EX-10.5 10 dex105.htm MANUFACTURING AGREEMENT  
Exhibit 10.5  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
EXECUTION COPY  
MANUFACTURING AGREEMENT  
BETWEEN  
NEW ABRAXIS, INC.  
(TO BE RENAMED ABRAXIS BIOSCIENCE, INC.)  
AND  
APP PHARMACEUTICALS, LLC  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
MANUFACTURING AGREEMENT  
THIS MANUFACTURING AGREEMENT (this “Agreement”) is made by and between New Abraxis, Inc., to be renamed Abraxis BioScience, Inc., a Delaware corporation (“NEW ALPHA”), and APP Pharmaceuticals, LLC, a Delaware limited liability company (“GENERICO”), as of this 13 day of November, 2007 (the “Effective Date”).  
RECITALS  
A. NEW ALPHA or one or more its subsidiaries has developed and owns the rights to the Product and the Pipeline Products (both as defined below).  
B. GENERICO has the capabilities, facilities and equipment designed for and capable of performing the Generico Manufacturing (as defined below) with respect to the Product and the Pipeline Products, and GENERICO desires to perform such Generico Manufacturing upon the terms and conditions contained herein.  
AGREEMENT  
NOW, THEREFORE, in consideration of the above Recitals, the mutual covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto hereby agree as follows:  
1. Definitions. For purposes of this Agreement, in addition to other defined terms set forth in this Agreement, the terms set forth below will have the following meanings:  
1.1 “Action” means any actual or threatened claim, suit, demand, arbitration, hearing, inquiry, proceeding, complaint, charge or investigation by or before any court, Regulatory Authority or arbitrator.  
1.2 “Affiliate” means, with respect to any Person, any entity controlling, controlled by or under the common control of such Person. Such entity will be considered an Affiliate only for the time during which such control exists. For the purpose of this Agreement, “control” (together with its correlative meanings “controlled by” or “under common control with”) means having, directly or indirectly, the power to direct or cause the direction of management and policies of such entity. For purposes of this Agreement, none of Gholdco or any of its subsidiaries, including GENERICO, shall be considered an affiliate of NEW ALPHA or any of its subsidiaries, and none of NEW ALPHA or any of its subsidiaries shall be considered an affiliate of Gholdco or any of its subsidiaries, including GENERICO.  
1.3 “Alternative Compensation Amount” has the meaning set forth in Section 2.8(B).  
1.4 “Annual Forecasts” means, for 2008, the annual forecasts of the aggregate units of Product and Pipeline Products to be supplied by GENERICO from each Facility that are attached as Part A of Schedule 1.4 hereto, and for subsequent years, the annual forecasts of the aggregate units of Product and Pipeline Products from each Facility provided by NEW ALPHA to GENERICO at  
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 least thirty (30) days prior to January 1 of that year; provided, however, that the forecasts provided by NEW ALPHA with respect to each year subsequent to 2008 shall not, without the approval of GENERICO (which approval shall not be unreasonably be withheld or delayed), provide for the supply of Product and Pipeline Products from any Facility that is more than (\*\*\*) of the aggregate units to be supplied from that Facility reflected in the estimates for 2009, 2010, 2011 and 2012 as set forth in Part B of Schedule 1.4. The 2009, 2010, 2011 and 2012 estimates shall not become “Annual Forecasts” for purposes hereof until provided by NEW ALPHA under the terms of this Agreement.  
1.5 “Breach” has the meaning set forth in Section 10.2.  
1.6 “cGMP(s)” means current good manufacturing practices established under the FDCA and the regulations promulgated thereunder; and other comparable laws and regulations of any competent Regulatory Authorities applicable to manufacturing activities or the Facility for the Product and Pipeline Products, all as amended from time to time.  
1.7 “Chemical Ingredients” means, with respect to the Product or any Pipeline Product, the active pharmaceutical ingredient(s) and human albumin in the Product or Pipeline Product, as applicable.  
1.8 “Chemical Solution” means end product obtained after New Alpha Manufacturing (other than the New Alpha Review and Release) is complete with respect to the Product or any Pipeline Product.  
1.9 “Chemical Testing” means in-process testing of the chemical properties of the Product or any Pipeline Product during the process of manufacturing Product or any Pipeline Product.  
1.10 “Claim Notice” has the meaning set forth in Section 12.3.  
1.11 “Competitor” means (\*\*\*).  
1.12 “Components” means all containers, closures, packaging components, labels and labeling necessary for the manufacture of the Product or any Pipeline Product as finished goods.  
1.13 “Damages” means any and all losses, liabilities, obligations, costs, expenses, damages or judgments of any kind or nature whatsoever (including reasonable attorneys’, accountants’ and experts’ fees, disbursements of counsel and other costs and expenses).  
1.14 “EMEA” means the European Medicines Evaluation Agency or any successor agency.  
1.15 “Effective Date” means the date written in the preamble of this Agreement, as set forth above.  
1.16 “Estimated Generico Manufacturing Plan” means NEW ALPHA’s estimate of the units of the Product with respect to which NEW ALPHA will place Purchase Orders during each month of each rolling 12-month period during the Term, which estimate will be delivered by NEW ALPHA to GENERICO on a monthly basis; provided, however, that in no event will a given monthly  
 2  
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 estimate vary by more than (\*\*\*) from the monthly estimate issued in respect of the immediately preceding month. The Estimated Generico Manufacturing Plan shall include, with respect to the Product, NEW ALPHA’s estimated requirements for commercial sale, clinical supply, validation, stability or other uses thereof, and for Generico Manufacturing at each Facility, during each month of the applicable rolling 12-month basis.  
1.17 “Facility” means (i) the Melrose Park Facility and (ii) the Grand Island Facility.  
1.18 “FDA” means the United States Food and Drug Administration or any other successor agency of the United States Federal Government.  
1.19 “FDA Modernization Plan” has the meaning set forth in Section 14.1(A).  
1.20 “FDCA” means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et. seq.), as amended from time to time.  
1.21 “Force Majeure” has the meaning set forth in Section 15.4(A).  
1.22 “GENERICO Indemnified Parties” has the meaning set forth in Section 12.2.  
1.23 “Generico Manufacture,” “Generico Manufactured” and “Generico Manufacturing” means the acquisition, sampling, testing and release of Components, the acquisition and sampling of Materials and testing of Materials supplied by GENERICO such as water for injection (“WFI”) and nitrogen, the sampling of Chemical Ingredients and the manufacturing, lyophilization, packaging, labeling, filling, holding, Microbiologic Testing of the Product and Pipeline Products as more fully set forth on Exhibit A. For the avoidance of doubt, Generico Manufacturing does not include New Alpha Manufacturing.  
1.24 “Generico Products” means all of the existing products being manufactured by GENERICO from time to time, including any variations of such products in formulation, dosage, delivery system, or the like (but, for the avoidance of doubt, in no event will the Generico Products include any product incorporating “nab” technology).  
1.25 “Gholdco” means Abraxis BioScience, Inc. (formerly known as Generico Holdings, Inc. and to be renamed APP Pharmaceuticals, Inc.), a Delaware corporation and the parent company of GENERICO.  
1.26 “Grand Island Facility” means GENERICO’s manufacturing facility(s) whether owned or leased located at 0000 Xxxxxx Xxxx, Xxxxx Xxxxxx, Xxx Xxxx.  
1.27 “Grand Island Lease” has the meaning set forth in Section 10.1.  
1.28 “HPFB” means the Health Products and Food Branch of Health Canada or any successor agency of the Canadian government.  
1.29 “IHI” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use or any successor thereto.  
 3  
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 1.30 “Indemnifiable Claim” has the meaning set forth in Section 12.3.  
1.31 “Indemnified Party” has the meaning set forth in Section 12.3.  
1.32 “Indemnifying Party” has the meaning set forth in Section 12.3.  
1.33 “Legal Requirement” means any federal, state or local law, ordinance, regulation, permit, order, writ, judgment, injunction, decree or award, or any rule, regulation or published guidelines or any statement having the effect of law, promulgated by any Regulatory Authority, including cGMPs.  
1.34 “Management Fee” has the meaning set forth in Section 13.  
1.35 “Materials” means, with respect to the Product or any Pipeline Product, all inactive raw materials and excipients, excluding human albumin, used in the formulation of the Product or any Pipeline Product necessary for their manufacture as finished goods.  
1.36 “Melrose Park EU Plan” has the meaning set forth in Section 14.2(A).  
1.37 “Melrose Park Facility” means GENERICO’s manufacturing facility(s) whether owned or leased located at 0000 Xxxx Xxxxxx, Xxxxxxx Xxxx, Xxxxxxxx.  
1.38 “Melrose Park Lease” has the meaning set forth in Section 10.1.  
1.39 “MHLW” means Japan’s ministry of Health, Labor and Welfare (also known as “Korosho”) or any successor agency of the government of Japan.  
1.40 “MOHFW” means India’s ministry of Health & Family Welfare or any successor agency.  
1.41 “Microbiologic Testing” means the microbiologic testing of the Product or any Pipeline Product, as applicable, at the beginning of Generico Manufacturing and at the completion of Generico Manufacturing.  
1.42 “New Alpha Manufacture,” “New Alpha Manufactured” and “New Alpha Manufacturing” means the acquisition, testing and release of Chemical Ingredients, the testing and release of Materials (other than Materials supplied by GENERICO such as WFI and nitrogen) and subsequent formulating, compounding and Chemical Testing of the Product or any Pipeline Products as more fully set forth on Exhibit A, and the New Alpha Review and Release.  
1.43 “New Alpha Review and Release” means the supervision and signoff contemplated by Section 2.9 of this Agreement and the written release of the Product or any Pipeline Product, as applicable, following the completion of the Generico Manufacturing with respect thereto.  
1.44 “Parties” means GENERICO and NEW ALPHA (“Party” meaning one of the Parties).  
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 1.45 “Person” means any natural person, corporation, partnership, limited partnership, limited liability company, proprietorship, other business organization, trust, union, association or Regulatory Authority.  
1.46 “Pipeline Products” means (A) XXX-000, XXX-000, XXX-000 and ABI-011 and (B) other products as identified by NEW ALPHA that GENERICO is reasonably capable of performing Generico Manufacturing at one or both of the Facilities, and (\*\*\*) and G-CSF (granulocyte-colony stimulating factor). Each of the Pipeline Products in clauses (A) and (B) shall either (x) involve substantially the same Generico Manufacturing steps, time and resources as the Product or (y) shall (i) not require any material addition, upgrade or modification to any GENERICO Facility (except where such addition, upgrade or modification would not otherwise have one of the effects described in clauses (ii) and (iii) below, and NEW ALPHA agrees to reimburse GENERICO in accordance with the last sentence of this Section 1.46 in respect thereof), (ii) not require any reallocation or diversion in any material respect of employees, space or other resources of GENERICO and (iii) not otherwise impair or disrupt in any material respect the ability of GENERICO to conduct its business or perform its obligations under this Agreement. NEW ALPHA shall reimburse GENERICO for all incremental costs reasonably incurred by GENERICO and paid to third parties (with the approval of NEW ALPHA not to be unreasonably withheld) as a result of GENERICO manufacturing any Pipeline Products described in clauses (A) and (B).  
1.47 “Product” means ABRAXANE®, a cremapahor-free pacilitaxel formulation, and any modifications thereto made by NEW ALPHA, subject to Section 2.2(G), and provided that, as modified, the product remains an injectible formulation of paclitaxel.  
1.48 “Product Liability Costs” has the meaning set forth in Section 9.6.  
1.49 “Product Liability Claim” means any Action by a third party and any appeal from any Action asserted by a third party with respect to the Product or any Pipeline Product alleging product liability, product defect, design, manufacturing, packaging or labeling defect, failure to warn, or any similar action relating to the formulation, manufacture, use or safety of the Product or any Pipeline Product, as applicable.  
1.50 “Projected Cycle Time” means, for any year, (i) with respect to NEW ALPHA, the projected lyophilizer cycle time required by NEW ALPHA for that year based on the most recent Annual Forecast determined without giving effect to the permitted (\*\*\*) increase in the definition of Annual Forecast or the (\*\*\*) increase permitted in Section 2.6 (i.e., not more than estimated in Schedule 1.4), and (ii) with respect to GENERICO, the projected lyophilizer cycle time required by GENERICO for that year based on the production forecasts for that year attached as part of Schedule 1.4 hereof.  
1.51 “Proprietary Information” means all information relating to the Product or any Pipeline Product, as applicable, concerning the properties, composition or structure of the Product or any Pipeline Product, as applicable, the New Alpha Manufacturing of the Product or any Pipeline Product, as applicable, or the machines used to New Alpha Manufacture the Product or any Pipeline Product, as applicable, the development, marketing or other commercialization of the Product or any Pipeline Product, as applicable, (including, without limitation, reagents, computer programs, algorithms, analytical methodology, suppliers of ingredients and  
 5  
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 equipment, names and expertise of employees and consultants, know-how, formulas, processes, ideas, inventions, whether patentable or not, schematics and other technical, business, financial, customer and product development plans, forecasts, strategies and information relating to the Product and the Pipeline Products), whether previously, currently or subsequently disclosed to the other Party. Technology, innovations, improvements and modifications relating to the Product or any Pipeline Product or made by or for NEW ALPHA or any of its subsidiaries will be considered Proprietary Information of NEW ALPHA.  
1.52 “Proprietary Rights” means any and all patent rights, copyrights, mask work, trade secret rights and all other intellectual and industrial property rights.  
1.53 “Proration Percentage” means, for any year, with respect to a Party, a fraction expressed as a percentage, the numerator of which is such Party’s Projected Cycle Time for such year and the denominator of which is the aggregate Projected Cycle Time of both Parties for such year.  
1.54 “Proration Period” has the meaning set forth in Section 2.7(A).  
1.55 “Purchase Order” means written orders for a quantity of the Product or a number of batches of any Pipeline Product issued by NEW ALPHA and placed with GENERICO. Each Purchase Order shall separately identify whether the Product or Pipeline Products subject to such Purchase Order are for commercial sale, clinical supply, validation, stability or other uses, and shall indicate the Facility at which the Generico Manufacturing shall occur, if applicable, and the Territory in which such quantities will be sold or used for clinical testing; provided, however, that such Purchase Order shall be in accordance with the applicable Estimated Generico Manufacturing Plan as set forth in Section 2.6.  
1.56 “Reasonable Efforts” means a reasonable sustained, continued and active application of diligent efforts, resources and urgency consistent with the manner in which such efforts were provided by New Abraxis, LLC (and its predecessor Abraxis BioScience, Inc.) and their subsidiaries prior to the Effective Date (but not including any historical preference or priority given to the Product as compared with GENERICO’s pharmaceutical products), and no less than the efforts, urgency and resources commonly used by GENERICO in manufacturing for its own business.  
1.57 “Recall” has the meaning set forth in Section 8.1.  
1.58 “Regulatory Approval” means (i) with respect to GENERICO, any and all actions required by a Regulatory Authority for the manufacture of the Product in the Territory, and (ii) with respect to NEW ALPHA, the filing and procurement of any registration, permit and approval required by applicable Regulatory Authorities for the importation, marketing, sale, distribution and use of the Product in the Territory.  
1.59 “Regulatory Authority” means (i) the FDA, (ii) with respect to the Grand Island Facility, the FDA and the EMEA, and (iii) subject to Section 2.2(C), the TGA, the MHLW, the MOHFW, the IHI and any other national, multinational, federal, state, provincial or local regulatory agency, department, bureau or other governmental entity in the Territory that has regulatory authority over the Product or any Pipeline Product.  
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 1.60 “Rejected Product” means batches of Product or Pipeline Product which are either (i) lost in production (or are not in compliance with the applicable Specifications, cGMPs, the FDCA and any other applicable Legal Requirements) as a result of the Generico Manufacturing or New Alpha Manufacturing or a failure or deficiency of the Generico Manufacturing or New Alpha Manufacturing, or (ii) determined by final decision of NEW ALPHA’s or GENERICO’s quality group not to be suitable for final release.  
1.61 “Specifications” means the description and attributes, Chemical Ingredients, Components and Materials for the Product or any Pipeline Product, along with manufacturing procedures for such Product. Specifications exclude NEW ALPHA Proprietary Information. The Specifications include without limitation:  
(A) sampling requirements (including lab and microbiological);  
(B) intermediate specifications;  
(C) processing aids;  
(D) finished Product release criteria;  
(E) stability specifications;  
(F) Microbiologic Testing methods; and  
(G) packaging, labels and labeling.  
1.62 “Supply Deficit Period” has the meaning set forth in Section 2.8(A).  
1.63 “Technology” means any and all ideas, techniques, inventions, methods, data, information, formulae, processes, trade secrets, analytical methodology, intellectual property, know-how, and test results, whether patentable or not, and whether or not reduced to practice, including Proprietary Rights, owned, controlled or otherwise in possession of or used by NEW ALPHA as of the Effective Date, or during the Term and necessary or useful to make, have made, develop, have developed, use, import, market, offer for sale or sell the Product or any Pipeline Product.  
1.64 “Term” has the meaning set forth in Section 10.1.  
1.65 “TGA” means the Therapeutic Goods Administration, Department of Health and Ageing, Australia.  
1.66 “Territory” means (\*\*\*).  
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 1.67 “Warehouse Services Agreement” means the Warehouse Services Agreement, dated as of the Effective Date, between New Abraxis, LLC and Generico, as it may be amended from time to time.  
2. Generico Manufacturing and Other Services.  
2.1 Subject to the terms, conditions and provisions of this Agreement, GENERICO hereby covenants and agrees that during the Term it will perform the Generico Manufacturing with respect to the Product and the Pipeline Products as requested by NEW ALPHA in accordance with the terms hereof. GENERICO will perform the Generico Manufacturing with respect to the Product and the Pipeline Products solely and exclusively for NEW ALPHA and its designees.  
2.2 GENERICO will, in good faith, use Reasonable Efforts to:  
(A) obtain and maintain such approvals and licenses as may be required by any Regulatory Authority or Legal Requirement for the manufacturing at the Facilities of the Product or any Pipeline Product for commercial sale or clinical development in the United States and its territories and possessions; without limiting the foregoing, GENERICO shall use Reasonable Efforts to obtain as promptly as practicable such approvals and licenses as may be required by any Regulatory Authority or Legal Requirement for the manufacturing of the Product for commercial sale in the United States on Line 6 of the Grand Island Facility; provided, however, that nothing in this sub-clause (A) shall be interpreted to require GENERICO to obtain any Regulatory Approvals for which NEW ALPHA is responsible pursuant to Section 2.3;  
(B) obtain and maintain such approvals and licenses as may be required by any Regulatory Authority or Legal Requirement for the manufacturing at the Grand Island Facility of the Product or any Pipeline Product for commercial sale or clinical development in the territories of the European Union; provided, however, that nothing in this sub-clause (B) shall be interpreted to require GENERICO to obtain any Regulatory Approvals for which NEW ALPHA is responsible pursuant to Section 2.3;  
(C) obtain and maintain such approvals and licenses as may be required by any Regulatory Authority or Legal Requirement for the manufacturing at the Grand Island Facility or Melrose Park Facility of the Product or any Pipeline Product for commercial sale or clinical development in other jurisdictions as shall be reasonably requested by NEW ALPHA; provided, however, that nothing in this Section 2.2(C) shall require GENERICO to obtain any such approvals or licenses in any jurisdiction unless both (a) doing so would not require (i) any material addition, upgrade or modification to any Facility (except where such addition, upgrade or modification would not otherwise have one of the effects described in clauses (ii) and (iii) below, and NEW ALPHA agrees to reimburse GENERICO in accordance with clause (b) below in respect thereof), (ii) would not require any reallocation or diversion in any material respect of employees, space or other resources of GENERICO and (iii) would not otherwise impair or disrupt in any material respect the ability of GENERICO to conduct its business or perform its obligations under this Agreement, and (b) NEW ALPHA agrees to reimburse GENERICO for all incremental costs reasonably incurred by GENERICO and paid to third parties (with the approval of NEW ALPHA not to be unreasonably withheld) as a result of obtaining any such approvals or licenses; and provided further that nothing in this sub-clause (C) shall be interpreted to require GENERICO to obtain any Regulatory Approvals for which NEW ALPHA is responsible pursuant to Section 2.3;  
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 (D) maintain such facilities, resources and personnel, and such industry expertise, as may be required for it to manufacture such units or batches of the Product and any Pipeline Product as may be required hereunder and GENERICO will inform NEW ALPHA of any planned modifications of GENERICO’s facilities, equipment and processes, prior to implementation, that could result in the need for any additional Regulatory Approvals with respect to the Product or any Pipeline Product (such notice to be in writing and with sufficient time to obtain any necessary Regulatory Approvals), and GENERICO and NEW ALPHA will reasonably agree on the manner and timing of such modifications;  
(E) perform the Generico Manufacturing in compliance with the terms and conditions of this Agreement, the Specifications, cGMPs, the FDCA and any and all other applicable Legal Requirements, and promptly provide NEW ALPHA with copies of any correspondence, including inspection reports, from Regulatory Authorities concerning GENERICO’s operation of the Facilities which could have any bearing in a material respect upon this Agreement together with any responses thereto;  
(F) implement, as soon as reasonably possible, any change or modification to the manufacture or Specifications of the Product or any Pipeline Product that are required or recommended by any Regulatory Authority or required by cGMPs or Legal Requirements; provided, however, that NEW ALPHA shall reimburse GENERICO for the reasonable out-of-pocket expenses incurred by GENERICO (with the approval of NEW ALPHA not to be unreasonably withheld) as a result of such change or modification to the extent that such change would not be necessary but for the manufacturing of the Product or the Pipeline Products;  
(G) implement, as soon as reasonably possible, any change or modification to the manufacture or Specifications of the Product or any Pipeline Product that are requested by NEW ALPHA; provided, however, that nothing in this Section 2.2(G) shall require GENERICO to implement any such change or modification unless both (a) doing so would not require (i) any material addition, upgrade or modification to any Facility (except where such addition, upgrade, or modification would not otherwise have one of the effects described in clauses (ii) and (iii) below, and NEW ALPHA agrees to reimburse GENERICO in accordance with clause (b) below in respect thereof), (ii) would not require any reallocation or diversion in any material respect of employees, space or other resources of GENERICO and (iii) would not otherwise impair or disrupt in any material respect the ability of GENERICO to conduct its business or perform its obligations under this Agreement, and (b) NEW ALPHA agrees to reimburse GENERICO for all incremental costs reasonably incurred by GENERICO and paid to third parties (with the consent of NEW ALPHA not to be unreasonably withheld) as a result of any such change or modification;  
(H) keep true, accurate and complete books, records, reports and accounts in connection with or relative to the Product and each Pipeline Product, and the Generico Manufacturing of the Product and the Pipeline Products, as well as any other books and records as may be required from time to time by Legal Requirements;  
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 (I) maintain batch records sufficient to trace the history of each batch, and representative samples from each batch of Product and Pipeline Product manufactured hereunder, for record keeping, stability testing and other regulatory purposes in accordance with the Specifications and Legal Requirements;  
(J) during the process of Generico Manufacturing, allow NEW ALPHA to undertake any Chemical Testing and other quality control measures reasonably requested by NEW ALPHA in order to comply with the Specifications and requirements of any Regulatory Authority; and  
(K) maintain each Facility in good working order and within cGMPs (e.g., qualification, calibration, maintenance, validation), including critical systems (e.g., WFI, HVAC, clean steam, compressed gasses, etc.); and  
(L) maintain all manufacturing equipment (other than dedicated nanotechnology equipment) in good working order and within cGMPs (e.g., qualification, calibration, maintenance, validation).  
2.3 NEW ALPHA or its licensees or designees will be solely responsible for obtaining and maintaining compliance with any Regulatory Approvals relating to the importation, marketing, sale, clinical testing, distribution and use of the Product or any Pipeline Product.  
2.4 NEW ALPHA, or any designee of NEW ALPHA, will have the right at any time upon prior reasonable notice and during regular business hours to inspect and examine the parts of the Facilities used in connection with and relative to the Product and the Pipeline Products and the Generico Manufacturing. Any such inspection or examination shall be scheduled at such time and conducted in such manner as to minimize disruption to GENERICO’s normal operations.  
2.5 NEW ALPHA will have the right, upon prior reasonable notice and during regular business hours, to audit and inspect any and all documents and records related to (A) GENERICO’s manufacture and supply of the Product and the Pipeline Products and (B) GENERICO’s performance under this Agreement, including GENERICO’s costs or expenses for which it is entitled to reimbursement hereunder. GENERICO will also permit representatives of any Regulatory Authority, including, but not limited to, the FDA or its agents, to visit and inspect any and all facilities used in the Generico Manufacturing of the Product and the Pipeline Products. This right of NEW ALPHA and the Regulatory Authorities includes access to audit any and all documents and records relating to GENERICO’s performance under this Agreement.  
2.6 On or promptly after the Effective Date and, thereafter, by the end of the first week of each month of the Term, NEW ALPHA will send to GENERICO an Estimated Generico Manufacturing Plan. The Parties acknowledge and agree that the Estimated Generico Manufacturing Plan is an estimate only and is not binding upon NEW ALPHA, except that the estimate for the next three  
 10  
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 months shall be binding. GENERICO shall supply the quantity of the Product and Pipeline Products reflected in Purchase Orders provided by NEW ALPHA from a particular Facility for a given month to the extent that such Purchase Orders are for no more than (\*\*\*) of the aggregate number of units of the Product from such Facility for such month reflected in the Estimated Generico Manufacturing Plan submitted at least ninety (90) days before the calendar month in which such Purchase Order is submitted. GENERICO shall not be obligated to supply the quantity of the Product or any Pipeline Product earlier than seventy five (75) days following the placement of the Purchase Order for the Product or any Pipeline Product. For the initial 90 days of this Agreement, GENERICO will supply the quantity of Product or Pipeline Product in accordance with orders placed by New Abraxis, LLC (or its predecessor Abraxis Bioscience, Inc.), which will, in accordance with the next sentence, be consistent with the Annual Forecast for 2008. GENERICO shall supply quantities of the Product and any Pipeline Product during any month of the Term in calendar year 2007 or 2008 in accordance with orders placed by New Abraxis, LLC (or its predecessors Abraxis Bioscience, Inc.) or Purchase Orders placed by NEW ALPHA as applicable; provided, that GENERICO shall not be obligated to supply units of Product and Pipeline Products from any Facility during any such month in excess of (\*\*\*) of the aggregate units of Product from such Facility reflected in the Annual Forecast for 2008. GENERICO shall not be obligated to supply in any year from a Facility a quantity of units of the Product and Pipeline Products that exceeds by more than (\*\*\*) the quantity of the Product indicated for such Facility in the Annual Forecast for such year. GENERICO shall, subject to Section 2.2 and this Section 2.6, use Reasonable Efforts to have the Generico Manufacturing with respect to quantities of the Product and Pipeline Products subject to a Purchase Order (or order referred to in the prior sentences) performed at the Facility specified in the applicable Purchase Order (or order referred to in the prior sentences) and otherwise in compliance with applicable Legal Requirements for the commercial sale or clinical testing of the Product or Pipeline Products in the Territory specified in the applicable Purchase Order; provided, however, that if the Facility specified in the applicable Purchase Order is the only Facility qualified to manufacture the Product or any Pipeline Product pursuant to applicable Legal Requirements and the rules of any applicable Regulatory Authority, then the Generico Manufacturing with respect thereto must be performed at the Facility specified in the Purchase Order. Until the Estimated Generico Manufacturing Plan is binding pursuant to this section, NEW ALPHA may substitute Product for any Pipeline Product (or Pipeline Product for Product) that is reflected on NEW ALPHA’s Annual Forecast or Estimated Generico Manufacturing Plan, subject to all of the limitations in this Agreement.  
2.7 In the event of any capacity constraints at any Facility or if GENERICO reasonably anticipates that there will be capacity constraints at any Facility:  
(A) GENERICO shall promptly notify NEW ALPHA in writing of any potential or actual capacity constraints, and GENERICO and NEW ALPHA shall promptly meet to discuss how to address such capacity constraints (the period during which such capacity constraints are reasonably anticipated to prevent satisfaction of all Purchase Orders for which GENERICO would otherwise be required to make delivery during such period, the “Proration Period”). At such meeting, GENERICO shall notify NEW ALPHA whether such capacity constraints will prevent GENERICO from satisfying Purchase Orders expected to be placed by NEW ALPHA pursuant to the current Estimated Generico Manufacturing Plan.  
 11  
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 (B) In connection with manufacturing of the Product for delivery during the Proration Period, the lyophilizers and filling lines approved for manufacturing the Product located at the Facilities shall be allocated equitably between the Parties according to the Proration Percentage.  
(C) GENERICO shall not in any event be responsible for any failure to manufacture Product due to capacity constraints so long as it complies with this Section 2.7 and uses Reasonable Efforts to eliminate, cure or overcome such capacity constraints and end the Proration Period as soon as reasonably practicable.  
(D) If at any time the resources available for manufacturing under this Agreement (other than with respect to lyophilizer and filing line capacity) are less than the aggregate demand of both Parties, the resources that are available shall be allocated equitably between the Parties.  
2.8 Notwithstanding Section 2.7, if during the Term of this Agreement:  
(A) If as a result of capacity constraints and the application of the Proration Percentage in accordance with Section 2.7, GENERICO is not required, in accordance with Section 2.7, to deliver sufficient units of the Product to fulfill the production forecasts set forth in the Estimated Generico Manufacturing Plan during any Proration Period (such Proration Period, the “Supply Deficit Period”), NEW ALPHA may, at its sole option, elect to require GENERICO to manufacture and deliver additional units of the Product in an amount necessary to fulfill the production forecasts for such Supply Deficit Period.  
(B) If NEW ALPHA so elects to have GENERICO manufacture and deliver additional Product during a Supply Deficit Period pursuant to Section 2.8(A), GENERICO shall be entitled to receive the following remuneration: After the end of each 90 day period during the Supply Deficit Period and at the end of the Supply Deficit Period, the Parties shall determine in good faith the amount of net profits attributable to the sale of Generico Products (determined in accordance with generally acceptable accepted accounting principles as consistently applied by GENERICO) that GENERICO would have realized (but did not realize) with respect to such 90-day or other period during the Supply Deficit Period had NEW ALPHA not exercised its option under Section 2.8(A), based on net profits attributable to the Generico Products realized by GENERICO during the most recent full fiscal quarter ending prior to the Supply Deficit Period, plus any penalties incurred by GENERICO under GENERICO’s customer contracts as a result of NEW ALPHA’s exercise of its option under Section 2.8(A) less (\*\*\*) of the total amount charged to NEW ALPHA for the additional units of the Product manufactured during such Supply Deficit Period to fulfill the production forecasts. Within sixty (60) days after the mutual determination of such amount (the “Alternative Compensation Amount”), NEW ALPHA shall pay to GENERICO an amount equal to such Alternative Compensation Amount. GENERICO shall use commercially reasonable efforts to maximize profits attributable to Generico Products in any Supply Deficit Period and to minimize the Alternative Compensation Amount, including, without limitation, by using production capacity available to GENERICO to manufacture higher margin products and seeking to purchase Generico Products equal to the amount of any shortfall from third-party suppliers.  
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Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 2.9 NEW ALPHA will provide, at its own cost, NEW ALPHA employees and personnel to supervise and approve in writing, each stage of the manufacturing process related to the manufacture of the Product and the Pipeline Products.  
2.10 In addition to Generico Manufacturing, during the Term, GENERICO will provide NEW ALPHA the additional services listed on Schedule 2.10 in return by payment of NEW ALPHA of the amounts set forth on such Schedule 2.10 following receipt of an invoice from GENERICO. Invoices will be issued by GENERICO promptly after each month-end during the Term of this Agreement, and payment shall be made, net 30 days after receipt by NEW ALPHA of an invoice, so long as the invoice complies with the terms and conditions of this Agreement.  
3. New Alpha Manufacturing.  
3.1 NEW ALPHA will perform the New Alpha Manufacturing and will procure Chemical Ingredients and supply to GENERICO the Chemical Solution at an agreed schedule in amounts and times sufficient in order for GENERICO to meet its obligations under Section 2.  
3.2 NEW ALPHA will for the New Alpha Manufacturing in good faith use Reasonable Efforts to:  
(A) have such resources and personnel, and such industry expertise, as may be required for it to perform the New Alpha Manufacturing as required hereunder;  
(B) perform the New Alpha Manufacturing in compliance with the terms and conditions of this Agreement, the Specifications, cGMPs, the FDCA and any and all other applicable Legal Requirements;  
(C) keep true, accurate and complete books, records, reports and accounts in connection with the New Alpha Manufacturing as well as any other books and records as may be required from time to time by any applicable Legal Requirement;  
(D) maintain all nanotechnology specific equipment in good working order and within cGMPs (e.g., qualification, calibration, maintenance, validation); and  
(E) arrange for pickup and transportation of finished Product and Pipeline Products; provided, that, during the period in which the Warehouse Services Agreement is in effect, GENERICO will in good faith use Reasonable Efforts to arrange for such pickup and transportation.  
3.3 Following completion of Generico Manufacturing, NEW ALPHA will perform Chemical Testing as required by applicable Legal Requirements. Section 6.1 shall govern release of any Product or Pipeline Product.  
3.4 GENERICO, or any designee of GENERICO, will have the right at any time upon prior reasonable notice and during regular business hours to inspect and examine NEW ALPHA’s portions of the Facilities used in connection with and relative to the Product and the Pipeline Products and the New Alpha Manufacturing thereof. Any such inspection and examination shall be scheduled at such time and conducted in such manner as to minimize disruption to NEW ALPHA’s normal operations.  
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Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 3.5 GENERICO will have the right, upon prior reasonable notice and during regular business hours, to audit and inspect any and all documents and records related to NEW ALPHA’s performance under this Agreement, including NEW ALPHA’s costs and expenses for which it is entitled to reimbursement hereunder. NEW ALPHA will also permit representatives of any Regulatory Authority, including, but not limited to, the FDA or its agents, to visit and inspect NEW ALPHA’s portions of the Facilities used in the New Alpha Manufacturing of the Product and the Pipeline Products. This right of GENERICO and the Regulatory Authorities includes access to audit any and all documents and records relating to NEW ALPHA’s performance under this Agreement. Sections 3.4 and 3.5 shall not be interpreted to require NEW ALPHA to provide or disclose any documents, records or other information to the extent constituting Proprietary Information.  
3.6 NEW ALPHA shall, at its option (as determined in its sole discretion), perform New Alpha Manufacturing with respect to GENERICO’s products, pending products and products under development as requested from time to time by GENERICO. The scope, timing and cost for any such New Alpha Manufacturing shall be as agreed between NEW ALPHA and GENERICO (in their sole discretion).  
4. Price and Payment.  
4.1 With the issuance by NEW ALPHA of a Purchase Order, NEW ALPHA shall designate whether (and, as applicable, what portion of) the ordered Product shall be used for commercial sale, clinical supply, validation, stability or other uses, and each Purchase Order with respect to quantities of the Product that will be commercially sold, shall indicate the Facility at which the Generico Manufacturing shall occur and the Territory in which such quantities will be sold. The price per unit of the Product, and the price per batch of any Pipeline Product, to be charged by GENERICO with respect to each unit or batched delivered by GENERICO shall be as set forth in Schedule 4.1. The price of the Product and any Pipeline Product will not include delivery of the Product or Pipeline Product to NEW ALPHA or any of its distributors. The risk of loss of any Product will transfer FOB shipping point (i.e., GENERICO manufacturing Facility).  
4.2 GENERICO will issue an invoice to NEW ALPHA for each Purchase Order, based upon and reflecting the applicable price. Invoices will be issued upon (i) written release of the Product or Pipeline Product by NEW ALPHA and (ii) delivery to NEW ALPHA’s common carrier for delivery. Payment shall be made, net 30 days after receipt by NEW ALPHA of an invoice, so long as the invoice complies with the terms and conditions of this Agreement. Notwithstanding the foregoing, payment with respect to Product or Pipeline Products that are Rejected Products shall be paid in accordance with Section 6.  
 14  
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 5. Regulatory Approval.  
5.1 GENERICO will use Reasonable Efforts to cooperate with NEW ALPHA and its licensees with respect to obtaining all Regulatory Approvals relating to the Product and the Pipeline Products in any Territory, subject to Section 2.2(C). Without limiting the foregoing, GENERICO will use Reasonable Efforts to provide NEW ALPHA with such data monitoring support and data analysis support related to manufacturing issues as NEW ALPHA may reasonably request. All data and information relating to such support with respect to the Product or any Pipeline Product will, if it relates solely to the Product or any Pipeline Product, be the exclusive property of NEW ALPHA and may be used by NEW ALPHA, at no cost to NEW ALPHA, in such manner as NEW ALPHA determines.  
5.2 GENERICO will use Reasonable Efforts to assist NEW ALPHA in the preparation and submission of a chemistry, manufacturing and controls (CMC) section and plant master file or other regulatory documents to any Regulatory Authority as reasonably requested by NEW ALPHA. Notwithstanding anything to the contrary in this Section 5.2, all CMC information that relates solely to the Product or any Pipeline Product will be owned exclusively by, and will be the exclusive Proprietary Information of, NEW ALPHA and any CMC information not relating solely to the Product or any Pipeline Product will, to the extent relating to the Product or any Pipeline Product, be owned by NEW ALPHA and will be Proprietary Information of NEW ALPHA and may be used by GENERICO, at no cost to GENERICO, subject to Section 11 hereof, in connection with the requirements of any Regulatory Authority.  
5.3 NEW ALPHA will use Reasonable Efforts to cooperate with GENERICO with respect to obtaining and maintaining all Regulatory Approvals relating to manufacturing of the Product and the Pipeline Products for commercial sale or clinical development in any Territory. Without limiting the foregoing, NEW ALPHA will use Reasonable Efforts to provide GENERICO with such data monitoring support and data analysis support related to the Generico Manufacturing of the Product and the Pipeline Products as GENERICO may reasonably request; provided, however, that nothing in this Section 5.3 shall be interpreted to require NEW ALPHA to provide or disclose any documents, records or other information that constitutes Proprietary Information. All data and information relating to such support with respect to the Product and any Pipeline Product will, to the extent it relates to the Product or any Pipeline Product, be the property of NEW ALPHA, and will be the Proprietary Information of NEW ALPHA, and any CMC information not relating solely to the Product or any Pipeline Product will, to the extent relating to the Product or any Pipeline Product, be owned by NEW ALPHA, and will be Proprietary Information of NEW ALPHA, and may be used by GENERICO, at no cost to GENERICO, subject to Section 11 hereof, in connection with the requirements of any Regulatory Authority.  
6. Rejected Product.  
6.1 NEW ALPHA will inspect pursuant to New Alpha Review and Release, and GENERICO will inspect pursuant to Generico Manufacturing, each batch of Product and Pipeline Product for compliance with the Specifications, cGMPs, the FDCA and any and all other applicable Legal Requirements. If after inspection of Product or Pipeline Product NEW ALPHA notifies GENERICO, or GENERICO notifies NEW ALPHA, that any Product or Pipeline Product is non-compliant, as determined by such Party’s testing and inspection of the Product or Pipeline Product, the Parties will in good faith attempt to mutually determine whether the failure of the Product or Pipeline Product, as applicable, to comply is a result of Generico Manufacturing or New Alpha Manufacturing and the provisions of Section 6.2 will apply; provided, however, that the provisions of Section 6.2 will not apply (and thus GENERICO will  
 15  
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 have no responsibility or liability relating to any non-compliance) with respect to any Pipeline Products in clause (A) or (B) of such definition unless, in any quarter beginning with the first quarter ending after the Effective Date, (\*\*\*) of such Pipeline Products are non-compliant; provided further, that Pipeline Products shall only be determined non-compliant if GENERICO fails to perform Generico Manufacturing according to the Specifications for such Pipeline Product provided by NEW ALPHA.  
6.2 If the Parties are unable to mutually determine whether the failure of the Product or Pipeline Products to comply is a result of Generico Manufacturing or New Alpha Manufacturing within 60 days of the delivery of a rejection notice by either Party, such dispute will be resolved by an independent, FDA-approved testing organization or consultant of recognized repute within the U.S. pharmaceutical industry, to be mutually designated by the Parties, the designation of which will not be unreasonably withheld or delayed by either Party. To the extent the Parties are unable to agree on a testing organization or consultant, each Party will designate one such entity and those two entities will agree on a mutually acceptable testing entity. The testing entity of the Product shall determine the source of the non-compliance (i.e., Generico Manufacturing or New Alpha Manufacturing). Both Parties will provide the testing entity with such information as the testing entity reasonably requires in order to make such determination; provided, however, that either Party may, to the extent it deems necessary, withhold from the independent third party testing entity any Proprietary Information. Any determination by the independent third party testing entity will be final and binding upon the Parties. If the independent third party testing entity states that it is unable to make a determination as a result of NEW ALPHA’s or GENERICO’s, as applicable, decision to not disclose Proprietary Information, the non-compliance of the applicable Rejected Product will be deemed to have resulted from (A) New Alpha Manufacturing in the event NEW ALPHA is the non-disclosing Party or (B) Generico Manufacturing in the event GENERICO is the non-disclosing Party. If the independent third party testing entity’s determination is inconclusive, then the non-compliance of such Rejected Product will be deemed to have resulted 50% from New Alpha Manufacturing and 50% from Generico Manufacturing. NEW ALPHA shall have the final determination over the disposition of any Product or Pipeline Product; provided, that no Product or Pipeline Product shall be released if either Party has determined that such Product or Pipeline Product is non-compliant. The Parties agree to handle the costs associated with Rejected Product manufactured for NEW ALPHA as follows:  
(A) To the extent that a Rejected Product is determined to be such as a result of the Generico Manufacturing or a failure or deficiency of the Generico Manufacturing, then GENERICO will replace the Rejected Product as promptly as practicable (if requested by NEW ALPHA) and, subject to clause (B) below, no payment shall be required to be made by NEW ALPHA in respect of such Rejected Product and any payment that may have been made shall, at NEW ALPHA’s election, be refunded by GENERICO within 30 days of such determination or credited to any amounts then owing by NEW ALPHA to GENERICO hereunder; provided, however, that GENERICO will not be obligated to replace and will not have any liability to NEW ALPHA in respect of the Rejected Product, unless the batches of the Rejected Product resulting from the Generico Manufacturing are more than (\*\*\*) of the total batches of Product (or (\*\*\*) of the total batches for Pipeline Products) manufactured for NEW ALPHA in any calendar year during the Term. To the extent the batches of Rejected Product exceed such (\*\*\*) or (\*\*\*), as applicable, GENERICO shall reimburse NEW ALPHA for the Chemical Ingredients and Materials used in the New Alpha Manufacturing of such excess Rejected Product.  
 16  
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 (B) To the extent that Rejected Product is determined to be such as a result of the New Alpha Manufacturing or a failure or deficiency of the New Alpha Manufacturing, then GENERICO shall invoice NEW ALPHA for the Product or Pipeline Product within 30 days of such determination. Payment shall be made, net 30 days after receipt by NEW ALPHA of an invoice, so long as the invoice complies with the terms and conditions of this Agreement.  
(C) In the event that the reason for the Rejected Product in part results from the Generico Manufacturing or a failure or deficiency of the Generico Manufacturing and in part from the New Alpha Manufacturing or a failure or deficiency of the New Alpha Manufacturing, then the costs of the Product or Pipeline Products, as applicable, shall be allocated in an equitable manner between the Parties.  
7. Adverse Experience Reporting. Each Party will promptly report to the other Party any information of which it becomes aware concerning any adverse drug experience in connection with the use of the Product, including the incidence and the severity thereof. Each Party shall be responsible for reporting adverse experiences in accordance with applicable Legal Requirements; provided, however, that NEW ALPHA will bear all reasonable expenses incurred by GENERICO and NEW ALPHA in connection therewith. NEW ALPHA will provide to GENERICO copies of any reports submitted to the FDA and/or Regulatory Authority relating to any adverse drug experiences that are reasonably significant. GENERICO shall be responsible for receiving and documenting any complaint regarding the Product, as well as forwarding the complaint information to the applicable Facility quality unit and responding to the customer.  
8. Recalls.  
8.1 Each Party shall promptly notify the other if such Party believes that a recall, withdrawal or field correction (each, a “Recall”) of the Product or any Pipeline Product may be necessary or advisable.  
8.2 NEW ALPHA shall be responsible for the Recall decision, notification of Regulatory Authorities, the Recall strategy and generation of the final Recall letter. During the period in which the Warehouse Services Agreement is in effect, if any, GENERICO will be responsible for executing the Recall, reconciling Product, preparing and submitting Recall status reports and termination requests to applicable Regulatory Authorities with respect to Recall of the Product and any Pipeline Product. Following termination of the Warehouse Services Agreement, NEW ALPHA will be responsible for all Recall activities with respect to Recall of the Product and any Pipeline Product that was not previously shipped from the Premises (as defined in the Warehouse Services Agreement) by GENERICO. In either case, NEW ALPHA shall (subject to Section 8.3) bear all expenses incurred by GENERICO (with the consent of NEW ALPHA not to be unreasonably withheld) and NEW ALPHA in connection with such Recall. Each of the Parties will reasonably cooperate with the other Party in connection with any Recall. Each Party will maintain complete and accurate Recall records relating to the Product or any Pipeline Product for any periods that are required by any Legal Requirements.  
 17  
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 8.3 In the event that it is determined that any Product or Pipeline Product is recalled as a result of GENERICO’s gross negligence, bad faith, intentional misconduct or intentional breach of this Agreement, then GENERICO shall bear all of the costs and expenses of such Recall, including without limitation expenses related to communications and meetings with all required Regulatory Authorities, customer credits for recalled stock, the cost of notifying customers and costs associated with shipment of recalled Product or Pipeline Product from customers and shipment of an equal amount of replacement Product or Pipeline Product to those customers, subject to Sections 12.2 and 12.8. In the event that any Product or Pipeline Product is recalled other than as a result of GENERICO’s gross negligence, bad faith, intentional misconduct or intentional breach of this Agreement (or for which the liability would exceed the limitations set forth in Section 12.9), then NEW ALPHA shall bear all of the costs and expenses of such Recall, including without limitation expenses related to communications and meetings with all required Regulatory Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product or Pipeline Product from customers and shipment of an equal amount of replacement Product to those customers. In the event that the reason for any Recall of Product hereunder is in part the responsibility of GENERICO as described herein and in part the responsibility of NEW ALPHA as described herein, then the expenses shall be allocated in an equitable manner between the Parties.  
8.4 If the Parties are unable to mutually agree on the source cause of the Recall within 5 days of the event causing the Recall, such dispute will be resolved in the same manner as set forth in Section 6.2. The fees and expenses of the testing entity making the determination will be paid by the Party against which the determination is made. NEW ALPHA shall have the final determination over the disposition of any Recalled Product.  
9. Product Liability.  
9.1 For so long as NEW ALPHA is commercially marketing and selling the Product, or conducting the New Alpha Manufacturing with respect to the Product or any Pipeline Product, it shall maintain product liability insurance with respect to the Product and the Pipeline Products, as applicable, with a reputable carrier, in the amounts set forth in Exhibit B, naming GENERICO and its Affiliates as additional insureds.  
9.2 For so long as GENERICO is performing Generico Manufacturing with respect to the Product or any Pipeline Product, it shall maintain product liability insurance with respect to the Product and the Pipeline Products, with a reputable carrier, in the amounts set forth in Exhibit C hereto, naming NEW ALPHA and its Affiliates as additional insureds.  
9.3 Each Party must notify the other Party as promptly as practicable if a Product Liability Claim is commenced or threatened against any Party. Each Party must cooperate with the other Party in connection with any Product Liability Claim that is commenced or threatened against the other Party.  
9.4 If a Product Liability Claim is asserted against both Parties, each Party will have the right, at its own cost (subject to Section 9.6), to designate counsel to defend itself in such Product Liability Claim. If a Product Liability Claim is brought against one Party but not the other Party, the named Party will (subject to Section 9.5) have absolute control of litigation, except that:  
(A) the other Party may appoint counsel to participate in the defense of such Product Liability Claim if the named Party reasonably determines that the participation would not adversely affect the attorney-client privilege; and  
 18  
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 (B) if the litigation could reasonably be expected to have an adverse effect on the development and commercialization of the Product or any Pipeline Product, the named Party will consult with the other Party regarding the conduct of the litigation if the named Party reasonably determines that the cooperation would not adversely affect the attorney-client privilege.  
9.5 Neither Party shall agree to a settlement of any Product Liability Claim without the consent of the other Party, in that other Party’s absolute discretion, if the settlement:  
(A) admits any liability of the other Party or any of its Affiliates with respect to such Product Liability Claim;  
(B) does not release the other Party and its Affiliates from all liabilities and obligations with respect to such Product Liability Claim; or  
(C) imposes non-monetary damages or injunctive or other equitable relief against the other Party or any of its Affiliates.  
9.6 NEW ALPHA will be solely responsible for any Damages payable by NEW ALPHA or GENERICO to third parties following final judgment or settlement of any Product Liability Claim arising from use or sales of the Product (collectively, “Product Liability Costs”), and must promptly pay or reimburse GENERICO if GENERICO pays or incurs any Product Liability Costs, subject to the immediately following sentence. GENERICO will be responsible for any Product Liability Costs to the extent they arise from or as a result of the negligence, bad faith, intentional misconduct or intentional breach of this Agreement by GENERICO, and must promptly pay or reimburse NEW ALPHA if NEW ALPHA pays or incurs any Product Liability Costs that arise from or relate to GENERICO’s gross negligence, bad faith, intentional misconduct or intentional breach of this Agreement, subject to Sections 12.2 and 12.8.  
10. Term and Termination.  
10.1 This Agreement will commence on the Effective Date and will continue through December 31, 2011 (the “Term”). The Term shall be automatically extended for an additional year until December 31, 2012 upon the occurrence of either (or both) of (i) GENERICO’S exercise of its option to extend the term of that certain Lease, dated as of the date hereof, between GENERICO and New Abraxis, LLC for the Melrose Park Facility (the “Melrose Park Lease”), so that the Melrose Park Lease expires on December 31, 2012 or (ii) New Abraxis, LLC’s exercise of its option to extend the term of that certain Lease, dated as of the date hereof, between GENERICO and New Abraxis, LLC for the Grand Island Facility (the “Grand Island Lease”), so that the Grand Island Lease expires on December 31, 2012.  
10.2 The non-defaulting Party may terminate this Agreement if the other Party commits a material breach or default (“Breach”) under this Agreement, which Breach is not remedied within 60 days after the receipt of written notice of the Breach by the non-defaulting Party (except as to the payment of money by NEW ALPHA, for which the cure period will be 20 days) and which  
 19  
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 Breach is continuing at the time of termination. Notwithstanding the foregoing, if the Breach is not curable in 60 days, and the breaching or defaulting Party in good faith notifies the other Party in writing prior to the 60 days that it is initiating cure of the Breach, and initiates cure of such Breach within 60 days and in good faith continues to attempt to cure the Breach, then this Agreement shall not be terminated pursuant to this Section 10.2. The right of a Party to terminate this Agreement provided in this Section 10.2 will not be affected in any way by its waiver of, or failure to take such action with respect to, any previous Breach.  
10.3 This Agreement may be terminated immediately by either NEW ALPHA or GENERICO if the other Party:  
(A) does not pay its debts generally as they become due, or is unable to pay its debts generally as they become due;  
(B) has or has instituted against it any proceeding seeking to adjudicate it bankrupt or insolvent, or seeking liquidation, winding up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency or reorganization or relief of debtors;  
(C) makes a general assignment for the benefit of creditors;  
(D) seeks the entry of an order for relief or the appointment of a receiver, liquidator, sequestrator, trustee, custodian or similar official for it; or  
(E) takes advantage of any other law or procedure for the protection of creditors.  
10.4 Termination is not the sole remedy under this Agreement, and whether or not termination is effected, all other remedies remain available to each Party.  
10.5 NEW ALPHA may terminate this Agreement for any reason at any time by giving GENERICO not less than 3 months prior written notice.  
10.6 Upon termination or expiration of this Agreement for whatever reason, the Parties shall reasonably cooperate with each other to transfer to NEW ALPHA all Chemical Ingredients, Materials, Components, finished goods inventory, retained samples, stability samples and work in process in the possession, custody or control of GENERICO (and NEW ALPHA shall reimburse GENERICO for its reasonable expenses occurred in procuring and manufacturing such items) and GENERICO shall use Reasonable Efforts to cooperate with NEW ALPHA with respect to technology transfer matters for the Product and Pipeline Products.  
11. Confidentiality.  
11.1 Each Party recognizes that the other Party holds its Proprietary Information as important. In particular, each Party recognizes that the other Party’s Proprietary Information (and the confidential nature thereof) is critical to the other Party’s business and that neither Party would enter into this Agreement without assurance that such information and the value thereof will be protected as provided in this Section 11 and elsewhere in this Agreement.  
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 11.2 Each Party must, therefore:  
(A) hold the other Party’s Proprietary Information in confidence and take reasonable precautions to protect the Proprietary Information (including, without limitation, no less than all precautions that it employs with respect to its own confidential materials);  
(B) except as required by law, regulation or legal process, not divulge (except pursuant to a sublicense expressly authorized in this Agreement) the other Party’s Proprietary Information or any information derived therefrom to any third person; provided, however, that if a Party is required to make any such disclosure of the other Party’s Proprietary Information, such Party shall give reasonable advance notice to the other Party of such required disclosure and will use reasonable efforts consistent with prudent business judgment to secure confidential treatment of such Proprietary Information prior to its disclosure (whether through protective orders or confidentiality agreements or otherwise); and provided, further that if GENERICO is required to disclose NEW ALPHA’s Proprietary Information that constitutes CMC information, GENERICO will provide NEW ALPHA with prompt written notice so that NEW ALPHA may seek, at NEW ALPHA’s expense, an appropriate protective order to avoid disclosure of such Proprietary Information. If NEW ALPHA has attempted and failed to obtain a protective order and GENERICO is, upon advice of its counsel, compelled to disclose Proprietary Information related to CMC information to prevent liability for contempt or other censure or penalty or other liability, GENERICO may disclose such portion of the Proprietary Information that is required to be disclosed, In such case, GENERICO will use Reasonable Efforts (at NEW ALPHA’s expense) so that confidential treatment will be accorded to any Proprietary Information so disclosed; and  
(C) not make any use whatsoever at any time of the other Party’s Proprietary Information except for purposes of and expressly authorized in this Agreement.  
11.3 Any employee or contractor given access to any Proprietary Information must have a legitimate “need to know” and must be bound in writing to maintain the confidence of information to which it is given access.  
11.4 Without granting any right or license, the disclosing Party agrees that the foregoing restrictions will not apply with respect to information that the receiving Party is able to demonstrate by competent evidence:  
(A) is in or (through no improper action or inaction by the receiving Party or any Affiliate of the receiving Party or their agents or employees) enters the public domain (and is readily available without substantial effort);  
(B) was rightfully disclosed to it by another Person without restriction; or  
(C) was independently developed by it by Persons without access to such information and without use of any of the disclosing Party’s Proprietary Information.  
 21  
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 11.5 Each Party’s obligations under this Section 11 will terminate five years after the date of termination or expiration of this Agreement. The Parties recognize and acknowledge that prior to the Effective Date of this Agreement, each Party has received the other Party’s Proprietary Information and each hereby agrees to protect the Proprietary Information to the same extent as set forth in this Section 11.  
11.6 Immediately upon termination or expiration of this Agreement, each Party will turn over to the other Party all Proprietary Information of the other Party and all documents or media containing any Proprietary Information and any and all copies or extracts thereof.  
11.7 Each Party acknowledges and agrees that due to the unique nature of Proprietary Information, there may be no adequate remedy at law for any breach of a Party’s obligations under this Section 11, that any breach may result in irreparable harm to the disclosing Party, and therefore, that upon any breach or any threat of breach, the disclosing Party will be entitled to appropriate equitable relief (without the posting of any bond) in addition to whatever remedies it might have at law in connection with any breach or enforcement of the receiving Party’s obligations under this Agreement or the unauthorized use or release of any Proprietary Information.  
11.8 GENERICO hereby acknowledges that it and its Affiliates do not have, and shall not acquire by virtue of this Agreement, any rights to or under any goodwill, trademark, tradename, copyright, patent or other intellectual property of NEW ALPHA or any of its Affiliates, nor in any of NEW ALPHA’s or its Affiliates’ trademarks or trade names appearing on the label or packaging materials of the Product or any of the Pipeline Products. GENERICO agrees to do nothing by act or omission which would impair NEW ALPHA’s or its Affiliates’ rights, ownership and title in the aforementioned.  
11.9 NEW ALPHA hereby acknowledges that it does not have, and shall not acquire by virtue of this Agreement, any rights to or under any goodwill, trademark, tradename, copyright, patent or other intellectual property of GENERICO, nor in any of GENERICO’s trademarks or trade names appearing on the label or packaging materials of the Product or any Pipeline Products. NEW ALPHA agrees to do nothing by act or omission which would impair GENERICO’s or its Affiliates’ rights, ownership and title in the aforementioned.  
11.10 If either Party becomes aware of any product or activity of any third Party that involves or may involve infringement or other violation of any Technology, that Party must promptly notify the other Party in writing of the infringement or violation. NEW ALPHA may in its discretion take or not take whatever action it believes is appropriate. GENERICO will fully cooperate with NEW ALPHA with respect to bringing any action, including joining as a party to the suit, if necessary, supplying essential documentary evidence and making essential witnesses then in its employ available, in each case only to the extent that such cooperation would not interfere with the operation of GENERICO’s business and subject to the reimbursement of GENERICO for reasonable out-of-pocket expenses incurred by it in connection with such cooperation.  
 22  
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 12. Indemnification.  
12.1 GENERICO agrees, subject to Sections 12.8 and 12.9, to indemnify, defend and hold harmless NEW ALPHA and its Affiliates and their respective officers, directors, employees and agents from any Damages incurred by or assessed against them resulting from a third party claim caused by or alleged to be caused by:  
(A) GENERICO’s gross negligence, bad faith, intentional misconduct or intentional failure to perform any of its obligations under this Agreement; and  
(B) any Product Liability Claim arising from the gross negligence or bad faith of, or intentional misconduct or intentional breach of this Agreement by, GENERICO or any GENERICO Affiliate.  
12.2 NEW ALPHA agrees to indemnify, defend and hold harmless GENERICO, its Affiliates, and their officers, directors, employees and agents (the “GENERICO Indemnified Parties”) from any Damages incurred by or assessed against them resulting from a third party claim caused by or alleged to be caused by:  
(A) NEW ALPHA’s failure to perform any of its obligations under this Agreement;  
(B) any Product Liability Claim arising from the (i) negligence, fraud or intentional misconduct of NEW ALPHA or any NEW ALPHA Affiliates or (ii) the New Alpha Manufacturing or any failure or deficiency in the New Alpha Manufacturing;  
(C) any claim that the manufacture, use or sale of the Product or any Pipeline Product infringes a patent or any other proprietary right of a third party;  
(D) any Recall, Product Liability Claim or other third-party claim (i) not arising from the gross negligence or bad faith of, or intentional misconduct or intentional breach of this Agreement by, the GENERICO Indemnified Parties or (ii) to the extent the liability of the GENERICO Indemnified Parties therefrom would result in the GENERICO Indemnified Parties being subject to liability for which GENERICO is not responsible under Section 12.9.  
12.3 If any Party entitled to be indemnified pursuant to this Section 12 (an “Indemnified Party”) receives notice of the assertion by any Person of any claim or of the commencement by any such Person of any Action (any such claim or Action being referred to herein as an “Indemnifiable Claim”) with respect to which another Party hereto (an “Indemnifying Party”) is or may be obligated to provide indemnification, the Indemnified Party must promptly notify the Indemnifying Party in writing (the “Claim Notice”). The failure to provide such notice will not relieve or otherwise affect the obligation of the Indemnifying Party to provide indemnification hereunder, except to the extent that any Damages directly resulted or were caused by such failure.  
12.4 The Indemnifying Party will have 30 days after receipt of the Claim Notice to undertake, conduct and control, through counsel of its own choosing and at its expense, the settlement or defense of the claim, and the Indemnified Party will cooperate with the Indemnifying Party in connection with the settlement or defense, if:  
(A) the Indemnifying Party permits the Indemnified Party to participate in the settlement or defense through counsel chosen by the Indemnified Party (subject to the consent of the Indemnifying Party, which consent shall not be unreasonably withheld);  
 23  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 (B) the fees and expenses of such counsel will not be borne by the Indemnifying Party; and  
(C) the Indemnifying Party does not settle any Indemnifiable Claim without the Indemnified Party’s consent. So long as the Indemnifying Party is vigorously contesting any Indemnifiable Claim in good faith, the Indemnified Party may not pay or settle the claim without the Indemnifying Party’s consent, which consent shall not be unreasonably withheld.  
12.5 If the Indemnifying Party does not notify the Indemnified Party within 30 days after receipt of the Claim Notice that it elects to undertake the defense of the Indemnifiable Claim described in the Claim Notice, the Indemnified Party has the right to contest, settle or compromise the Indemnifiable Claim in the exercise of its reasonable discretion. However, the Indemnified Party must notify the Indemnifying Party of any compromise or settlement of any such Indemnifiable Claim.  
12.6 Notwithstanding anything in this Section 12 to the contrary, GENERICO is not entitled to assume the defense for any Indemnifiable Claim (and will be liable for the reasonable fees and expenses incurred by the Indemnified Party in defending the claim) if the Indemnifiable Claim seeks an order, injunction or other equitable relief (or other relief for other than money damages) against NEW ALPHA or its Affiliates which NEW ALPHA determines, after conferring with its counsel, cannot be separated from any related claim for money damages and which, if successful, would adversely affect the commercialization of the Product or any Pipeline Product. However, if an equitable relief portion of the Indemnifiable Claim can be separated from that for money damages, GENERICO may assume the defense of the portion relating to money damages.  
12.7 In calculating any amount that any Indemnifying Party is required to pay an Indemnified Party in respect of Damages provided under this Agreement, such amount shall be (A) reduced to take into account any net tax benefit realized by the Indemnified Party arising from the incurrence or payment by the Indemnified Party of such Damages and (B) increased to take into account any net tax cost incurred by the Indemnified Party as a result of the receipt or accrual of payments hereunder (grossed-up for such increase), in each case determined by treating the Indemnified Party as recognizing all other items of income, gain, loss, deduction or credit before recognizing any item arising from such Damages (provided that if the tax benefit or cost is realized in a tax period following the period in which the indemnity payment is made, the tax benefit or cost amount (as the case may be) shall be paid over when realized).  
12.8 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NEITHER PARTY WILL BE LIABLE HEREUNDER FOR MONETARY DAMAGES UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER  
 24  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOSS OF PROFITS FROM THE USE OF (OR INABILITY TO USE) THE TECHNOLOGY, THE DEVELOPMENT OR COMMERCIALIZATION OF THE PRODUCT OR OTHERWISE IN CONNECTION WITH, OR ARISING OUT OF, THIS AGREEMENT, OTHER THAN WITH RESPECT TO DAMAGES FOR GENERICO EXTRAORDINARY FAILURE (as defined in Section 12.9)  
12.9 Notwithstanding anything herein to the contrary, in no event will the GENERICO Indemnified Parties have any liability to NEW ALPHA or any of its Affiliates, or to any third party in connection with this Agreement, for monetary Damages in excess of $100 million in the aggregate, except to the extent that such Damages are the result of (A) one of GENERICO’s (or one of its parent entity’s) executive officers, in bad faith, affirmatively instructing employees of GENERICO to materially breach GENERICO’s obligation to manufacture the Product or any Pipeline Product under this Agreement or (B) any intentional failure by GENERICO, in bad faith, to cure any material breach of GENERICO’s obligation to manufacture the Product or any Pipeline Product under this Agreement (which is capable of being cured) following notice thereof in accordance with Section 15.3 (if such breach is not cured within a reasonable period of time following receipt of such notice of such breach) (any of the occurrences set forth in sub clauses (A) and (B) of this Section 12.9, “GENERICO Extraordinary Failure”).  
13. Management Fee. NEW ALPHA will pay GENERICO a facility management fee (the “Management Fee”) equal to $3,000,000 for each of the 2008, 2009 and 2010 calendar years, or a total of $9,000,000, such payment to be made within 30 days following the end of the applicable calendar year. The Management Fee shall be in addition to, and not in lieu of, any amounts otherwise payable under this Agreement. In addition, the Management Fee shall be reduced to the extent employees of GENERICO at the Melrose Park Facility are transferred to NEW ALPHA as more fully described in Section 14.5 below.  
14. Melrose Park and Grand Island Facilities.  
14.1 FDA Compliance.  
(A) Each of NEW ALPHA and GENERICO shall cooperate reasonably and in good faith with the other Party to develop a mutually acceptable plan to modernize the Melrose Park Facility as requested or required by the FDA or that, in both Parties’ reasonable judgment, are necessary to maintain FDA Regulatory Approvals (the “FDA Modernization Plan”). All costs and expenses contemplated by the FDA Modernization Plan shall be borne by NEW ALPHA. The scope and timing of implementation of, and expenditures under, the FDA Modernization Plan shall be mutually determined in good faith between the Parties.  
(B) GENERICO will, in good faith, execute the actions contemplated by the FDA Modernization Plan, subject to NEW ALPHA’s review and approval. NEW ALPHA shall reimburse GENERICO for all out-of pocket costs to third parties reasonably incurred (with the approval of NEW ALPHA not to be unreasonably withheld) in connection with GENERICO’s performance of such actions. In connection with such actions, GENERICO will not in any event be obligated to incur incremental shutdown time outside the ordinary course of its business, reduce in any material respect production capacity available for producing Generico Products (or, without the consent of NEW ALPHA, the Product or any Pipeline Product) or otherwise impact or disrupt in any material respect GENERICO’s or NEW ALPHA’s business.  
 25  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 14.2 EU Compliance.  
(A) To the extent requested by NEW ALPHA, GENERICO shall cooperate reasonably and in good faith in connection with NEW ALPHA’s preparation of a plan to obtain necessary Regulatory Approvals from the EMEA with respect to the Melrose Park Facility (the “Melrose Park EU Plan”). All costs and expenses contemplated by the Melrose Park EU Plan shall be borne by NEW ALPHA (unless GENERICO initiates plans to commercialize its products or product candidates in Europe, in which case the Parties shall allocate the costs and expenses contemplated by the Melrose Park EU Plan between them equitably in good faith). Subject to Section 14.2(B) below, the scope and timing of implementation of, and expenditures under, the Melrose Park EU Plan shall be in the sole discretion of NEW ALPHA.  
(B) During the term of the Melrose Park Lease, GENERICO will, in good faith, complete the actions required under the Melrose Park EU Plan as soon as reasonably practicable following the Effective Date. In connection with such actions, GENERICO will not in any event be obligated to incur incremental shutdown time outside the ordinary course of its business, reduce in any material respect production capacity available for producing Generico Products (or, without the consent of NEW ALPHA, the Product or any Pipeline Product) or otherwise impact or disrupt in any material respect GENERICO’s or NEW ALPHA’s business or the actions required by the FDA Modernization Plan. The Parties acknowledge that the FDA Modernization Plan shall not in any event include any incremental costs included in the Melrose Park EU Plan.  
14.3 Decommissioned Equipment. GENERICO will not de-commission, modify, move or fail to maintain any equipment or systems or revise approved regulatory processes related to systems and equipment in the Melrose Park Facility that is operational as of the Effective Date such that the equipment or system would require re-validation in accordance with FDA regulatory requirements. For the avoidance of doubt, in no event will GENERICO have any obligation to re-validate any equipment or system that is decommissioned as of the Effective Date.  
14.4 Melrose Park Equipment. GENERICO will maintain the equipment and systems in the Melrose Park Facility in reasonably good working order.  
14.5 Melrose Park Facility Conveyance/Transfer.  
(A) Transfer of Employees at Melrose Park Facility. To the extent reasonably requested by NEW ALPHA, GENERICO shall cooperate reasonably and in good faith with NEW ALPHA with respect to the transfer of GENERICO’s employees at the Melrose Park Facility to NEW ALPHA. If and to the extent NEW ALPHA hires any such employees, the Management Fee shall be reduced on a dollar-for-dollar basis based upon the total compensation (i.e., base salary, bonus, medical benefits, equity incentives, etc.) paid to such employees.  
 26  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 (B) Training. NEW ALPHA shall have the right to train and integrate all appropriate personnel of GENERICO with respect to Nab technology. In connection with such training, GENERICO will not in any event be obligated to incur incremental shutdown time outside the ordinary course of its business, reduce in any material respect production capacity available for producing Generico Products (or, without the consent of NEW ALPHA, the Product or any Pipeline Product) or otherwise impact or disrupt in any material respect GENERICO’s or NEW ALPHA’s business.  
 14.6 Contract Manufacturing and Alpha Manufacturing.  
(A) To the extent of excess capacity at the Melrose Park Facility (in all cases after satisfying 100% of NEW ALPHA’s and GENERICO’s actual demand for the Product, Pipeline Products and Generico Products, as applicable, GENERICO will undertake any contract manufacturing opportunities presented by NEW ALPHA subject to the following:  
(i) GENERICO will in no event be required to contract manufacture any products that then compete with any of its products, pending products or products (it being understood that the foregoing shall not apply with respect to Pipeline Products);  
(ii) GENERICO will have sole discretion to decide on key terms of contract manufacturing (including but not limited to price, liability provisions, duration, volume levels);  
(iii) NEW ALPHA will bear all responsibility for sourcing all such contract manufacturing opportunities;  
(iv) GENERICO will receive the net proceeds from any contract manufacturing performed by GENERICO; and  
(v) GENERICO contract manufacturing shall not obligate NEW ALPHA to perform contract manufacturing following the end of the Term, except with NEW ALPHA’s prior written consent.  
(B) Subject to Section 14.6(A)(i) above, GENERICO will, in good faith, consider opportunities to provide access, at dedicated times, during which NEW ALPHA employees may utilize the equipment in the Melrose Park Facility for contract manufacturing (performed by NEW ALPHA employees, all costs of which are to be borne by NEW ALPHA), in all cases subject to the following sentence. GENERICO will not in any event be obligated to incur incremental shutdown time outside the ordinary course of its business, reduce in any material respect production capacity available for producing Generico Products (or, without the consent of NEW ALPHA, the Product or any Pipeline Product) or otherwise impact or disrupt in any material respect GENERICO’s or NEW ALPHA’s business or the actions required by the FDA Modernization Plan. NEW ALPHA will receive any proceeds from any contract manufacturing performed by NEW ALPHA.  
 27  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 15. Miscellaneous Provisions.  
15.1 Independent Contractors. NEW ALPHA and GENERICO are independent Parties, and nothing contained herein will be construed to create a joint venture, partnership or similar relationship. Neither Party is authorized to, nor will it, make any statements, claims, representations, warranties or otherwise act in any way so as to incur any liability whatsoever for which the other Party may become directly, indirectly or contingently liable.  
15.2 Assignment. The rights and obligations of the Parties under this Agreement may not be assigned or transferred in any manner, including, without limitation, by operation of law, sale of stock or sale of assets, without the prior written approval, which shall not be unreasonably withheld, of the other Party (and any attempt to do so will be void) except that rights to payment of money may be assigned without such approval. Despite the foregoing, in no event will NEW ALPHA be obligated to consent to an assignment of this Agreement to a Competitor.  
15.3 Notices. Any and all notices given pursuant to this Agreement shall be in writing and shall be deemed duly given (a) on the date of delivery if delivered personally, (b) upon confirmation of receipt if delivered by facsimile, (c) on the first business day following the date of dispatch if delivered by a recognized next-day courier service, or (d) on the date received if delivered by registered or certified mail, return receipt requested, postage prepaid. All notices hereunder shall be delivered as set forth below, or pursuant to such other instructions as may be designated in writing by the Party to receive such notice:  
If to NEW ALPHA to:  
Abraxis BioScience, Inc.  
00000 Xxxxxxxx Xxxxxxxxx  
Xxxxx 0000  
Xxx Xxxxxxx, XX 00000  
Fax: (000) 000-0000  
Attention: Chief Executive Officer  
with a copy to:  
Abraxis BioScience, Inc.  
00000 Xxxxxxxx Xxxxxxxxx  
Xxxxx 0000  
Xxx Xxxxxxx, XX 00000  
Fax: (000) 000-0000  
Attention: General Counsel  
If to GENERICO to:  
APP Pharmaceuticals, Inc.  
0000 Xxxx Xxxxxxxxx Xxxx, Xxxxx 000X  
Xxxxxxxxxx, Xxxxxxxx 00000  
Fax: (000) 000-0000  
Attention: Chief Executive Officer  
 28  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 with a copy to:  
APP Pharmaceuticals, Inc.  
0000 Xxxx Xxxxxxxxx Xxxx, Xxxxx 000X  
Xxxxxxxxxx, Xxxxxxxx 00000  
Fax: (000) 000-0000  
Attention: General Counsel  
15.4 Force Majeure.  
(A) The obligations of a Party hereunder will be suspended during the time and to the extent that such Party is prevented from complying therewith due to any event or circumstances beyond the reasonable control and without the fault or negligence of the affected Party (which circumstance is hereinafter referred to as “Force Majeure”), including but not limited to floods, fire, storms, earthquakes, lockouts, explosion, hostilities, war (whether declared or undeclared), acts of terrorism, civil disturbances, order or acts of any government, whether de jure or de facto or any official purporting to act under authority of any such government (other than as to Regulatory Approval), illegality arising from domestic or foreign laws or regulations, insurrections, quarantine or custom restrictions (other than due to the action or inaction of the Party claiming a Force Majeure), acts of God or other similar events beyond the reasonable control of, as the case may be, NEW ALPHA or GENERICO which results in hindrance of the performance by the Party of its obligations hereunder.  
(B) As soon as possible after being affected by a Force Majeure circumstance, the affected Party must furnish to the other Party all particulars of the Force Majeure and the manner in which its performance is thereby prevented or delayed. The Party whose obligations hereunder have been suspended will promptly and diligently pursue appropriate action to enable it to lift the Force Majeure situation, except that Party shall not be obligated to settle any strike, lockout or other labor difficulty on terms contrary to its wishes.  
15.5 Amendment and Waiver. This Agreement (including the Exhibits hereto) may be amended, modified, superseded or cancelled, and any other of the terms or conditions hereof may be modified, only by a written instrument executed by both Parties or, in the case of a waiver, by the Party waiving compliance. Failure of either Party at any time or times to require performance of any provision hereof will in no manner affect the right of such Party at a later time to enforce the same, and no waiver of any nature, whether by conduct or otherwise, in any one or more instances, will be deemed to be or considered as a further or continuing waiver of any provision of this Agreement.  
15.6 Severability. If any one or more of the agreements, provisions or terms contained herein are declared invalid, illegal or unenforceable in any respect, the validity of the remaining agreements, provisions or terms contained will shall in no way be affected, prejudiced or invalidated thereby.  
 29  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 15.7 Entire Agreement. This Agreement, together with the Exhibits hereto and the Specifications, contains the entire agreement between the Parties, and supersedes any agreements between them with respect to the subject matter hereof.  
15.8 Section Headings; Recitals. The section headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. The recitals are hereby incorporated into this Agreement by reference.  
15.9 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the substantive law (without regard to conflicts of law provisions) of the State of Delaware.  
15.10 Consent to Jurisdiction. Each of GENERICO and NEW ALPHA irrevocably agrees that any legal action or proceeding with respect to this Agreement, the transactions contemplated hereby, any provision hereof, the breach, performance, validity or invalidity hereof or for recognition and enforcement of any judgment in respect hereof brought by another Party or its successors or permitted assigns shall be brought and determined in any federal or state court located in the State of Delaware, and each of GENERICO and NEW ALPHA hereby irrevocably submits with regard to any such action or proceeding for themselves and in respect to their property, generally and unconditionally, to the exclusive jurisdiction of the aforesaid courts. Each of GENERICO and NEW ALPHA hereby irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement, the transactions contemplated hereby, any provision hereof or the breach, performance, enforcement, validity or invalidity hereof, (A) any claim that it is not personally subject to the jurisdiction of the above-named courts for any reason other than the failure to lawfully serve process, (B) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) and (C) to the fullest extent permitted by applicable laws, that (i) the suit, action or proceeding in any such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper and (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.  
15.11 No Strict Construction. The language used in this Agreement will be deemed to be the language chosen by the Parties hereto to express their mutual intent, and no rule of strict construction will apply to any term or condition of this Agreement.  
15.12 Survival. Except to the extent that any monies are owed and not yet paid and for the provisions of Sections 1, 2.2(H), 2.2(I), 2.5, 3.2(C), 3.5, 5.1 (last sentence), 5.2 (last sentence), 5.3 (last sentence), 6, 8, 9, 10, 11, 12 and 15, none of the provisions herein shall survive termination or expiration of this Agreement. Sections 2.2(H), 2.5, 3.2(C) and 3.5 shall survive until the seventh anniversary of the termination or expiration of this Agreement.  
15.13 Counterparts. This Agreement may be executed in separate counterparts, each of which will be deemed to be an original, but which together will constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission shall be effective as an original executed signature page.  
 30  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 15.14 Enforcement. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed by the Parties in accordance with their specific terms. It is accordingly agreed that the Parties shall be entitled to specific performance of the terms hereof, this being in addition to any other remedy to which a Party is entitled at law or in equity.  
[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]  
 31  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 IN WITNESS WHEREOF, the Parties hereto have executed this Manufacturing Agreement as of the date and year first written above.  
 NEW ABRAXIS, INC.  
By: /s/ Xxxxxxx Soon-Shiong  
Name: Xxxxxxx Soon-Shiong  
Title: CEO  
APP PHARMACEUTICALS, LLC  
By: /s/ Xxxxxxx Soon-Shiong  
Name: Xxxxxxx Soon-Shiong  
Title: CEO  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 EXHIBIT A  
DESCRIPTION OF PRODUCT, OR PIPELINE PRODUCTS, PROCESSING  
(\*\*\*).  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 EXHIBIT B  
NEW ALPHA INSURANCE  
$25,000,000 per incident and in the aggregate  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 EXHIBIT C  
GENERICO INSURANCE  
$25,000,000 PER INCIDENT AND IN THE AGGREGATE  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 SCHEDULE 1.4  
PART A  
2008 ANNUAL FORECAST  
Melrose Park  
 GENERICO Lyophilizer Cycles:  
 (\*\*\*)   
NEW ALPHA Lyophilizer Cycles:  
 (\*\*\*)   
Units (in millions)  
 GENERICO Lyophilizer-produced Units  
 (\*\*\*)   
NEW ALPHA Lyophilizer-produced Units  
 (\*\*\*)   
Grand Island  
GENERICO Lyophilizer Cycles:  
 (\*\*\*)   
NEW ALPHA Lyophilizer Cycles:  
 (\*\*\*)   
Units (in millions)  
 GENERICO Lyophilizer-produced Units  
 (\*\*\*)   
NEW ALPHA Lyophilizer-produced Units  
 (\*\*\*)   
PART B  
2009, 2010, 2011 AND 0000 XXXXXXXXX  
Xxxxxxx Xxxx  
 2009 2010 2011 2012  
GENERICO Lyophilizer Cycles:  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
NEW ALPHA Lyophilizer Cycles:  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
Units (in millions)  
 GENERICO Lyophilizer-produced Units  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
NEW ALPHA Lyophilizer-produced Units  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 Grand Island  
 2009 2010 2011 2012  
GENERICO Lyophilizer Cycles:  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
NEW ALPHA Lyophilizer Cycles:  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
Units (in millions)  
 GENERICO Lyophilizer-produced Units  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
NEW ALPHA Lyophilizer-produced Units  
 (\*\*\*) (\*\*\*) (\*\*\*) (\*\*\*)  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 SCHEDULE 1.66  
TERRITORIES  
 •   
European Economic Area  
 •   
(\*\*\*)  
 •   
Australia  
 •   
Japan  
 •   
China (including Hong Kong and Macau)  
 •   
India  
 •   
Republic of Korea  
 •   
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 •   
Gulf States (including Saudi Arabia, United Arab Emirates, Kuwait, Oman and Dubai)  
 •   
(\*\*\*)  
 •   
(\*\*\*)  
 •   
(\*\*\*)  
 •   
(\*\*\*)  
 •   
(\*\*\*)  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 SCHEDULE 2.10  
OTHER SERVICES  
 Service  
 Charges1   
Assumptions  
Manufacturing-Related Information Technology Support  
 (\*\*\*) (\*\*\*)  
Corporate QA, including;  
 • establishment of quality systems and regulatory oversight;  
 • review of suppliers to ensure quality systems requirements are met;  
 • review of internal functions to ensure quality systems requirements are met;  
 • provide polices, SOPs & protocols support to all functions;  
 • provide warehousing support to ensure materials have been received, sampled and shipped according to requirements;  
 • review of product development reports;  
 • calibration, maintenance and preventive maintenance of analytical equipment; and  
 (\*\*\*) (\*\*\*)  
1  
Charges shall be increased each year by (\*\*\*). Actual charges will be based upon time and materials.  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 Service  
 Charges1   
Assumptions  
• QA, validation and change control of multi-site computer systems.  
 Corporate QC, including;  
 • analytical testing of raw materials and components; and  
 • validation of analytical equipment and software systems.  
 (\*\*\*) (\*\*\*)  
CGMP and other plant-related training  
 (\*\*\*) (\*\*\*)  
Note: Redacted portions have been marked with (\*\*\*). The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.  
 SCHEDULE 4.1  
UNIT COST FOR ABRAXANE2  
 1. (\*\*\*) for units manufactured at 0000 Xxxx Xxxxxx, Xxxxxxx Xxxx, Xxxxxxxx.  
 2. (\*\*\*) for units manufactured at 0000 Xxxxxx Xxxx, Xxxxx Xxxxxx, Xxx Xxxx.  
BATCH COST FOR ANY PIPELINE PRODUCT  
 •   
Actual cost for Generico Manufacturing, plus (\*\*\*). The actual cost for Generico Manufacturing of Pipeline Products shall be verified and approved by NEW ALPHA prior to their production.  
2  
Charges shall be increased each year by (\*\*\*).