18-01982-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, January 12, 2018 6:44 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.5 to the 3/31/07 10-Q, filed by Alpharma, Inc. on 5/1/2007. Confidential treatment was sought as to certain portions when initially filed with the Commission.

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

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

Sincerely,

Mark

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

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

Office of FOIA Services

January 26, 2018

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

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-01982-E

Dear Mr. Edwards:

This letter is in response to your request, dated January 12, 2018 and received in this office on January 16, 2018, for Exhibit 10.5 to the March 31, 2007, 10-Q, filed by Alpharma, Inc. on May 1, 2007.

The search for responsive records has resulted in the retrieval of 65 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at fultonc@sec.gov or 202-551-8186. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius 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,

Charlotte Fulton
FOIA Research Specialist

Enclosure

10.5

EXECUTION COPY

DEVELOPMENT AND LICENSE AGREEMENT

BETWEEN

TRIS PHARMA, INC.

AND

ALPHARMA BRANDED PRODUCTS DIVISION INC.

DATED

MARCH 28, 2007

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LIST OF EXHIBITS

DEVELOPMENT AND LICENSE AGREEMENT

THIS DEVELOPMENT AND LICENSE AGREEMENT is made as of this 28th day of March, 2007 (the "*Effective Date*"), and is entered into by and between Tris Pharma, Inc., a corporation organized and existing under the laws of the State of New Jersey, having offices located at 2033 Route 130; Suite D, Monmouth Junction, New Jersey 08852 ("*Tris*") and Alpharma Branded Products Division Inc., a corporation organized and existing under the laws of the State of Delaware, having offices located at One New England Avenue, Piscataway, New Jersey 08854 ("*Alpharma*").

PRELIMINARY STATEMENTS

A. Tris owns and has all right, title and interest in, or has acquired the exclusive rights to, the Tris Technology (as defined below).

B. Alpharma has expertise in the commercialization and marketing of pharmaceutical drug products in the Territory.

C. Alpharma is interested in collaborating with Tris in the development of the Product (as defined below) using the Tris Technology in exchange for the rights to license, commercialize and market such products in the Territory (as defined below), and Tris is willing to grant Alpharma such rights, and manufacture and supply the Product, all upon the terms and conditions set forth in this Agreement (as defined below).

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, the Parties (as defined below) hereby agree as follows:

1. DEFINITIONS.

1.1 "*AAA*" shall have the meaning assigned to such term in Section 15.2.

1.2 "*Affiliate*" shall mean, with respect to a Party, any entity controlling, controlled by, or under common control with, such Party, for only so long as such control exists. For these purposes, "*control*" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity.

1.3 "*Agreement*" shall mean this collaboration agreement together with all exhibits, schedules and attachments hereto.

1.4 "*Alpharma*" shall have the meaning assigned to such term in the preamble.

1.5 *"Anti-caking Complex"* shall mean pharmaceutical compositions comprising the Compound complexed with an ion exchange resin and having a diffusion barrier coating for use in the manufacture of the Subsequent Product and Initial Product.

1.6 "*Anti-Kickback Statute*" shall mean the Federal Health Care Programs Anti-Kickback Law, Title 42 of the U.S. Code Section 1320a-7b(b).

1.7 "*API*" shall mean the Compound(s) comprising the Product.

1.8 "*Audited Party*" shall have the meaning assigned to such term in Section 6.6.

1.9 "*Auditing Party*" shall have the meaning assigned to such term in Section 6.6.

1.10 "*Bankruptcy Code*" shall have the meaning assigned to such term in Section 13.7.2.

1.11 "*Basic Transfer Price*" shall have the meaning assigned in Section 8.1.3.

1.12 "*Bioequivalence*" *or* "*Bioequivalent*" shall mean having C_{MAX} and AUC each within 80% to 125% of the KADIAN® Referenced Product as the reference drug, as defined under the FDA definition for bioequivalence.

1.13 "*Blocking Patent*" means any valid patent issued to a Third Party that would be infringed by the manufacture, use, sale, offer for sale or importation of a Product in the Territory.

1.14 "*Breaching Party*" shall have the meaning assigned to such term in Section 13.3.

1.15 "*Calendar Quarter*" shall mean a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively.

1.16 "*cGMP*" shall mean current Good Manufacturing Practice and General Biological Products Standards as promulgated under and in accordance with the FDC Act, Parts 210, 211, and 600-680. To the extent consistent with U.S. law, "*cGMP*" shall also include practices and standards described in the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC, including Annex 18 thereof, and ICH Q7A.

1.17 "*Commercial Supply Agreement*" shall have the meaning assigned to such term in Section 8.2.6.

1.18 "*Commercial Transfer Price*" shall have the meaning assigned in Section 8.2.6.

1.19 "*Commercialization Program*" shall have the meaning assigned to such term in Section 5.1.

1.20 "*Commercially Reasonable Efforts*" shall mean, with respect to a Party, those efforts and diligence in, as applicable, the research, development and commercialization of a Product, such reasonable efforts and diligence to be in accordance with the efforts and resources a reasonably comparable pharmaceutical company would use for a product owned by it, or to which it has rights, which is of similar market potential, at a similar stage in its product life, taking into account the establishment of the Product in the marketplace, the competitiveness of the marketplace, the proprietary position of the Product, the regulatory structure involved, the profitability of the Product (without regard to the royalties being paid pursuant to this Agreement) and other relevant factors.

1.21 "*Compound*" shall mean morphine sulfate and/or morphine polystyrene.

1.22 "*Confidential Information*" shall mean, with respect to either Party, all confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which are disclosed by or on behalf of such Party to the other Party pursuant to, and in contemplation of, this Agreement, including, without limitation, information relating to the Tris Technology or any Product or proprietary commercial information developed by such Party; *provided, that* such Confidential Information is identified as confidential either: (i) at the time of disclosure; or (ii) if disclosed verbally or visually, designated as confidential in writing, within thirty (30) days of disclosure.

1.23 *"DEA"* shall mean the US Drug Enforcement Agency.

1.24 "*DEA Quota Estimate*" shall have the meaning assigned to such term in Section 8.3.3.

1.25 "*Development and Regulatory Program*" shall have the meaning set forth in Section 4.1.

1.26 *"Development Committee"* shall have the meaning assigned to such term in Section 3.2.

1.27 "*Disclosing Party*" shall have the meaning assigned to such term in Section 11.1.

1.28 *"DMF"* shall mean have the meaning assigned to such term in Section 4.3.2, and all references to the DMF throughout this Agreement shall refer to the open portion of the DMF unless specific reference is made to the closed portion of the DMF, which contains the confidential and proprietary information of Tris.

1.29 "*Effective Date*" shall have the meaning assigned to such term in the preamble of this Agreement.

1.30 "*Exclusivity Period*" shall have the meaning assigned to such term in Section 3.6.2(a).

1.31 "*Executive Officers*" shall mean, with respect to Tris, the Chief Executive Officer of Tris, and, with respect to Alpharma, the President of Alpharma.

1.32 "*EXW*" shall mean Ex Works as defined in the International Chamber of Commerce Incoterms 2000.

1.33 "*FDA*" shall mean the United States Food and Drug Administration, or any successor thereto.

1.34 "*FDC Act*" shall mean that federal statute entitled the Federal Food, Drug, and Cosmetic Act and enacted in 1938 as Public Law 75-717, as such may have been amended, and which is contained in Title 21 of the C.F.R. Section 301 *et seq*.

1.35 "*First Commercial Sale*" shall mean the first sale of the Subsequent Product and Initial Product, considered individually, for which payment has been received for use or consumption by the general public of such Product on a country-by-country basis in the Territory after all required Registrations have been granted. First Commercial Sale shall not include the sale of any Product for use in clinical trials or for compassionate use prior to Registration.

1.36 "*Force Majeure*" shall have the meaning assigned to such term in Section 14.

1.37 *"Fully-Burdened Manufacturing Cost"* shall mean costs (i) incurred in connection with the manufacture, labeling and packaging of each of the Subsequent Product and the Initial Product and/or the manufacture of the Anti-caking Complex, as the case may be, including the cost of direct materials (including API) and labor and variable overhead incurred in manufacturing plus the fully absorbed allocation of fixed overhead (including without limitation a reasonable allocation of idle plant charges, provided that the plant is operating at a level of at least 80% of capacity, otherwise such allocation shall be made based on that assumption), in each case with respect to the facility at which such Product (or Anti-caking Complex) are manufactured, but shall not include any costs related to batches which do not meet Specifications

or mark-up in addition to the twenty-five percent (25%) set forth in Section 8.2.6; and (ii) of DEA and controlled substance compliance reasonably allocated to the Product or Anti-caking Complex; in each case determined in accordance with GAAP; provided that, as of the Effective Date, such Fully Burdened Manufacturing Cost for the Product shall not exceed $ 0.0035 per mg of Compound (in weight equivalence with morphine sulfate) contained in the finished Product (or Anti-caking Complex) and may be increased thereafter to reflect no more often than once each calendar year in a maximum amount equal to the increase in the US Producer's Price Index during the then latest competed calendar year for which information is available. Notwithstanding the foregoing, the Parties shall adjust the Fully-Burdened Manufacturing Cost whenever the cost of raw materials (including API) shall increase.

1.38 "*GAAP*" shall mean generally accepted accounting principles in the United States, consistently applied by the Party at issue.

1.39 *"Generic Product"* shall mean, with respect to any Product or the KADIAN® Referenced Product, a pharmaceutical product designated by the FDA in the Orange Book as an AB rated product to such Product or the KADIAN® Referenced Product, as the case may be.

1.40 "*Inability to Supply*" shall mean Tris' failure to adequately supply Alpharma with ninety percent (90%) of the quantities of Product (or the Anti-caking Complex) ordered by Alpharma in accordance with the terms of this Agreement and within the volume limitations set forth in Section 8.4.1 within fifteen (15) days of the date established under this Agreement for such delivery.

1.41 "*Indemnitee*" shall have the meaning assigned to such term in Section 12.3.

1.42 "*Infringement*" shall have the meaning assigned to such term in Section 9.4.1.

1.43 *"Initial Platform Technology,"* with respect to the Initial Product, shall mean and include that certain technology that is the subject matter of US Patent Application No. 60/783,181 for "Modified Release Formulations Containing Drug-Ion Exchange Resin Complexes," and any improvement thereto whether patentable or not.

1.44 *"Initial Product"* shall mean the pharmaceutical formulation developed under this Agreement that is demonstrated to have Bioequivalence to KADIAN® Referenced Product (or as to which Alpharma elects to proceed hereunder without Bioequivalence) containing the Compound as its single active ingredient in a Initial tablet extended-release formulation using Tris' Initial Platform Technology, at those specific strengths that are developed as part of the Development and Regulatory Program. In the event that the Initial Product is not Bioequivalent to the KADIAN® Referenced Product, Alpharma shall have the option, but not the obligation, to proceed with the Development and Regulatory Program as if the Initial Product achieved Bioequivalence.

1.45 "*Invention*" shall mean any new or useful process, machine, manufacture, or composition of matter relating to or comprising the Product, and any improvement, enhancement, modification or derivative work to any Tris Technology, that is conceived or first reduced to practice or first demonstrated to have utility during the Term in connection with the Parties' activities under this Agreement.

1.46 *"JDA"* shall mean the Joint Defense Agreement between the Parties executed and dated concurrently with the execution and date of this Agreement.

1.47 *"KADIAN® NT"* shall mean the abuse deterrent form of the KADIAN® Reference Product which is presently the subject of Phase III trials being performed by, or on behalf of, Alpharma.

1.48 *"KADIAN® Referenced Product"* shall mean all of the finished dosage strengths of the oral dosage extended-release capsule formulation containing the active drug substance morphine sulfate as its sole active ingredient currently marketed or currently approved by the FDA for sale by Alpharma in the United States under Alpharma's trademark "KADIAN"®.

1.49 "*Knowledge*" shall mean, when used with respect to Tris, the actual knowledge of the representatives of Tris listed on *Exhibit 1.49*, as of the Effective Date.

1.50 "*Licensed Patent Action*" shall have the meaning assigned to such term in Section 9.6.

1.51 "*Long-Term Inability to Supply*" shall mean Tris' failure to adequately supply Alpharma with at least seventy-five percent (75%) of the quantities of Product (or the Anti-caking Complex) ordered by Alpharma in accordance with the terms of this Agreement in any two (2) consecutive Calendar Quarters or for any two (2) Calendar Quarters within any twelve (12) month period for any reason including an event of Force Majeure.

1.52 "*Marketing Plan*" shall have the meaning assigned to such term in Section 5.2.3.

1.53 "*Milestone Event*" shall have the meaning assigned to such term in Section 4.6.2.

1.54 "*Net Sales*" shall mean, with respect to each of the Subsequent Product and the Initial Product, considered individually, the gross amount invoiced for sales of such in arm's length sales by Alpharma, its Affiliates and permitted sublicensees, if any, to Third Parties, commencing with the First Commercial Sale of such Product, less the following deductions from such gross amounts which are actually incurred, allowed, accrued or specifically allocated: (i) credits, price adjustments or allowances for damaged products (to the extent not covered by insurance), returns or rejections of Product; (ii) normal and customary trade, cash and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing which have already been included in the gross amount invoiced); (iii) chargeback payments, fees and rebates (or the equivalent thereof) granted to group purchasing organizations, managed health care organizations, wholesalers, PBM's or other similar organizations or to federal, state/provincial, local and other governments, including their agencies, or to trade customers; (iv) any invoiced freight, postage, shipping, insurance and other transportation charges; and (v) sales, value-added (to the extent not refundable in accordance with applicable law), and excise taxes, tariffs and duties, and other taxes directly related to the sale (but not including taxes assessed against the income derived from such sale). In the event any other deductions from gross sales are permissible under GAAP to compute net sales, the Parties agree to enter into good faith negotiations to add such further deductions to the definition of Net Sales provided that the Parties concur that such addition is consistent with the intent of this Agreement. Net Sales, as set forth in this definition, shall be calculated applying, in accordance with GAAP, the standard accounting practices that Alpharma customarily applies to branded products.

1.55 "*Non-breaching Party*" shall have the meaning assigned to such term in Section 13.3.

1.56 "*Notice of Intent*" shall have the meaning assigned to such term in Section 8.7.2.

1.57 "*Opioid*" shall mean hydrocodone, hydromorphone, oxycodone, levorphanol, meperidine, methadone, dihydrocodeine, codeine, dihydromorphone, and morphine, and any complexes of the foregoing compounds, or pharmaceutically acceptable salts thereof.

1.58 "*Option*" shall have the meaning assigned to such term in Section 3.6.2(a).

1.59 "*Oral Containing Product*" shall mean any pharmaceutical product which (i) has as its sole active ingredient morphine sulfate, morphine polystyrene or any morphine complex, and pharmaceutically acceptable salts thereof, for any indications, or (ii) is a combination product with more than one active ingredient, but one such active ingredient is morphine sulfate, morphine polystyrene or any morphine complex, and pharmaceutically acceptable salts thereof.

1.60 "*Oxy Program*" shall have the meaning assigned to such term in Section 3.6.2(a).

1.61 "*Party*" shall mean, as applicable, Tris or Alpharma and, when used in the plural, shall mean Tris and Alpharma.

1.62 "*PDMA*" shall mean the Prescription Drug Marketing Act of 1987, Title 21 of the U.S. Code of Federal Regulations, Parts 203 and 205, as amended, and any final regulations or guidances promulgated, from time-to-time, thereunder.

1.63 "*Pilot Study(ies)*" shall mean one or more *in vivo* pharmacokinetic studies establishing Bioequivalence (excluding confidence intervals) to the KADIAN® Referenced Product on human subjects.

1.64 "*Pivotal Study(ies)*" shall mean one or more human pivotal pharmacokinetic studies establishing Bioequivalence, including statistical requirements (confidence intervals) to KADIAN® Referenced Product for inclusion in a Registration Application to support Registration as more fully defined in Section 320.23 of Title 21 of the U.S. Code of Federal Regulations in the U.S.

1.65 "*Presentation Form*" shall mean, individually, a solid product and a liquid product.

1.66 "*Product*" or "*Products*" shall mean the Subsequent Product and/or the Initial Product.

1.67 "*Product Development Plan*" or "*PDP*" shall have the meaning assigned to such terms in Section 4.2.

1.68 "*Q1*," "*Q2*," "*Q3*," and "*Q4*" shall have the meaning assigned to such terms in Section 8.3.1.

1.69 "*Receiving Party*" shall have the meaning assigned to such term in Section 11.1.

1.70 "*Registration*" shall mean, with respect to each country in the Territory, approval of the Registration Application for each of the Subsequent Product and the Initial Product, considered individually, filed in such country, including pricing or reimbursement approvals, where applicable, by the Regulatory Authority in such country.

1.71 "*Registration Application*" shall mean any filing(s) made with the Regulatory Authority in any country in the Territory for regulatory approval of the marketing, manufacture and sale (and pricing when applicable) of the Product in such country and all data or other information related to any said filing.

1.72 "*Regulatory Authority*" shall mean, the FDA and DEA in the U.S., and any health and drug enforcement regulatory authority(ies) in any other country in the Territory that is a counterpart to the FDA or DEA and has responsibility for granting regulatory approval for the marketing, manufacture, and sale of each of the Subsequent Product and the Initial Product, considered individually, or procurement and use of the API in such country, including, but not limited to, pricing and reimbursement approvals, and any successor(s) thereto as well as any state or local health and drug enforcement regulatory authorities having jurisdiction over any activities contemplated by the Parties.

1.73 "*Royalty Term*" shall have the meaning assigned to such term in Section 6.1.1.

1.74 "*Serious Adverse Drug Experience*" shall have the meaning assigned to such term in Section 10.1.2.

1.75 "*Specifications*" shall mean the confidential specifications governing the manufacture of and quality control testing procedures for the Product as agreed to in writing by the Parties, as the same may be modified, in writing, from time to time, in accordance with Section 8.5.2 or Section 8.5.3.

1.76 "*Stability and Clinical Profile*" shall mean the agreed upon profile for the Pilot Study(ies) and/or Pivotal Study(ies) and three (3)-month stability testing results with respect to the Product.

1.77 "*Subsequent Platform Technology,*" with respect to the Subsequent Product, shall mean and include that certain technology that is the subject matter of US Patent Application No. 60/783,181 for "Modified Release Formulations Containing Drug-Ion Exchange Resin Complexes," and any improvements thereto whether patentable or not.

1.78 "*Subsequent Product*" shall mean the pharmaceutical formulation developed under this Agreement that is demonstrated to have Bioequivalence to KADIAN® Referenced Product (or as to which Alpharma elects to proceed hereunder without Bioequivalence) containing the Compound as its single active ingredient in a Subsequent extended-release suspension formulation with a concentration of at least 30 mg/15 ml using Tris' Subsequent Platform Technology, at one (1) specific strength that is developed as part of the Development and Regulatory Program. In the event that the Subsequent Product is not Bioequivalent to the KADIAN® Referenced Product, Alpharma shall have the option, but not the obligation, to proceed with the Development and Regulatory Program as if the Subsequent Product achieved Bioequivalence.

1.79 "*Term*" shall have the meaning assigned to such term in Section 13.1.

1.80 "*Territory*" shall mean the United States, Canada and Mexico.

1.81 "*Third Party*" shall mean any person who or which is neither a Party nor an Affiliate of a Party.

1.82 "*Third Party Second Manufacturing Site*" means a site operated by an entity other than Tris to manufacture some or all of the Products (or Anti-caking Complex) hereunder.

1.83 "*Trademarks*" shall have the meaning assigned to such term in Section 7.3.

1.84 "*Tris*" shall have the meaning assigned to such term in the preamble.

1.85 "*Tris Know-how*" shall mean any and all unpatented formulae, processes, trade secrets, technologies and know-how including Inventions, whether or not patentable, including, without limitation, synthesis, preparation, recovery and purification processes and techniques, control methods and assays, chemical data, toxicological, and pharmacological data and techniques, clinical data, medical uses, forms, formulations and specifications, and which: (i) relates to the Tris Platform Technology; and (ii) are useful or necessary for the development, manufacture, use, offer for sale or sale of the Product in the Territory; and in each case, which Tris owns or controls on the Effective Date or during the Term.

1.86 "*Tris Marks*" shall have the meaning assigned to such term in Section 7.3.

1.87 "*Tris Patent Rights*" shall mean all patents (including, without limitation, all reissues, extensions, substitutions, re-registrations, re-examinations, re-validations, supplementary protection certificates and patents of addition and patents issued after the Effective Date but during the Term) and patent applications (including, without limitation, all provisional applications, continuations, continuations-in-part and divisions) including those Tris Patent Rights set forth on *Exhibit 1.86*, as the same may be modified, in writing, from time to time by Tris, and which: (i) claim or otherwise cover the Tris Platform Technology, including any patented Inventions relating thereto; and (ii) are useful or necessary for the development, manufacture, use, offer for sale or sale of the Product in the Territory; and in each case, which Tris owns or controls on the Effective Date or during the Term.

1.88 *"Tris Platform Technology"* shall mean the Subsequent Platform Technology and/or the Initial Platform Technology.

1.89 *"Tris Second Manufacturing Site"* means a site operated by Tris which is physically separate and regulated by the FDA separately from the primary facility which is being utilized by Tris for the manufacture of the Products (or Anti-caking Complex) hereunder which maintains operational resources (including without limitation all machinery and equipment) to manufacture the Products and the Anti-caking Complex.

1.90 "*Tris Technology*" shall mean the Tris Patent Rights and Tris Know-how.

1.91 "*United States*" or "*U.S.*" shall mean The United States of America, including its possessions, territories and commonwealths.

1.92 "*Valid Claim*" shall mean a claim of an issued patent or pending patent applications contained in the Tris Patent Rights covering Product that has not (a) expired or been canceled, (b) been declared invalid or unenforceable by a decision of a court or other appropriate body of competent jurisdiction, from which no appeal is or can be taken, (c) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (d) been abandoned, disclaimed or dedicated to the public.

1.93 "*Validation Batches*" shall mean batches of the Product that are produced to confirm reproducibility of manufacturing process in a form as required to support the validation of commercial supply with the applicable Regulatory Authorities.

2. REPRESENTATIONS, WARRANTIES AND COVENANTS.

2.1 *By Both Parties*. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

2.1.1 such Party: (A) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (B) has the corporate

power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (C) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such Party and would not materially adversely affect such Party's ability to perform its obligations under this Agreement;

2.1.2 such Party: (A) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (B) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except to the extent that enforceability may be limited by applicable bankruptcy, insolvency or other laws affecting the enforcement of creditors' rights generally and subject to the general principles of equity (regardless of whether enforcement is sought in a court of law or equity);

2.1.3 such Party has obtained all necessary consents, approvals and authorizations of all governmental authorities and Third Parties required to be obtained by such Party in connection with this Agreement, other than any approvals related to the Product required of applicable Regulatory Authorities as may be required under this Agreement from time to time; and

2.1.4 the execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (A) do not conflict with or violate any requirement of all applicable national, federal, state and local laws, rules or regulations; and (B) do not conflict with, or constitute a default under, any material contractual obligation of such Party.

2.2 *By Tris*. Tris represents, warrants and covenants to Alpharma that:

2.2.1 To Tris' Knowledge as of the Effective Date, Tris owns or has exclusive rights to all of the Tris Know-how in existence on the Effective Date, and the exclusive right to grant licenses with respect thereto, and shall use Commercially Reasonable Efforts to maintain the Tris Know-how as a trade secret of Tris to the extent that Tris does not seek to obtain patent protection for such Tris Know-how.

2.2.2 The Tris Patent Rights in existence as of the Effective Date are identified on *Exhibit 1.86*, and Tris is the owner of the entire right, title and interest in and to the Tris Patent Rights.

2.2.3 As of the Effective Date, no Third Party has any option, assignment, license or other right with respect to the Tris Technology for the manufacture, use or sale of the Subsequent Product or the Initial Product within the Territory.

2.2.4 To Tris' Knowledge as of the Effective Date, all relevant material, non-cumulative prior art has been identified to Alpharma in connection with the Tris Patent Rights in existence as of the Effective Date. Prior art listed in any Information Disclosure Statement of the Tris identified prior art and prior art cited in the patent applications and granted patent specifications and in the file wrappers have not been separately identified by Tris to Alpharma.

2.2.5 As of the Effective Date, Tris has not received a written claim or demand, legal or administrative proceeding alleging, nor does Tris have any Knowledge leading it to believe that the use of Tris Technology in connection with using, making, selling, offering for sale or having made the Product on the Effective Date infringes any valid issued patent claim (applied to Third Party issued patents in the same way that Valid Claim applies to issued Tris Patent Rights), except (i) those claims that contain one or more limitations that define

pharmacokinetic parameters, dissolution profiles, in vitro or in vivo and/or blood levels, or solubility of an Opioid, and (ii) Subject Patent(s) in the JDA; and in each case of clauses (i) and (ii), about which Tris makes no representations or warranties whatsoever;

2.2.6 As of the Effective Date, to Tris' Knowledge, none of the Tris Know-how in existence on the Effective Date was obtained by Tris or its Affiliates in violation of any contractual or fiduciary obligation to which Tris or its Affiliates or any of their respective employees or staff members are or were bound, or by the misappropriation of the trade secrets of any Third Party.

2.2.7 As of the Effective Date, Tris and its Affiliates have not entered into, and during the Term will not enter into, any agreement with any Third Party which is in conflict with the rights granted to Alpharma under this Agreement.

2.2.8 During the Term, Tris shall comply with all applicable federal, state, local and foreign laws in connection with its performance of the Development and Regulatory Program except to the extent that any noncompliance would not have a material adverse effect upon its ability to perform its obligations under this Agreement and with good laboratory and clinical practices and cGMP, as applicable, and will conduct such activities in accordance with Sections 4 and 8.

2.2.9 As of the Effective Date, Tris is in compliance in all respects with all applicable rules and regulations of the FDA and any other Regulatory Authority except to the extent that any noncompliance would not have an adverse effect upon its ability to perform its obligations under this Agreement.

2.3 *By Alpharma.* Alpharma represents, warrants and covenants to Tris that:

2.3.1 Alpharma shall comply with all applicable federal, state, local and foreign laws in connection with the performance of its responsibilities under the Development and Regulatory Program and the Commercialization Program, including, without limitation, the FDC Act, the PDMA, and the Anti-Kickback Statute and all federal, state and foreign health care fraud and abuse statutes and regulations, and all DEA and other controlled substance regulations and laws, and will conduct such activities in accordance with Sections 4 and 5, except to the extent that any noncompliance would not have an adverse effect upon its ability to perform its obligations under this Agreement; and

2.3.2 As of the Effective Date Alpharma has not entered, and during the Term will not enter, into any agreement with any Third Party that would preclude it from performing its obligations under this Agreement.

2.4 *Disclaimers.*

2.4.1 Other than as set forth in this Agreement, Tris hereby expressly disclaims all representations and warranties relating to the Products and the Tris Technology including, without limitation, any representation or warranty as to the validity or enforceability of any Tris Technology, the non-infringement of any Third Party patent or other intellectual property right or the prospects or likelihood of development or commercial success of any Product.

2.4.2 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT , NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, OR NON-INFRINGEMENT.

3. CONSULTATIONS.

3.1 *General.* Each Party shall consult with the other Party from time to time during the term as appropriate, as well as upon request from the other Party, in order to provide the other Party with a reasonable opportunity to review and evaluate the current status, progress made to date and to receive feedback from the other Party regarding the overall strategy of the Parties under this Agreement as well as planning and overseeing the implementation of the Development and Regulatory Program and the Commercialization Program. Each Party shall use Commercially Reasonable Efforts to undertake their respective activities and fulfill with respective responsibilities under the Development and Regulatory Program and the Commercialization Program to further the development and commercialization of the Product. Consistent with the foregoing, each Party shall take reasonable efforts to solicit input from the other Party and take into reasonable consideration the recommendations and concerns raised by the other Party regarding the Development and Regulatory Program and the Commercialization Program; *provided however:* (A) Tris shall retain the final right of decision with respect to all matters relating to the formulation and supply of the Product under the Development and Regulatory Program, other than adopting or making material changes to any PDP, which changes to any PDP are to be made with the approval of the Committee and the mutual written consent of the Parties; and (B) Alpharma shall retain the final right of decision, which in all cases shall be made in good faith using reasonable business judgment, and shall not be unreasonably delayed and in any event within sixty (60) days with respect to all matters relating to the clinical trials (including without limitation any "go/no-go" decision based upon the results of such trials) and, Registration of the Product under the Development and Regulatory Program and all matters under the Commercialization Program.

3.2 *Development Committee.* To further the objectives relating to the Development and Regulatory Program set forth in Section 3.1, within fourteen (14) days after the Effective Date, the Parties shall establish a joint development project team to carry out the day to day activities of the Development and Regulatory Program, (the "*Development Committee*") consisting of an equal number of representatives from each of Alpharma and Tris, the exact number of which shall be as the Parties agree, from time to time. Initially, the Development Committee shall consist of four (4) individuals; two (2) of whom shall be nominated by Tris; and two (2) of whom shall be nominated by Alpharma. Such members of the Development Committee shall consist of business and development personnel from each of Tris and Alpharma, who are appropriately skilled and knowledgeable in relation to the development of the Products in the Territory and who are deemed necessary to accomplish or have accomplished the work according to the Product Development Plan. Until receipt of approval of the Registration for the first Product in the Territory, Tris shall designate the chairperson and Alpharma shall designate the secretary of the Development Committee. Following receipt of approval of the Registration for the first Product in the Territory, provided that, and for so long as, work under the Development and Regulatory Program continues, Alpharma shall designate the chairperson and Tris shall designate the secretary of the Development Committee. Each shall serve co-terminus one (1) year terms, commencing on the Effective Date or an anniversary thereof, as the case may be. Such person shall be named no later than ten (10) days after the commencement of his or her term. The Development Committee shall be discontinued after all work under the Development and Regulatory Program has been completed.

3.2.1 The Development Committee shall perform the following responsibilities:

(a) review and approve each Product Development Plan and each update or amendment thereto;

(b) monitor the performance of the Parties pursuant to each Product Development Plan;

(c) monitor activities related to manufacturing in connection with the Development and Regulatory Program;

(d) review and approve any proposed labeling and packaging for the Product in the Territory;

(e) review and approve "go/no-go" decisions in connection with the Development and Regulatory Program;

(f) determine if the Stability and Clinical Profile of the Products have been met based upon the results of the Pilot Study(ies) and/or Pivotal Study(ies);

(g) determine the optimal batch size for the commercial manufacture of the Products used to manufacture Product (or Anti-caking Complex) to maximize use of the machinery and equipment and taking into consideration expected market demand;

(h) discuss pre-launch marketing plans and strategies;

(i) perform such other responsibilities as may be assigned to the Development Committee as may be mutually agreed upon by the Parties from time to time.

3.2.2 All Development Committee meetings shall be as often as the members may determine, but in any event not less than six (6) times per calendar year. Such meetings may be held in person, or any means of telecommunications or video conference, as the members deem necessary or appropriate, *provided* that at least one committee meeting per year shall be held in person and the location of such in person meeting shall alternate between Alpharma's and Tris' offices. A quorum for Development Committee meetings shall be two (2) members, with at least one (1) from each Party.

3.2.3 The Development Committee may make decisions with respect to any matter that relates to the Development and Regulatory Program and shall use Commercially Reasonable Efforts to resolve all such matters. All decisions of the Development Committee shall be made by unanimous vote or written consent, with Alpharma and Tris each having, collectively, one vote in all decisions. The chairperson shall attempt to mediate and resolve all matters in dispute brought before the Development Committee; however, any matters that cannot be resolved by the Development Committee shall be decided by the relevant Party as provided in Section 3.1.

3.2.4 Minutes for each of the Development Committee meetings shall be drafted by the secretary of the meeting and sent to the chairperson of the Committee for comment promptly after each such meeting (but in no event more than twenty (20) days). All actions noted in the minutes are to be reviewed and approved at subsequent meetings of the Development Committee; *provided*, that if the Parties cannot agree as to the content of the minutes, such minutes will be finalized to reflect such disagreement.

3.2.5 Each Party shall bear all its own costs, including expenses incurred by the members nominated by it in connection with their activities as members of the Development Committee.

3.3 *Liaison.* Each of the Parties shall at all times during the term of this Agreement nominate and maintain one or more of its experienced employees with skills appropriate to the

Development and Regulatory Program and the Commercialization Program to act as a liaison with the other Party and to be a point of contact for communicating Development and Regulatory Program and Commercialization Program matters.

3.4 *Responsibilities of Tris.* Consistent with Section 3.1, Tris shall have primary responsibility for planning and overseeing the implementation of the product development portion of the Development and Regulatory Program and shall cooperate with Alpharma with respect to certain aspects of the regulatory portion of the Development and Regulatory Program. Without limiting the foregoing, Tris shall:

3.4.1 design and determine the Product Development Plan, and each annual update to each PDP, and revise same, from time to time, as needed, and review and approve all such PDPs and any amendments thereto through the Development Committee;

3.4.2 conduct all activities under the Product Development Plan other than the Pilot Study(ies) and Pivotal Study(ies) and the Registration of the Product;

3.4.3 determine and review with Alpharma the selection of formulation of the Product and the use of the Tris Technology in the Parties' development efforts, as well as any changes to same;

3.4.4 cooperate with Alpharma as reasonably requested in Alpharma's preparation and review all Registration Applications, including the IND and NDA for the Product;

3.4.5 establish a manufacturing process pursuant to which clinical quantities of the Products, commercial quantities of the Products and/or commercial quantities of the Anti-caking Complex for use in the manufacture of the Product will be produced in conformity with the requirements of this Agreement;

3.4.6 be responsible for the progress of the Product development portion of the Development and Regulatory Program;

3.4.7 through the Development Committee process including Alpharma's rights set forth in Section 3.1, review and approve "go/no-go" decisions and recommendations as part of the Development and Regulatory Program;

3.4.8 review and provide comment on each Marketing Plan, and each annual update to each Marketing Plan;

3.4.9 at Tris' request, obtain from Alpharma and review information, data and reports (including such information as marketing budgets, sales forecasts and sales and marketing plans) arising from and generated by Alpharma in connection with the Commercialization Program in the ordinary course of Alpharma's business;

3.4.10 at Tris' request, obtain quarterly updates from Alpharma and review the progress of the Commercialization Program;

3.4.11 deliver the appropriate launch quantities of the Products (and/or the Anti-caking Complex), each to be manufactured and delivered to Alpharma and its agents in accordance with the requests as to timing and quantity of Alpharma; and

3.4.12 perform such other responsibilities as may be agreed upon by the Parties in writing from time to time.

3.5 *Responsibilities of Alpharma*. Consistent with Section 3.1, Alpharma shall have primary responsibility for planning and overseeing the implementation of the Commercialization Program and the regulatory portion of the Development and Regulatory Program. Without limiting the foregoing, Alpharma shall:

3.5.1 conduct all Pilot Study(ies) and Pivotal Study(ies) under the Product Development Plan;

3.5.2 review and evaluate the progress of the Development and Regulatory Program;

3.5.3 determine and approve each Marketing Plan, and each annual update to each Marketing Plan;

3.5.4 use Commercially Reasonable Efforts to determine and approve the launch of the Products in the U.S. and, at Alpharma's discretion, in each other country in the Territory as soon as practicable following Registration of such Product in such country, and in connection therewith provide Tris with the timing and quantities of Products (and/or Anti-caking Complex) required for each launch and all other necessary or useful pre-launch information to enable Tris to deliver the appropriate launch quantities of the Product to be manufactured and delivered to Alpharma and its agents by Tris;

3.5.5 at Tris' request, provide information, data and reports (including such information as marketing budgets, sales forecasts and sales and marketing plans) arising from and generated in the ordinary course of Alpharma's business in connection with the Commercialization Program;

3.5.6 be responsible for the Commercialization Program;

3.5.7 through the Development Committee process including Alpharma's rights set forth in Section 3.1, review and approve "go/no-go" decisions and recommendations as part of the Development and Regulatory Program;

3.5.8 prepare and file, and communicate with the Regulatory Authority with respect to, all Registration Applications in the U.S., including the IND and NDA for the Product, and, at Alpharma's discretion, in the other countries of the Territory;

3.5.9 in the event that Alpharma has the right to have Tris manufacture Anti-caking Complex pursuant to Section 8.9.1, establish a manufacturing process pursuant to which commercial quantities of the Initial Product and the Subsequent Product utilizing Anti-caking Complex supplied hereunder will be produced in full conformity with the requirements of this Agreement

3.5.10 perform such other responsibilities as may be agreed upon by the Parties in writing from time to time.

3.6 *Further Agreements*. In further consideration of the rights and responsibilities of the Parties set forth herein, the Parties agree as follows:

3.6.1

(a) During the Term (including the end of the Term due to the early termination of this Agreement with respect to the Subsequent Product pursuant to any Section of this Agreement), other than in connection with its performance pursuant to the terms of this

Agreement, Tris shall not directly or indirectly use for itself or otherwise use, sell, assign, license or make available to any Third Party the Tris Technology (i) for use in connection with the filing of any Registration Applications with a Regulatory Authority in the Territory with respect to any Oral Containing Product in the same Presentation Form as the Subsequent Product or (ii) for the manufacture in the Territory of any Oral Containing Product in the same Presentation Form as the Subsequent Product, except if such manufacture is done in connection with any product that is licensed for market and sale outside the Territory.

(b) During the Term (including the end of the Term due to the early termination of this Agreement with respect to the Initial Product pursuant to any Section of this Agreement other than as specifically otherwise provided in this Section 3.6.1), other than in connection with its performance pursuant to the terms of this Agreement, Tris shall not directly or indirectly use for itself or otherwise use, sell, assign, license or make available to any Third Party the Tris Technology (i) for use in connection with the filing of any Registration Applications with a Regulatory Authority in the Territory with respect to any Oral Containing Product in the same Presentation Form as the Initial Product or (ii) for the manufacture in the Territory of any Oral Containing Product in the same Presentation Form as the Initial Product, except if such manufacture is done in connection with any product that is licensed for market and sale outside the Territory.

(c) After the First Commercial Sale of the Initial Product, and except if the provisions of Section 3.6.1(d) or 3.6.1(e) provide for earlier termination of such restrictions, the restrictions set forth in Section 3.6.1(b) shall continue after the Term (i) for a period of five (5) years thereafter if this Agreement is terminated by Alpharma as to Initial Products pursuant to Section 13.3, or (ii) for a period of two (2) years thereafter if this Agreement is terminated by Tris as to Initial Products pursuant to Section 13.3.

(d) In the event the Initial Product receives Registration from the FDA, the restrictions on Tris set forth in Section 3.6.1(b) shall terminate with respect to the Initial Product immediately (and prior to the end of the Term): (A) if, and at the time, the KADIAN® Referenced Product is being offered for commercial sale by Alpharma on or after the six (6) month anniversary of the later of (i) receipt of Registration of the Initial Product in the U.S. from the FDA, or (ii) the delivery by Tris of launch quantities of commercial supply of the Initial Product as ordered by Alpharma in accordance with Section 8 and the Commercial Supply Agreement; or (B) provided there is no Generic Product to the KADIAN® Referenced Product or the Initial Product, if the Net Sales of the Initial Product are not at least $30,000,000 in any full Calendar Year after the later of receipt of Registration for the Initial Product from the FDA or delivery by Tris of launch quantities; or (C) if there is a Generic Product to the KADIAN® Referenced Product or the Initial Product, then upon the first to occur of: (i) the Net Sales of the Initial Product are less than $5,000,000 in the first full Calendar Year following the later of receipt of the Registration for the Initial Product from the FDA or delivery by Tris of launch quantities, (ii) the Net Sales of the Initial Product are not at least $10,000,000 in the second full Calendar Year following the later of receipt of the Registration for the Initial Product from the FDA or delivery by Tris of launch quantities; (iii) the Net Sales of the Initial Product are not at least $15,000,000 in the third full Calendar Year following the later of receipt of the Registration for the Initial Product from the FDA or delivery by Tris of launch quantities, and (iv) the Net Sales of the Initial Product are not at least $20,000,000 in each full Calendar Year thereafter.

(e) Notwithstanding anything to the contrary in Sections 3.6.1(c) and 3.6.1(d), during the Term of this Agreement and for such longer periods as set forth in clauses (x) and (y), except in connection with the performance of its obligation under this Agreement, Tris shall not, directly or indirectly: (x) in the event Alpharma terminates this Agreement as to the Initial Product pursuant to Section 13.5.1 or 13.5.2, for a period of two (2) years thereafter submit a Registration Application with the FDA utilizing the Tris Technology for any Oral

Containing Product in the same Presentation Form as the Initial Product, or (y) at any time reference any Alpharma NDA in any regulatory filing related to an Oral Containing Product in the same Presentation Form as the Initial Product. Tris shall ensure that any agreement that it enters with respect to the use of the Tris Technology in Oral Containing Products shall include Alpharma as a third party beneficiary. Tris shall provide Alpharma with an excerpt from any such agreement with a Third Party that sets forth such third party beneficiary provision.

3.6.2

(a) During the Term of this Agreement, and for the period from the Effective Date to the earlier of (i) six months after the Effective Date, or (ii) three (3) months after the date of receipt of sucessful results of the first Pilot Study (the *"Exclusivity Period"*), Tris hereby grants to Alpharma an exclusive option (the *"Option"*) to negotiate for an exclusive (even as to Tris) license throughout the Territory, with the right to grant sublicenses in accordance with Section 7.2, under the Tris Technology (including Tris Technology which may result from the Oxy Program, as hereinafter defined), to conduct a program with oxycodone (the *"Oxy Program"*) akin to the Development and Regulatory Program and the Commercialization Program, with respect to any product, including both a product in the same Presentation Form as the Subsequent Product and a product in the same Presentation Form as the Initial Product and to manufacture, use, market, sell, have sold and distribute any products resulting from the Oxy Program, in the Territory. Alpharma shall have the exclusive right during the Exclusivity Period to exercise the Option, pursuant to written notice to Tris, to have Tris enter into negotiations with Alpharma for the foregoing relating to the Oxy Program, and the parties shall negotiate the terms under which the Oxy Program shall operate, provided however such terms shall be no less favorable to Alpharma than those set forth herein for the Subsequent Products.

(b) Upon Tris' receipt of the notice by Alpharma exercising the Option,, the Parties shall promptly enter into good faith negotiations regarding the Oxy Program. Unless otherwise agreed to by the Parties in writing, if the Parties fail to enter an agreement with respect to the Oxy Program within forty-five (45) days after the date of receipt of the notice exercising the Option, then for a period of six (6) months after the conclusion of such negotiations, Tris shall not be permitted to enter into a similar arrangement with a Third Party relating to the Oxy Program on terms more favorable, taken as a whole and based on net present value, to such Third Party than the terms last offered by Alpharma to Tris. At the request of Alpharma, at least five (5) business days prior to entering into an agreement relating to the Oxy Program with a Third Party, Tris shall provide, subject to a confidentiality agreement reasonably acceptable to Tris, its calculations to evidence compliance with this Section 3.6.2(a) to an independent auditor selected by Alpharma and reasonably acceptable to Tris, solely for the purpose of having such auditor verify such compliance. Such accounting firm shall not disclose such calculations or the relative valuations to Alpharma, and shall only confirm, or not, such compliance. Alpharma shall pay the cost of any such audit.

3.6.3

(a) For purposes of the restrictions set forth in Section 3.6.3(b), the applicable period shall be from the Effective Date, and during the Term of this Agreement, provided that Alpharma is developing, marketing or selling a Subsequent Product under this Agreement, continuing until the earliest of: (i) ten (10) years after the First Commercial Sale of the Subsequent Product, (ii) the end of the first full calendar year following receipt of the Registration for the Subsequent Product from the FDA in the event that Net Sales for such calendar year have not reached $4,000,000; (iii) the end of the second full calendar year following receipt of the Registration for the Subsequent Product from the FDA in the event that Net Sales for such calendar year have not reached $10,000,000; (iv) the end of the third full calendar year following receipt of the Registration for the Subsequent Product from the FDA in

the event that Net Sales for such calendar year have not reached $15,000,000; (v) the end of the fourth full calendar year following receipt of the Registration for the Subsequent Product from the FDA in the event that Net Sales for such calendar year have not reached $20,000,000; (vi) the end of the fifth full calendar year following receipt of the Registration for the Subsequent Product from the FDA in the event that Net Sales for such calendar year have not reached $30,000,000; or (vii) the entry of a Generic Product of the Subsequent Product or any other sustained release Subsequent morphine product indicated for pain management that has twice a day, or less frequent, dosing pursuant to such product's label and not using Tris Technology. Otherwise, such restriction shall end when Alpharma is no longer developing, marketing or selling a Subsequent Product under this Agreement for any reason.

(b) For the period defined in Section 3.6.3(a), Tris shall not, either itself or otherwise through a Third Party use, sell, assign, license or make available to any Third Party the Tris Technology for use in connection with the marketing or sale of any liquid Opioid product indicated on its label for the management of pain for marketing or sales directly or indirectly to the institutional customer market in the United States and Mexico, which is comprised of long-term care facilities, nursing homes, hospitals, hospices and other similar institutional customers. In addition to all remedies that Alpharma has in equity or law for breach of the foregoing, Tris shall ensure that any agreement that it enters with respect to any liquid Opioid product indicated for the management of pain with a Third Party for the United States or Mexico shall include Alpharma as a third party beneficiary, in the event that such liquid Opioid product is sold or marketed into the institutional customer market in the United States and Mexico. Tris shall provide Alpharma with an excerpt from any such agreement with a Third Party that sets forth such third party beneficiary provision. For avoidance of doubt this Section 3.6.3(b) shall not limit the ability of Tris or its licensees and sublicensees to market and sell liquid Opioid products indicated for the management of pain, other than Oral Containing Products, to other than the institutional customer market in the United States and Mexico, including without limitation office-based physician or retail office-based markets in the United States and Mexico.

3.6.4 Without limiting Alpharma's rights under Sections 3.5.8 or 4.4, Alpharma may request, and upon such request, Tris shall, in collaboration with Alpharma, prepare all Registration Applications, including the IND and NDA for the reference listed doses of the Products in the U.S. In addition, Alpharma may request that Tris file such Registration Applications in Alpharma's name and after Alpharma's full review. Alpharma may at anytime withdraw its request and complete such Registration Applications without the assistance of Tris. As compensation for taking the actions set forth in this Section, Tris shall receive a total of $350,000 upon its completion, in a manner reasonably acceptable to Alpharma, of all Registration Application necessary in connection of such Products in the U.S., with $175,000 payable upon Tris' commencement of the first such Registration Application following Alpharma's request, and the balance payable upon the submission to the FDA of the last Registration Application contemplated by the Parties pursuant to this Agreement. If Tris is requested to take actions under this Section with respect to the Registration Applications but does not complete said Registration Applications, regardless of the cause or reason, Tris shall be entitled to retain the initial payment of $175,000. In addition to the foregoing payments, Alpharma shall pay for any filing fees (e.g., PDUFA fees) in connection with the filing of the foregoing Registration Applications. In the event that Alpharma requests any strength (after the first strength) of the Initial Product which requires additional Pilot Study(ies) or Pivotal Study(ies) for Registration, the Parties shall negotiate in good faith an appropriate fee for such work.

4. DEVELOPMENT AND REGULATORY PROGRAM.

4.1 *Overview of the Development and Regulatory Program; Initial Development and Regulatory Program Activities.* Within thirty (30) business days following the Effective Date, the Parties shall commence a program of research, formulation, pre-clinical, clinical development, process development, stability studies, scale-up, analytical work and validation batches for the Product designed to develop the Products and obtain Registration in the sequence set forth in Section 4.2 (the "*Development and Regulatory Program*"), for commercialization of the Products by Alpharma in accordance with Section 5. Each of the Parties shall perform the Development and Regulatory Program in a good scientific manner, and in compliance with all applicable laws, rules and regulations and shall endeavor to achieve the approval of the Products within the Territory efficiently and expeditiously. Each Party shall proceed diligently with its portion of the Development and Regulatory Program allocating sufficient time, effort, equipment and skilled personnel to complete all activities successfully and promptly.

4.2 *Product Development Plan.* The Parties shall, through the Development Committee, prepare an annual product development plan for the Products in the Territory (the "*Product Development Plan*" or "*PDP*") setting forth the plan of research, development and regulatory activities to be undertaking by the Parties, which shall be approved by and updated quarterly by the Committee and be further subject to the mutual agreement of the Parties. The initial PDP for the Product shall be attached to this Agreement as *Exhibit 4.2*, shall provide that initial product development work will be performed with respect to the Initial Product. In the event that a determination is made under Section 3.2.1(f), pursuant to the process set forth in Section 3.1, of the successful completion of the Pilot Study(ies) demonstrating Bioequivalence of the Initial Product to KADIAN® Referenced Product, then Alpharma shall proceed with the Subsequent Product development program and provide prompt written notice to Tris. In the event that a determination is made under Section 3.2.1(f), pursuant to the process set forth in Section 3.1, that the Pilot Study(ies) did not demonstrate Bioequivalence of the Initial Product to KADIAN® Referenced Product, then Alpharma shall determine whether to continue with the Initial Product development program and whether to commence the Subsequent Product development program. In such event, Alpharma shall have the right, in its sole discretion, to continue with the Initial Product development program independent of its decision with respect to whether to commence the Subsequent Product development program. Such determinations shall be made by Alpharma and communicated to Tris within fifteen (15) days after the results of the Pilot Study(ies) has been reviewed by the Development Committee. The PDP shall set forth which Pilot Study(ies) and Pivotal Study(ies) are currently contemplated by the Parties.

4.3 *Responsibilities of Tris under the Development and Regulatory Program.* As part of the Development and Regulatory Program, and subject to the funding obligations of the Parties set forth in Sections 4.4.11 and 4.6, Tris shall:

4.3.1 have the right and responsibility to manufacture, or, with the consent of Alpharma, have manufactured, and supply the Products for all pre-clinical and clinical uses and the Products for commercial uses, the manufacture of which shall be in accordance with the Specifications, the terms of this Agreement and all applicable US Federal laws, rules and regulations including, but not limited to, cGMP and all applicable laws and regulations in the jurisdictions in the Territory in which Alpharma intends to market and sell the Products. Notwithstanding the foregoing, in the event that Alpharma shall have the right to require Tris to manufacture and supply to Alpharma (or its designee) Anti-caking Complex pursuant to Section 8.9.1 for use in the manufacture of the Products, then thereafter Alpharma (or its designee) shall have the right, as contemplated in this Agreement, to manufacture or have manufactured for commercial uses the finished packaged form of the Products;

4.3.2 during the Development and Regulatory Program, keep Alpharma informed, through regular, periodic written reports, which may be brief summaries, at least once in each Calendar Quarter and through such meetings, review of relevant files and data and facility visits as Alpharma may reasonably request, of all development progress being made by Tris with respect to all activities related to the Products; prepare, and file the drug master file for the Anti-caking Complex and its process of the manufacture of the Products with the FDA (which shall include substantially the items listed on *Exhibit 4.3.2* attached hereto) (the *"DMF"*) in support of Alpharma's Registration Applications for the Products with the Regulatory Authorities and provide Alpharma with the right to cross-reference the DMF in its Registration Applications for the Products with the Regulatory Authorities; provided that, except as otherwise provided in this Agreement, Tris shall have no obligation to provide Alpharma with a copy of the DMF, but it shall provide such materials, including without limitation a copy of the DMF for review by independent patent counsel reasonably acceptable to Tris for the sole purpose of advising Alpharma with respect to freedom to operate issues related to the Tris Technology. During the period that Tris is preparing the DMF, Tris and Alpharma shall consult and discuss any additional activities, in addition to those set forth on *Exhibit 4.3.2*, that will be reasonably necessary or required for FDA approval with respect to the DMF. In the event that the Parties cannot agree on such additional activities, then Tris shall engage a consultant to review the items on *Exhibit 4.3.2* and determine whether any other activities are necessary for such FDA approval. Tris shall retain Lachman or such other consultant as may be mutually agreeable to both Parties. Alpharma shall reimburse Tris for seventy-five percent (75% of the costs of such consultant, up to a maximum reimbursement amount of $100,000). The consultant shall provide a report of its recommendations to both Parties, and both Parties shall be entitled to meet and discuss such report with such consultant. After the final report issues, both Parties shall accept and implement the recommendations contained in the report;

4.3.3 take the lead in, and be responsible for, all communications with the FDA arising during review of the DMF for the Products submitted by Tris;

4.3.4 promptly upon availability and in accordance with the timeline set forth in the Development Plan deliver to Alpharma sufficient quantities of the Initial Product from the batch utilized for the Pivotal Study(ies), for Alpharma to conduct testing in accordance to the Protocol entitled "Extractability of Morphine Sulfate and other Opioids from Extended Release Capsule and Tablet Formulations", attached hereto as *Exhibit 4.3.4*. In the event that the results of such testing do not, in Alpharma's reasonable judgment based upon the percentage and rate of active drug released by each of the Initial Product and the KADIAN® Referenced Product in the conduct of the testing pursuant to such protocol, achieve the abuse deterrent characteristics for the Initial Product that are substantially similar to or superior to the KADIAN® Referenced Product, then Alpharma shall have the right to terminate this Agreement, with no further payments due or owing to Tris;

4.3.5 pay one hundred percent (100%) of the cost of any Product used in a maximum of two (2) 3-way Pilot Study(ies) and one (1) Pivotal Study(ies) (fed, fast and steady state) for each of the Subsequent Product and the Initial Product and pay fifty percent (50%) of the cost of any additional Pilot Study(ies) or Pivotal Study(ies) (including Product costs) as required by Section 4.4.11;

4.3.6 pay fifty percent (50%) of any CRO penalty costs incurred by Alpharma that arise as a sole and direct result of any delay in delivery of Product to be used in the Pilot Study(ies) and/or Pivotal Study(ies) referenced in Section 4.3.5, where such delivery is the responsibility of Tris pursuant to the timelines set forth in the PDP or as otherwise determined by the Development Committee, provided that Alpharma has placed orders for such requirements as required pursuant to Section 8.2.4;

4.3.7 be responsible for the QA release of all Product that will be used in the Pilot Study(ies) and Pivotal Study(ies), and ship such Product to Alpharma, unless otherwise instructed by Alpharma with respect to the shipping destination;

4.3.8 if Alpharma determines, pursuant to Section 4.2, that the results of the Pilot Study(ies) for the Initial Product support initiation of the Subsequent Product development program, Tris shall commence such program within fifteen (15) days after Alpharma gives the instruction contemplated by Section 4.4.8; and

4.3.9 perform such other responsibilities with respect to the Development and Regulatory Program as may be determined by the Committee and mutually agreed upon by the Parties from time to time.

4.4 *Responsibilities of Alpharma under the Development and Regulatory Program.* As part of the Development and Regulatory Program, and subject to the funding obligations of the Parties set forth in Section 4.4.11 and 4.6, Alpharma shall:

4.4.1 prepare and file with the Regulatory Authorities those regulatory filings deemed necessary or desirable by Alpharma to undertake the development activities contemplated by the Development and Regulatory Program;

4.4.2 prepare and file those Registration Applications and other regulatory filings deemed necessary or desirable by Alpharma with the Regulatory Authorities to obtain all Registrations that Alpharma deems necessary or desirable to market and sell the Products in the United States and, in Alpharma's discretion, in each other country in the Territory;

4.4.3 take the lead in, and be responsible for, all communications with the Regulatory Authorities arising during review of the Registration Applications for the Products submitted by Alpharma (or by Tris on behalf of Alpharma pursuant to Section 3.6.4), *provided* that Alpharma will: (i) consult in advance with Tris with respect to any substantive or material filings or correspondence with the Regulatory Authorities to be made by Alpharma in accordance with this Agreement and the Development and Regulatory Program; and (ii) promptly provide Tris copies of any correspondence received from the Regulatory Authorities;

4.4.4 file the IND and NDA for the Products;

4.4.5 own and maintain all Registration Applications, Registrations and other regulatory filings and approvals for the Products in the Territory;

4.4.6 prepare the product label included in the Registration for the Products in the Territory, subject to review and approval of any proposed labels by the Development Committee;

4.4.7 keep Tris informed as to the status of all Registration Applications and other regulatory filings made pursuant to this Agreement;

4.4.8 if Alpharma determines, pursuant to Section 4.2, that the results of the Pilot Study(ies) for the Initial Product support initiation of the Subsequent Product development program, then Alpharma shall give Tris instructions to commence such program within fifteen (15) days after such determination is made;

4.4.9 subject to the confidentiality obligations under Section 11, grant Tris the right to use and cross-reference all pre-clinical and clinical data, INDs, clinical trial protocols and plans, Registration Applications, including Registrations and other regulatory filings,

studies, information and materials relating to the development of the Products in the Territory for use by Tris or its licensees and sublicensees solely in connection with the regulatory approval of the Products outside of the Territory;

4.4.10 provide a reasonably sufficient number of lots of KADIAN® Referenced Product to be used as the reference drug in the Bioequivalence studies;

4.4.11 design the protocols for the Pilot Study(ies) and Pivotal Study(ies) and select and engage a CRO to perform the Pilot Study(ies) and Pivotal Study(ies) and make all required payments directly to the CRO conducting same; provided that Alpharma shall be required to fund, for each of the Initial Product and the Subsequent Product, a maximum of two 3-way Pilot Study(ies) and one Pivotal Study(ies) (fed, fast and steady state) for each of the Products, including the cost incurred for the conduct of any in vivo studies related to alcohol (provided that subject to the payments set forth below, Tris shall pay all costs associated with in vitro studies related to alcohol), the out-of-pocket expenses of any Pilot Study(ies) or Pivotal Study(ies) paid to Third Parties (including Product costs paid to a Third Party or Product supply, development and testing costs incurred by Tris, either internally or from a Third Party, for the manufacture of the Products by Tris). Alpharma shall pay for costs incurred by Tris either internally of from a Third Party, for the conduct of any in vitro studies required by the FDA or requested by Alpharma to support its regulatory filings or marketing efforts (*e.g.,* dose proportionality/bridging studies, drug abuse studies), plus ten percent (10%). For any studies in excess of the three studies referred to herein for each Product: (i) to be agreed upon by the Parties; and (ii) to be funded equally by each of Alpharma and Tris using such methods and procedures as the Parties shall agree upon at such time; provided that the Parties may agree that some or all of Tris' contribution may be provided in the form of credits against future milestones or royalties. For clarity, in the event that Alpharma wishes to include any dosage strength which requires additional Pilot Study(ies) or Pivotal Study(ies) for Registration, the Parties shall negotiate in good faith an appropriate fee for such work, and Tris shall not be required to fund fifty percent (50%) of the costs associated with additional studies as a result thereof.

4.4.12 use Commercially Reasonable Efforts to cause the CRO to initiate and complete the Pilot Study(ies) in conformity with the time frame contained in the Development and Regulatory Program.;

4.4.13 use Commercially Reasonably Efforts to cause the CRO to initiate and complete the Pivotal Study(ies) in conformity with the time frame contained in the Development and Regulatory Program;

4.4.14 select and manage the business relationship with the API supplier; and

4.4.15 perform such other responsibilities with respect to the Development and Regulatory Program as may be determined by the Committee and mutually agreed upon by the Parties from time to time.

4.5 *Conduct of Development and Regulatory Program.* The Parties, acting in accordance with this Section 4 and the applicable PDPs, as updated, shall use Commercially Reasonable Efforts to develop and obtain Registration of the Products in the United States and, in Alpharma's discretion, in each other country in the Territory. Without limiting the generality of the foregoing, during the term of the Development and Regulatory Program, Tris and Alpharma shall:

4.5.1 cooperate with each other to implement the PDP, as updated, and such other activities that, from time to time, the Parties mutually decide are necessary or useful for the success of the Development and Regulatory Program;

4.5.2 use Commercially Reasonable Efforts to perform the work set out to be performed by such Party in the PDP;

4.5.3 conduct its activities under the Development and Regulatory Program in good scientific manner, and in compliance in all material respects with all requirements of applicable laws, rules and regulations, and all other requirements of any applicable cGMP, good laboratory practice and current good clinical practice to attempt to achieve the objectives of the Development and Regulatory Program efficiently and expeditiously;

4.5.4 maintain records, in sufficient detail and in good scientific manner, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in connection with the Development and Regulatory Program in the form required under all applicable laws and regulations; and

4.5.5 allow representatives of the other Party, upon reasonable prior written notice and during normal business hours, to visit such Party's facilities where any activities under the Development and Regulatory Program are being conducted, and consult, during such visits and by telephone, with personnel performing work on the Development and Regulatory Program, so long as such visits and consultations are not unreasonably disruptive; *and provided that* each Party shall be required to provide the other Party a list of any consultants and/or representatives of the first Party at least ten (10) days in advance of such consultant/representatives first visit to the second Party, and the second Party shall not be required to permit visits from any consultant/representative of the first Party also engaged by any Third Party reasonably determined by the first Party to be a competitor of the first Party. Each Party, its representatives and consultants shall maintain any information received (whether by observation or otherwise) during such visit in confidence in accordance with Section 11 and shall not use such information except to the extent otherwise permitted by this Agreement.

4.6 *Development and Regulatory Funding; Development Milestones.*

4.6.1 Except to the extent specifically stated herein, each Party shall bear all costs incurred by it in conducting their respective activities under the Development and Regulatory Program.

4.6.2 In partial consideration for the development of the Products hereunder, Alpharma shall pay to Tris the milestone payment amounts set forth below within thirty (30) days of the first achievement of the following milestone events (each, a "*Milestone Event*"), except that the payment due upon Milestone Event 1 (the execution of this Agreement) shall be due and payable on the Effective Date:

Milestone Event	**Initial Product**	**Subsequent Product**
1. Upon the execution of this Agreement	$1,500,000	
2. Upon a determination under Section 3.2.1(f), pursuant to the process set forth in Section 3.1, of the successful completion of Pilot Study demonstrating Bioequivalence of Initial Product to KADIAN® Referenced Product, or if Alpharma decides to continue the development of the Initial Product after completion of the Pilot Study	$500,000	

Milestone Event	Initial Product	Subsequent Product
3. Upon a determination under Section 3.2.1(f), pursuant to the process set forth in Section 3.1, of the successful completion of Pivotal Study demonstrating Bioequivalence of Initial Product to KADIAN® Referenced Product, or if Alpharma decides to continue the development of the Initial Product after completion of the Pivotal Study	$1,000,000	
4. Upon written notice under Section 4.2 to initiate the development program for the Subsequent Product		$500,000
5. Upon a determination under Section 3.2.1(f), pursuant to the process set forth in Section 3.1, of the successful completion of Pilot Study demonstrating Bioequivalence of the Subsequent Product to KADIAN® Referenced Product, or if Alpharma decides to continue the development of the Subsequent Product after completion of the Pilot Study		$1,000,000
6. Upon a determination under Section 3.2.1(f), pursuant to the process set forth in Section 3.1, of the successful completion of Pivotal Study demonstrating Bioequivalence of the Subsequent Product to KADIAN® Referenced Product, or if Alpharma decides to continue the development of the Subsequent Product after completion of the Pivotal Study		$1,000,000
7. Upon submission to the FDA of an NDA application for the Initial Product and the Subsequent Product	$500,000	$500,000
8. Upon FDA approval of Registration for each respective Products	$500,000	$500,000
9. Upon delivery of launch quantities of Product, provided that such launch quantities of each Product have been delivered to Alpharma or its agents within four (4) months of receipt of firm order from Alpharma for launch quantity for each respective Product.	$500,000	$250,000
10. Upon the listing in the Orange Book of the first issued U.S. Tris patent having at least one claim which covers one or both Products.	$750,000 (if patent covers the Initial Product)	$500,000 (if patent covers the Subsequent Product)

4.6.3 In addition to the milestone payments, Alpharma shall pay to Tris: (i) $150,000 for each strength (after the first strength) of the Initial Product (up to 8) which requires one registration batch, and (ii) $250,000 for each strength (after the first strength) which requires three registration batches, in each case which Alpharma requests in writing be included in the

Development and Regulatory Program; provided that in the event that the batch size for a registration batch for either clause (i) or clause (ii) exceed 200,000 tablets, Alpharma shall pay Tris an additional $ 0.0035 per mg of Compound (in weight equivalence with morphine sulfate) contained in t each tablet in excess of 200,000. Fifty percent (50%) of such payment shall be sent together with the written request with the remainder of the payment to be made within thirty (30) days after Tris delivers the results of the stability testing under the Development and Regulatory Program related to such additional strength. In the event that there are additional requirements necessary for the development of additional strengths, formulations or dosages that are not anticipated by this Section, the Parties agree to negotiate in good faith the appropriate fees for such work.

5. COMMERCIALIZATION PROGRAM.

5.1 *Generally.* The commercialization program for each of the Products shall begin at a time reasonably in advance of the anticipated approval date of the NDA for said Product and Alpharma shall use Commercially Reasonable Efforts to effect activities to sell, offer for sale, advertise, market, promote, launch (including pre-launch marketing) and commercialize the Product in the United States and, in Alpharma's discretion, in each other country in the Territory during the Term as set forth in this Agreement (the "*Commercialization Program*").

5.2 *Alpharma Responsibilities; Rights.* Subject to Section 5.3, Alpharma, either itself or by and through its Affiliates, permitted sublicensees and contracted Third Parties, shall be responsible for, and shall have the exclusive right to engage in, all marketing, advertising, promotion, launch and sales activities in connection with the marketing of the Products in the Territory. As part of the Commercialization Program, subject to Section 5.2.9, Alpharma shall:

5.2.1 use Commercially Reasonable Efforts to perform pre-commercialization analysis, planning, market preparation, and related marketing activities for the Products in the United States;

5.2.2 use Commercially Reasonable Efforts to commercialize the Products in the United States and, in Alpharma's discretion, in each other country in the Territory after having obtained all Registrations necessary to market and sell each Product in each such country, including, in each case to use Commercially Reasonable Efforts to launch each Product in each country within four (4) months thereafter;

5.2.3 commencing with the calendar year in which launch of a Product is expected, at Tris' request, deliver to Tris for its review and comment, a proposed overview marketing plan for each Product including activities expected to be undertaken during the upcoming calendar year as part of the Commercialization Program in the Territory and a timeline and budget for undertaking the same in the form prepared by Alpharma in the ordinary course of business (such plan, an "*Marketing Plan*"). In addition, Alpharma shall deliver any material modifications made to any Marketing Plan on a Calendar Quarter basis in the form prepared by Alpharma in the ordinary course of business;

5.2.4 carry out the distribution, marketing and sales of the Products in the United States and, at Alpharma's discretion, the other countries in the Territory;

5.2.5 conduct the Commercialization Program in compliance in all material respects with applicable laws; rules and regulations in the Territory;

5.2.6 use Commercially Reasonable Efforts to manage reimbursement for the Products in the appropriate reimbursement channels (health maintenance organizations, pharmacy benefit management companies and institutional customers);

5.2.7 at the request of Tris, provide periodic updates of all sales and marketing activities being taken pursuant to the Marketing Plan, not more frequently than once every Calendar Quarter, in reasonable detail of all Alpharma's efforts in this regard; and

5.2.8 maintain records, which shall be complete and accurate in all material respects and shall fully and properly reflect all revenues in connection with the Product.

5.2.9 Notwithstanding anything to the contrary elsewhere in this Agreement, Alpharma shall have full discretion to introduce or maintain the KADIAN® Referenced Product or KADIAN® NT (or any other replacement or successor thereto containing the Compound but not making use of the Tris Technology) on the market and position such product or products as Alpharma deems to be in its best interest; all without regard to any adverse effect on the economics payable to Tris hereunder.

5.3 *Product Termination.*

5.3.1 In the event that Alpharma fails to: (A) launch the Subsequent Product or Initial Product (considered individually) in the United States within six (6) months of completion of all activities (including, if required, receipt of Registration) required for the marketing of said Product therein, provided that such time period shall be extended by the delay caused by any event outside the control of Alpharma that directly delays any such Product launch; or (B) utilize Commercially Reasonable Efforts to market said Product within the United States and such failure continues for sixty (60) days after written notice thereof was provided to Alpharma by Tris (or, if such failure cannot be cured within such sixty (60)-day period, if Alpharma does not commence and diligently continue actions to cure such failure during such sixty (60)-day period), Tris shall have the right, in its sole discretion, to terminate the Commercialization Program and this Agreement with respect to such Product in the Territory, in accordance with Section 13.4.2.

5.3.2 Notwithstanding anything set forth in the preceding to the contrary, nothing set forth in this Section 5.3 is intended to relieve Alpharma of its obligations to use Commercially Reasonable Efforts to commercialize, market and sell the Product in the Territory as required hereunder.

6. ROYALTIES; SALES MILESTONES; PAYMENT.

6.1 *Royalties.*

6.1.1 As partial consideration to Tris for the license and other rights granted to Alpharma under this Agreement, during the Term Alpharma shall pay to Tris a royalty on the sale of the Products in each country in the Territory by Alpharma, its Affiliates and permitted sublicensees equal to (x) fifteen percent (15%) of Net Sales of the Subsequent Product, and (y) (A) twelve percent (12%) of Net Sales of the Initial Product on the first $100,000,000 of Net Sales in each of the first three (3) twelve (12) month periods of commercial sales commencing with the first calendar month in which the launch of the Initial Product occurs, and (B) twelve and one-half percent (12.5%) of Net Sales of the Initial Product for all other Net Sales not included in clause (A); in each of case for the longer of: (i) twenty (20) years after the First Commercial Sale of each of the Subsequent Product and Initial Product, considered individually, in such country in the Territory; or (ii) so long as the manufacture, use or sale of said Product by any entity other than Tris would infringe a Valid Claim of any Patent Rights included in the Tris Technology in such country in the Territory in the absence of the license set forth in the Agreement or (iii) the commercial launch of a second Generic Product equivalent to said Product in such country in the Territory by a Third Party unrelated to the party that launched the first such Generic Product (the "*Royalty Term*").

6.1.2 In the event that a Generic Product to the Subsequent Product or the Initial Product is being sold in any country in the Territory, for any Calendar Quarter in which sales of the Subsequent Product or the Initial Product, as the case may be, measured on a number of units sold basis are at least fifty percent (50%) lower than the average number of units of Product sold by Alpharma and its Affiliates and sublicensees during each of the four Calendar Quarters prior to the launch of such Generic Product, then the Net Sales royalty set forth in Section 6.1.1 for either the Subsequent Product or the Initial Product, as the case may be, shall be reduced on a country-by-country basis to 5%.

For purposes of clarity, the foregoing royalty reduction shall not apply to any Calendar Quarter in which the number of units of Product sold by Alpharma and its Affiliates and sublicensees are not at least fifty percent (50%) lower than the average number of units of Product sold in the four Calendar Quarters prior to launch of such Generic Product, as described above.

6.1.3 If either Party deems it necessary to obtain a license, or other rights to any Blocking Patents with respect to any Product, such Party shall notify the other Party.

(a) If the other Party agrees, then the Parties shall discuss in good faith the procedure by which the Parties will seek to obtain such license or other rights. The costs paid to a Third Party (including royalties upfront, initial, milestone and periodic payments, court awarded damages and settlement payments) associated with obtaining such license or other rights shall be shared equally by the Parties in the following manner: all costs shall be paid by Alpharma to such Third Party, *provided* that fifty percent (50%) of such costs shall be reimbursed to Alpharma by crediting at any one time (until such time as Alpharma has recovered such costs) up to thirty-three percent (33%) of any royalty payments due with respect to Net Sales of such Product; and Alpharma may carry forward any unreimbursed amount to be credited against future payments due with respect to Net Sales of such Product until the full fifty percent (50%) of such costs (including royalties upfront, initial, milestone and periodic payments, court awarded damages and settlement payments) paid by Alpharma have been fully recaptured by Alpharma.

In the case where the Blocking Patent is one of the Subject Patent(s) as such term is defined in the JDA the costs paid to a Third Party (including royalties upfront, initial, milestone and periodic payments, court awarded damages and settlement payments) associated with obtaining such license or other rights shall be borne by the Parties in the following manner: all costs shall be paid by Alpharma to such Third Party, *provided* that seventy five percent (75%) of such costs shall be reimbursed to Alpharma by (i) Tris, within thirty (30) days after receipt of written request therefor (together with evidence of such costs) paying to Alpharma an amount equal to the lesser of seventy-five percent (75%) of: (A) such documented costs paid to the Third Party at the time of obtaining such license or other right, or (B) the royalties paid by Alpharma during the then immediately preceding twenty four (24) months with respect to Net Sales of such Product, and (ii) thereafter crediting at any one time (until such time as Alpharma has recovered such costs) up to seventy five percent (75%) of any royalty payments due with respect to Net Sales of such Product; and Alpharma may carry forward any unreimbursed amount to be credited against future payments due with respect to Net Sales of such Product until the full seventy five percent (75%) of such costs (including royalties upfront, initial, milestone and periodic payments, court awarded damages and settlement payments) paid by Alpharma have been fully recaptured by Alpharma.

(b) If the other Party disagrees with the initial assessment, the Parties shall obtain an opinion of independent patent counsel reasonably acceptable to both Parties to make such determination, and such opinion shall be binding on both Parties. In the event that such opinion indicates that there is a Blocking Patent with respect to a Product, then the Parties

shall immediately proceed in the manner provided in Section 6.1.3(a). The Party making the incorrect assessment shall be solely responsible for all attorney fees incurred in connection with this Section 6.1.3(b).

6.1.4 Notwithstanding anything contained herein to the contrary, Alpharma agrees that, with respect to the Subsequent Product, not later than the during the following full calendar years following the year in which said Product receives an approved NDA from the FDA, Alpharma, together with its Affiliates and permitted sublicensees, if any, shall achieve the following minimum Net Sales of the Subsequent Product in the Territory, each as set forth in the following table:

Full Calendar Year	Minimum Net Sales
4	$4,000,000
6	$6,000,000
8	$8,000,000

In the event Alpharma fails to achieve the Minimum Net Sales requirements with respect to the Subsequent Product as set forth in this Section 6.1.4 during any Full Calendar Year noted in the table above for any reason other than an directly attributable to an Inability to Supply, Tris shall, as the sole right and remedy available to it under this Agreement, be entitled to terminate this Agreement with respect to the Subsequent Product pursuant to Section 13.4.1, provided that for all purposes hereunder Alpharma may satisfy its Minimum Net Sales requirements by the payment of an amount equal to 15% of the Net Sales shortfall for such Full Calendar Year.

6.2 *Sales Milestones.* In partial consideration for the development of the Subsequent Product hereunder, Alpharma shall pay to Tris the milestone payment amounts set forth below within thirty (30) days of the first achievement of the following milestone events:

6.2.1 Upon annual calendar year total Net Sales of the Subsequent Product in the Territory exceeding $10,000,000 for the first time, a milestone payment of $1,000,000 shall be paid by Alpharma to Tris;

6.2.2 Upon annual calendar year total Net Sales of the Subsequent Product in the Territory exceeding $20,000,000 for the first time, a milestone payment of $2,000,000 shall be paid by Alpharma to Tris;

6.2.3 Upon annual calendar year total Net Sales of the Subsequent Product in the Territory exceeding $30,000,000 for the first time, a milestone payment of $3,000,000 shall be paid by Alpharma to Tris; and

6.2.4 Upon annual calendar year total Net Sales of the Subsequent Product in the Territory exceeding $50,000,000 for the first time, a milestone payment of $5,000,000 shall be paid by Alpharma to Tris.

For example, and not by way of limitation, if in the first part of a given calendar year annual calendar year Net Sales of the Subsequent Product in the Territory exceeding $10,000,000 for the first time, then the $1,000,000 milestone payment shall be paid, and if later in the same calendar year annual calendar year Net Sales of the Subsequent Product in the Territory exceeding $20,000,000 for the first time, then another milestone payment in the amount of $2,000,000 shall be paid with the caveat that each of the individual milestone payments set forth in Sections 6.2.1

through 6.2.4 shall be paid only once. Furthermore, the Parties agree that no sales milestones are due with respect to the Initial Product.

6.3 *Payments.*

6.3.1 Beginning with the Calendar Quarter in which the First Commercial Sale of each of the Subsequent Product and Initial Product is made in the Territory, and for each Calendar Quarter thereafter, royalty payments shall be made by Alpharma to Tris pursuant to Section 6.1 within forty-five (45) days following the end of each relevant Calendar Quarter. Each royalty payment shall be accompanied by a report, summarizing the total gross sales of each Product, on a country-by-country basis, total Net Sales for each (including an itemization of the deductions applied to such gross sales to derive such Net Sales) during the relevant Calendar Quarter, the calculation of royalties, if any, due thereon, and any credits or reductions being claimed. In the event that no royalties are payable in respect of a given Calendar Quarter, Alpharma shall submit a royalty report so indicating.

6.3.2 All other payments to be made under this Agreement shall be made in accordance with the terms set forth in the applicable Section(s) regarding such payments.

6.4 *Mode of Payment; Interest.*

6.4.1 All payments required under this Agreement shall be made in U.S. dollars, regardless of the country(ies) in which sales are made, via wire transfer of immediately available funds as directed by Tris from time to time. For the purposes of computing Net Sales of the Product sold in a currency other than U.S. dollars, such currency shall be converted into U.S. dollars at an exchange rate equal to the buy rate of U.S. dollars published in the East Coast Edition of *The Wall Street Journal* for the last business day of the applicable Calendar Quarter. Such payments shall be without deduction of exchange, collection or other charges.

6.4.2 Tris shall be entitled to interest on all late payments. Such interest shall be calculated from the date such amount was due until the date such amount is actually paid, at the rate of two percent (2%) over the prime rate of interest reported in *The Wall Street Journal* (East Coast Edition) for the date such amount was due.

6.5 *Records Retention.* Commencing with the First Commercial Sale of the Product, Alpharma shall keep complete and accurate records pertaining to the sale of Product for a period of three (3) calendar years after the year in which such sales occurred, and in sufficient detail to permit Tris to confirm the accuracy of the royalties paid by Alpharma hereunder.

6.6 *Audits.* At the request and expense of either Party ("*Auditing Party*"), the other Party ("*Audited Party*") shall permit an independent, certified public accountant appointed by the Auditing Party and reasonably acceptable to the Audited Party, at reasonable times and upon reasonable written notice, to examine such records as may be necessary for the sole purpose of verifying the calculation of the Fully Burdened Manufacturing Cost, the calculation of and reporting of Net Sales and the correctness of any royalty or other payment made under this Agreement for any period within the preceding three (3) years. Said accountant shall not disclose to the Auditing Party or any other person any information, except that such accountant may disclose to the Auditing Party the fact of a deficiency, the lack of a deficiency or any overpayment, and the degree thereof, including the dollar amount. All results of any such examination shall be made available to the Audited Party. In the event that any audit reveals an under-payment or an overpayment in the amount of royalties or other payment obligation that should have been paid by the Audited Party to the other, then the underpayment amount shall be paid, or the over payment amount shall be returned, within forty-five (45) days after the Party to receive such payment makes a demand therefore, plus interest thereon if such amount is in

excess of five percent (5%) of the amount that actually should have been paid. Such interest shall be calculated from the date such amount was due or over-paid until the date such amount is actually paid, at the rate of two percent (2%) over the prime rate of interest reported in the East Coast Edition of *The Wall Street Journal* for the date such amount was due. In addition, if the underpayment or overpayment is in excess of five percent (5%) of the amount that actually should have been paid, then, if the Party receiving payment hereunder has paid for the audit, the paying Party shall reimburse the Auditing Party for the reasonable cost of such audit.

6.7 *Taxes.* In the event that a Party is mandated under the laws of a country to withhold any tax to the tax or revenue authorities in such country in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party, *provided* that the withholding Party shall take reasonable and lawful actions, at the other Party's sole cost, to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the United States Internal Revenue Service related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

6.8 *Bartering and Bundling Prohibited.* Alpharma, their Affiliates and permitted sublicensees shall not accept or solicit any bartered goods or services for the sale of any Product. The Product may not be sold in any bundled transaction with any other products or any service by Alpharma (or Tris) or their respective Affiliates or permitted sublicensees unless a reasonable pro-rata allocation of the payments received in such bundled transaction is attributable to the Product contained in the bundle.

7. GRANT OF RIGHTS.

7.1 *License Grants; Covenants.*

7.1.1 Subject to the terms and conditions of this Agreement, Tris hereby grants to Alpharma, an exclusive, (even as to Tris) license throughout the Territory, with the right to grant sublicenses in accordance with Section 7.2, under the Tris Technology, to conduct the Development and Regulatory Program and the Commercialization Program, with respect to the Products including Tris Technology which may result from the Development and Regulatory Program and to use, market, sell, have sold and distribute such Product in the Territory; *provided, however*, that nothing in this Section 7.1 shall alter the rights of Tris contained in this Agreement to manufacture the Product.

7.1.2 Subject to the terms and conditions of this Agreement, Alpharma on behalf of itself (including its Affiliates) and its (sub)licensees (and its and their successors and assigns), shall covenant not to sue Tris or any of its Affiliates or sublicensees (or any of its or their permitted successors or assigns) under or in connection with, and shall agree not to commence, aid, prosecute, or cause to be commenced, aided or prosecuted, any action or other proceeding against any such entity with respect to any Alpharma intellectual property that would be infringed or misappropriated by the manufacture or use of the Products (or the Anti-caking Complex) in the Territory.

7.1.3 Except as expressly set forth in this Agreement, no license is granted by Tris under its rights in any Tris Technology or Alpharma as to any Alpharma right whatsoever for any activities by the licensee that are outside the scope of the license grant in this Section 7.1,

or outside the scope of the licensee's rights and responsibilities under the Development and Regulatory or Commercialization Programs.

7.2 *Sublicensing*. Alpharma may grant sublicenses of the licenses granted to Alpharma under Section 7.1; *provided, however*, that no sublicense granted by Alpharma pursuant to this Section 7.2 shall be valid unless: (i) Alpharma shall submit all proposed sublicense agreements to Tris for approval, which approval shall not be unreasonably withheld or delayed and which approval shall not be required in connection with a sublicense to an Affiliate of Alpharma; (ii) Alpharma shall guarantee and be responsible for the making of all payments due, and the making of any reports under this Agreement, with respect to sales of Products by its Affiliates or sublicensees and their compliance with all applicable terms of this Agreement; (iii) each Affiliate or sublicensee agrees in writing to maintain books and records and permit licensor to review such books and records pursuant to the relevant provisions; (iv) such sublicense agreement requires it to continue in full force and effect in accordance with the terms and conditions of the respective sublicense agreement upon the termination of this Agreement, and permits licensee to assign to licensor such sublicense agreements; and (v) such sublicense agreement requires such sublicensee to observe all other applicable terms of this Agreement. In addition, no sublicense granted by Alpharma pursuant to this Section 7.2 shall be valid unless each such Affiliate or sublicensee agrees in writing to maintain appropriate records and permit Tris, jointly with Alpharma to inspect such records and visit such facilities pursuant to the relevant provisions of Sections 5.2.8, 6.5 and 6.6, and to observe all other applicable terms, of this Agreement. Alpharma shall promptly provide Tris with notice of any sublicense granted pursuant to this Section 7.2, and provide a copy of the executed sublicense agreement to Tris upon its request.

7.3 *Trademarks; Logos*. Alpharma shall market the Products throughout the Territory under a trademark or trademarks (collectively, the "*Trademarks*") selected by Alpharma. Alpharma shall own all right, title and interest in and to such Trademarks. Subject to applicable law and the approval of the applicable Regulatory Authorities, all labeling and packaging for all Products to be marketed and sold in the Territory shall contain the Tris trade name or logo and a reference to the brand name selected by Tris for the Subsequent Platform Technology or the brand name selected by Tris for the Initial Platform Technology, as applicable indicating that the Product utilizes one of the Tris Platform Technologies (collectively, the "*Tris Marks*"); provided that the use and depiction of the Tris Marks on the Product packaging and other written materials will be subordinate to and less prominent than the use of the Trademarks. Except as otherwise expressly provided in this Agreement, Tris shall own all right, title and interest in and to all such Tris Marks and Alpharma shall own all right, title and interest in and to the Trademarks. In connection with this Section 7.3:

7.3.1 Tris hereby grants to Alpharma a royalty-free license, with the right to sublicense pursuant to the terms of Section 7.2, to use the Tris Marks, in each country of the Territory, for the Term of this Agreement, or as provided in Section 13.8, in connection with the marketing and promotion of the Product as contemplated in this Agreement. The ownership and all goodwill from the use of the Tris Marks shall vest in and inure to the benefit of Tris. Tris reserves all rights not expressly granted herein.

7.3.2 Alpharma hereby grants to Tris a royalty-free license to use the Trademarks solely in connection with the manufacture of the Products to be sold by Alpharma under this Agreement. The ownership and all goodwill from the use of the Trademarks shall vest in and inure to the benefit of Alpharma. Alpharma reserves all rights not expressly granted herein.

7.3.3 Alpharma hereby acknowledges the exclusive ownership of Tris of the Tris Marks furnished by Tris (or its Affiliates) for use in connection with the Products.

Alpharma shall not, during the Term or thereafter, except as otherwise provided in Section 13.8, register, use, or attempt to obtain any right in and to any such Tris Marks or in and to any name, logo or trademark confusingly similar thereto. Tris hereby acknowledges Alpharma's exclusive ownership rights in the Trademarks, and accordingly agrees that at no time during or after the term of this Agreement to challenge or assist others to challenge the Trademarks or the registration thereof or attempt to register any trademarks, trade names or logos confusingly similar to such Trademarks.

7.3.4 All representations of the Tris Marks that Alpharma intends to use shall first be submitted to Tris for approval (which shall not be unreasonably withheld or delayed) of design, color, and other details or shall be exact copies of those used by Tris and shall in any event comply with all usage guidelines reasonably established and communicated to Alpharma in writing by Tris from time to time. Any change in Tris guidelines shall require that (a) Alpharma be permitted to sell any Product in stock complying with the "pre-change" guidelines and (b) Tris pay the reasonable cost of Alpharma complying with any changed guidelines. Alpharma shall submit representative promotional materials using any Tris Mark to Tris for Tris' prompt review and comment prior to their first use and prior to any subsequent change or addition to such promotional materials.

8. MANUFACTURING AND SUPPLY.

8.1 *Validation Batches.*

8.1.1 Based on purchase orders submitted by Alpharma to Tris at least one hundred eighty (180) days prior to the requested delivery date, Tris shall manufacture Validation Batches in a quantity as requested by Alpharma for each of the Initial Product and Subsequent Product, provided that Tris shall cooperate with Alpharma and use Commercially Reasonable Efforts to make such Validation Batches in shorter periods of time to allow Alpharma to optimize the dating of the Product in such Validation Batches after launch.

8.1.2 Except as set forth in Section 8.1.3, Alpharma shall not make any payments to Tris for Validation Batches of the Product produced hereunder.

8.1.3 In the event any such Validation Batches meet the Specifications, regardless of whether such Validation batches can be used and sold by Alpharma for commercial purposes, Alpharma shall be responsible for paying Tris its aggregate cost of goods, calculated on a Fully-Burdened Manufacturing Cost basis (the *"Basic Transfer Price"*) plus (i) 25% if such Validation Batches are sold by Alpharma as set forth in Section 8.4.2, plus royalties on the sale of such Validation Batch(es) in accordance with Section 6.1, 6.3 and 6.4, or (ii) 10% if such Validation Batches are not sold by Alpharma. In the event any such Validation Batches do not meet the Specifications, Tris shall be responsible for the costs of appropriately destroying such Validation Batches. The Basic Transfer Price shall also be used to price commercial supply of the Product as set out below.

8.1.4 During the process of manufacturing the Validation Batches, the Development Committee shall determine under Section 3.2.1(g), pursuant to the process set forth in Section 3.1, the optimal batch size for Product. Thereafter, Alpharma's forecasts and orders pursuant to Sections 8.3 and 8.4 shall be in multiples of such batch size.

8.2 *Supply of the Product; Reserved Capacity.*

8.2.1 Tris, at its cost and expense, shall have available in a timely manner, for exclusive use hereunder, the facilities and equipment reasonably necessary to meet the supply obligations anticipated under the Development and Regulatory Program and Commercialization

Program and the commercial requirements for the Product (and/or Anti-caking Complex). From the Effective Date and thereafter during the Term, subject to the terms and conditions of this Agreement, Tris shall supply: (i) at its sole cost and expense all of the Parties requirements of the Product for clinical use; and (ii) all of Alpharma's requirements for, and Alpharma shall purchase from Tris all of such requirements for, the Product and/or all of the Anti-caking Complex required to manufacture Alpharma's requirements for the Products for commercial use in the Territory. Tris shall not supply the Product (or Anti-caking Complex), directly or indirectly to any Third Party except for sale outside the Territory.

8.2.2 Tris shall use Commercially Reasonable Efforts to obtain adequate quantities of API for the development (based on the timing of clinical supply requirements as set forth in the timelines in the PDP or as otherwise determined by the Development Committee) and, based on the forecasts provided by Alpharma pursuant to Section 8.3, for the manufacture of all Product (and/or Anti-caking Complex) for which Tris has manufacturing responsibility hereunder, which shall be in a form mutually acceptable to Tris and Alpharma and which shall be obtained from a supplier or suppliers designated by Alpharma.

8.2.3 Tris shall manufacture all Product (and/or Anti-caking Complex for use in the manufacture of the Products) in a manner which is consistent with industry standards and all applicable laws, rules and regulations in the Territory including, but not limited to, cGMP and DEA regulations.

8.2.4 Tris shall use Commercially Reasonable Efforts to provide Alpharma with Product as and when reasonably required for clinical trials in packaged finished form, provided that Alpharma has provided advance written notice to Tris of its requirements for same at least seventy-five (75) days prior to the requested dates.

8.2.5 Tris shall use Commercially Reasonable Efforts to obtain approval from the DEA for the timely procurement and use of sufficient quantities of API to carry out its obligations hereunder.

8.2.6 All Product (or Anti-caking Complex) supplied to Alpharma for commercial use shall be at a purchase price equal to the Basic Transfer Price plus 25% of the Basic Transfer Price (the *"Commercial Transfer Price"*). Notwithstanding anything contained herein to the contrary, the Parties agree to use Commercially Reasonable Efforts to enter into a separate commercial supply agreement together with an appropriate technical and quality agreement (collectively, the "*Commercial Supply Agreement*") not later than twelve (12) months after the Effective Date, which Commercial Supply Agreement shall contain, among other things, terms substantially the same as those set forth in Sections 8.1 through 8.11 and Section 10 (with such additional detail as the Parties deem appropriate), and the relevant defined terms used in such Sections.

8.2.7 Based on Alpharma's current forecasted requirements for Product, Tris shall reserve and keep available for Alpharma the capacity to manufacture and supply those quantities set forth in such forecasts. Therefore, in the event that Alpharma does not place firm orders pursuant to Section 8.4 (for Q1 requirements) for at least 75% of the number of units of Product shown in Q2 of any given forecast (as required by clause B of Section 8.4.1), Alpharma shall pay Tris fifty percent (50%) of the then current Basic Transfer Price for such unordered number of units of Product. Following the end of each Calendar Quarter, Tris shall submit an invoice to Alpharma for such unordered batches at the foregoing price (based on average units of Product yielded per batch), and Alpharma shall pay such invoices within thirty (30) days after receipt. For example, using the example set forth in Section 8.4.1, in the next rolling forecast following the example (when Q2 becomes Q1), Alpharma would be required to place orders for at least 750,000 units of Product If Alpharma placed orders for 650,000 units, then Tris would

invoice Alpharma for 50% of the Basic Transfer Price for 100,000 units of Product. In the forecast following (when Q3 becomes Q1) Alpharma would be required to place orders for at least 500,000 units of Product (75% of 67% of 1,000,000 units). If Alpharma placed orders for 350,000 units, then Tris would invoice Alpharma for 50% of the Basic Transfer Price for 150,000 units of Product. Any payments made pursuant to this Section 8.2.7 shall be applied to the calculation of any adjustments made to the Basic Transfer Price as provided in Section 8.4.2(a) and the Commercial Transfer Price as provided in Section 8.4.2(b).

8.3 *Forecasts.*

8.3.1 *Initial forecast:* Commencing not less than nine (9) months prior to the anticipated shipment date for commercial launch quantities of each of the Initial Product and the Subsequent Product (treated separately) in the Territory, and thereafter, no later than one hundred five (105) days prior to the first day of each Calendar Quarter (*"Q1"*), Alpharma shall provide Tris with a non-binding, good faith forecast of estimated quantities in units for the Product and/or Anti-caking Complex for the following twelve (12)-month period (*i.e.*, Q1 and the next three Calendar Quarters (*"Q2,"* *"Q3,"* and *"Q4"*)), by Calendar Quarters.

8.3.2 *Launch and ongoing forecast:* Commencing not less than one hundred five (105) days prior to the anticipated shipment date for commercial launch quantities of each of the Initial Product and the Subsequent Product (treated separately) in the Territory, and thereafter, no later than one hundred five (105) days prior to the first day of each Calendar Quarter following the First Commercial Sale of each such Product (Q1 of such forecast), Alpharma shall provide Tris with a rolling forecast of estimated quantities in units for the Product and/or Anti-caking Complex for the following twelve (12)-month period (*i.e.*, Q1 and the next three Calendar Quarters (Q2, Q3, and Q4)), by Calendar Quarters, provided, that Q1 and Q2 of each such forecast shall indicate requirement in each such Calendar Quarter by month, and Q1 of each such forecast shall be binding. Such forecasts shall be revised and updated quarterly, using quantities in multiples of the relevant batch size for each Product as determined pursuant to Section 8.1.4, with each such forecast due one hundred five (105) days prior to the first day of each Calendar Quarter; .

8.3.3 *Forecast for DEA Quota:* In addition to the foregoing forecasts, upon a reasonable notice period to be agreed to by the Parties for the year of anticipated launch and no later than March 15th of each year commencing with the year following the year of anticipated launch of each of the Initial Product and the Subsequent Product (treated separately) in the U.S., Alpharma shall provide a good faith estimate (each, a *"DEA Quota Estimate"*) of its requirements of such Product for purposes of the DEA quota.

8.4 *Orders; Delivery; Payment.* Together with each forecast provided under Section 8.3, Alpharma shall place its firm order for Q1 of such forecast with Tris, setting forth units (using quantities in multiples of the relevant batch size for each Product as determined pursuant to Section 8.1.4), delivery dates and shipping instructions with respect to each shipment of Product and/or Anti-caking Complex for delivery. Each firm order submitted by Alpharma to Tris shall include delivery dates which provide Tris with a lead time of not less than one hundred five (105) days for such delivery. Tris shall accept such orders from Alpharma, subject to the other terms and conditions of this Agreement.

8.4.1 Notwithstanding the foregoing, commencing with the first forecast provided by Alpharma pursuant to Section 8.3, Tris will be required to accept firm orders for Product and/or Anti-caking Complex placed in Q1 only for quantities which are not less than 75% but not more than 125%, of the quantities of such Product and/or Anti-caking Complex reflected for Q2 in the forecast provided immediately preceding the most recent forecast plus any shortfall from deliveries required in Q1. In each quarterly forecast (A) the quantities which may

be reflected for Q2 shall not be less than 67% nor more than 133% of the quantities of such Product and/or Anti-caking Complex reflected for Q3 in the immediately preceding forecast and (B) the quantities which may be reflected for Q3 shall be at the discretion of Alpharma. In the event that Alpharma does not execute a firm order in any Q1 for at least 75% of the quantities of such Product and/or Anti-caking Complex reflected for Q2 in the forecast provided immediately preceding the most recent forecast, Tris shall be obligated to accept such lesser order but the provisions of Section 8.2.7 shall apply. For example, if a forecast indicates requirements for 1,000,000 units in each of Q1 through Q4, then the subsequent forecast must show at least 750,000 units, but not more than 1,250,000 units in Q1 (Q2 of the previous forecast), and at least 670,000 units, but not more than 1,330,000 units in Q2 (Q3 of the previous forecast),and the next subsequent forecast must show at least 500,000 units, but not more than 1,500,000 units in Q1 (Q2 of the previous forecast). In addition, Tris is not obligated to accept purchase orders if the aggregate amount of API required for manufacturing of both the Initial Product and the Subsequent Product in the aggregate exceeds the sum of the DEA Quota Estimates for the Initial Product and the Subsequent Product provided by Alpharma under 8.3.3 for the year. In the event that Alpharma requires additional Products, the Parties will work together and cooperate to attempt to obtain an increase of the DEA quota. Tris will, upon the request of Alpharma made in connection with any binding purchase order, use Commercially Reasonable Efforts to supply quantities of Product and/or Anti-caking Complex exceeding of the amounts set forth in this Section 8.4.1.

8.4.2

(a) Immediately prior to the commencement of commercial supply of Product, Tris shall provide Alpharma with its best estimate of the Basic Transfer Price for Product (or Anti-caking Complex) and Alpharma shall make payments for Product (or Anti-caking Complex) based on such estimated Basic Transfer Price plus 25% within thirty (30) days after delivery of the Product (or Anti-caking Complex). Thereafter, and for the next four (4) full Calendar Quarters, within thirty (30) days after the end of each such Calendar Quarter, Tris shall provide to Alpharma an updated estimate of the Basic Transfer Price for Product (or Anti-caking Complex) and Alpharma shall make payments for Product (or Anti-caking Complex) based on such updated estimated Basic Transfer Price plus 25% within thirty (30) days after delivery of the Product (or Anti-caking Complex). Within thirty (30) days after the end of each calendar year, Tris shall provide Alpharma with the actual Commercial Transfer Price for the Product (or Anti-caking Complex) for such calendar year, and shall promptly refund (or at Alpharma's sole option, credit) any overpayments made. In the event of an underpayment, Alpharma shall pay any such underpayment within thirty (30) days of notice from Tris; provided that, in the event Alpharma does not agree with the Commercial Transfer Price and uses Section 8.4.2(c) for resolution, Alpharma shall pay the last agreed upon Commercial Transfer Price for the Product (or Anti-caking Complex) within thirty (30) days of notice from Tris, and shall pay the balance, if any, within thirty (30) days after the Commercial Transfer Price is finally determined pursuant to Section 8.4.2(c), or receive a credit that can be applied to the next shipment(s) of Product (or Anti-caking Complex).

(b) After the first four (4) full Calendar Quarters of commercial supply, Tris shall use the actual Commercial Transfer Price for the previous calendar year for purposes of invoicing Alpharma for Product (or Anti-caking Complex) and Alpharma shall make payments for Product (or Anti-caking Complex) based on such estimated Commercial Transfer Price within thirty (30) days after delivery of the Product (or Anti-caking Complex). Within thirty (30) days after the end of each calendar year, Tris shall provide Alpharma with the actual Commercial Transfer Price for the Product (or Anti-caking Complex) for such calendar year, and shall promptly refund (or at Alpharma's sole option, credit) any overpayments made. In the event of an underpayment, Alpharma shall pay any such underpayment within thirty (30) days of notice from Tris; provided that, in the event Alpharma does not agree with the Commercial

Transfer Price and uses Section 8.4.2(c) for resolution, Alpharma shall pay the last agreed upon Commercial Transfer Price for the Product (or Anti-caking Complex) within thirty (30) days of notice from Tris, and shall pay the balance, if any, within thirty (30) days after the Commercial Transfer Price is finally determined pursuant to Section 8.4.2(c), or receive a credit that can be applied to the next shipment(s) of Product (or Anti-caking Complex).

(c) In the event that Alpharma does not agree with the actual Commercial Transfer Price provided by Tris under either Section 8.4.2(a) or 8.4.2(b), the Parties shall meet in an good faith attempt to reach an agreement as to the Commercial Transfer Price (and Alpharma shall have reasonable access to the books and records of Tris prior to such meeting) but, if such agreement is not reached within ten (10) days either Party can cause the dispute to be presented to an independent certified public accounting firm of national standing (which firm shall have no regular business relationship with either Party). The finding of such firm shall be binding upon the Parties absent manifest error. Expenses of such review shall be borne by the Party adversely affected by such firm's findings.

8.4.3 Alpharma's orders shall be made pursuant to purchase orders which are in a form mutually acceptable to the Parties, to the extent that such form is not inconsistent with the terms of this Agreement. ANY ADDITIONAL OR INCONSISTENT TERMS OR CONDITIONS OF ANY PURCHASE ORDER, ACKNOWLEDGMENT OR SIMILAR STANDARDIZED FORM GIVEN OR RECEIVED PURSUANT TO THIS AGREEMENT SHALL HAVE NO EFFECT AND SUCH TERMS AND CONDITIONS ARE HEREBY EXCLUDED.

8.4.4 Tris shall ship and deliver quantities of Product and/or Anti-caking Complex ordered by Alpharma in accordance with the terms of this Agreement on the dates specified in Alpharma's purchase orders submitted in accordance with Section 8.4. All Product and/or Anti-caking Complex shall be delivered EXW Tris' New Jersey manufacturing facility. The carrier shall be selected by Alpharma. Each shipment shall be insured for the benefit of Alpharma. All shipping and insurance costs, as well as any special packaging expenses, shall be paid by Alpharma.

8.5 *Conformity; Specifications; Quality Control.*

8.5.1 Tris represents and warrants that all Product and/or Anti-caking Complex supplied hereunder will be manufactured, stored and tested at facilities which are approved by the FDA and any other relevant Regulatory Authority and shall conform with the current cGMP and Specifications in effect for the Product and Anti-caking Complex at the time of shipment and any other mandatory standards for the Product and Anti-caking Complex, in accordance with the regulatory specifications and methods described and approved in the Registration and that the Product and Anti-caking Complex when delivered will not be adulterated or misbranded under the FDA Act and will have an expiry date of at least eighteen (18) months from the date of delivery to Alpharma; provided that Tris shall use reasonable commercial efforts to take such actions as necessary to obtain a longer expiry date from the appropriate Regulatory Authority. Tris will take all actions reasonably required to receive all required DEA approvals in order to purchase adequate quantities of API for the Product and Anti-caking Complex required to be supplied to Alpharma from a supplier or suppliers designated by Alpharma.

8.5.2 Tris shall have the right to change, and Alpharma shall have the right to request a change in, the Specifications of any of the Products or the Anti-caking Complex if, in such Party's reasonable opinion, such Product or Anti-caking Complex when manufactured in accordance with the then-current Specifications is likely to infringe the intellectual property rights of a Third Party; *provided, that,* in no event shall any modification be made to the method

or process of manufacture or production of the Product or Anti-caking Complex, which modification shall have the effect of requiring Alpharma to supplement or amend the Registration of any of the Product, without the written consent of Alpharma, which shall not be unreasonably withheld.

8.5.3 Either Party shall have the right to request a change to the Specifications, from time to time, to accommodate the demands or requests of any applicable Regulatory Authority in the Territory, at any time during the Term, on not less than twelve (12)-months' (or such shorter period required by a Regulatory Authority) prior written notice to the other Party; provided that all changes to Specifications shall be implemented pursuant to the formal change control policy as set forth in the Commercial Supply Agreement.

(a) To the extent that Tris desires to implement any change to Specifications which is not required pursuant to Section 8.5.3(c), Tris shall obtain the consent of Alpharma (which shall not be unreasonably withheld or delayed) regarding such proposed change to Specifications. If consent from Alpharma is obtained, Tris shall be responsible for making any required filing with respect to such change and for any for the cost and expense of implementing such change to Specifications, including any costs and expenses incurred by Alpharma in connection therewith.

(b) To the extent that Alpharma desires to have any change to Specifications implemented which is not required pursuant to Section 8.5.3(c), Alpharma shall obtain the consent of Tris (which shall not be unreasonably withheld or delayed) regarding such proposed change to Specifications. If consent from Tris is obtained, Alpharma shall be responsible for making any such change to the Specifications, including the cost and expense of implementing such change to Specifications, and any costs and expenses incurred by Tris in connection therewith.

(c) If any proposed change in Specifications is in response to a pronouncement of the FDA, a change in controlling compendial monograph, an event of Force Majeure, or a change in applicable law, each Party will cooperate with the other in any reasonable manner to effect such change in a timely manner. Alpharma shall be responsible for the cost and expense of implementing such change to Specifications, including any costs and expenses incurred by Tris in connection therewith. Notwithstanding the foregoing, if the proposed change to the Specifications is due to a deficiency that is substantially and directly caused by Tris or substantially and directly related to the Tris Technology, then Tris shall be responsible for the cost and expense of implementing such change to Specifications, including any costs and expenses incurred by Alpharma in connection therewith.

(d) If any such change pursuant to this Section 8.5.3 will result in an increase in production costs to Tris, Tris shall be entitled to reflect such increase in the Commercial Transfer Price. Alpharma shall be responsible for, and bear all incremental cost incurred by Tris of, any changes in Product or (to the extent applicable) Anti-caking Complex labeling, packaging, package inserts, quality control and assurance activities, testing, or validation required by the applicable Regulatory Authorities in the Territory. In the event that any change to Specifications is implemented, the Parties agree to cooperate with each other in good faith to enable each Party to comply with the terms of this Agreement.

(e) Solely to facilitate change control activities and manufacturing audits pursuant to Section 8.5.6, Alpharma shall be permitted to designate one Quality Assurance representative, who shall be reasonably acceptable to Tris and who shall be required to execute a confidential disclosure agreement with Tris in form and substance reasonably acceptable to Tris, who shall be provided with full access to all documentation at Tris' facility relating to the manufacture of Products and/or Compound/Complex Resin, including the closed portion of the

DMF. Such access shall be provided solely at Tris' facility, and no copies will be permitted to be made and no notes will be permitted to be taken without Tris' prior approval; *provided, however,* that such Quality Assurance representative shall be permitted access to the closed portion of the DMF up to two times per calendar year until three (3) years after Registration in the U.S. for the Product is obtained from the FDA. At any time during the Term of this Agreement, upon the request of Alpharma due to problems or potential areas of deficiency with respect to the DMF, Alpharma shall be permitted to have additional necessary personnel, each of whom shall be reasonably acceptable to Tris and each of whom shall be required to execute a confidential disclosure agreement with Tris in form and substance reasonably acceptable to Tris, have full access to the closed portion of the DMF. The Quality Assurance representative of Alpharma shall review and approve Tris' change control process for the DMF that will be followed in the event that Tris proposes to make any changes to the DMF with respect to the Product. Such review and approval shall not be unreasonably withheld or delayed.

8.5.4 Tris shall conduct, or cause to be conducted, quality control testing of the Product and Anti-caking Complex prior to shipment, in accordance with the Specifications. Tris or its designee shall retain records pertaining to such testing, batch records and records otherwise required by any Regulatory Authority in connection with the manufacture, storage or shipping of the Product or Anti-caking Complex for the period required by any Regulatory Authority in any country in the Territory. At any time prior to one (1) year after the expiration date of the Subsequent Product or the Initial Product into which the Anti-caking Complex were incorporated, Tris shall allow Alpharma, upon reasonable advance notice, to inspect any such records. Each shipment of Product and Anti-caking Complex shall be accompanied by a copy of all in-process and finished product test results for the API, Anti-caking Complex and Product, as well as all documentation regarding deviations and investigations resulting from such testing and/or batch processing, except for that which is part of Tris' closed section of the DMF or other information deemed proprietary to Tris; provided, however, if after Alpharma's review of such documentation regarding deviations and investigations resulting from the testing and/or batch processing, Alpharma reasonably requires information contained in any portion of the closed section of the DMF or other information deemed proprietary to Tris to assess such deviations and investigations, Alpharma shall be permitted to have necessary personnel, each of whom shall be reasonably acceptable to Tris and each of whom shall be required to execute a confidential disclosure agreement with Tris in form and substance reasonably acceptable to Tris, have the right to review such information at Tris' location. After three (3) years from the First Commercial Sale, the Parties shall review and decide what documents are to be eliminated from all such documents that are burdensome.

8.5.5 Tris shall annually make available to Alpharma copies of stability data for the Product and Anti-caking Complex. Any significant trends shall be promptly reported to Alpharma in writing.

8.5.6 For so long as Tris is manufacturing Products or Anti-caking Complex under the Commercial Supply Agreement, Alpharma shall have the right, at its sole cost and expense, during normal business hours and upon ten (10) days' prior notice, to have a duly authorized representative conduct compliance inspections or other inspections, audits and investigations to ensure that Tris' handling, manufacture, testing, storage and shipping of the Products or Anti-caking Complex comply with cGMP, all applicable laws and the Specifications; provided, however, that such inspection, audit or investigation shall not unreasonably interfere with the operations at Tris' facilities and shall not occur more than once per Calendar Year unless Section 8.5.7 applies. In all cases, such Alpharma representatives shall fully comply with Tris' procedures in Tris' facility including procedures adopted for the purpose of protecting the confidential information and/or manufacturing processes of Third Parties from observation by Alpharma's representatives.

8.5.7 If two (2) or more shipments per calendar year of Product and/or Anti-caking Complex are finally determined to be rejectionable, in whole or in part, by Alpharma in accordance with Section 8.6, Alpharma shall be entitled to inspect the facilities at which such Product and/or Anti-caking Complex are manufactured not more than once each calendar quarter during the continuation of such manufacturing problem and such inspection shall be in addition to the annual inspection provided for in Section 8.5.6; provided, however, that access to the closed portion of the DMF shall only be provided to Alpharma representatives if necessary for resolution of the manufacturing problem, in which case each of whom shall be reasonably acceptable to Tris and each of whom shall be required to execute a confidential disclosure agreement with Tris in form and substance reasonably acceptable to Tris. Tris shall permit representatives of any Regulatory Authority to gain access to Tris facilities, books and records as may be necessary or required. Tris shall notify Alpharma as soon as Tris becomes aware of any proposed inspection relating to the Product and/or Anti-caking Complex, permit Alpharma to have a representative present at said inspection and promptly provide Alpharma with copies of any reports or observations made by such Regulatory Authorities, which shall be redacted to omit any confidential or proprietary information of Tris. If after Alpharma's review of such reports or observations, Alpharma reasonably requires information contained in any portion of the closed section of the DMF or other information deemed proprietary to Tris to assess such reports and observations, Alpharma shall be permitted to have necessary personnel, each of whom shall be reasonably acceptable to Tris and each of whom shall be required to execute a confidential disclosure agreement with Tris in form and substance reasonably acceptable to Tris, have the right to review such information at Tris' location.

8.6 *Acceptance/Rejection.* Alpharma may test, or cause to be tested, the Product and/or Anti-caking Complex in accordance with testing methods established by the Parties in the Commercial Supply Agreement within forty-five (45) days of receipt of a particular shipment at Alpharma's facilities. During such forty-five (45) day period, Alpharma shall store and handle such Product and/or Anti-caking Complex in accordance with the requirements contained in the Specifications. Alpharma or its designee shall have the right to reject any shipment of Product or Anti-caking Complex made to it under this Agreement that does not meet the Specifications then in effect when received by it.

8.6.1 All Product and Anti-caking Complex delivered to Alpharma hereunder shall be deemed to materially conform with the applicable Specifications unless Tris receives from Alpharma written notice, not later than (i) forty-five (45) days after Alpharma's receipt of a given shipment if the non-conformity consists of a patent defect (a defect which could have been discovered through testing in accordance with the testing methods established above) or (ii) forty-five (45) days after Alpharma's discovery of a latent defect (a defect which could not have been discovered through testing in accordance with the testing methods established above), specifying the shipment, purchase order number and the exact nature of the failure of such shipment to conform, along with reasonable evidence of such non-conformity (including a sample of the Product or Anti-caking Complex from the shipment analyzed).

8.6.2 If, after its own analysis of the sample provided in accordance with Section 8.6.1, Tris confirms such non-conformity, then Tris shall replace such shipment at its expense, including charges incurred by Alpharma for shipping, labeling and storage, if applicable. If, after its own analysis, Tris does not confirm such non-conformity, the Parties shall agree to retest the shipment or otherwise in good faith attempt to agree upon a settlement of the issue. In the event that the Parties cannot resolve the issue, the Parties shall submit the samples of the disputed Product or Anti-caking Complex to an independent testing laboratory, to be agreed upon by the Parties, for testing in accordance with the Specifications. Notwithstanding anything contained in this Agreement to the contrary, the findings of such laboratory shall be binding on the Parties, absent manifest error. Expenses of such testing shall be borne by the Party adversely affected by such findings. In the event that any such shipment or batch of

Product or Anti-caking Complex is ultimately agreed or found not to meet the Specifications then in effect, Tris agrees to replace such shipment at its expense, including charges incurred by Alpharma for shipping and/or storage, if applicable. Alpharma shall return any such rejected shipment to Tris if so instructed by Tris, at Tris' expense or Alpharma shall destroy such rejected shipment at Tris' expense.

8.6.3 Notwithstanding any other provision of this Agreement, Alpharma shall not be required to pay for any shipment of Product or Anti-caking Complex that fails to meet the Specifications, but Alpharma shall be obligated to pay in full for any rejected shipment of Product or Anti-caking Complex that is subsequently determined to meet the Specifications. At Alpharma's option any such refund or credit may be applied against royalties or Commercial Transfer Price due and owing Tris from Alpharma and, in such event, shall be reflected in the statements submitted by Alpharma pursuant to Section 6.3.1.

8.7 *Manufacturing Plan.* At least one (1) year prior to the anticipated launch of a Product, Tris shall prepare a plan for the commercial manufacture of the Product in the form prepared by Tris in the ordinary course of Tris' business, shall thereafter update such plan each Calendar Quarter during which there are any material changes, additions or amendments to the plan and from time-to-time provide Alpharma with such backup information with respect to such plan as Alpharma reasonably requests.

8.7.1 Such plan shall include a mechanism for addressing any Inability to Supply in the event that such occurs, which shall include involving representatives of Alpharma in a discussion to determine the best options to remedy such Inability to Supply.

8.7.2 In connection with such plan, at any time on or after the date of the First Commercial Sale of any one of the Products, Alpharma shall have the right to give Tris notice of its intent to require a second manufacturing site for the Products (*"Notice of Intent"*). Within thirty (30) days after such notice Tris shall give Alpharma a written response indicating whether it will comply with the Alpharma request through the establishment of a Third Party Second Manufacturing Site or a Tris Second Manufacturing Site. Within ten (10) days after receipt of Tris' response, Alpharma shall give notice indicating whether it desires Tris to proceed with its indicated plan for a second manufacturing site. If Alpharma elects not to proceed with a second manufacturing site, Alpharma shall retain the right to give Tris one or more additional Notices of Intent at anytime during the Term; provided that Alpharma shall not have the right to give more than one Notice of Intent in any six (6) month period.

8.7.3 If, pursuant to Section 8.7.2, Tris indicates that it intends to provide a second manufacturing site through the use of a Third Party Second Manufacturing Site and Alpharma elects to proceed, Tris shall establish a Third Party Second Manufacturing Site within eighteen (18) months after the date of Alpharma's election to proceed. In connection with such arrangement between Tris and such Third Party, Tris shall use reasonable efforts to provide that such Third Party agrees to: (i) have and at all times maintain unused operational resources (including without limitation all machinery and equipment to manufacture the Products and Anti-caking Complex) at the Third Party Manufacturing Site, and possess the financial resources reasonably sufficient to carry out the manufacturing of the Products (and Anti-caking Complex) in the quantities forecasted under this Agreement; (ii) accept a transfer of the Tris Technology to the full extent necessary to enable the operator of the Third Party Manufacturing Site to manufacture the Product; (iii) possess all Registrations required to manufacture the Products (and Anti-caking Complex); (iv) be at all times in compliance with all applicable federal, state and local laws related to the manufacture of the Products (and Anti-caking Complex), except to the extent that any noncompliance would not have a material adverse effect upon the ability to manufacture the Products (and Anti-caking Complex) and (v) be at all times in compliance with good laboratory and clinical practices, cGMP and all applicable rules and regulations of the FDA

and any other Regulatory Authority except to the extent that any noncompliance would not have an adverse effect upon the Third Party Manufacturing Site's ability to manufacture the Products (and Anti-caking Complex).

8.7.4 If, pursuant to Section 8.7.2, Tris indicates that it intends to provide a second manufacturing site through the use of a Tris Second Manufacturing Site and Alpharma elects to proceed, Tris shall establish a Tris Second Manufacturing Site within fifteen (15) months after the date of Alpharma's election to proceed. Tris shall ensure that a Tris Second Manufacturing Site complies with the requirements set forth in clauses (i) through (v) of Section 8.7.3.

8.7.5 In the event that Tris, at Alpharma's election, proceeds with its plan to establish a second manufacturing site, either through the use of a Third Party Second Manufacturing Site or through the use of a Tris Second Manufacturing Site, Alpharma shall pay, or reimburse Tris for, Tris' fully-burdened costs for internal work conducted by Tris, plus all out-of-pocket costs and expenses incurred by Tris and such Third Party (if any), to obtain approval of such site by the Regulatory Authorities, bio-studies, validation batches, and the like, plus ten percent (10%).

8.7.6 In connection with the establishment of the Tris Second Manufacturing Site, Alpharma shall advance the sum of $3 million by making payments, at its option, either directly to Tris or to the suppliers of the machinery and equipment to be included in the Tris Second Manufacturing Site. In connection with the foregoing advance, (i) Tris shall reimburse Alpharma for one hundred percent (100%) of such costs by crediting at any one time (until such time as Alpharma has recovered such costs) up to twenty percent (20%) of any royalty payments due with respect to Net Sales of Products, and (ii) Tris shall immediately take all action reasonably necessary or appropriate to grant and perfect in favor of Alpharma (A) a security interest in the machinery and equipment and the Tris Technology to be located in or utilized at the Tris Second Manufacturing Site which shall be a first priority purchase money security interest in such machinery and equipment, and (B) grant to Alpharma and record a mortgage upon the land and building constituting the Tris Second Manufacturing Site, which shall be subordinate to any mortgage provided by Tris upon the land and building to its primary lender for the site, and (iii) such security interest and mortgage shall provide Alpharma, subject in the case of the mortgage to the terms and conditions of any inter-creditor agreement required to be entered into by Alpharma with any of Tris' mortgage lenders, with the right to foreclose upon the secured and mortgaged property upon any termination of this Agreement by Alpharma pursuant to Section 13.3. Tris may utilize the Tris Second Manufacturing Site for other products; provided that such use does not prevent the Site from meeting all of the requirements set forth herein and provided further that, at all times from and after the establishment of the Site, Tris shall utilize the Tris Second Manufacturing Site for a minimum of approximately twenty-five percent (25%) of the ongoing requirements for the Products.

8.7.7 For avoidance of doubt, in the event that Tris elects to establish a second manufacturing site other than in accordance with the requirement of Alpharma set forth in Section 8.7.2, all costs incurred in connection therewith shall be borne by Tris.

8.8 *Inability to Supply.* Tris shall notify Alpharma: (i) as promptly as possible, but in no event more than thirty (30) days after Tris' receipt of a firm order from Alpharma as provided in Section 8.4, or (ii) immediately upon becoming aware of an event of Force Majeure under Section 14 or any other event that would result in an Inability to Supply. In addition, in the event that (A) Tris fails to ship the quantities of any of Products or Anti-caking Complex ordered by Alpharma within the limits set forth in Section 8.4.1; (B) Products or Anti-caking Complex shipped does not meet applicable Specifications; or (C) of any other supply shortfall, any of which results in an Inability to Supply; in such event, the Parties shall:

8.8.1 Convene a meeting within five (5) days thereafter so that the Parties may discuss how to remedy such actual or anticipated Inability to Supply pursuant to the manufacturing plan and establish a reasonable recovery plan designed to resolve the situation as quickly as reasonably possible. Tris shall implement all reasonable measures to promptly remedy such shortage and shall give equal priority in its plant scheduling and use of its plant capacity (including the scheduling of overtime and any other actions) to timely provide all Product and Anti-caking Complex ordered hereunder as Tris provides to other products being manufactured in such facility, and in any event the percentage of plant capacity applied to all Products shall not be below the percentage applied to such Products immediately prior to such shortage.

8.8.2 In the event of any actual Inability to Supply, and following the meeting of the Parties as set forth in Section 8.8.1, Alpharma may cancel, without charge or penalty, all or any portion of any firm order(s) relating to either the Product or Anti-caking Complex during the period in which such Inability to Supply occurs and continues to occur.

8.9 *Long-term Inability to Supply; Election of Remedies.* In addition to the rights contained in Section 8.7.6 and any other remedies it may have at law or equity at anytime after a Long-Term Inability to Supply the Product (or Anti-caking Complex), Alpharma shall have the right to:

8.9.1 elect to require Tris, for the remainder of the Term, to manufacture and supply Anti-caking Complex instead of Product to Alpharma, in which case all terms and conditions of this Agreement and the Commercial Supply Agreement relating to the supply of Product shall be deemed to refer to and apply to Anti-caking Complex, and Alpharma shall have the right to manufacture finished, packaged and labeled Product from the Anti-caking Complex, and Tris shall grant Alpharma a license under the Tris Technology to permit Alpharma to do so; OR

8.9.2 if the Long-Term Inability to Supply includes an inability to supply Anti-caking Complex, elect to enter into an agreement with a Third Party for the manufacture and supply of said Product (including Anti-caking Complex) (i) in the case of the initial incident which constitutes a Long-Term Inability to Supply, for the reasonably expected duration of the Long-Term Inability to Supply; or, if longer, for such period of time as is commercially reasonably to offer to said alternative supplier in order to secure a commitment to supply the Product (and/or Anti-caking Complex) or (ii) upon a second incident which constitutes a Long-Term Inability to Supply for the remainder of the Term. Upon a Long-Term Inability to Supply, unless due to an event of Force Majeure, Tris shall pay to Alpharma an amount equal to its lost profits resulting from such Long-Term Inability to Supply; provided that such payment shall not exceed $1.5 million.

8.9.3 In addition, upon a Long-Term Inability to Supply, Tris at its cost shall cooperate with Alpharma to transfer the Tris Technology necessary to enable Alpharma or a Third Party manufacturer (if a Third Party on terms and conditions reasonably acceptable to Tris regarding the protection of Tris' intellectual property relating thereto), to manufacture the Product (and, if Alpharma makes an election under Section 8.9.2, the Anti-caking Complex) for marketing and sales of the Product by Alpharma in the Territory.

In the event that Alpharma's rights under this Section 8.9 become exercisable due to an event of Force Majeure, before Alpharma can exercise its rights set forth in this Section, Tris shall have a reasonable opportunity to demonstrate to Alpharma that Tris will be able to be positioned to manufacture and supply Alpharma's requirements for Product and/or Anti-caking Complex sooner than a Third Party manufacturer after curing the event of Force Majeure. Alpharma shall

determine, using reasonable business judgment, whether to have a Third Party or Tris supply the Product (and/or Anti-caking Complex) thereafter.

8.10 *Alpharma Obligations.* In the event that Alpharma has the right to have Tris manufacture Anti-caking Complex pursuant to Section 8.9.1 and Alpharma obtains the right and responsibility to manufacture, or have manufactured, the Products with Anti-caking Complex provided by Tris for commercial uses, the manufacture of which shall be in accordance with the Specifications, the terms of this Agreement and all applicable U.S. Federal laws, rules and regulations including, but not limited to, cGMP and all applicable laws and regulations in the jurisdictions in the Territory in which Alpharma intends to market and sell the Product, and Alpharma shall provide indemnity to Tris for claims arising from such manufacture (comparable to Section 12.1.3) in addition to the indemnification provided in Section 12.2, which terms and conditions shall be provided in further detail in the Commercial Supply Agreement.

8.11 *Limitation of Liability.*

8.11.1 EXCEPT AS SPECIFICALLY PROVIDED IN SECTION 8.9.2, NEITHER PARTY SHALL NOT BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, PUNITIVE OR OTHER INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF SECTION 8 OF THIS AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STATUTE, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES.

8.11.2 Except as specifically provided in Section 8.9.2, in no event shall Tris be liable under Section 8 of this Agreement or the Commercial Supply Agreement for an amount in excess of one hundred percent (100%) of the aggregate of all amounts received by Tris under Section 8 of this Agreement and the Commercial Supply Agreement.

9. OWNERSHIP; PATENTS.

9.1 *Ownership.* Tris shall retain all right, title and interest in and to the Tris Technology.

9.2 *Inventions.* Each Party shall solely own all right, title and interest in and to any and all Inventions first conceived or reduced to practice by it in the course of the Development and Regulatory Program. Any and all Inventions first conceived or reduced to practice by the Parties jointly shall be owned by Tris if such Invention would have been within the definition of Tris Technology if existing on the date of this Agreement or by Alpharma if such Invention relates to the Compound. All Inventions owned by Tris shall be subject to the licenses granted in Section 7.1 and may be used by Alpharma within the scope of the license granted in Section 7.1 during the Term and by Tris during the Term for other than the Product, and after the Term for any lawful purpose. Nothing herein is intended to provide Alpharma or any such Third Party with freedom to operate with respect to, or grant a license to, the Tris Technology other than as specifically provided in Section 7.1.

9.3 *Patent Prosecution and Maintenance.*

9.3.1 Tris shall have full responsibility for, and shall control the preparation and prosecution of, and the maintenance of, all patent applications and patents relating to the Tris Technology and the Inventions owned solely by it throughout the Territory at its sole cost and expense. Alpharma shall have full responsibility for, and shall control the preparation and prosecution of, and the maintenance of, all patent applications and patents relating to the Compound owned solely by it throughout the Territory at its sole cost and expense. The Party

holding such patent prosecution rights shall have the sole right to determine whether any Invention is patentable, and if so, shall, in its sole discretion, determine whether or not to proceed with the preparation and prosecution of a patent application covering any such Invention.

9.3.2 Alpharma agrees to cooperate with Tris, at the cost of Tris, to execute all lawful papers and instruments, to make all rightful oaths and declarations, and to provide consultation and assistance as may be necessary in the preparation, prosecution, maintenance and enforcement of all such Tris Patent Rights.

(a) Tris agrees to cooperate with Alpharma, at the cost of Alpharma, to execute all lawful papers and instruments, to make all rightful oaths and declarations, and to provide consultation and assistance as may be necessary in the preparation, prosecution, maintenance and enforcement of all such Alpharma patents and patent applications relating to the Compound for use within the scope of this Agreement.

(b) For avoidance of doubt, nothing in this Agreement provides any right for Tris, its Affiliates or licensees in and to any know-how or patent rights presently held, or developed by Alpharma during the Term relating to the KADIAN® Referenced Product.

9.4 *Patent Enforcement.*

9.4.1 If either Party learns of an infringement, unauthorized use, misappropriation or ownership claim or threatened infringement or other such claim (an "*Infringement*") by a Third Party by reason of the use or sale of a product or compound (including a Generic Product) in any country in the Territory that is or reasonably could be directly substitutable with the Product being marketed and sold in such country in the Territory, such Party shall within five (5) business days notify the other Party in writing and shall promptly provide such other Party with available evidence of such Infringement.

9.4.2 If any such Infringement relates to the use of the Tris Technology to infringement by Third Party(ies) of Tris Patent Rights or any Tris Mark in the Territory, Tris shall have the first right, but not the duty, to institute infringement actions against Third Parties. If Tris (or its designee) does not secure actual cessation of such Infringement or institute an infringement proceeding against an offending Third Party within sixty (60) days of learning of such Infringement, and Alpharma reasonably believes that such Infringement adversely impacts its sales of the affected Product, Alpharma will so notify Tris, in writing, and Alpharma shall at its option and cost institute infringement proceedings. Tris agrees to cooperate with Alpharma, at the cost of Alpharma, to execute all lawful papers and instruments, to make all rightful oaths and declarations, and to provide consultation and assistance as may be necessary in the infringement litigation.

9.4.3 For all other Infringement claims relating to the Product, including Infringements relating to the Trademarks, Alpharma shall have the first right, but not the duty, to institute infringement actions against such Third Party. If Alpharma does not secure actual cessation of such Infringement or institute an infringement proceeding against an offending Third Party within sixty (60) days of learning of such Infringement, and Tris reasonably believes that such Infringement adversely impacts its sales of the affected Product, Tris will so notify Alpharma, in writing, and Alpharma shall at its option and cost institute infringement proceedings. Tris agrees to cooperate with Alpharma, at the cost of Alpharma, to execute all lawful papers and instruments, to make all rightful oaths and declarations, and to provide consultation and assistance as may be necessary in the infringement litigation.

9.4.4 Each Party shall execute all necessary and proper documents, take such actions as shall be appropriate to allow the other Party to institute and prosecute such

infringement actions and shall otherwise cooperate in the institution and prosecution of such actions (including, without limitation, consenting to being named as a nominal party thereto). Any award paid by Third Parties as a result of such an infringement action (whether by way of settlement or otherwise) shall be allocated as follows: (i) if Tris has instituted and maintained such action alone, Tris shall be entitled to deduct all costs and expenses incurred by Tris with respect to such action and, if after such deduction any funds shall be retained by Tris, Tris shall pay Alpharma the remainder of the funds minus the royalty due Tris if such remaining funds constituted Net Sales; and (ii) if Alpharma has instituted and maintained such action alone, Alpharma shall be entitled to deduct all costs and expenses incurred by Alpharma with respect to such action and, if after such deduction any funds shall be retained by Alpharma, but Alpharma shall pay Tris a royalty as if such remaining funds constituted Net Sales. Notwithstanding the foregoing, in the event that the infringing product is a Generic Product, such that Alpharma has reduced the royalty rate being paid to Tris pursuant to Section 6.1.2, then if Tris obtains the recovery, Tris shall be entitled to retain from such portion due to Alpharma the difference between the royalty actually paid on Net Sales of Product pursuant to Section 6.1.2 and the amount that should have been paid pursuant to Section 6.1.1; and if such portion is insufficient to make up such different, or if Alpharma is the Party that obtains the recovery, Alpharma shall promptly pay to Tris such amount as in necessary to make up such difference. In all cases, the royalty rate shall be the rate set forth in the relevant Section 6.1.1 or 6.1.2, adjusted as provided in Section 9.6, if applicable.

9.4.5 In no event shall Alpharma have any right to settle, compromise or grant a Third Party infringer a license under any infringed patents or trademarks with respect to any Infringement claims relating to the Product relating to the use of the Tris Technology or any Tris Mark in the Territory, and Tris shall only have the right to engage in such settlement, compromise and licensing with the consent of Alpharma, which shall not be unreasonably withheld or delayed. In no event shall Tris have any right to settle, compromise or grant a Third Party infringer a license under any infringed patents or trademarks with respect to any Infringement claims relating to the Compound or any Trademarks in the Territory, and Alpharma shall only have the right to engage in such settlement, compromise and licensing with the consent of Tris, which shall not be unreasonably withheld.

9.5 *Infringement Action by Third Parties.*

9.5.1 Each Party shall within five (5) business days notify the other Party in writing upon becoming aware of any claim by a Third Party, whether raised directly or by way of counterclaim or affirmative defense, against Alpharma and/or Tris for alleged infringement of Third Party patent rights through the making, having made, using, selling, or having sold any Product in the Territory.

9.5.2 If such infringement claim relates to the Tris Technology and is covered by Section 12.1.4, or the Tris Marks, then the defense of such suit shall be controlled by Tris, at its sole cost and expense. Tris shall be solely responsible for any damages or other payments related to such claim (whether the claim is made against either or both Parties) and shall also have the right to control settlement of such claim; *provided, however,* that any such settlement shall not, without Alpharma's consent, adversely impact Alpharma's rights or reasonable economic expectations hereunder. Any monetary award recovered from such suit shall be retained by Tris.

9.5.3 Unless otherwise covered by Section 9.5.2 (and except as provided in Section 9.5.4), if such infringement claim relates to the Tris Technology, the Parties shall discuss, in good faith, how best to control the defense of any such claim; *provided, however*, that Alpharma will control the defense of such a claim and shall also have the right to control settlement of such claim; provided that no such settlement shall be entered into which adversely

impacts the Tris Technology without the consent of Tris, which shall not be unreasonably withheld or delayed. The costs and expenses of defending any suit under this Section 9.5.3 and any damages resulting from such suit (including, but not limited to, the cost of withdrawing the Product from the market) shall be borne by the Parties as follows: fifteen percent (15%) by Tris, and eighty-five percent (85%) by Alpharma, and any monetary awards recovered from such suit shall be shared by the Parties as follows: each Party shall be entitled to recovery all costs and expenses incurred by such Party with respect to such action on a pro rata basis and, if after such recovery of all such costs and expenses, any funds shall remain, Tris shall be entitled to fifteen percent (15%) and Alpharma shall be entitled to eighty-five percent (85%). If such infringement claim which relates to Tris Technology encompasses both Products under this Agreement and products controlled by parties other than Alpharma, Alpharma's share of the damages shall be limited to Alpharma's percentage of the total sales of all products encompassed by the litigation claim (including the Products).

9.5.4 In the event that a patent infringement suit under Section 9.5.3 is brought under any patents defined as the Subject Patent(s) in the JDA the costs and expenses of such litigation and any damages resulting from such suit (including but not limited to the cost of withdrawing the Product from the market) shall be borne by the Parties as follows: seventy-five percent (75%) by Tris, and twenty-five percent (25%) by Alpharma. From the date of the institution of such patent infringement suit and until complete and final resolution of such suit, Alpharma shall pay seventy five percent (75%) of the royalty payments due to Tris under this Agreement with respect to the claimed infringing Product into an escrow account to be established at a mutually acceptable financial institution pursuant to an escrow agreement among the Parties and such financial institution in form and substance reasonably acceptable to all parties thereto. Such amounts shall be held in escrow until a complete and final resolution of the patent infringement suit. During the pendency and upon completion of the suit, Alpharma shall be responsible to pay all such costs, expenses and damages to any Third Party; provided that seventy five percent (75%) of such costs shall be reimbursed to Alpharma by Tris: (i) first, by release of the funds being held in escrow (and any remaining funds, if any, being held in escrow shall at such time be released to Tris), (ii) second, by Tris, within thirty (30) days after receipt of written request therefor (together with evidence of such costs) paying to Alpharma an amount equal to the balance of such costs, provided that such amount shall not exceed seventy-five(75%) of the amount of royalties paid by Alpharma with respect to Net Sales of such Product during the twenty four (24) months immediately preceding the date of the institution of such patent infringement suit, and (iii) thereafter crediting at any one time (until such time as Alpharma has recovered such costs) up to seventy five percent (75%) of any royalty payments due with respect to Net Sales of such Product; and Alpharma may carry forward any unreimbursed amount to be credited against future payments due with respect to Net Sales of such Product until the full seventy five percent (75%) of such costs paid by Alpharma have been fully recaptured by Alpharma. Any monetary awards recovered from such suit shall be shared by the Parties as follows: each Party shall be entitled to recovery all costs and expenses incurred by such Party with respect to such action on a pro rata basis and, if after such recovery of all such costs and expenses, any funds shall remain, Tris shall be entitled to seventy-five percent (75%) and Alpharma shall be entitled to twenty-five percent (25%).

9.5.5 Unless otherwise covered by Sections 9.5.2, 9.5.3 or 9.5.4, with respect to infringement claims relating to the Product, as well as infringements relating to the Trademarks, Alpharma will be responsible for and will control the defense and/or settlement of such claim. Alpharma shall be responsible for defending any and all such suits, at its own expense, and shall be responsible for all damages incurred as a result thereof. Tris hereby agrees to assist and cooperate with Alpharma, at Alpharma's reasonable request and expense, in the defense of any such suit (including, without limitation, consenting to being named as a nominal party thereto). If Alpharma finally prevails and receives an award from such Third Party as a result of such action (whether by way of judgment, award, decree, settlement or otherwise),

Alpharma shall be entitled to deduct all costs and expenses incurred by Alpharma with respect to such action and, if after such deduction any funds shall be retained by Alpharma, but Alpharma shall pay Tris a royalty as if such remaining funds constituted Net Sales.

9.5.6 Except as specifically set forth in Section 9.5.4, during the pendency of any action under this Section 9.5, and thereafter, Alpharma shall continue to make all payments due under this Agreement.

9.6 *No Contest Provision.* Alpharma and its Affiliates and sublicensees shall not make any request for, or filing or declaration of, or undertake any action involving, any interference, opposition, challenges as to ownership, assertions of invalidity or unenforceability, revocation or reexamination relating to any Tris Patent Rights before any court, agency or other tribunal (*"Licensed Patent Action"*). If the foregoing restriction is held to be invalid or is enjoined by a court of competent jurisdiction, or otherwise notwithstanding the foregoing restriction, any Licensed Patent Action occurs, then the royalty set forth in Section 6.1.1 on Net Sales of the Subsequent Product shall increase to 21%, the royalty set forth in Section 6.1.1 on Net Sales of the Initial Product shall increase to 17.5%, the royalty set forth in Section 6.1.2 shall increase to 7% and Alpharma shall promptly pay all attorney fees and fees of other professionals as and when incurred by Tris in the defense, prosecution and/or settlement of any Licensed Patent Action in addition to any other relief available to it at law or in equity. If the foregoing increase in royalties are held to be invalid or is enjoined by a court of competent jurisdiction, then Tris shall have the right to immediately terminate this Agreement by sending written notice of such termination to Alpharma, which termination shall have the same effect as a termination by Tris for breach by Alpharma.

10. REGULATORY MATTERS.

10.1 *Adverse Reaction Reporting.*

10.1.1 Each of Tris and Alpharma shall report to the other Party any information of which such Party has knowledge concerning any adverse drug experience in connection with the use of the Product (which shall include, for the avoidance of doubt, any side effect, customer complaint, reported defect, adverse reaction, injury or toxicity or sensitivity reaction in connection with the separate use of the API or any Tris Technology incorporated into the Product), including the incidence or severity thereof, associated with non-clinical toxicity studies, clinical uses, studies, investigations or tests, whether or not determined to be attributable to the Product, within two business days or ninety-six (96) hours of obtaining such knowledge. Reports of routine adverse drug experiences of the type defined in Section 314.80 (or Section 600.80, as applicable) of Title 21 of the U.S. Code of Federal Regulations shall be provided by such Party to the other Party within fifteen (15) days of filing such reports. Notwithstanding the foregoing, any reports required to be given to Tris pursuant to the foregoing sentences shall only be made upon the request of Tris, if such reports are required in connection with Tris' development, manufacturing, marketing or sale of Products outside the Territory, either directly or indirectly. Prior to such period, Alpharma shall provide an annual report, promptly after Alpharma provides such a report to the FDA, providing summary information with respect to all adverse drug experiences in connection with the use of the Product. Reports of any event that is both unexpected and a Serious Adverse Drug Experience shall be made available by one Party to the other Party within five (5) days after a Party becomes aware of same. Upon receipt of any such information concerning any event that is both unexpected and a Serious Adverse Drug Experience by either Tris or Alpharma, the Parties shall promptly consult each other and use Commercially Reasonable Efforts to arrive at a mutually acceptable procedure for taking such possible actions as appropriate or required under the circumstances (with Alpharma providing, at its expense, information gathering and related services with respect to any such report); *provided, however*, that nothing contained herein shall be construed as restricting the right or

duty of either Party to make a report or submission to the FDA or take any other action that it deems to be appropriate or required by applicable law or regulation.

10.1.2 For purposes of this Agreement, "*Serious Adverse Drug Experience*" means any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition as more fully defined in Section 314.80 (or Section 600.80, as applicable) of Title 21 of the U.S. Code of Federal Regulations in the U.S., and with respect to every other country in the Territory, the equivalent regulation(s) for such country. An unexpected adverse drug experience is one that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity.

10.1.3 Each Party shall promptly report to the other Party the information set forth above affecting the Product in any country in the Territory. In addition to the reports required above each Party shall give to the other notice of any event required to be reported to any Regulatory Authority within the Territory upon a basis which permits the timely reporting thereof to such Regulatory Authority.

10.1.4 Each Party shall immediately notify the other of any communication with or information received from the FDA or any other Regulatory Agency with respect to any pending or threatened action or any other matter related to an incident within the ambit of Section 10.1.1. Each Party agrees that if it contracts with a Third Party for research to be performed by such Third Party relating to the Product, that Party agrees to require such Third Party to report to the contracting Party the information set forth above.

10.1.5 Alpharma and Tris will notify each other by fax (and confirm receipt of the same), within three (3) business days, of all complaints received by either Party related to Product. Alpharma will ensure that complainants will be responded to on all complaints associated with Product sold by Alpharma. The Parties will cooperate in the investigation of all complaints with respect to the Product.

10.1.6 The details of adverse drug experience and product complaint reporting shall be stipulated in separate agreements to be entered into by the Parties in due course, which shall specify the Parties respective duties relating to such reporting include allocating responsibility for: (A) information gathering and related services with respect to any such reports; and (B) reporting adverse drug experiences to Alpharma, at its expense.

10.1.7 Any information required pursuant to this Section 10.1 shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

(a) in the case of Tris, to:

Tris Pharma, Inc.
2033 Route 130; Suite D
Monmouth Junction, New Jersey 08852
Attention: Director for QA and Regulatory Affairs
Facsimile No.: 732.940.2855
Telephone No.: 732.940.2800

(b) in the case of Alpharma, to:

Alpharma Branded Products Division Inc.
One New England Avenue
Piscataway, New Jersey 08854
Attention: Senior Director, Medical Affairs/ Pharmacovigilance
Facsimile No.: 732.465.3651
Telephone No.: 732.465.3604

or to such other address for such Party as it shall have specified by like notice to the other Party, *provided* that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third business day after such notice or request was deposited with the U.S. Postal Service.

10.2 *Recall; Withdrawal.*

10.2.1 In the event that any Product sold pursuant to this Agreement should be alleged or proven not to meet its Specifications or other mandatory standards for the Product, either Party shall notify the other Party immediately, and both Parties shall cooperate fully regarding the investigation and disposition of any such matter. If Alpharma, in its discretion, recalls, detains or retains the Product (voluntarily or by order of a Regulatory Authority), Tris agrees to reasonably cooperate in such actions, at Alpharma's sole expense, except as set forth in Section 10.2.2.

10.2.2 In the event a recall, detention or retention action of the Product is due to any breach by Tris or its Affiliates of any warranty set forth herein or in the Commercial Supply Agreement, then and in such event, Tris shall bear all reasonable direct, documented costs associated with said action, including, without limitation, refund of the Commercial Transfer Price, and related royalty payments, of the quantity of Product so recalled, detained or retained, and shall bear the actual cost of conducting such action or withdrawal, including costs imposed by the applicable Regulatory Authority(ies) such as costs for detention and inspection, in accordance with the recall guidelines of the applicable Regulatory Authority(ies) or standard U.S. pharmaceutical industry practices. In the event the it cannot be determined after reasonable investigation whether a recall, detention or retention action is due to a Tris breach as referenced above, the costs of such action (as defined in the previous sentence) shall be shared equally by the Parties hereto.

11. CONFIDENTIAL INFORMATION.

11.1 *Confidentiality.* A receiving Party (the "*Receiving Party*") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in

this Agreement any Confidential Information which is disclosed to it by the other Party (the "*Disclosing Party*") or otherwise received, accessed or developed by a Receiving Party in connection with the execution, delivery and performance of this Agreement. Each Party agrees that all such Confidential Information: (i) shall not be used by the Receiving Party except in connection with the activities contemplated by this Agreement or in order to further the purposes of this Agreement; (ii) shall be maintained in confidence by the Receiving Party; and (iii) shall not be disclosed by the Receiving Party to any Third Party who is not a consultant of, or an advisor to, the Receiving Party or an Affiliate or sublicensee of the Receiving Party, and who in each case has signed a confidentiality agreement containing provisions at least as stringent as that set forth in this Agreement, without the prior written consent of the Disclosing Party.

11.2 *Exceptions to Obligation.* The obligations of confidentiality and non-use set forth in Section 11.1 shall not apply to any such Confidential Information which:

11.2.1 either before or after the date of the disclosure to the Receiving Party becomes published or otherwise part of the public domain through no fault or omission on the part of the Receiving Party or its Affiliates or Third Party consultants or advisors;

11.2.2 either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party or its Affiliates or Third party consultants or advisors by sources other than the Disclosing Party rightfully in possession of the Confidential Information and without restriction as to confidentiality or use;

11.2.3 is independently developed by or for the Receiving Party or its Affiliates without reference to or in reliance upon the Disclosing Party's Confidential Information as demonstrated by competent written records; or

11.2.4 is required to be disclosed under applicable laws or regulations or an order by a court or other regulatory body having competent jurisdiction; *provided, however,* that except where impracticable, the Receiving Party shall give the Disclosing Party reasonable advance notice of such disclosure requirement (which shall include a copy of any applicable subpoena or order) and shall cooperate with the Disclosing Party to oppose, limit or secure confidential treatment for such required disclosure. In the event of any such required disclosure, the Receiving Party shall disclose only that portion of the Confidential Information of the Disclosing Party that the Receiving Party is legally required to disclose.

11.3 *Exclusions.* The restrictions contained in this Section 11 shall not apply to Confidential Information that: (i) is submitted by the Receiving Party to governmental authorities to facilitate the issuance of Registrations for the Product, provided that reasonable measures shall be taken to assure confidential treatment of such information; or (ii) is provided by the Receiving Party to Third Parties under confidentiality provisions at least as stringent as those in this Agreement, for consulting, manufacturing development, manufacturing, external testing, marketing trials and, with respect to either Party, to Third Parties who are sublicensees or other development/marketing partners of such Party with respect to any of the subject matter of this Agreement.

11.4 *Limitations on Use.* Each Party shall limit the use, and cause each of its Affiliates and its sublicensees to limit the use, of any Confidential Information obtained by such Party from the other Party, its Affiliates or its sublicensees, pursuant to this Agreement or otherwise, so that such use is solely in connection with the activities or transactions contemplated hereby.

11.5 *Remedies.* Each Party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security,

enjoining or restraining the other Party from any violation or threatened violation of this Section 11.

12. INDEMNIFICATION; INSURANCE.

12.1 *By Tris.* Tris shall indemnify, defend and hold harmless Alpharma, its Affiliates, and sublicensees and their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses (including the reasonable fees of attorneys and other professionals) for claims of any Third Party arising out of or resulting from:

12.1.1 any acts or failure to act which constitutes a default of Tris' obligations under this Agreement;

12.1.2 negligence or wrongful intentional acts or omissions of Tris or its Affiliates, and their respective directors, officers, employees and agents, in connection with the activities contemplated under this Agreement; or

12.1.3 any warranty claims, Product recalls or any tort claims of personal injury (including death) or property damage relating to or arising out of any sale, offer for sale or importation of any Product by Alpharma to the extent due to the Product or Anti-caking Complex manufactured by, or on behalf of, Tris not meeting the Specifications for the Product or Anti-caking Complex or which was not manufactured in accordance with applicable laws or with cGMP, but only to the extent not due to the negligence or wrongful intentional acts or omissions of Alpharma or its Affiliates or sublicensees, and their respective directors, officers, employees and agents; or

12.1.4 any breach of any representation or warranty made by Tris pursuant to Sections 2.1 or 2.2.

12.2 *By Alpharma.* Alpharma shall indemnify, defend and hold harmless Tris, and its Affiliates, and their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses (including the reasonable fees of attorneys and other professionals) for claims of any Third Party arising out of or resulting from:

12.2.1 Any acts or failure to act which constitutes a default of Alpharma's obligations under this Agreement;

12.2.2 negligence or wrongful intentional acts or omissions of Alpharma or its Affiliates or sublicensees, and their respective directors, officers, employees and agents, in connection with the activities contemplated under this Agreement; or

12.2.3 unless covered by Section 12.1.3, any warranty claims, Product recalls or any tort claims of personal injury (including death) or property damage relating to or arising out of any sale, offer for sale or importation of any Product by Alpharma, its Affiliates or permitted sublicensees, including without limitation any liabilities relating to abuse of the Product by end users; or

12.2.4 any breach of any representation or warranty made by Alpharma pursuant to Sections 2.1 or 2.3.

12.3 *Notice.* In the event that any person (an "*Indemnitee*") entitled to indemnification under Section 12.1 or 12.2 is seeking such indemnification, such Indemnitee shall inform the indemnifying Party of the claim as soon as reasonably practicable after such Indemnitee receives notice of such claim, shall permit the indemnifying Party to assume direction and control of the

defense of the claim (including the sole right to settle it at the sole discretion of the indemnifying Party, provided that such settlement does not impose any obligation on the Indemnitee or the other Party) and shall cooperate as requested (at the expense of the indemnifying Party) in the defense of the claim.

12.4 *Complete Indemnification.* Indemnification hereunder shall include the reasonable costs and expenses of the Parties relating to legal fees and expenses, actually incurred by an Indemnitee in connection with enforcement of Sections 12.1 and 12.2.

12.5 *Insurance.* Each Party shall maintain at all times during the term of this Agreement and for a period of five (5) years after the expiration of termination thereof, if such policy is written on a claims made basis, a "broad form" commercial general liability insurance policy including product/completed operations, contractual liability and upon such terms (including deductible, limits and self-insured retentions), as is customary for the activities to be conducted by it under this Agreement and is appropriate to cover its indemnification obligations hereunder (provided that product liability/completion operations coverage shall be with limits of not less than seven million dollars ($7,000,000 per occurrence and in the aggregate); provided that Tris shall not be required to maintain product liability coverage until the First Commercial Sale of a Product occurs. Each Party shall name the other Party as an additional insured as its Interest may appear in such insurance policies.

In addition, Tris shall maintain "all risk" property and business interruption insurance for any loss or damage to real and personal property (e.g. building, machinery & equipment), raw material supplies (including API) and finished Product (or Anti-caking Complex). The property insurance should be based on replacement cost for real & personal property and selling price for finished Product.

Each Party shall furnish to the other Party evidence of such insurance, upon request. All insurance policies shall endeavor to provide for a minimum of thirty (30) days advance notice to the recipient of the certificate of cancellation of such insurance.

13. TERM; TERMINATION.

13.1 *Term.* The term of this Agreement (the "*Term*") shall begin on the Effective Date and, unless earlier terminated pursuant to the other provisions of this Section 13, shall expire with respect to each of the Subsequent Product and Initial Products on the expiration of the latest of their respective Royalty Terms in all countries on a country-by-country basis in the Territory.

13.2 *Right to Extend Term.* Alpharma shall have the right to extend the Term of this Agreement on one or more occasions upon the following terms and conditions:

13.2.1 Alpharma shall notify Tris in writing at least two (2) years prior to the anticipated expiration of the Term of this Agreement pursuant to Section 13.1 (or upon the date of entry of a second Generic Product to a Product if the Term expires by reason of such entry) that Alpharma desires to extend the Term of this Agreement, and shall include a term sheet with Alpharma's proposal for the terms of such extension, including the length of the extended term.

13.2.2 upon receipt of such notice, Tris shall enter into good faith negotiations with Alpharma regarding the terms of such extension, including the extension of the Royalty Term, if any. If the Parties reach an agreement on such terms no later than eighteen (18) months prior to the anticipated expiration of the original or extended Term of this Agreement pursuant to Section 13.1, the Parties shall execute an amendment to this Agreement reflecting such terms.

13.3 *Termination for Cause*. Either Party (the "*Non-breaching Party*") may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity with respect to the Subsequent Product or Initial Products (considered individually), in the event the other Party (the "*Breaching Party*") shall have materially breached or defaulted in the performance of any of its material obligations hereunder with respect to such Product and such breach or default shall have continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party (or, if such breach or default cannot be cured within such sixty (60)-day period, if the Breaching Party does not commence and diligently continue actions to cure such breach or default during such sixty (60)-day period). In addition, if a breach or default or group of related breaches or defaults by a Breaching Party within the preceding sentence also materially affects the entirety of this Agreement, and such breach or default or group of related breaches or defaults shall have continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party (or, if such breach(es) or default(s) cannot be cured within such sixty (60)-day period, if the Breaching Party does not commence and diligently continue actions to cure such noticed breach(es) or default(s) during such sixty (60)-day period), the Non-breaching Party may, without prejudice to any other remedies available to it at law or in equity with respect to any Product, terminate this Agreement in its entirety. Any such termination under this Section shall become effective at the end of such sixty (60)-day period unless the Breaching Party has cured any such noticed breach(es) or default(s) prior to the expiration of such sixty (60)-day period (or, if such breach(es) or default(s) cannot be cured within such sixty (60)-day period, if the Breaching Party has commenced and diligently continued actions to cure such breach(es) or default(s)). Provided however that the sixty (60) day cure period set forth above shall not apply to any breach if, within the twelve months prior to the commencement of such breach, the Breaching Party had been given notice of a similar breach for which it was entitled to a sixty (60) day cure period hereunder. The right of either party to terminate this Agreement as provided in this Section 13.3 shall not be affected in any way by its waiver or failure to take action with respect to any previous breach or default. Any event or circumstance which permits a Party to terminate this Agreement under Sections 13.4, 13.5 or 13.7 or to terminate with respect to a country or countries under Sections 5.3 or 6.1.4 shall not be a breach under this Section 13.3. Notwithstanding anything in this Section 13.3, no breach by Tris under Section 8 of this Agreement shall be cause for Alpharma to terminate this Agreement pursuant to this Section 13.3. If a breach by Tris under Section 8 results in an Inability to Supply or a Long-term Inability to Supply, Alpharma shall rely on its rights and remedies as provided in Section 8. The Commercial Supply Agreement shall provide for other remedies for Alpharma in the event of a breach of the Commercial Supply Agreement by Tris.

13.4 *Other Termination Rights of Tris*. Tris shall have the right to terminate this Agreement, either in its entirety or, if so limited below with respect to either the Subsequent or the Initial Product, as the case may be, in the event that:

13.4.1 Alpharma fails to comply with the Minimum Net Sales obligations set forth in Section 6.1.4 (subject to the make-up provision set forth therein) with respect to the Subsequent Product Tris shall have the right to terminate Alpharma's right to sell the Subsequent Product upon giving Alpharma notice of such termination within six (6) months after the end of the calendar year in which Alpharma failed to meet such Minimum Net Sales requirements, which termination shall be effective immediately upon such notice;

13.4.2 Tris' right under Section 5.3.1 arises, Tris shall have the right to terminate this Agreement as to each of the Subsequent Product and the Initial Product (considered individually) in the Territory by giving Alpharma notice of such termination, which termination shall be effective immediately upon such notice.

13.4.3 If Alpharma is not developing the Subsequent Product, and Alpharma ceases to develop the Initial Product, then Tris shall have the right to terminate this Agreement as to the Product as to which development has ceased by giving Alpharma notice of such termination, which termination shall be effective thirty (30) days after the date of such notice, unless during such period Alpharma takes the actions set forth in either clause (i) or (ii) of the last sentence of this Section 13.4.3. With respect to the Subsequent Product, Alpharma shall be deemed to not be developing such Product in the event that it decides, pursuant to Section 4.2, that the results of the Pilot Study(ies) for the Initial Product do not support initiation of the Subsequent Product development program or, if Alpharma decides to proceed with the development of the Subsequent Product, thereafter in the event that there are no significant development or regulatory activities for a period of three (3) consecutive months. Alpharma shall be deemed to not be developing the Initial Product in the event that there are no significant development or regulatory activities for a period of three (3) consecutive months. Provided however, the requirement for significant activities on the part of Alpharma shall be tolled for any period or periods of time during which Alpharma is awaiting a response from a Regulatory Authority. Upon receipt of such notice and during such thirty (30) day period, Alpharma may either: (i) provide satisfactory evidence that it had been conducting significant development or regulatory activities during such previous three (3) consecutive month period, or (ii) conduct activities sufficient to cure such lack of significant activities (or, if such lack of significant activities cannot be cured within such thirty (30)-day period, if Alpharma commences and diligently continues actions to cure such lack of significant activities).

13.5 *Other Termination Rights of Alpharma.* Alpharma shall have the right to terminate this Agreement, either in its entirely or, if so limited below with respect to either the Subsequent or Initial Product, as the case may be, in the event that:

13.5.1 the FDA indicates that it will require clinical trials to demonstrate efficacy or safety in order to issue an NDA for the Subsequent Product or Initial Product, Alpharma shall have the right to terminate this Agreement as to such Product upon giving Tris written notice of such termination within thirty (30) days after the date upon which the FDA requirements are communicated to Alpharma in writing by the FDA; or

13.5.2 in it's reasonable judgment the results of the testing of the Initial Product identified in Section 4.3.4 do not demonstrate that the abuse deterrent characteristics for the Initial Product are substantially similar to or superior to the KADIAN® Referenced Product, upon Alpharma giving Tris written notice of the termination of this Agreement (which shall be a termination as to all Products) within the thirty (30) day period after Alpharma receives the results of such study(ies).

13.6 *No Termination for Long-Term Inability to Supply.* If there is a Long-Term Inability to Supply either the Subsequent Product or Initial Product which, regardless of the cause or reason, is not fully replaced by Product manufactured at a Tris Second Manufacturing Site or Third Party Second Manufacturing Site, Alpharma shall only have the right to terminate the right of Tris to manufacture such Product or Anti-caking Complex, as appropriate, hereunder as more fully described in Section 8.9 and to be provided in the Commercial Supply Agreement.

13.7 *Termination for Insolvency.*

13.7.1 Subject to applicable law, Tris may terminate this Agreement, if, at any time, Alpharma shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of Alpharma or of substantially all of its assets, or if Alpharma proposes a written agreement of composition or extension of substantially all of its debts, or if Alpharma shall be served with an involuntary petition against it, filed in any

insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if Alpharma shall propose or be a party to any dissolution or liquidation, or if Alpharma shall make an assignment of substantially all of its assets for the benefit of creditors.

13.7.2 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 Title 11, United States Code (the "*Bankruptcy Code*") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to all documents embodying, any such intellectual property or relating to obtaining protection of or maintaining same, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

13.8 *Effect of Expiration or Termination.*

13.8.1 Following the expiration of the Term with respect to the Product in any country in the Territory, pursuant to Section 13.1 (but subject to any extension of the Term pursuant to Section 13.2), (i) the license granted to Alpharma in Section 7.1.1 shall convert to a non-exclusive, royalty-free, perpetual, irrevocable and sublicensable right and license to the same extent that Alpharma continued to have such license rights in such country immediately prior to the expiration of the Term; and (ii) the covenant not to sue granted to Tris in Section 7.1.2 as it relates to the Subsequent Product shall become perpetual and irrevocable to the same extent that Tris continued to have such right immediately prior to the expiration of the Term. For the avoidance of doubt, nothing in this Section 13.8.1 shall obligate either Party to transfer any technology to enable the other Party to exercise any right or license to the technology of the other Party.

13.8.2 If this Agreement is terminated by Tris with respect to the Subsequent Product pursuant to any of Sections 9.6, 13.3, 13.4, 13.7 or 14, or if this Agreement is terminated with respect to the Subsequent Product by Alpharma pursuant to Section 13.5, then: (i) Alpharma shall promptly transfer to Tris, at Alpharma's expense, copies of all data, reports, records, materials that relate solely to such Product in the Territory for the use by Tris only with respect to such Product therein, including without limitation all clinical data and other information developed pursuant to the Development and Regulatory Program; (ii) at Alpharma's expense, provide Tris with all information necessary or desirable to cross-reference and/or assume responsibility for any regulatory filings in Alpharma's name with respect to such Product in the Territory; (iii) return to Tris all relevant records and materials in Alpharma's possession or control containing Confidential Information of Tris relating solely to such Product in the Territory (*provided* that Alpharma may keep one copy of such Confidential Information for archival purposes only); (iv) the licenses granted under Section 7.1 shall terminate with respect to such Product in the Territory; (v) Alpharma shall assign to Tris all sublicense agreements granted by Alpharma under this Agreement with respect to such Product in the Territory; and (vi) any licenses granted by Tris to Alpharma with respect to the Tris Marks as related to such Product in the Territory shall immediately terminate. Thereafter, all Tris' obligations to Alpharma with respect to such Product shall cease in the Territory.

13.8.3 If this Agreement is terminated by Tris with respect to the Initial Product pursuant to any of Sections 9.6, 13.3, 13.4, 13.7 or 14, or if this Agreement is terminated with respect to the Initial Product by Alpharma pursuant to Section 13.5, then: (i) at Alpharma's expense, provide Tris with all information necessary or desirable to cross-reference any regulatory filings in Alpharma's name with respect to such Product for Tris' use outside the Territory; (ii) return to Tris all relevant records and materials in Alpharma's possession or

control containing Confidential Information of Tris relating solely to such Product in the Territory (*provided* that Alpharma may keep one copy of such Confidential Information for archival purposes only); (iii) the licenses granted under Section 7.1 shall terminate with respect to such Product in the Territory; and (iv) any licenses granted by Tris to Alpharma with respect to the Tris Marks as related to such Product in the Territory shall immediately terminate. Thereafter, all Tris' obligations to Alpharma with respect to such Product shall cease in the Territory. If this Agreement is terminated by Tris with respect to the Initial Product pursuant to any of Sections 13.3, 13.4, 13.7 or 14, Tris' sole right and remedy, in addition to the foregoing, shall be damages proximately resulting from any breach by Alpharma of its obligations as set forth in this Agreement.

13.8.4 In addition to what is provided in Section 13.8.2, if this Agreement is terminated by Tris with respect to the Subsequent Product pursuant to Section 13.4.1, Tris shall, subject to any credits available to Tris, (i) pay Alpharma's out-of-pocket costs in connection with the portion of the Development and Regulatory Program related to the Subsequent Product and fifty percent (50%) of the development milestones related to the Subsequent Product paid to Tris under Sections 4.6.2 and 6.2 of this Agreement, and (ii) pay to Alpharma a royalty on the sale of the Subsequent Product in each country in the Territory equal to ten percent (10%) of Net Sales of said Product for the longer of: (A) twenty (20) years after the First Commercial Sale of the Subsequent Product in such country in the Territory; or (B) so long as the manufacture, use or sale of the Subsequent Product would infringe a Valid Claim of any Patent Rights included in the Tris Technology in such country in the Territory in the absence of a license thereunder, or (C) the commercial launch of a second Generic Product equivalent to the Subsequent Product in such country in the Territory by a Third Party unrelated to the party that launched the first such Generic Product. In the event that such a Generic Product is being sold in any country in the Territory, then the Net Sales royalty set forth in this Section for the Subsequent Product shall be reduced on a country-by-country basis to 5%.

13.8.5 In addition to what is provided in Sections 13.8.2 and 13.8.3, if this Agreement is terminated by Tris with respect to either Product pursuant to any of Sections 9.6, 13.3, 13.7 or 14: (i) Alpharma's rights with respect to any outstanding amounts paid to Tris to fund the Development and Regulatory Program respect to the terminated Product shall cease; and (ii) such termination right shall be in addition to any other remedies available at law or in equity with respect to the Subsequent Product and damages proximately resulting from any breach by Alpharma with respect to the Initial Product.

13.8.6 If Tris' right to manufacture either the Subsequent Product or the Initial Product is terminated pursuant to Section 13.6, the license granted by Section 7.1 shall be expanded by adding thereto an Alpharma right to manufacture the Subsequent Product or the Initial Product (including the Anti-caking Complex), as the case may be, or have the Subsequent Product or the Initial Product (including the Anti-caking Complex), as the case may be, manufactured, and all rights and obligations from and after the date of such termination related to the manufacture of the Subsequent Product or the Initial Product (including the Anti-caking Complex), as the case may be, by Tris (other than as related to Products delivered by Tris prior to such termination) shall terminate.

13.8.7 If Alpharma has offered an extension of the Royalty Term pursuant to Section 13.2.1 upon the same monetary terms as contained in Section 6 of this Agreement and Tris does not agree to such extension or if this Agreement is terminated by Alpharma with respect to any Product (or both Products, as the case may be) pursuant to any of Sections 13.3 or 14, in addition to any other remedies available at law or in equity, then: (i) any licenses granted by Alpharma to Tris with respect to the Trademarks as related to said Product shall immediately terminate; (ii) Tris shall, at its sole cost and expense: (A) promptly return to Alpharma all applicable data and materials transferred by Alpharma to Tris hereunder including, without

limitation, all records and materials in Tris' possession or control containing Alpharma's Confidential Information related to the terminated Product (provided that Tris may keep one (1) copy of such Confidential Information for archival purposes only); and (B) provide Alpharma with all information necessary or desirable to cross-reference any regulatory filings in Tris' name with respect to the terminated Product; (iii) transfer to Alpharma all other information and inventory of Product and the like manufactured or acquired by or for the benefit of Alpharma and relating to the terminated Product, provided, however, that Alpharma shall pay to Tris the Commercial Transfer Price for any such inventory of Product within fifteen (15) days after shipment thereof; (iv) Tris shall cooperate with Alpharma to transfer the Tris Technology necessary to enable a Alpharma or a Third Party manufacturer (if a Third Party, on terms and conditions reasonably acceptable to Tris regarding the protection of Tris' intellectual property relating thereto), to manufacture the terminated Product for marketing and sales of said Product in the Territory; and (v) the licenses granted under Sections 7.1 with respect to the terminated Product shall continue in full force and effect on a perpetual basis, subject to and in accordance with the terms and conditions of this Agreement, and Alpharma shall thereafter, in connection with such license, be obligated to pay Tris a royalty of five percent (5%) of Net Sales in lieu of the royalty obligation set forth in Section 6.1 and all other payment obligations hereunder except for Product shipped prior to the date of termination.

13.8.8 In addition to what is provided for in Section 13.8.6, if this Agreement is terminated by Alpharma pursuant to Section 13.3, Alpharma shall have the rights set forth in Section 8.7.6.

13.8.9 For avoidance of doubt, upon the termination of this Agreement, regardless of the cause or reason, Tris shall have no right to (i) use any of the Trademarks, including without limitation the mark "KADIAN®", and Alpharma shall have no right to use the Tris Marks and (ii) any data, reports, records, materials that relate solely to such Initial Product, including without limitation any clinical data and other information developed pursuant to the Development and Regulatory Program or any information related to or the right to cross-reference regulatory filings in Alpharma's name with respect to such Initial Product in the Territory.

13.9 *Accrued Rights; Surviving Obligations.*

13.9.1 Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

13.9.2 All of the Parties' rights and obligations under Sections 1, 6.4, 6.5, 6.6, 6.7, 7.3, 9.1, 9.2, 9.4 (to the extent relating to a claim arising during the Term of the Agreement), 9.5 (to the extent relating to a claim arising during the Term of the Agreement), 10.2, 11, 12, 13.8, 13.9, 15 and 16 shall survive termination, relinquishment or expiration of this Agreement.

14. FORCE MAJEURE.

Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money due hereunder) shall not be considered a breach of this Agreement, and the time required for performance shall be extended for a period equal to the period of such delay, if such delay has been caused by or is the result of acts of God; acts of public enemy; insurrections; terrorism, riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; earthquakes; floods; shortages of energy; governmental prohibition or restriction; or other unforeseeable causes beyond the

reasonable control and without the fault or negligence of the Party so affected ("*Force Majeure*"). The Party so affected shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall be excused from the performance, or the punctual performance, of such obligations, as the case may be, from the date of such notice, up to a maximum of one hundred eighty (180) days, after which time (or such earlier time if it is readily apparent to the Party not affected by the event of Force Majeure that such event will exceed one hundred eighty (180) days in duration) the Party not affected, may terminate this Agreement with respect to the Product(s) as to which the Force Majeure condition exists. To the extent possible, each Party shall use reasonable diligent efforts to avoid or minimize the duration of any Force Majeure.

15. DISPUTE RESOLUTION.

15.1 *Referral to Executive Officers.* The Parties recognize that disputes as to certain matters may from time to time arise during the Term of this Agreement which relate to a Party's rights and/or obligations hereunder. If the Parties cannot resolve any such dispute within thirty (30) calendar days after notice of a dispute from one Party to another, any Party may, by notice to the other Party, have such dispute referred to the Executive Officers. The Executive Officers shall meet promptly to negotiate in good faith the matter referred and to determine a resolution. During such period of negotiations, any applicable time periods under this Agreement shall be tolled. If the Executive Officers are unable to determine a resolution in a timely manner, which shall in no case be more than thirty (30) days after the matter was referred to them, the matter may be resolved through arbitration in accordance with the arbitration provisions set forth in Section 15.2, upon notice by a Party on the other Party specifically requesting such arbitration.

15.2 *Arbitration.* Where a Party has served a written notice upon another requesting arbitration of a dispute pursuant to this Section 15.2, any such arbitration shall be submitted to final and binding arbitration under the then current commercial arbitration rules of the American Arbitration Association (the "*AAA*") in accordance with this Section 15.2. The place of arbitration of any dispute shall be Newark, New Jersey. Such arbitration shall be conducted by three (3) arbitrators, one (1) appointed by each of Tris and Alpharma and the third (3rd) selected by the first two (2) appointed arbitrators. Each arbitrator shall be a person with relevant experience in the pharmaceutical industry. Tris and Alpharma shall instruct such arbitrators to render a determination of any such dispute within four (4) months after the appointment of the third arbitrator. Any award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrators shall be equally shared between the Parties unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party or Parties (including reasonable attorneys' fees) against the other Party or Parties, as the case may be. This Section 15.2 shall not prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by any other Party which would cause irreparable harm to the first Party.

16. MISCELLANEOUS.

16.1 *Relationship of Parties.* Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.

16.2 *Assignment.* Except pursuant to a sublicense permitted under this Agreement, neither Party shall be entitled to assign its rights or delegate its obligations hereunder without the

express written consent of the other Party hereto, except that either Party may assign its rights and transfer its duties hereunder to an Affiliate or in connection with the merger of the Party into a Third Party or in connection with the sale of all or substantially all of the Party's assets. No assignment and transfer shall be valid or effective unless done in accordance with this Section 16.2 and unless and until the assignee/transferee shall agree in writing to be bound by the provisions of this Agreement.

16.3 *Books and Records.* Any books and records to be maintained under this Agreement by a Party shall be maintained in accordance with GAAP.

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

16.5 *Notice.* Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

in the case of Tris, to:	Tris Pharma, Inc. 2033 Route 130; Suite D Monmouth Junction, New Jersey 08852 Attention: Ketan Mehta Facsimile No.: 732.940.2855 Telephone No.: 732.940.2800
with a copy to:	Reed Smith LLP Princeton Forrestal Village 136 Main Street; Suite 250 Princeton, New Jersey 08543 Attention: Diane Frenier, Esq. Facsimile No.: 609.951.0824 Telephone No.: 609.514.5999
in the case of Alpharma, to:	Alpharma Branded Products Division Inc. One New England Avenue Piscataway, New Jersey 0702408854 Attention: President Facsimile No.: 732-465-3679 Telephone No.: 732-465-3614
with a copy to:	Alpharma Branded Products Division Inc. One New England Avenue Piscataway, NJ 08854 Attention: Vice President, Law Facsimile No.: 732-465-3640 Telephone No.: 732-465-3647

or to such other address for such Party as it shall have specified by like notice to the other Party, *provided* that notices of a change of address shall be effective only upon receipt thereof. With respect to notices given pursuant to this Section 16.5: (i) if delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request

was given; (ii) if sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service; and (iii) if sent by certified mail, the date of delivery shall be deemed to be the fifth business day after such notice or request was deposited with the applicable national postal service.

16.6 *Use of Name.* Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

16.7 *Public Announcements.* Except as required by law or regulation (including, without limitation, disclosure requirements of the U.S. Securities and Exchange Commission, Nasdaq or any other stock exchange on which securities issued by a Party are traded), neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld, provided that it shall not be unreasonable for a Party to withhold consent with respect to any public announcement containing any financial terms or any of such Party's Confidential Information. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text prior to such announcement and with financial terms sufficiently in advance of the scheduled release of such announcement to afford such other Party a reasonable opportunity to review and comment upon the proposed text. Nothing in this Section 16.7 will prohibit either Party from disclosing this Agreement or the subject matter hereof to any potential investor, investment banker or the like for the purpose of raising financing, provided that such disclosures are subject to appropriate confidentiality provisions and limited to use for evaluation of such financing.

16.8 *Waiver.* A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

16.9 *Compliance with Law.* Nothing in this Agreement shall be deemed to permit a Party to export, re-export or otherwise transfer the Product sold under this Agreement without compliance with applicable laws.

16.10 *Severability.* If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

16.11 *Amendment.* No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

16.12 *Governing Law.* This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware without regard to conflict of law principles and the Parties hereby submit and consent to the jurisdiction of the federal or state courts in

Delaware for the resolution of disputes under this Agreement that require the involvement of a court.

16.13 *Entire Agreement.* This Agreement, together with all exhibits and schedules hereto, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and merges all prior discussions and negotiations between them, and neither of the Parties shall be bound by any conditions, definitions, warranties, understandings or representations with respect to such subject matter other than as expressly provided herein or as duly set forth on or subsequent to the date hereof in writing and signed by a proper and duly authorized officer or representative of the Party to be bound thereby.

16.14 *Parties in Interest.* All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.

16.15 *Descriptive Headings.* The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

16.16 *Construction of Agreement.* The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.

16.17 *Waiver of Jury Trial.* EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT. EACH PARTY HERETO (i) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THAT FOREGOING WAIVER, AND (ii) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND ANY RELATED INSTRUMENTS, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 16.17.

16.18 *Counterparts.* This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures shall be treated as original signatures.

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IN WITNESS WHEREOF, each of the Parties has caused this Development and License Agreement to be executed by its duly authorized representative as of the date first above written.

TRIS PHARMA, INC.

By: _____
Name: Ketan Mehta
Title: President and Chief Executive Officer

ALPHARMA BRANDED PRODUCTS DIVISION INC.

By: _____
Name: Dr. Ronald Warner
Title: President