetes Product for a total of no more than **[five million, two hundred and fifty thousand dollars (\$5.25M)]**. A Secondary Indication, however, is not a Secondary Product.

A Secondary Product is subject to **[one half]** of the original milestone payments set forth above with respect to the Diabetes Product (for a total not to exceed **[\$5.25M]**). In the event the

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initial Second Product is not successful, the Licensee may develop other replacement Secondary Products, paying only those milestones not previously paid for the development of a Secondary Product. In no instance shall total milestone payments for Secondary Products exceed **[five million two hundred and fifty thousand dollars]**.

Additional Licensed Products after the first two successful Licensed Products (or success of the Diabetes Product and a Secondary Indication for such Diabetes Product) shall be subject to royalty payments only and shall not be subject to milestone development payments.

Notwithstanding anything to the contrary, the total amounts payable to Licensor under this Section 3.5 shall not exceed **[\$15,750,000]**, and each milestone above shall only be payable once, with respect to the first Diabetes Product or Secondary Product, as applicable, to achieve such milestone.

3.6 Minimum Payments. Beginning with respect to calendar year 2009, if the total amounts payable under this Section 3 with respect to Net Sales and milestones achieved during a particular calendar year ("Earned Payments") do not equal or exceed the amount noted below for such calendar year, Licensee shall pay Licensor, in addition to any Earned Payments for such calendar year, an amount equal to the difference between such Earned Payments and the amount noted below for such calendar year. Any amounts paid under this Section 3.6 shall be fully creditable against, and deducted from, any milestone payments due under Section 3.5.

<u>CALENDAR YEAR</u>	<u>MINIMUM PAYMENTS</u>
2009	\$ [150,000]
2010	\$ [200,000]
2011	\$ [250,000]
2012 and every year thereafter.....	\$ [250,000]

As an example of the payment contemplated by this Section 3.6, if Net Sales during calendar year 2014 total **[\$500,000]**, and no milestones triggering any payment under Section 3.5 are achieved during calendar year 2014, Licensee shall pay Licensor, in addition to royalty payments of **[\$50,000]** under Section 3.2 (assuming there are no royalty adjustments pursuant to Sections 3.3 or 3.4), **[\$200,000]** under this Section 3.6.

Notwithstanding anything to the contrary, Licensor's sole and exclusive remedy with respect to Licensee's failure to pay, as the total amount paid under this Section 3 with respect to a particular calendar year, the amounts listed above shall be the right, following sixty (60) days' written notice to Licensee of such failure without cure, to terminate this Agreement and Licensee's rights hereunder. Payments due under this Section 3.6 shall be made within sixty (60) days of the end of the relevant calendar year, consistent with Section 3.7.

3.7 Payments and Payment Reports. Except as otherwise provided herein, all royalties and payments due under this Section 3 shall be paid within sixty (60) days of the end of the relevant calendar quarter for which the applicable Net Sales occur, subject, with respect to Net Sales by Third Party sublicensees, to any longer reporting periods which may be agreed to

by Licensee or its Affiliates with respect to such sublicensees. Each royalty payment shall be accompanied by a statement stating (as applicable) the number, description, and aggregate Net Sales, by country, of each Licensed Product sold during the relevant calendar quarter by Licensee and its Affiliates and Third Party sublicensees and detailing the calculation of royalties and milestones due for such calendar quarter.

3.8 Payment Method. All payments due under this Agreement to Licensor shall be made by check or bank wire transfer in immediately available funds to an account designated by Licensor. All payments hereunder shall be made in the legal currency of the United States of America, except as provided in Section 3.10.

3.9 Taxes. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("VAT") imposed upon such payments. For the case charging or imposition of VAT is legally required due to (i) Licensor's sale to, merger with, acquisition by, or assignment of this Agreement to an Affiliate or Third Party located in, or otherwise subject to the laws of, a jurisdiction other than Licensor's Original Jurisdiction, or any other action of Licensor that causes it or this Agreement to become subject to the laws of another jurisdiction, or (ii) a change in the laws of Licensor's potential future jurisdiction, and such VAT will not be fully refundable for the Licensee this VAT will be reimbursed by the Licensor to the extent not refundable. In addition, in the event any of the payments made by Licensee pursuant to Section 3 become subject to withholding taxes under the laws of any jurisdiction, such amounts payable to Licensor shall be reduced by the amount of taxes deducted and withheld, and Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Licensor an official tax certificate or other evidence of such tax obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Licensor to claim such payment of taxes. No deduction shall be made, or a reduced amount shall be deducted, to the extent the Licensee is timely furnished with necessary documents certifying, consistent with applicable laws, rules, and regulations, that the payment is exempt from tax or subject to a reduced tax rate. Any such withholding taxes required under applicable law to be paid or withheld shall be an expense of, and borne solely by, Licensor.

Each Party will provide the other Party with reasonable assistance to enable the other Party to recover any of the above-described taxes as permitted by law, provided that if a Party reasonably incurs any Third Party costs in rendering such assistance (including but not limited to reasonable, documented attorneys' fees), the Party requesting such assistance shall promptly reimburse the assisting Party for such costs.

3.10 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country under such country's applicable law, royalties accrued in that country shall be paid to Licensor in the country in local currency by deposit in a local bank designated by Licensor, unless the Parties otherwise agree.

3.11 Sublicenses. For avoidance of doubt, the Parties agree that in the event that Licensee grants licenses or sublicenses to Third Parties to sell Licensed Products, Licensee shall use commercially reasonable efforts to include in such licenses or sublicenses an obligation for the licensee or sublicense to account for and report its sales of Licensed Products on a basis reasonably sufficient to enable Licensee to pay Licensor the royalties due under this Agreement.

3.12 Foreign Exchange. Conversion of sales recorded in local currencies to U.S. dollars will be performed in a manner consistent with Licensee's reasonable practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates. Licensee shall notify Licenser of the conversion method(s) used by Licensee.

3.13 Interest. If Licensee fails to make any payment when due to Licenser under this Agreement, then interest shall accrue on a daily basis at a rate equal to the thirty (30) day U.S. dollar LIBOR rate effective for the date that payment was due, as published by *The Wall Street Journal*. The obligation to pay interest on such late payments set forth herein shall not be construed to limit or restrict Licenser's right to terminate this Agreement in accordance with the terms and conditions of Section 8.3.

3.14 Records; Audits. Licensee shall keep or cause to be kept such records as are required to determine, in a manner consistent with generally accepted accounting principles in the United States, the sums or credits due under this Agreement. At the request (and expense) of Licenser, Licensee and its Affiliates and sublicensees shall permit an independent certified public accountant appointed by Licenser and reasonably acceptable to Licensee, at reasonable times not more than once a year and upon reasonable notice, to examine only those records as may be necessary to determine, with respect to any calendar year ending not more than three (3) years prior to Licenser's request, the correctness or completeness of any royalty report or payment made under this Agreement. Licenser shall promptly provide a copy of the results of any such audit to Licensee. Licenser shall bear the full cost of the performance of any such audit, unless such audit discloses an underpayment exceeding five percent (5%) of the amount actually due hereunder, in which case Licensee shall bear the reasonable, documented cost of the performance of such audit. Licensee shall promptly pay to Licenser the amount of any underpayment of royalties revealed by an examination and review. Any overpayment by Licensee of royalties or any other amount paid to Licenser revealed by an examination and review shall, in Licensee's sole discretion, (i) be fully-creditable against future payments under this Agreement or (ii) refunded to Licensee within ten (10) business days of its request.

4. DILIGENCE; DEVELOPMENT ASSISTANCE.

4.1 Licensee shall, during the Term, use Diligent Efforts to pursue the research, development, and commercialization of at least one Licensed Product. As between the Parties, Licensee will own all Regulatory Approvals and Regulatory Filings for each country in the Territory for Licensed Products.

4.2 Upon execution of this Agreement, Licenser shall provide to the Licensee, at no additional cost, all Licensed Know-How, which shall include but not be limited to all pre-clinical or clinical data, trade secrets, human safety data, preliminary efficacy data, and other regulatory data related to any Licensed Product in its possession.

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Licensor shall, at Licensor's cost, take any and all actions requested by the Licensee to effect the purposes of the foregoing as promptly as practicable following the execution of this Agreement, which shall include but not be limited to taking all reasonable actions necessary to enable the Licensee to undertake the manufacture, development and commercialization of Licensed Products under this Agreement. Such actions shall include providing the Licensee with:

- a. copies of all regulatory submissions;
- b. any communications with Governmental Authorities and the minutes of any meetings with Governmental Authorities relating to any Licensed Product;
- c. DMFs and any trial, drug, device, or other master files relating to any Licensed Product, including copies of all case report forms;
- d. copies of all listings and tables of results from the clinical trials relating to any Licensed Product;
- e. copies of all treatment-related serious adverse event reports from the clinical trials relating to any Licensed Product;
- f. storage of and access permission to any retained samples of materials used in clinical trials relating to any Licensed Product;
- g. access to contract and clinical research organizations involved in the preclinical studies and clinical trials relating to any Licensed Product;
- h. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Licensed Product; and

i. all other information that the Licensee may reasonably request that may be useful to the Licensee for the manufacturing of Licensed Products or conducting preclinical studies and clinical trials and other Development activities with respect to each Licensed Product, and the Commercialization of Licensed Products.

Further, for a period of sixty (60) months following the Effective Date, the Licensor shall promptly provide such technical assistance to Licensee as Licensee requests regarding the Licensed Technology, Licensed Patents, Licensed Products, and Licensor's efforts with respect to Regulatory Filings or its seeking of Regulatory Approval for any Licensed Product(s). Such technical assistance and transfer shall be limited to no greater than two hundred forty (240) person-hours.

4.3 Within ten (10) business days of any request of Licensee made in writing during the first year following the Effective Date, Licensor shall provide Licensee with, as requested by Licensee, all or a portion of the materials described on Schedule 4.3 (the "Existing Materials"), free and clear of all claims, liens, and encumbrances, and any supporting documentation with respect thereto.

5. PATENT PROSECUTION AND MAINTENANCE.

5.1 Unless and until Licensee exercises its rights under Section 5.3 below, Licensor shall be responsible for, and be obligated to diligently pursue the preparation, filing, prosecution (including but not limited to, by conducting interferences, oppositions and reexaminations or other similar proceedings), maintenance (by timely paying all maintenance fees, renewal fees and other applicable fees and costs), and extension of any Patents within the Licensed Patents. Licensor will regularly advise Licensee of the status of all pending patent applications in the Licensed Patents, including any related hearings or other proceedings, and, at Licensee request, will provide Licensee with copies of all documentation concerning such applications, including all correspondence to and from any Governmental Authority. Licensor shall consult with and obtain written consent from Licensee prior to abandoning any Licensed Patent or any claim contained therein, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensor will solicit Licensee's advice and review of such applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and will take into account Licensee's reasonable comments related thereto. The reasonable, documented costs incurred following the Effective Date with respect to the filing, prosecution, and maintenance of Licensed Patents shall be borne by Licensee, subject to Sections 5.2 and 5.4 below.

5.2 Licensor will provide reasonable advance written notice of any required foreign patent filings and associated fees. Licensee must thereafter inform Licensor in writing which foreign countries, if any, in which Licensee desires patent protection and Schedule 1.24 will be amended in writing to reflect those designations. Licensor may elect to seek patent protection in countries not so designated by Licensee, in which case Licensor shall be responsible for expenses attendant thereto as described in Section 5.4. However, in such instances, such patent applications will not be Licensed Patents, Schedule 1.24 shall be deemed to be so amended accordingly, if necessary, and Licensee forfeits all rights under this Agreement to such patent applications and resulting patents in such countries.

5.3 Licensee shall have the right to assume primary responsibility for all activities associated with the prosecution of Licensed Patents under this Agreement, provided that it first provides Licensor with written notice of its desire to assume such responsibilities and obtains Licensor's written approval of the legal counsel that Licensee shall retain for such purposes, such approval not to be unreasonably withheld. It is understood and agreed that in the event Licensee assumes such responsibilities, it shall keep Licensor advised as to the status of the Licensed Patents by providing Licensor, in a timely manner, with copies of all official documents and correspondence relating to the prosecution, maintenance, and validity of the Licensed Patents. Licensee shall consult with Licensor in such prosecution and maintenance, shall diligently seek advice of Licensor on all matters pertaining to the Licensed Patents, shall diligently seek reasonably strong and broad claims under the Licensed Patents, and shall not abandon prosecution of any Licensed Patents or any of the claims of the Licensed Patents without first notifying Licensor in a timely manner of Licensee's intention and reason therefor, and providing Licensor with reasonable opportunity to assume responsibility for prosecution and maintenance of the appertaining Licensed Patents (which thereafter shall be subject to the other provisions of this Section 5 that regard Licensed Patents). All decisions with respect to the prosecution of the Licensed Patents by Licensee pursuant to this Section 5.3 shall be made by Licensee. Licensee's

obligations under this Section 5.3 shall include, without limitation, an obligation to inform Licensor in a timely manner (no less than thirty (30) days prior to the appertaining filing deadlines) that Licensee will not pursue patents in any non-U.S. country so that Licensor may pursue such patents if it so desires. In such case, upon the date of such filing of such patent applications by Licensor, such patents and patent applications shall not be considered Licensed Patents, Licensee shall be deemed to have forfeited all rights under this Agreement to such patent applications and resulting patents, and Schedule 1.24 shall be deemed to be so amended. For avoidance of doubt, it is understood that Licensee shall assume direct and full responsibility for payment of expenses it incurs as a result of its assumption of responsibility for prosecution of Licensed Patents under this Section 5.3.

5.4 If Licensee provides Licensor with written notification that it will no longer support the filing, prosecution, or maintenance of a specified patent(s) and/or patent application(s) within the Licensed Patents, then Licensee's responsibility for fees and costs related to the filing, prosecution, and maintenance of such subject Licensed Patents will terminate sixty (60) days after Licensor's receipt of such written notification. However, in such instances, sixty (60) days after Licensor's receipt of written notification, such patents and/or patent applications will no longer be included in Licensed Patents (and Schedule 1.24 shall be deemed to be so amended accordingly), and Licensee surrenders all rights under this Agreement to such patents, patent applications, and any patents issuing therefrom.

5.5 Patent Term Extensions. Licensee shall promptly notify Licensor of the issuance of each Regulatory Approval and, where reasonably possible and reasonably useful or materially valuable in the commercialization of Licensed Products, use Diligent Efforts to apply or enable Licensor to apply for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by applicable laws, rules, regulations, or guidelines (collectively, "Patent Term Extensions") in the relevant country of the Territory. Licensor shall, to the extent reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to, if and as requested by Licensee, obtain (or assist the Licensee in obtaining) all available Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable, reasonably possible to obtain, and reasonably useful or valuable in the commercialization of Licensed Products

6. PATENT INFRINGEMENT.

6.1 Notice. If either Party becomes aware of any actual, potential, or alleged infringement of any Licensed Patents, such Party shall give to the other Party prompt and reasonably detailed written notice of such actual, potential, or alleged infringement.

6.2 Infringement of Licensed Patents. With respect to any actual, potential, or alleged infringement of the rights granted to Licensee hereunder with respect to the Licensed Patents, Licensee shall have the first and primary right, but not the obligation, to, in its sole discretion, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, on its behalf or in Licensor's name, if necessary, with respect to such alleged infringement. If, within twelve (12) months of the notice above, Licensee (i) shall have been unsuccessful in persuading the alleged infringer to desist, (ii)

shall not have brought and shall not be diligently prosecuting an infringement action, or (iii) has not entered into settlement discussions with respect to such infringement, or if Licensee notifies Licensor that it has decided not to undertake any of the foregoing against any such alleged infringer, then Licensor shall then have the right to bring suit to enforce the rights granted to Licensee hereunder with respect to Licensed Patents at its own expense. In any such litigation brought by Licensee, Licensee shall have the right to use and sue in Licensor's name and join Licensor as a party to such litigation, and Licensor shall cooperate reasonably, as requested by Licensee and at Licensee expense (which expense shall be reasonable).

6.3 Infringement of Third Party Rights. If a claim is brought by a Third Party alleging patent infringement by Licensee, Licensor, their Affiliates, or their sublicensees with respect to the manufacture, use, sale, offer for sale or importation of Licensed Products, or any third party challenges the validity or enforceability of any claims of any Licensed Patents, each Party will give prompt written notice to the other Party of such claim. The Parties shall promptly use commercially reasonable efforts to consult in good faith to develop a commercially reasonable strategy or strategies, which shall take into account the reasonable economic interests of both parties, for jointly and/or cooperatively responding to any such infringement claim or challenge to the validity or enforceability of any Licensed Patents. If (i) the efforts of the Parties are unable to agree upon such a strategy within fifteen (15) business days of the notice described above or (ii) Licensor does not use commercially reasonable efforts to consult in good faith with Licensee concerning such a strategy, as described above, Licensee shall have the first and primary right (but not the obligation) at its own expense to defend, control the defense of, and/or settle any such infringement claim against Licensee, its Affiliates, or their sublicensees or challenge of the validity or enforceability of the Licensed Patents, using counsel of its own choice. Licensor shall cooperate reasonably, as requested by Licensee and at Licensee expense (which expense shall be reasonable). With respect to any such defense. If, within six (6) months of the expiration of the fifteen (15) business day period noted above, Licensee (i) shall have been unsuccessful in defending such a challenge to the validity or enforceability of any claim of the Licensed Patents, (ii) shall not have brought and shall not be diligently prosecuting litigation with respect to such challenge, or (iii) has not entered into settlement discussions with respect to such challenge, or if Licensee notifies Licensor that it has decided not to undertake any of the foregoing with respect to such challenge, then Licensor shall then have the right, at its expense, to defend any Third Party challenge to the validity or enforceability of any claims in the Licensed Patents (but not any other claim or allegation referenced above except with respect to any defense of any Third Party claim of infringement by Licensor), and Licensee shall cooperate, as reasonably requested by Licensor and at Licensor expense, with respect to any such defense.

6.4 Litigation Control. Unless otherwise agreed upon by the Parties in writing with respect to any joint or cooperative strategy developed under Section 6.3, the Party pursuing or controlling any action or defense under Section 6.2 or 6.3 (the "Controlling Party") shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action or defense, provided, however, that (i) the Controlling Party shall consult with the other Party (the "Secondary Party") prior to entering into any settlement thereof and (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) materially limits the scope, validity, or enforceability of any Licensed Patents or, if Licensee is the Secondary Party, Patents owned or controlled by Licensee, (2) subjects the Secondary Party to any non-indemnified liability or obligation, or (3) admits fault or wrongdoing on the part of Secondary Party must, in

each case, be approved in writing by Secondary Party, such approval not to be unreasonably withheld. The Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within ten (10) business days of any request for such approval by the Controlling Party, provided that (i) in the event Secondary Party wishes to deny such approval, such notice shall include a written description of Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (ii) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such ten (10) business day period. Any recovery or damages received by the Controlling Party with respect to the infringement of the Licensed Patents shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses incurred in connection with such action, and the remainder shall be split ninety percent (90%) to Controlling Party and ten percent (10%) to Secondary Party. Notwithstanding the foregoing, the Secondary Party, at its expense, shall have the right to be represented by counsel of its choice in any such proceeding.

6.5 Reimbursement. Unless otherwise agreed upon by the Parties in writing with respect to any joint or cooperative strategy developed under Section 6.3, the Controlling Party shall invoice the Secondary Party for any reasonable, documented costs incurred that are to be borne by the Controlling Party pursuant to this Section 6. The Controlling Party shall pay the Secondary Party such amounts within thirty (30) days of its receipt of any such invoice.

6.6 Trademarks. Licensee may, in its sole discretion, select trademarks for the Licensed Product and shall own all such trademarks. To the extent Licensee pursues trademarks for Licensed Products, as between the parties, Licensee shall have the sole responsibility for the filing, prosecution and maintenance of registrations of product trademarks for Licensed Products, at its sole expense.

7. CONFIDENTIALITY

7.1 Treatment of Confidential Information. The Parties agree that during the Term, and for a period of five (5) years after the end of the Term, a Party receiving Confidential Information of the other Party will (a) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary industrial information of similar kind and value (but at a minimum each Party shall use commercially reasonable efforts), (b) not disclose such Confidential Information to any Third Party without prior consent of the other Party, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement.

7.2 Exceptions. A Party shall not have the obligations set forth in Section 7.1 with respect to any portion of such Confidential Information that it can show by adequate documentation:

- (a) is publicly disclosed by the disclosing Party, either before or after it becomes known to the receiving Party;

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(b) was known to the receiving Party, without obligation to keep it confidential, prior to when it was received from fee disclosing Party, as demonstrated by receiving Party's written records;

(c) is subsequently disclosed to the receiving Party without obligation of confidentiality or limitation on use by a Third Party lawfully in possession thereof without obligation to keep it confidential;

(d) has been published by a Third Party; or

(e) has been independently developed by the receiving Party without the aid, application or use of Confidential Information.

7.3 Authorized Disclosure. Notwithstanding Section 7.1, a Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is necessary in the following instances:

- (a) filing or prosecuting Patents pursuant to Section 5;
- (b) Regulatory Filings;
- (c) prosecuting or defending litigation relating to Licensed Products;
- (d) complying with applicable laws and governmental regulations; and
- (e) disclosure, in connection with the performance of this Agreement or exercise of the licenses or rights conveyed herein, to Affiliates, licensees, sublicensees, employees, consultants, or agents of either Party, each of whom prior to disclosure must be bound by substantially similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 8.

7.4 Terms of the Agreement. The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to individuals or entities covered by Section 7.3(e) above, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 7. Disclosure of the terms of this Agreement (but not other Confidential Information received from the other Party) may also be made by Licensee, under obligations of confidentiality and non use at least equivalent in scope to those set forth in this Section 7, to actual or potential bankers, lenders, investors, acquirors, acquisition targets, and strategic partners of Licensee.

7.5 Publicity. Licensee shall be entitled, in its sole discretion, to make public announcements regarding its Development and Commercialization of Licensed Products. In addition, Licensee may make a public statement concerning the Agreement or the progress of the Licensed Products where such statement is required by law, applicable stock exchange regulation or legal proceedings. In connection with any filing described in the foregoing sentence, Licensee shall use commercially reasonable efforts to obtain confidential treatment of trade secret

information. In any event, Licensee agrees to take all reasonable action to avoid disclosure of Confidential Information except as permitted hereunder, and shall cooperate with each other with respect to all such disclosures. Except as explicitly permitted by this Agreement, neither Party will make any public announcement regarding the terms of or events related to the Agreement without the prior consent of the other Party.

7.6 Publications. Neither Licensor nor its employees, contractors, investigators, directors, officers, or shareholders shall publish or present any information with respect to any Licensed Product or Licensed Technology without Licensee's prior consent (which may be withheld in Licensee's sole and final discretion), except as required under Section 7.3(d).

8. TERM AND TERMINATION

8.1 Term. This Agreement shall become effective on the Effective Date and shall continue on a Licensed Product-by-Licensed Product and country-by-country basis until the earlier of (i) expiration of the Royalty Term with respect to the applicable Licensed Product in the applicable country or (ii) the effective date of termination pursuant to Section 8.2 or 8.3 (the "Term"). Upon expiration of this Agreement pursuant clause (i) above, Licensee and its Affiliates shall have the perpetual, unrestricted, fully-paid, royalty-free right, with rights of sublicense, to make, have made, use, sell, offer for sale, and import Licensed Products in the applicable country.

8.2 Termination by Licensee. Licensee may terminate this Agreement at any time upon thirty (30) days prior written notice to Licensor.

8.2A Termination for Failure to Pay Upfront Fee. In the event the payment required under Section 3.1 is not paid within thirty (30) days of the Effective Date, this Agreement shall automatically terminate.

8.3 Mutual Termination Rights. Either Party will have the right to terminate this Agreement upon the following:

(a) It reasonably believes that the other Party is in material breach of this Agreement, in which case the non-breaching Party may deliver written notice of such material breach to the other Party, such notice to describe in detail the nature of such breach. The allegedly breaching Party shall have sixty (60) days from receipt of such notice to cure such breach. Any such termination shall become effective at the end of such 60-day period unless the breaching Party has cured any such breach or default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, the breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within one hundred twenty (120) days after notice thereof was provided to the breaching Party by the non-breaching Party to remedy such default); or

(b) the other Party is generally unable to meet its debts when due, or makes a general assignment for the benefit of its creditors, or there shall have been appointed a receiver, trustee or other custodian for such Party for or a substantial part of its assets, or any case or

proceeding shall have been commenced or other action taken by or against such Party in bankruptcy or seeking the reorganization, liquidation, dissolution or winding-up of such Party or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law, and any such event shall have continued for sixty (60) days undismissed, unstayed, unbonded and undischarged. In such circumstances, the other Party may, upon notice to such Party, terminate this Agreement, such termination to be effective upon such Party's receipt of such notice.

8.4 Effects of Termination.

(a) Except as set forth in Section 8.1, upon any termination of this Agreement, all licenses granted by Licensor to Licensee under this Agreement shall terminate and Licensee and its Affiliates shall cease Development and Commercialization of all Licensed Products, provided that, notwithstanding the foregoing, Licensee and its Affiliates shall have the privilege, subject to the payment of royalties as required under Section 3, of (i) completing the manufacture of any Licensed Products in the process of manufacture as of the effective date of such termination (the "Termination Date"), (ii) selling such Licensed Products and all finished Licensed Products in Licensee's possession or under its control as of the Termination Date for a period of one year following the Termination Date upon commercially reasonable conditions, and (iii) completing performance of all contracts entered into with third parties prior to the Termination Date (1) for the marketing, sale, or manufacture of Licensed Products or (2) requiring the use of technology claimed in the Licensed Patents or Licensed Products for a period of one year following the Termination Date. Notwithstanding any provision herein to the contrary, no termination of this Agreement by Licensor shall be construed as a termination of any valid sublicense granted by Licensee, Its Affiliates, or its sublicensees with respect to the rights granted under this Agreement. Upon termination of this Agreement by Licensor each sublicense shall, to the extent not imposing obligations on Licensor in excess of those contained herein, be automatically assigned to Licensor.

(b) Termination of this Agreement shall not terminate the obligations of Licensee to make any payments then owing through the date of termination or the obligations of confidentiality imposed on either party.

(c) The remedies set forth in this Section 8 are not exclusive, and shall not limit any other legal or equitable remedies that are available to the parties.

8.5 Survival. The following provisions shall survive any expiration or termination of this Agreement: Sections 1, 3.14, 6 (with respect to infringements during the term of this Agreement), 7, 8.1, 8.4, 8.5, 9.3, 10, and 11, together with any sections referenced in such surviving provisions or necessary to give them effect.

9. REPRESENTATIONS AND WARRANTIES

9.1 General Representations and Warranties. Each Party represents and warrants to the other that, as of the date hereof:

(a) it is duly organized and validly existing under the laws of its jurisdiction of organization, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

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(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(c) this Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any Governmental Authority having jurisdiction over it;

(d) it is aware of no action, suit or inquiry or investigation instituted by any governmental agency that questions or threatens the validity of this Agreement; and

(e) all necessary consents, approvals and authorizations of all Governmental Authorities and other parties required to be obtained by such Party to enter into this Agreement have been obtained (provided, however, that the foregoing shall not be construed as a representation or warranty concerning governmental authorizations and non-infringement of intellectual property rights of Third Parties disclaimed in Section 9.3 below).

9.2 Licensor Representations and Warranties. Licensor represents, warrants, and covenants that:

(a) Licensor has not, and during the term of the Agreement will not, grant any right to any Third Party relating to Licensed Technology, Licensed Patents, or Licensed Know-How which conflicts with the rights granted to Licensee hereunder;

(b) During the term hereof, Licensor will not, without the prior written consent of Licensee, encumber any portion of the Licensed Technology, Licensed Patents, or Licensed Know-How with liens, mortgages, security interests or another similar interest that would give the holder the right to convert the interest into ownership, unless the encumbrance is expressly subject to the licenses herein;

(c) The Licensor has (or will have at the time performance is due) maintained and will maintain and keep in full force and effect all agreements necessary to perform its obligations, and grant the rights granted to Licensee, hereunder;

(d) Licensor does not have any present knowledge from which one would reasonably conclude that the Licensed Patents are invalid or that Licensee's exercise of its rights hereunder would infringe patent rights of any Third Party;

(e) The Licensed Patents listed on Schedule 1.24 are, as of the Effective Date, the only patents or patent applications Controlled by Licensor claiming Licensed Products, any technology embodied or described in the Licensed Technology, or the manufacture, use, or application of any of the foregoing.

(f) Each item included in the Licensed Patents that is registered, filed or issued under the authority of an appropriate Governmental Authority is and at all times has been in compliance with all legal requirements applicable thereto, and all filings, payments, and other

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actions required to be made or taken to maintain each item of the Licensed Patents in full force and effect have been made by the applicable deadline. Furthermore, (1) no application for a patent or for a copyright, mask work or trademark registration or any other type of intellectual property protection included in the Licensed Technology (including but not limited to Licensed Patents) filed by or on behalf of Licensor or any licensor thereof with respect thereto has been abandoned or allowed to lapse and (2) no provisional patent application has expired without the filing of a nonprovisional patent application that claims the benefit of such provisional patent application.

(g) Neither Licensor nor any Affiliate thereof is a party to or otherwise bound by any oral or written contract or agreement that will result in any third party obtaining any interest in, or that would give to any third party any right to assert any claim in or with respect to, any rights granted to Licensee under this Agreement;

(h) Licensor has furnished to Licensee all tangible manifestations of the Licensed Technology which Licensor owns or possesses as of the Effective Date;

(i) Licensor has taken reasonable measures, using reasonable business judgment, to protect the confidentiality of the Licensor Know How;

(j) With respect to the Licensed Technology and the technology claimed in the Licensed Patents, as applicable:

1. none of the Licensed Patents is the subject of any pending interference, opposition, cancellation or other protest proceeding;

2. relative to the Licensed Patents, the technology claimed therein, Licensed Know-How, and Licensed Products, Licensor does not have any knowledge of any claim pending, threatened, or previously made alleging infringement or misappropriation of any patent, trade secret, or other intellectual property right of any third party; and

3. Licensor is not aware of any Third Party activities which would constitute misappropriation or infringement of the Licensed Technology (including but not limited to Licensed Patents);

(k) Licensor owns all right, title, and interest to all Licensed Technology, free and clear of any liens, claims, and encumbrances of any party, and none of the Licensed Technology has been obtained by Licensor pursuant to any license or other agreement with any third party (other than by assignment from the Inventors);

(l) Licensor has not received nor been the subject of, nor is it aware of any information for which one would reasonably expect Licensor to receive or be the subject of, any correspondence or other action on the part of any Regulatory Authority which would or could reasonably be expected to have a material adverse effect on the Development or Commercialization of any Licensed Product;

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(m) Licensor does not own or have rights to any Regulatory Approvals or Regulatory Filings regarding any Licensed Product, and, to Licensor's knowledge, no Licensed Product or product incorporating or utilizing any Licensed Technology has been approved by any Governmental Authority in any jurisdiction for marketing or sale for human use;

(n) Licensor has not received, nor is it aware of, any information which would or could reasonably be expected to have a material adverse effect on the Licensee's development or commercialization of any Licensed Products (including but not limited to the obtaining of Regulatory Approvals);

(o) Licensor has not received from the FDA, the U.S. Drug Enforcement Administration ("DEA"), or any similar state, local, federal, or foreign Governmental Authority any written notice regarding the approvability or approval of any Licensed Product. No Licensed Product has been withdrawn, suspended or discontinued by the Licensor as a result of any action by the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, either within or outside the U.S. (whether voluntarily or otherwise). With respect to any Licensed Products, no officer, employee or, to the knowledge of the Licensor, agent of the Licensor has made any untrue statement of a material fact or a fraudulent statement to the FDA, DEA or any similar state, local, federal, or foreign Governmental Authority, failed to disclose any material fact required to be disclosed to the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, or committed an act, made a statement or failed to make a statement that, at the time such act, statement or omission was made, could reasonably be expected to provide a basis for the FDA, the DEA or any similar state, local, federal or foreign Governmental Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy, nor has any director, officer, employee or, to the knowledge of the Licensor, agent of the Licensor been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Article 335a(a) (or any similar law or regulation) or authorized by 21 U.S.C. Article 335a(b) (or any similar law or regulation);

(p) All necessary consents, approvals and authorizations of all Governmental Authorities and other parties required to be obtained by Licensor to perform its obligations under this Agreement have been obtained;

(q) Licensor does not own or Control any rights to any trademarks, service marks, trade dress, or similar intellectual property rights with respect to Licensed Products;

(r) As determined in accordance with applicable patent laws, there are no inventors, named or unnamed, with respect to the technology claimed in the Licensed Patents other than the inventors named on the Patents described on Schedule 1.24; and

(s) Licensor owns all right, title, and interest to the Existing Materials, free and clear of all liens, claims, and encumbrances, and the Existing Materials conform to the description thereof provided on Schedule 4.3 without material defect or contamination.

9.3 Disclaimer Concerning Technology. EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED,

EXCEPT FOR THOSE SET FORTH IN THIS AGREEMENT, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, (A) BOTH PARTIES ACKNOWLEDGE AND AGREE THAT, NOTWITHSTANDING THE DILIGENT EFFORTS OF THE PARTIES, THERE ARE NO ASSURANCES THAT A LICENSED PRODUCT WILL BE SUCCESSFULLY DEVELOPED OR COMMERCIALIZED BY LICENSEE, OR THAT REQUIRED GOVERNMENTAL APPROVALS IN CONNECTION WITH THE MANUFACTURE, CLINICAL DEVELOPMENT AND/OR COMMERCIALIZATION OF LICENSED PRODUCTS CAN OR WILL BE OBTAINED, AND (B) EACH PARTY EXPRESSLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, TO THE CONTRARY.

10. INDEMNITIES; LIMITS ON LIABILITY

10.1 Mutual Indemnification. Subject to Sections 10.2 and 10.3, each Party hereby agrees to indemnify, defend and hold the other Party, its Affiliates, its licensees, and its and their officers, directors, employees, consultants, contractors, sublicensees and agents (collectively, "Representatives") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation arising out of any such Claim (as defined in this Section 10.1), (collectively, "Damages") resulting from claims, suits, proceedings or causes of action ("Claims") brought by a Third Party against a Party or its Representatives based on: (a) material breach by the indemnifying Party of this Agreement, (b) failure to comply with any applicable law, rule, or regulation by such indemnifying Party in connection with the performance of its obligations hereunder or the exercise of licenses or rights conveyed hereunder, or (c) gross negligence or willful misconduct by such indemnifying Party, its Affiliates, or their respective employees, contractors or agents, except, in each case, to the extent such Damages arise from the gross negligence or willful misconduct of the other Party or its Representatives.

10.2 Indemnification by Licensee. Licensee hereby agrees to indemnify, defend and hold Licensor and its Representatives harmless from and against any Damages resulting from Claims brought by a third party against Licensor or its Representatives resulting directly or indirectly from Licensee's Development, Commercialization, manufacture, use or sale of Licensed Products, except to the extent such Damages are subject to indemnification by Licensee pursuant to Section 10.1.

10.3 Notification. In the event that any Third Party asserts a claim with respect to any matter for which a Party (the "Indemnified Party") is entitled to indemnification hereunder (a "Third Party Claim"), then the Indemnified Party shall promptly notify the Party obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby. Indemnifying Party may assume the complete control of the defense, compromise or settlement of any Third Party Claim (provided that any settlement of any Third Party Claim that (i) subjects Indemnified Party to any non-indemnified liability or (ii) admits fault or wrongdoing on the part of Indemnified Party will require the prior written consent of such Indemnified Party, provided such consent will not be unreasonably withheld),

including, at its own expense, employment of legal counsel, and at any time thereafter Indemnifying Party will be entitled to exercise, on behalf of Indemnified Party, any rights which may mitigate the extent or amount of such Third Party Claim; provided, however, that if Indemnifying Party has exercised its right to assume control of such Third Party Claim, Indemnified Party (i) may, in its sole discretion and at its own expense, employ legal counsel to represent it (in addition to the legal counsel employed by Indemnifying Party) in any such matter, and in such event legal counsel selected by Indemnified Party will be required to reasonably confer and cooperate with such counsel of Indemnifying Party in such defense, compromise or settlement for the purpose of informing and sharing information with Indemnifying Party; (ii) will, at Indemnifying Party's own expense, make available to Indemnifying Party those employees, officers, contractors, and directors of Indemnified Party whose assistance, testimony or presence is necessary or appropriate to assist Indemnifying Party in evaluating and in defending any such Third Party Claim; provided, however, that any such access will be conducted in such a manner as not to unreasonably interfere with the operations of the businesses of Indemnified Party; and (iii) will otherwise fully cooperate with Indemnifying Party and its legal counsel in the investigation and defense of such Third Party Claim.

10.4 Exclusion of Damages. IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT, UNLESS SUCH DAMAGES ARE DUE TO THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF THE LIABLE PARTY. NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 10.1 AND 10.2 ABOVE OR EITHER PARTY'S LIABILITY FOR PATENT INFRINGEMENT OR BREACH OF SECTIONS 2.1 OR 7.

11. MISCELLANEOUS

11.1 Entire Agreement; Amendment. This Agreement, including the exhibits attached hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

11.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the

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Parties, including without limitation, an act of God, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe; provided, however, the payment of invoices due and owing hereunder shall not be delayed by the payer because of a force majeure affecting the payer, unless such force majeure specifically precludes the payment process.

11.3 Governing Law. This Agreement shall be interpreted and construed in accordance with the laws of the State of North Carolina, excluding that body of law known as choice of law, and shall be binding upon the parties hereto in the United States and worldwide. All disputes with respect to this Agreement shall be brought and heard either in the North Carolina state courts located in Wake County, North Carolina, or the federal district court for the Eastern District of North Carolina located in Raleigh, North Carolina. The parties to this Agreement each consent to the in personam jurisdiction and venue of such courts and agree that service of process upon them in any such action may be made if delivered in person, by courier service, by telegram, by telefacsimile or by first class mail, and shall be deemed effectively given upon receipt.

11.4 Notices. Any notices, approvals, or consents required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, postage prepaid, or by internationally recognized express delivery service or personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

For Licensors: Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, CT 06516
Attn: _____
Fax: _____

For Licensee: Dara BioSciences, Inc.
4505 Falls of Neuse Road, Suite 125
Raleigh, NC 27609
Attn: John Didsbury, Chief Scientific Officer
Fax: (919) 861-0239

11.5 United States Dollars. References in this Agreement to "Dollars" or "\$" shall mean the legal tender of the United States of America.

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

11.7 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior consent of the other, which consent shall not be

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unreasonably withheld; provided, however, that Licensee may make such an assignment without Licensor's consent (a) to an Affiliate or in conjunction with a merger, acquisition, reorganization, consolidation, or sale of all or substantially all of the business or assets of Licensee to which this Agreement pertains, or (b) if Licensee or its Affiliates is required to, or reasonably believes that it will be required to, divest any Licensed Product or a competing product in order to comply with law or the order of any Governmental Authority as a result of a merger or acquisition. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment or attempted assignment by either Party in violation of the terms of this Section 11.7 shall be null and void and of no legal effect.

11.8 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.

11.9 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments (including without limitation patent assignments), and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

11.10 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering into this Agreement may be realized.

11.11 Headings. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.

11.12 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

[SIGNATURE PAGE TO FOLLOW.]

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IN WITNESS WHEREOF, the Parties have executed this Agreement by their proper officers as of the date and year first above written.

DARA BIOSCIENCES, INC.

BAYER PHARMACEUTICALS CORPORATION

BY: /s/ Richard A. Franco

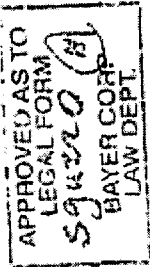
BY: /s/ R.C. Seaton

NAME: RICHARD A. FRANCO

NAME: R.C. SEATON

TITLE: PRESIDENT & CEO

TITLE: SR. VICE PRESIDENT



Confidential

IN WITNESS WHEREOF, the Parties have executed this Agreement by their proper officers as of the date and year first above written.

DARA BIOSCIENCES, INC.

BY: /s/ Richard Franco

NAME: RICHARD FRANCO

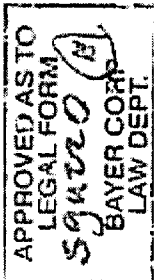
TITLE: PRESIDENT & CEO

BAYER PHARMACEUTICALS CORPORATION

BY: /s/ R.C. Seaton

NAME: R.C. SEATON

TITLE: SR. VICE PRESIDENT



Schedule 1.24

Licensed Patents

WO 2003/011842 with Priority Date 2001-07-27: Indane acetic acid derivatives and their use as pharmaceutical agents, intermediates, and method of preparation

WO 2003/089418 with Priority Date 2002-04-16: Indane acetic acid derivatives and their use as pharmaceutical agents

WO 2004/058174 with Priority Date 2002-12-20: Indane acetic acid derivatives and their use as pharmaceutical agents, intermediates, and method of preparation

WO 2004/098498 with Priority Date 2003-04-28: Indane acetic acid derivatives and their use as pharmaceutical agents

WO 2004/011446 A1 with Priority Date 2002-07-26; Indane, dihydrobenzofurane and tetrahydronaphthalene carboxylic acid derivatives and their use as antidiabetics*

WO 2004/082601 A2 with Priority Date 2003-03-13: Method of treating diabetes and diabetes-related disorders*

* The parties acknowledge that the two patent applications designated with the '*' may have been abandoned, in whole, in part, or with respect to certain jurisdictions, prior to the Effective Date.

Schedule 1.31

PPAR Assay

Description of the test system:

A chimeric system was used, in which the ligand binding domain (LBD) of the human PPAR protein is fused to the DNA binding domain (DBD) of the yeast transcription factor GAL4. The GAL4-PPAR- α , - γ or - δ . LBD fusion construct plus a reporter construct containing GAL4 binding sites in front of the luciferase gene were co-transfected and stably expressed in Chinese hamster ovary (CHO-K1, ATCC CCL61) cells. The PPAR-LBD mediated induction of luciferase gene expression correlates with relative light units (RLU) detected by a standard luciferase assay.

Cloning of human PPAR-LBD-GAL4 vector constructs:

Three human PPAR isoforms have been cloned for specificity testing. The GAL4- **PPAR α** LBD and **GAL4-PPAR γ LBD** expression constructs contain the ligand binding domain of PPAR α (aa 167-468, NCBI Acc. No. L02932) and PPAR γ (aa 203-506, NCBI Acc. No. AB005526), respectively. The human GAL4-PPAR δ expression construct contains the ligand binding domain (LBD) of PPAR δ (aa 138-442). The LBD receptor fragments have been amplified by PCR and cloned into the pcDNA3.1-GAL4-DBD vector downstream of the GAL4-DNA binding domain GAL4-DBD. This vector contains the GAL4-DBD (aa 1-147) of the pFC2-dbd vector (Stratagene). The reporter construct pFRLuc (Stratagene), which contains five copies of the GAL4 binding site in front of the minimal thymidine kinase promoter leads to the expression of the firefly luciferase (*Photinus pyralis*) after activation of the **PPAR δ** LBD-GAL4 fusion protein by ligand binding.

Transactivation assays using human PPAR-LBD-GAL-4 expressing CHO cells:

Stably transfected CHO (Chinese hamster ovary) cells (**PPAR α** GAL4, **PPAR γ** GAL4 or **PPAR δ** GAL4) were seeded in Optimem media (Invitrogen) containing 2 % delipidated serum (Hyclone), 1.35 mM Sodiumpyruvate (Invitrogen) and 0.2% Sodiumbicarbonate (Invitrogen). One day before the test day 1×10^5 cells per well (50 μ L) were seeded on a 96 well plate format (Greiner). After cultivation for 24h in a CO₂ Incubator (96% humidity, 5% v/v CO₂, 37°C) the medium was replaced by the same medium without serum (50 μ L). Stock solutions of compounds were prepared in DMSO and dilutions for dose-response curves were prepared in medium. In the case of agonistic determinations the compounds were directly added to the cells (2x concentration in 50 μ L). Luciferase activity was measured after 5 to 6 hours of incubation with a video camera system. The measured relative light units (RLUs) led to a sigmoid dose response curve with increasing compound concentrations. EC₅₀ values were calculated from dose-response curves using the computer program GraphPad PRISM® (Version 3.02). |

Schedule 4.3

Existing Material

BAY 68-2959 in reasonable amounts to be agreed upon in good faith by the parties as soon as reasonably practicable following the Effective Date based on the amount available to Licensor.

For BAY 68-2959, the following material (research grade quality, non-GLP) is available in amounts exceeding 1 g:

230 g [ethyl [(1S)-5-hydroxy-2,3-dihydro-1H-inden-1-yl]acetate] (intermediate for the synthesis of BAY 68-2959)

32 g Bay 68-2959 Lot. No. fje-57053-38-D

35 g Bay 68-2959 Lot. No. fje-57053-38-D hand ground

25 g Bay 68-2959 Lot. No. fje-57053-38-D micronized