Exhibit 10.65  
\* Portions of this document marked [\*] are requested to be treated confidentially.  
EXECUTION COPY  
MANUFACTURING AND SUPPLY AGREEMENT  
between  
SALIX PHARMACEUTICALS, INC.  
and  
GLENMARK PHARMACEUTICALS LTD.  
Dated as of December 9, 2008  
TABLE OF CONTENTS  
 ARTICLE I. DEFINITIONS.......................................................................................................................................................  
 1  
ARTICLE II. MANUFACTURING.............................................................................................................................................  
 8  
2.1  
 Supply Obligations.....................................................................................................................................................  
 8  
2.2  
 Forecasting, Order and Delivery of Compound..........................................................................................................  
 8  
2.3  
 Raw Materials.............................................................................................................................................................  
 9  
2.4  
 Invoice and Payment...................................................................................................................................................  
 10  
2.5  
 Price............................................................................................................................................................................  
 10  
2.6  
 Warranty......................................................................................................................................................................  
 12  
2.7  
 Failure or Inability to Supply Compound...................................................................................................................  
 12  
2.8  
 Limitations of Current Capacity..................................................................................................................................  
 14  
2.9  
 Costs and Expenses.....................................................................................................................................................  
 15  
2.10  
 Amendment of Specifications.....................................................................................................................................  
 15  
2.11  
 Quality Agreement......................................................................................................................................................  
 16  
2.12  
 Quality Control Analyses and Release.......................................................................................................................  
 16  
2.13  
 Maintenance of Facility..............................................................................................................................................  
 16  
2.14  
 Regulatory Cooperation of Glenmark.........................................................................................................................  
 17  
2.15  
 Inspection by Salix......................................................................................................................................................  
 17  
2.16  
 Notification of Regulatory Inspections; Communications.........................................................................................  
 17  
2.17  
 Recalls and Withdrawals............................................................................................................................................  
 17  
2.18  
 Compliance with Applicable Laws.............................................................................................................................  
 18  
2.19  
 Retention of Manufacturing Records and Samples....................................................................................................  
 18  
2.20  
 No Other Supply.........................................................................................................................................................  
 19  
2.21  
 Shortages.....................................................................................................................................................................  
 19  
2.22  
 Second Source.............................................................................................................................................................  
 19  
ARTICLE III. GLOBAL COORDINATION...............................................................................................................................  
 19  
3.1  
 Global Cooperation and Coordination........................................................................................................................  
 19  
3.2  
 Consultation................................................................................................................................................................  
 20  
3.3  
 Regulatory Matters.....................................................................................................................................................  
 20  
3.4  
 Trademarks.................................................................................................................................................................  
 21  
ARTICLE IV. INTELLECTUAL PROPERTY............................................................................................................................  
 21  
4.1  
 Ownership...................................................................................................................................................................  
 21  
4.2  
 Patent Maintenance and Prosecution..........................................................................................................................  
 23  
4.3  
 Enforcement of Invention Patents...............................................................................................................................  
 25  
4.4  
 Third Person Litigation...............................................................................................................................................  
 26  
4.5  
 Third Party Licenses...................................................................................................................................................  
 27  
ARTICLE V. REPRESENTATIONS AND WARRANTIES; COVENANTS............................................................................  
 27  
5.1  
 Representations and Warranties of Each Party..........................................................................................................  
 27  
5.2  
 Additional Warranties and Covenants of Glenmark...................................................................................................  
 28  
5.3  
 Disclaimer of Other Warranties..................................................................................................................................  
 28  
 -i-  
ARTICLE VI. CONFIDENTIALITY..........................................................................................................................................  
 29  
6.1  
 Confidential Information............................................................................................................................................  
 29  
6.2  
 Exceptions to Confidentiality.....................................................................................................................................  
 29  
6.3  
 Disclosure...................................................................................................................................................................  
 30  
6.4  
 Notification.................................................................................................................................................................  
 30  
6.5  
 Remedies.....................................................................................................................................................................  
 30  
6.6  
 Use of Names..............................................................................................................................................................  
 30  
6.7  
 Press Releases.............................................................................................................................................................  
 31  
ARTICLE VII. TERM AND TERMINATION............................................................................................................................  
 31  
7.1  
 Term............................................................................................................................................................................  
 31  
7.2  
 Termination.................................................................................................................................................................  
 31  
7.3  
 Effect of Expiration or Termination...........................................................................................................................  
 32  
ARTICLE VIII. INDEMNIFICATION.......................................................................................................................................  
 33  
8.1  
 Glenmark Indemnification..........................................................................................................................................  
 33  
8.2  
 Salix Indemnification..................................................................................................................................................  
 34  
8.3  
 Indemnification Procedure..........................................................................................................................................  
 34  
8.4  
 Insurance.....................................................................................................................................................................  
 36  
8.5  
 Limitation on Damages...............................................................................................................................................  
 37  
ARTICLE IX. MISCELLANEOUS............................................................................................................................................  
 37  
9.1  
 Notices........................................................................................................................................................................  
 37  
9.2  
 Force Majeure.............................................................................................................................................................  
 38  
9.3  
 Entire Agreement; Amendment..................................................................................................................................  
 39  
9.4  
 Further Assurances.....................................................................................................................................................  
 39  
9.5  
 Successors and Assigns..............................................................................................................................................  
 39  
9.6  
 Dispute Resolution......................................................................................................................................................  
 39  
9.7  
 Governing Law; Jurisdiction; Venue; Service............................................................................................................  
 39  
9.8  
 Third Party Beneficiaries............................................................................................................................................  
 40  
9.9  
 Export Control............................................................................................................................................................  
 40  
9.10  
 Assignment.................................................................................................................................................................  
 40  
9.11  
 Waiver.........................................................................................................................................................................  
 41  
9.12  
 Severability.................................................................................................................................................................  
 41  
9.13  
 Independent Contractors.............................................................................................................................................  
 41  
9.14  
 Construction................................................................................................................................................................  
 42  
9.15  
 Remedies.....................................................................................................................................................................  
 42  
9.16  
 Counterparts; Facsimile Execution.............................................................................................................................  
 42  
9.17  
 English Language........................................................................................................................................................  
 42  
9.18  
 Attorneys’ Fees...........................................................................................................................................................  
 43  
 Schedules and Exhibits  
Schedule 1.6 Capped Price  
Schedule 1.17 Current Capacity  
Schedule 1.31 Fully-Allocated Manufacturing Costs  
Schedule 1.40 Glenmark Territory  
 ii  
Schedule 1.81 Specifications  
Schedule 2.2(c) Full Production Lot Size  
Schedule 2.5(c) Fixed Price  
Schedule 2.5(d) Compensation to Glenmark for Use of Third Party Manufacturer  
Schedule 2.8(c) Compound Equipment Usage  
Exhibit A Example of Scale-Up Plans  
 iii  
This MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”), dated as of December 9, 2008 (the “Effective Date”), is made by and between Salix Pharmaceuticals, Inc., a Delaware corporation (“Salix”), and Glenmark Pharmaceuticals Ltd., a corporation organized under the laws of India (“Glenmark”). Salix and Glenmark are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”  
RECITALS  
WHEREAS, subject to the terms and conditions set forth in this Agreement, Salix wishes to have Glenmark manufacture and supply the Compound (as defined below) for Salix, and Glenmark wishes to manufacture and supply, or have manufactured and supplied through its Affiliate, Glenmark Generics Ltd., the Compound for Salix.  
NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:  
ARTICLE I. DEFINITIONS  
As used herein, the following terms shall have the following meanings:  
1.1 “Actual Cost” has the meaning set forth in Section 2.5(a).  
1.2 “Affiliate” of a Person means any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, such first Person. “Control” and, with correlative meanings, the terms “controlled by” and “under common control with”, means to possess the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract or otherwise.  
1.3 “Agreement” has the meaning set forth in the preamble hereto.  
1.4 “Applicable Law” means applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of Regulatory Authorities, that may be in effect from time to time.  
1.5 “Calendar Year” means each successive period of twelve (12) consecutive calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31, 2008 and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.  
1.6 “Capped Price” has the meaning set forth in Schedule 1.6.  
1.7 “Certificate of Analysis” has the meaning set forth in the Quality Agreement.  
1.8 “Certificate of Compliance” has the meaning set forth in the Quality Agreement.  
1.9 “CMC Data” means the chemistry, manufacturing and controls data required by Applicable Law to be included in a New Drug Application (as defined in the FFDCA and the regulations promulgated thereunder) for a Product or in any other Marketing Authorization outside the United States.  
1.10 “Compound” means oligomeric proanthocyanidin (OPC) of varying chain lengths with an average molecular weight of approximately 2000 daltons (Crofelemer) meeting the Specifications.  
1.11 “Compound Equipment” means the Napo-Provided Equipment and the Scale-Up Equipment.  
1.12 “Compound Invention Patents” has the meaning set forth in Section 4.2(a)(i).  
1.13 “Compound Inventions” means any and all Inventions relating to the Compound or any derivatives thereof or other compounds related thereto, that are conceived, discovered, developed or otherwise made, solely by a Party or jointly by or on behalf of the Parties as a result of or in connection with this Agreement, but excluding the Glenmark Inventions.  
1.14 “Confidential Information” means any and all information or material that, at any time before or after the Effective Date, has been or is provided or communicated to the Receiving Party by or on behalf of the Disclosing Party pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto; any data, ideas, concepts or techniques contained therein; and any modifications thereof or derivations therefrom. Confidential Information may be disclosed either orally, visually, electronically, in writing, by delivery of materials containing Confidential Information or in any other form now known or hereafter invented; provided, however, that notwithstanding the Party that disclosed such information or material, (a) all information and materials regarding the Compound, including the Specifications, Salix Information, and Compound Inventions, shall be Confidential Information of Salix and not the Confidential Information of Glenmark, and Salix will be deemed to be the Disclosing Party, and Glenmark will be deemed to be the Receiving Party, with respect thereto, and (b) Glenmark Information shall be Confidential Information of Glenmark and not the Confidential Information of Salix, and Glenmark will be deemed to be the Disclosing Party, and Salix will be deemed to be the Receiving Party, with respect thereto.  
1.15 “Courts” has the meaning set forth in Section 9.7(b).  
 2  
1.16 “CPL” means crude plant latex of croton lechleri that meets the Specifications.  
1.17 “Current Capacity” means the capacity of Glenmark’s equipment and process in place as of the Effective Date to conduct the Manufacturing process, as set forth on Schedule 1.17, unless and until increased pursuant to a Scale-Up Plan.  
1.18 “Disclosing Party” means the Party disclosing Confidential Information.  
1.19 “Dispute” has the meaning set forth in Section 9.6.  
1.20 “Drug Master File” means any drug master file filed with the FDA with respect to a Product, and any equivalent filing in other countries or regulatory jurisdictions.  
1.21 “Effective Date” has the meaning set forth in the preamble hereto.  
1.22 “European Union” or “EU” means the economic, scientific and political organization of member states of the European Union, and which, as of the Effective Date, consists of Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, and that certain portion of Cyprus included in such organization.  
1.23 “Excluded Lists” means the United States Department of Health and Human Service’s List of Excluded Individuals/Entities and the General Services Administration’s Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs.  
1.24 “Exploit” means to make, have made, import, use, sell, offer for sale or otherwise dispose of a compound, product or process, including all discovery, research, development, commercialization, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, exportation, transportation, distribution, promotion and marketing of such compound, product or process.  
1.25 “Facility” means the Manufacturing facility of Glenmark’s Affiliate, Glenmark Generics Ltd., located at 0000, XXXX Xxxxxxxxxx Xxxxxx, Xxxxxxxxxx, Xxxxx 393 002.  
1.26 “FDA” means the United States Food and Drug Administration and any successor agency thereto.  
1.27 “FFDCA” means the United States Federal Food, Drug, and Cosmetic Act, as amended.  
1.28 “Firm Forecast” has the meaning set forth in Section 2.2(b).  
 3  
1.29 “Fixed Price” has the meaning set forth in Section 2.5(c).  
1.30 “Forecast” has the meaning set forth in Section 2.2(b).  
1.31 “Fully-Allocated Manufacturing Cost” or “FAMC” has the meaning set forth in Schedule 1.31.  
1.32 “Glenmark” has the meaning set forth in the preamble hereto.  
1.33 “Glenmark Activities” has the meaning set forth in Section 2.8(c).  
1.34 “Glenmark Indemnified Parties” has the meaning set forth in Section 8.2.  
1.35 “Glenmark Information” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, technical assistance, designs, assembly procedures, specifications, assays, test methods, analytical methods, and other material or information owned or controlled by Glenmark and its Affiliates and necessary or useful for the Manufacture of the Compound, excluding Glenmark Inventions.  
1.36 “Glenmark Invention Patents” has the meaning set forth in Section 4.2(b)(i).  
1.37 “Glenmark Inventions” has the meaning set forth in Section 4.1(b).  
1.38 “Glenmark Policies” has the meaning set forth in Section 8.4(b).  
1.39 “Glenmark-Supplied Material” means all ingredients, raw materials, packaging and labeling components, and all other supplies of any kind used in connection with Manufacturing the Compound, excluding the Salix-Supplied Material.  
1.40 “Glenmark Territory” shall mean the countries set forth on Schedule 1.40.  
1.41 “GMP” means current good manufacturing practices as required under the FFDCA and as set forth by the FDA in regulations promulgated at 21 C.F.R. Parts 210 and 211, and in applicable FDA guidance and policy documents.  
1.42 “Xxxxx-Xxxxxx Act” means the Drug Price Competition and Patent Term Restoration Act of 1984, as amended.  
1.43 “Indemnification Claim Notice” has the meaning set forth in Section 8.3(a).  
1.44 “Indemnified Party” has the meaning set forth in Section 8.3(a).  
1.45 “Indemnifying Party” has the meaning set forth in Section 8.3(a).  
 4  
1.46 “Informational Forecast” has the meaning set forth in Section 2.2(a).  
1.47 “Invention” means any discovery, improvement, process, formula, data, invention, know-how, trade secret, procedure, device, or other intellectual property, whether or not patentable, including any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging of a compound or product or any discovery or development of a new indication for a compound or product.  
1.48 “Joint Invention Patents” has the meaning set forth in Section 4.2(c)(i).  
1.49 “Joint Inventions” means any manufacturing technique, process or Compound derivative that is not derived from or based on the Specifications, any Salix Information, Compound Invention or Glenmark Information that is conceived, discovered, developed or otherwise made, jointly by or on behalf of the Parties as a result of or in connection with this Agreement, but excluding the Glenmark Inventions.  
1.50 “Launch Date” means the first date on which Salix anticipates requiring supply of Compound hereunder in order to make Product available for commercial sale or distribution.  
1.51 “Losses” has the meaning set forth in Section 8.1.  
1.52 “Manufacture” and “Manufacturing” means (a) the manufacturing, processing, formulating, packaging, labeling, holding, storage, warehousing, and quality control testing of a pharmaceutical product or compound and (b) the holding, storage or warehousing of raw materials, finished product or work in process.  
1.53 “Marketing Authorization” means an approved New Drug Application as defined in the FFDCA and the regulations promulgated thereunder, or any corresponding foreign application, registration or certification, necessary or reasonably useful to market any Product in a country or regulatory jurisdiction in the Territory other than the United States, including applicable pricing and reimbursement approvals.  
1.54 “Material(s)” means the Glenmark-Supplied Material and the Salix-Supplied Material.  
1.55 “Napo” means Napo Pharmaceuticals, Inc.  
1.56 “Napo-Glenmark Agreement” means that certain Collaboration Agreement entered into on July 2, 2005, by and between Glenmark and Napo, as amended through the Effective Date.  
1.57 “Napo-Provided Equipment” has the meaning set forth in Section 2.8(b).  
1.58 “Other Product Entry” has the meaning set forth in Section 7.2(c)(iii).  
1.59 “Party” and “Parties” has the meaning set forth in the preamble hereto.  
 5  
1.60 “Patents” means the Compound Invention Patents, the Glenmark Invention Patents and the Joint Invention Patents.  
1.61 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.  
1.62 “Policies” means the Glenmark Policies and the Salix Policies.  
1.63 “Product” means a pharmaceutical product that contains the Compound as an active ingredient.  
1.64 “Purchase Order” means a written purchase order that sets forth, with respect to the period covered thereby, (a) the quantities of Compound to be delivered by Glenmark to Salix and (b) the required delivery dates therefor.  
1.65 “Purchase Price” has the meaning set forth in Section 2.5(a).  
1.66 “Quality Agreement” means the quality assurance agreement to be agreed between the Parties relating to the Manufacture of the Compound in accordance with Section 2.11, as such agreement shall be amended from time to time.  
1.67 “Recalls” shall have the meaning set forth in Section 3.3(e).  
1.68 “Receiving Party” means the Party receiving Confidential Information.  
1.69 “Recipients” has the meaning set forth in Section 6.1.  
1.70 “Regulatory Approval” means, with respect to any particular country, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the Exploitation of a Product in such country (or, if applicable, the EU), including, where applicable, (a) approval of a Product in such country (or, if applicable, the EU), including any Marketing Authorization and supplements and amendments thereto; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.  
1.71 “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Compound or a Product in any country or jurisdiction in the Specified Territory.  
1.72 “Regulatory Documentation” means (a) submissions to any Regulatory Authority, including investigational new drug applications, New Drug Applications (as defined in the FFDCA and the regulations promulgated thereunder), Drug Master Files,  
 6  
correspondence with regulatory agencies (registrations and licenses, regulatory drug lists, advertising and promotion documents), period safety update reports, adverse event files, complaint files and manufacturing records and, if applicable, any updates or supplements to any of the foregoing, (b) any minutes or contact logs with respect to any telephone conferences conducted with any Regulatory Authority relating to the subject matter described in Section 1.72(a) and (c) any written correspondence received from any Regulatory Authority.  
1.73 “Salix” has the meaning set forth in the preamble hereto.  
1.74 “Salix Indemnified Parties” has the meaning set forth in Section 8.1.  
1.75 “Salix Information” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, technical assistance, designs, assembly procedures, specifications, assays, test methods, analytical methods, and other material or information owned or controlled by Salix and its Affiliates and necessary or useful for the Manufacture of the Compound.  
1.76 “Salix Policies” has the meaning set forth in Section 8.4(a).  
1.77 “Salix-Supplied Material” means the CPL used in connection with Manufacturing the Compound.  
1.78 “Scale-Up Equipment” has the meaning set forth in Section 2.8(c).  
1.79 “Scale-Up Plan Effective Date” has the meaning set forth in Section 2.8(c).  
1.80 “Scale-Up Plans” means the adaptations, scale-ups or improvements to Glenmark’s Manufacturing equipment or process, and any required investments relating thereto, in order to satisfy Salix’s anticipated annual requirements in excess of the Current Capacity. A non-binding example of such proposal is set forth on Exhibit A.  
1.81 “Specifications” means, with respect to the Compound, those Compound-related specifications set forth on Schedule 1.81 and, with respect to CPL, those CPL-related specifications set forth on Schedule 1.81, in each case as the same may be amended from time to time in accordance with the terms hereof.  
1.82 “Specified Territory” means the United States, the EU and India, together with such additional countries or territories as may be agreed by the Parties pursuant to written amendment to this Agreement. The Parties agree that upon the proposal by Salix of additional countries or territories to be included in the definition of “Specified Territory,” they will negotiate in good faith in respect of the inclusion of such additional countries or territories in such definition, including with respect to the appropriate allocation between the Parties of any additional costs anticipated as a result thereof.  
 7  
1.83 “Territory” means the entire world.  
1.84 “Term” has the meaning set forth in Section 7.1.  
1.85 “Testing Expert” has the meaning set forth in Section 2.7(d).  
1.86 “Third Party Claim” has the meaning set forth in Section 8.3(b).  
1.87 “Third Party Manufacturer” means any Third Party manufacturer of the Compound designated by Salix, other than an Affiliate of Glenmark.  
1.88 “Third Party Manufacturer License” means the license described in Schedule 1.88.  
1.89 “United States” means the United States of America.  
ARTICLE II. MANUFACTURING  
2.1 Supply Obligations. Subject to the terms and conditions hereof, Glenmark shall Manufacture or have Manufactured by its Affiliate, Glenmark Generics Ltd., and supply to Salix, and Salix shall purchase from Glenmark, such quantities of Compound as Salix may order pursuant to Purchase Orders in accordance with the terms hereof from time to time during the Term.  
2.2 Forecasting, Order and Delivery of Compound.  
(a) At least [\*] days prior to the first day of each Calendar Year during the Term commencing with the Calendar Year in which the Launch Date is anticipated to occur, Salix shall deliver to Glenmark a written good faith forecast estimating, on a quarterly basis, the quantities of Compound that Salix expects to purchase from Glenmark during such Calendar Year (each, an “Informational Forecast”); provided that in the event that the Launch Date is anticipated to occur in Calendar Year [\*], Salix shall deliver to Glenmark the Informational Forecast in respect of Calendar Year [\*] on a date reasonably agreed by the Parties. Each Informational Forecast shall be non-binding and shall be used by Glenmark for planning purposes only.  
(b) On or before the fifteenth (15th) day of each month, commencing at least [\*] months prior to the month in which the Launch Date is anticipated to occur, Salix shall deliver to Glenmark a written good faith forecast estimating the quantities of Compound that Salix expects to purchase from Glenmark for each month during the following [\*] months (each, a “Forecast”). The [\*] months of each Forecast shall be a “Firm Forecast”. Except as provided in Section 2.2(c), each Forecast shall be non-binding and shall be used by Glenmark for planning purposes only.  
(c) Without duplication of any previously delivered Purchase Order, each Firm Forecast shall be accompanied by a Purchase Order for Compound to be  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 8  
delivered to Salix during each of the [\*] months, respectively, set forth in such Firm Forecast. The quantity of Compound specified in any Purchase Order for delivery in any month (i) shall be in multiples of the full production lots of Compound set forth on Schedule 2.2(c) and (ii) shall not be less than [\*] percent ([\*]%) nor more than [\*] percent ([\*]%) of the quantities specified in any previous Firm Forecast applicable to such month. In no event shall the delivery date of Compound for any Purchase Order be less than [\*] months from the date of the Purchase Order; provided, however, that such period shall be shortened to [\*] months so long as Salix has fulfilled its obligations under Section 2.3(b) to provide to Glenmark the Salix-Supplied Material in respect of such Purchase Order.  
(d) Glenmark shall, within [\*] business days after Glenmark receives each Purchase Order submitted in accordance with Section 2.2(c), accept in writing such Purchase Order. Glenmark shall be deemed to have accepted such Purchase Order if such Purchase Order is not rejected in writing by Glenmark in such [\*] business day period. Salix shall be obligated to purchase, and Glenmark shall be obligated to deliver by the required delivery date set forth therein, such quantities of Compound as are set forth in each Purchase Order. In the event that the terms of any Purchase Order are not consistent with or are in addition to the terms of this Agreement, the terms of this Agreement shall prevail.  
(e) Glenmark shall deliver the quantities of Compound set forth in each Purchase Order by the required delivery date set forth in such Purchase Order DDU (as defined in Incoterms 2000) the port of entry in any Specified Territory (or, in the case of the EU, any member state of the EU) other than India designated by Salix; provided, however, that (i) Glenmark shall only engage such carriage, insurance or other providers in connection with such delivery as are designated by Salix in the applicable Purchase Order, (ii) Salix shall bear costs and expenses for (A) carriage and insurance of the Compound from the Facility and (B) clearance of Compound through customs in the destination country and (iii) in the event any claim arises against any such carriage, insurance or other provider, Glenmark, as promptly as possible, shall assign such claim to Salix. All Compound shall be labeled in accordance with Applicable Law and packed for shipping in accordance with packing instructions provided by Salix. Title to and risk of loss of Compound shall pass to Salix at the time of delivery.  
(f) Each delivery of Compound shall be accompanied by (i) a Certificate of Analysis, (ii) a Certificate of Compliance, (iii) such other documents as may be required pursuant to the Quality Agreement, and (iv) documentation necessary for the sale or import of the Compound.  
2.3 Raw Materials.  
(a) In any given month, Glenmark shall maintain an inventory of Materials in sufficient quantities, and shall use its commercially reasonable efforts, to  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 9  
supply Salix with quantities of Compound that are up to [\*] percent ([\*]%) of the quantities specified in any Firm Forecast applicable to such month.  
(b) Simultaneous with delivery of each Firm Forecast by Salix to Glenmark, Salix shall deliver to Glenmark at the Facility such quantities of Salix-Supplied Material as are necessary for Manufacture of Compound in accordance with each Firm Forecast, free of charge to Glenmark. Glenmark shall use the Salix-Supplied Material solely for the purpose of Manufacturing the Compound for supply to Salix. In the event Salix fails to deliver Salix-Supplied Material in quantities and quality necessary for Glenmark to Manufacture Compound in accordance with the applicable Purchase Order, such failure shall be deemed a force majeure event for which Glenmark’s obligation to supply to Salix shall be excused until such force majeure event has been corrected or eliminated.  
(c) Each Party shall be responsible for auditing and qualifying its respective third party supplier(s) of Materials and obtaining supplies of Materials in accordance with the applicable Specifications. All Materials shall conform to the applicable Specifications and any applicable Drug Master File, as further referenced in any applicable Regulatory Documentation.  
2.4 Invoice and Payment. Glenmark promptly shall invoice Salix for all quantities of Compound delivered in accordance herewith. Payment with respect to Compound delivered shall be due [\*] days from the date of invoice to Salix; provided that if Salix rejects such Compound pursuant to Section 2.7, then payment shall be due within [\*] days after receipt by Salix of notice from the Testing Expert that the invoiced Compound is conforming or, subject to Section 2.7, receipt by Salix of replacement Compound, as the case may be; provided further, if Salix disputes any portion of an invoice, it shall pay the undisputed portion and shall provide Glenmark with written notice of the disputed portion and its reasons therefor, and Salix shall not be obligated to pay such disputed portion. The Parties shall use good faith efforts to resolve any such disputes promptly. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control. Payment of invoices shall be made by wire transfer to an account designated in writing by Glenmark in United States Dollars. If any currency conversion shall be required in connection with any payment hereunder, such conversion shall be made each calendar quarter using an exchange rate that is the arithmetic average of the daily exchange rates (obtained as described below) during such calendar quarter. Each daily exchange rate shall be obtained from The Xxxx Xxxxxx Xxxxxxx, Xxxxxxx Xxxxxx Xxxxxx Edition, or, if not so available, as otherwise agreed by the Parties.  
2.5 Price.  
(a) The purchase price per kilogram (the “Purchase Price”) for all Compound delivered hereunder shall equal Glenmark’s Fully-Allocated Manufacturing Cost plus [\*] percent ([\*]%). Along with each acceptance of a Purchase Order  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 10  
pursuant to Section 2.2(d), Glenmark shall also confirm the Purchase Price applicable for such Purchase Order, based on the formula set forth in the preceding sentence. If Glenmark fails to confirm the Purchase Price for any Purchase Order, the Purchase Price for such Purchase Order shall be the [\*]. No later than thirty (30) days following each anniversary of the first day of the month in which Glenmark commences commercial supply to Salix, Glenmark shall calculate its actual Fully-Allocated Manufacturing Cost of manufacturing Compound supplied to Salix in the [\*] percent ([\*]%) (the “Actual Cost”). If the Purchase Price paid by Salix for Compound is within [\*] ([\*]%) of the Actual Cost, no reconciliation of the Purchase Price will be made between the Parties. If the Purchase Price paid by Salix for Compound is greater than the Actual Cost by more than [\*] percent ([\*]%), Glenmark shall reimburse Salix for such amount in excess of [\*] percent ([\*]%) within [\*] days of such determination. If the Purchase Price paid by Salix for Compound is less than the Actual Cost by more than [\*] percent ([\*]%), Salix shall reimburse Glenmark for such amount in excess of [\*] percent ([\*]%) within [\*] days of such determination.  
(b) Glenmark shall provide Salix with access to such books, records, and financial and other information, including in respect of the details of its arrangements with third parties for the supply of Materials, as Salix may reasonably request in order to establish that the Purchase Price for Compound supplied hereunder is in compliance with the provisions of Section 2.5(a).  
(c) The Parties acknowledge that there are other terms negotiated between Napo and Glenmark in connection with the execution of this Agreement. Section 2.5(a) notwithstanding, the Purchase Price for supply of Compound by Glenmark to Salix during the [\*] months following the Effective Date shall be fixed at the purchase price set forth in Schedule 2.5(c) (“Fixed Price”); provided that the Parties shall review such Fixed Price every [\*] months following the Effective Date and (i) in the event the FAMC plus [\*] percent ([\*]%) at such time is less than such Fixed Price, the Fixed Price shall be adjusted downward to equal such FAMC plus [\*] percent ([\*]%) and, (ii) in the event the FAMC plus [\*] percent ([\*]%) at such time is greater than such Fixed Price, the Fixed Price shall be adjusted upward to equal such FAMC plus [\*] percent ([\*]%) up to a maximum amount equal to the Capped Price. In no event shall the aggregate quantity of Compound purchased hereunder at the Fixed Price exceed [\*] kilograms ([\*]). Salix acknowledges and understands that as of the Effective Date the Fixed Price does not reflect Glenmark’s Fully-Allocated Manufacturing Cost plus [\*] percent ([\*]%) as of the Effective Date and such Fixed Price is only being offered as a short term accommodation.  
(d) The Parties acknowledge that Glenmark has invested significant resources in developing and optimizing the manufacturing process for the Manufacture of Compound. In the event that Salix uses a Third Party Manufacturer, Salix shall provide compensation to Glenmark as set forth in Schedule 2.5(d), subject to all of the limitations set forth in such Schedule including the limitation with respect to the [\*] year duration of such obligations.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 11  
2.6 Warranty. In connection with each delivery of Compound to Salix hereunder, Glenmark hereby represents and warrants to Salix as of the date of the delivery of such Compound to Salix as follows: (a) such Compound is in conformity with the Specifications and the Certificate of Analysis therefor provided pursuant to Section 2.2(f); (b) such Compound has been Manufactured in conformance with GMP, all other Applicable Law, this Agreement and the Quality Agreement; (c) title to such Compound will pass to Salix free and clear of any security interest, lien or other encumbrance; (d) such Compound has been Manufactured at the Facility and those portions of the Facility used in the Manufacture of the Compound are in compliance with all Applicable Law at the time of such Manufacture (including applicable GMP and inspection requirements of FDA and other Regulatory Authorities); (e) the expiration date of such Compound is no earlier than [\*] months after the date of delivery thereof (or such longer period after the date of delivery thereof as may be supported by ongoing stability studies, it being acknowledged that a [\*] month period must be allowed for packaging and shipment); (f) such Compound has not been adulterated (as such term is defined in the FFDCA) at the time of shipment by Glenmark from the Facility; (g) such Compound may be introduced into interstate commerce pursuant to the FFDCA and similar provisions of other Applicable Law in the Specified Territory; and (h) neither Glenmark nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or any similar law in any country in the Specified Territory or listed on either Excluded List or any similar list in any country in the Specified Territory; provided that, with respect to any such similar laws or lists in any country in the Specified Territory other than the United States, Salix has identified for Glenmark with specificity such law or list.  
2.7 Failure or Inability to Supply Compound.  
(a) In the event that Glenmark, at any time during the Term, shall have reason to believe that it will be unable to supply Salix with the full quantity of Compound forecasted to be ordered or actually ordered by Salix in a timely manner and in conformity with the warranties set forth in Section 2.6, Glenmark shall promptly notify Salix thereof. Promptly thereafter, the Parties shall meet to discuss how Salix shall obtain such full quantity of conforming Compound. Compliance by Glenmark with this Section 2.7(a) shall not relieve Glenmark of any other obligation or liability under this Agreement, including any obligation or liability under Section 2.7(b) or 2.7(c).  
(b) Subject to Section 2.7(f), if Glenmark fails to deliver the full quantity of Compound specified in a Purchase Order by [\*] days after the required delivery date specified therein and in conformity with the warranty set forth in Section 2.6, then Salix may, at its option, (i) cancel all or any portion of such Purchase Order, in which event Salix shall have no liability with respect to the portion of such Purchase Order so cancelled, or (ii) accept late delivery of all or any portion of the Compound specified in such Purchase Order.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 12  
(c) Subject to Section 2.7(f), if Glenmark fails to deliver the full quantity of Compound specified in a Purchase Order by [\*] days after the required delivery date specified therein and in conformity with the warranty set forth in Section 2.6, then Salix may, at its option, (i) accept late delivery of all or any portion of the Compound specified in such Purchase Order, (ii) terminate its obligations under Section 2.1 in whole or in part by written notice to Glenmark or (iii) provide written notice to Glenmark of its intention to qualify a Third Party Manufacturer for the Compound, in which event Glenmark shall use its commercially reasonable efforts promptly to assist Salix to qualify such Third Party Manufacturer designated by Salix to Manufacture such Compound, and provide, to such Third Party Manufacturer such technical assistance, as Salix may reasonably request and such Third Party Manufacturer may reasonably require in order to Manufacture the Compound without charge to Salix, except that Salix shall be responsible for the out of pocket expenses incurred by Glenmark in providing such technical assistance and provided further that the technical assistance is for no more than [\*] (equal to [\*] work hours each). Glenmark shall also promptly grant to such Third Party Manufacturer a Third Party Manufacturer License, provided that Salix shall compensate Glenmark in the manner set forth in Schedule 2.5(d), subject to all of the limitations set forth in such Schedule including the limitation with respect to the [\*] year duration of such obligations and Schedule 1.31, Section III.  
(d) In the event that Salix determines, within [\*] days after delivery thereof by Glenmark (or within [\*] days after discovery of any non-conformity that could not reasonably have been detected by a customary inspection on delivery, so long as such discovery is during the production of Product, but in no event more than [\*] months after delivery of Compound by Glenmark), that any Compound supplied by Glenmark does not conform to the warranties set forth in Section 2.6, Salix shall give Glenmark notice thereof (including a sample of such Compound, if applicable). Glenmark shall undertake appropriate evaluation of any such sample and shall notify Salix whether it has confirmed such nonconformity within [\*] days after receipt of such notice from Salix. If Glenmark notifies Salix that it has not confirmed such nonconformity, then the Parties shall submit the dispute to an independent testing laboratory or other appropriate expert mutually acceptable to the Parties (the “Testing Expert”) for evaluation. Both Parties shall cooperate with the Testing Expert’s reasonable requests for assistance in connection with its evaluation hereunder. The findings of the Testing Expert shall be binding on the Parties, absent manifest error. The expenses of the Testing Expert shall be borne by Glenmark if the testing confirms the nonconformity and otherwise by Salix. If the Testing Expert or Glenmark confirms that a lot of Compound does not conform to the warranties set forth in Section 2.6, then Glenmark, at Salix’s option, promptly shall (A) supply Salix with a conforming quantity of Compound at Glenmark’s expense or (B) reimburse Salix for the Purchase Price paid by Salix with respect to such non-conforming Compound if already paid. In addition, Glenmark promptly shall reimburse Salix for all costs incurred by Salix with respect to such non-conforming Compound, including the Salix-Supplied Material. Salix shall have the right to offset any such costs against any payments owed by Salix to Glenmark under this Agreement. Glenmark immediately shall notify Salix if at any time it discovers that any Compound delivered hereunder does  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 13  
not conform to the Specifications. Notwithstanding any other provision of this Section 2.7(d), Glenmark shall have no liability hereunder to the extent any such liability is attributable to (i) a failure of Salix-Supplied Material to conform to applicable Specifications or (ii) Salix-Supplied Material having been adulterated (as such term is defined in the FFDCA) prior to the time of delivery to Glenmark.  
(e) Subject to Salix’s right to indemnification under Section 8.1, the rights and remedies provided in this Section 2.7 shall be cumulative and shall be Salix’s sole and exclusive remedy with respect to Glenmark’s failure to supply Compound that conforms to the warranties set forth in Section 2.6, or Glenmark’s inability to supply Compound pursuant to any accepted Purchase Order.  
(f) The rights and remedies provided in Sections 2.7(b) and (c) shall be subject to Salix fulfilling its obligations under Section 2.3(b).  
2.8 Limitations of Current Capacity.  
(a) The Parties acknowledge the Current Capacity production constraints of Glenmark, and, subject to Section 2.8(b), agree that the estimation of the maximum annual quantities of the Compound that Glenmark is capable of delivering to Salix as of the Effective Date are as set forth on Schedule 1.17.  
(b) Glenmark shall bear the expenses for the required civil, mechanical, HVAC, electrical and instrumentation, qualified utilities, environment and safety and consultancy charges for manufacturing state I and II of the Compound at the Facility. Napo has provided, at its sole cost and expense, the required [\*] as of the Effective Date (the “Napo-Provided Equipment”).  
(c) In anticipation of Salix’s annual requirements exceeding the amount of Compound permitted by Current Capacity, the Parties shall discuss in good faith the Scale-Up Plans. Glenmark agrees to use its commercially reasonable efforts to implement any agreed upon Scale-Up Plan as promptly as possible and the cost of such implementation shall be borne by Salix, including the purchase and installation of any equipment needed for the Scale-up Plans and any replacement for Napo-Provided Equipment purchased and installed after the Effective Date (the “Scale-up Equipment”). Until such time as Glenmark has been afforded a reasonable period of time to implement a Scale-Up Plan (the date on which such period expires, the “Scale-Up Plan Effective Date”), Glenmark’s inability to supply Compound in excess of the amount set forth on Schedule 1.17 per year shall not be construed as a material breach of this Agreement. Glenmark shall have the right to use all Compound Equipment to (i) carry out any research, development scale-up and other activities relating to the Compound, provided, however, that such usage shall not exceed [\*] percent ([\*]%) of such Compound Equipment’s capacity and (ii) subject to Section 2.21, [\*] permitted pursuant to the Napo-Glenmark Agreement (collectively, the “Glenmark Activities”). Glenmark shall reimburse Salix in accordance with the terms set forth in Schedule 2.8(c).  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 14  
(d) Salix acknowledges and agrees that the Scale-Up Plan as set forth on Exhibit A is for illustrative purposes only and Glenmark has no obligations to achieve the targets set forth therein.  
2.9 Costs and Expenses. Except as otherwise explicitly set forth herein, [\*] shall be solely responsible for all costs and expenses incurred in connection with the Manufacture of Compound hereunder, including costs and expenses of personnel, quality control testing, Manufacturing facilities and equipment, and Glenmark-Supplied Materials.  
2.10 Amendment of Specifications.  
(a) In the event that an amendment to the Specifications, the Manufacturing process, or the test methods for the Compound is required in writing by any Regulatory Authority, Salix promptly shall provide Glenmark with appropriate documentation relating to any such changes to the Specifications or Manufacturing process to the extent that such changes affect Glenmark’s Manufacturing of the Compound hereunder. So long as the process capability can meet such amendment to Specifications or Manufacturing process required by the Regulatory Authority, Glenmark shall promptly implement such changes in accordance with the change control procedures applicable under GMP. In the event that the process capability cannot meet such an amendment to Specifications or Manufacturing process required by the Regulatory Authority, then the Parties will pursue good faith discussions with respect to the identification and implementation of arrangements that will permit Glenmark to meet such amendment. Salix may request any other amendment to the Specifications, the Manufacturing process, or the test methods for the Compound, in which event the Parties shall meet to discuss such proposed amendment in good faith. Salix promptly shall provide Glenmark with appropriate documentation relating to any such changes to the Specifications or Manufacturing process to the extent that such changes affect Glenmark’s Manufacturing of the Compound hereunder. Promptly thereafter, Glenmark shall use its commercially reasonable efforts to implement any such change agreed to by the Parties. Glenmark shall not, in any respect, amend, modify or supplement the Specifications, the Manufacturing process, or the test methods for the Compound or any Materials or sources of Materials used in connection with Manufacturing the Compound without the prior written consent of Salix.  
(b) [\*] shall reimburse [\*] for reasonable expenses that are actually incurred by [\*] in connection with any amendment of the Specifications or the Manufacturing process for the Compound required by Salix, including reasonable costs of capital equipment and process upgrades and obsolescence of Materials, goods-in-process, and finished goods not suitable for other use in the business or operations of Glenmark or any of its Affiliates; provided, however, that [\*] liability for such reimbursement shall be limited to levels of inventory that are customary in pharmaceutical manufacturing operations.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 15  
(c) [\*] shall be solely responsible for any and all increased costs or expenses incurred by [\*] or [\*] as a result of any amendment of the Specifications or the Manufacturing process for the Compound (i) requested by Glenmark and consented to by Salix or (ii) required by Salix as a result of Glenmark’s failure to Manufacture the Compound in conformity with the Specifications.  
2.11 Quality Agreement. Within [\*] days after the Effective Date, and in any event, prior to any commercial sale of the Compound, Salix and Glenmark shall prepare and enter into a reasonable and customary quality assurance agreement, upon terms generally consistent with the existing quality agreement between Glenmark and Napo with such modifications thereto as either Party may reasonably request (the “Quality Agreement”). Each Party shall duly and punctually perform all of its obligations under the Quality Agreement.  
2.12 Quality Control Analyses and Release. Glenmark shall be responsible for all quality control analyses of the Compound and all Compound shall be released by Glenmark, in each case in accordance with the terms of the Quality Agreement.  
2.13 Maintenance of Facility.  
(a) Except as otherwise approved in writing by Salix, Glenmark shall Manufacture the Compound exclusively at the Facility under GMP.  
(b) Glenmark shall ensure that any and all licenses, registrations, and Regulatory Authority approvals required by Applicable Law are and shall be obtained in connection with the Facility and equipment used in connection with the Manufacture of the Compound by Glenmark.  
(c) Glenmark shall maintain the Facility and such equipment in a state of repair and operating efficiency consistent with the requirements of the Specifications, the Regulatory Approvals, GMP and all other Applicable Law.  
(d) Glenmark shall maintain in the Facility adequate and segregated holding accommodations for the Compound and the Materials used in Manufacturing the Compound in accordance with the Specifications, the Regulatory Approvals, GMP and all other Applicable Law.  
(e) Glenmark shall only use disposal services or sites that have appropriate environmental permits and are in compliance with Applicable Law.  
2.14 Regulatory Cooperation of Glenmark. Glenmark shall cooperate with any reasonable requests for assistance from Salix with respect to obtaining and maintaining any and all Regulatory Approvals, including by:  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 16  
(a) at Salix’s cost and expense, making its employees, consultants and other staff available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning the Compound and the Product; and  
(b) at Salix’s cost and expense, disclosing and making available to Salix, in such form as may be required by any applicable Regulatory Authority, all Manufacturing and quality control data, CMC Data and other information related to the Compound and the Manufacturing process therefor as is reasonably necessary to prepare, file, obtain and maintain any Regulatory Approval.  
2.15 Inspection by Salix. Glenmark agrees that Salix and its agents shall have the right [\*] each Calendar Year, upon reasonable prior notice to Glenmark and during normal business hours, to inspect those portions of the Facility where Manufacture of the Compound takes place, as well as the Manufacturing of the Compound, including inspection of (a) the Materials used in the Manufacture of the Compound, (b) the holding facilities for such Materials, (c) the equipment used in the Manufacture of the Compound, and (d) all records relating to such Manufacturing and the Facility (only to the extent they relate to the Compound). Following such audit, Salix shall discuss its observations and conclusions with Glenmark and Glenmark shall use its commercially reasonable efforts to implement such corrective actions as may be requested reasonably and in good faith by Salix within [\*] days after notification thereof by Salix or such longer period as may be reasonable in the circumstances as determined by Glenmark after consultation with Salix or agreed by the Parties.  
2.16 Notification of Regulatory Inspections; Communications. Glenmark shall notify Salix by telephone within [\*] hours, and in writing within [\*] business days, after learning of any proposed visit or inspection by any Regulatory Authority, the specific (but not necessarily exclusive) focus of which is on those portions of the Facility where Manufacture of the Compound takes place or on operations of the Facility material to the Manufacture of the Compound, and shall use its commercially reasonable efforts to permit Salix or its agents to be present and participate in such visit or inspection. For purposes of clarity, routine inspection of the Facility which may include inspection of those portions of the Facility where Manufacture of the Compound takes place shall not trigger Glenmark’s notification obligation under this Section 2.16.  
2.17 Recalls and Withdrawals. [\*] promptly shall [\*] for all costs incurred by [\*] in connection with recalls, market withdrawals, and returns and destruction of Product containing any non-conforming Compound (as determined pursuant to Section 2.7(d)) as and to the extent and only to the extent any such recall, market withdrawal or return or destruction of Product is the direct result of [\*]’s breach of its warranties under Section 2.6 or [\*]’s gross negligence or willful misconduct. [\*] shall have the right to offset any such costs against any payments owed by [\*] to [\*] under this Agreement. All other costs for recalls, market withdrawals and returns and destruction of Product shall be the sole and exclusive responsibility of [\*] (including any recalls, market withdrawals and returns  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 17  
and destruction of Product as and to the extent attributable to the failure of [\*] to conform to applicable Specifications).  
2.18 Compliance with Applicable Laws. Glenmark shall comply, and shall cause each of its Material suppliers (other than Salix and its Affiliates) to comply, with GMP and all other Applicable Law in carrying out the Manufacturing of the Compound and its other duties and obligations under this Agreement.  
2.19 Retention of Manufacturing Records and Samples.  
(a) Glenmark shall generate, retain and maintain:  
(i) all records necessary to comply with GMP and all other Applicable Law relating to the Manufacture of the Compound. Without limiting the foregoing, records shall be made concurrently with the performance of each step in the Manufacture of the Compound and in such a manner that at any time successive steps in the Manufacture and distribution of any batch may be traced by an inspector. Such records shall be legible and indelible, shall identify the person immediately responsible, shall include dates of the various steps and be as detailed as necessary for a clear understanding of each step by an individual experienced in the manufacture of pharmaceutical products;  
(ii) all Manufacturing records, standard operating procedures, equipment log books, batch manufacturing records, laboratory notebooks and all raw data relating to the Manufacturing of the Compound;  
(iii) samples of each batch and Materials. Samples shall include a quantity of representative material of each batch and Materials sufficient to perform at least full duplicate quality control testing, and shall specify the dates of Manufacture and packaging thereof. Samples so retained shall be selected at random from either final container material or from bulk and final containers; provided that they include at least one final container as a final package, or package-equivalent of such filling of each batch. Such sample shall be stored at temperatures and under conditions which will maintain the identity and integrity of the relevant sample; and  
(iv) such other records and samples that Glenmark maintains in the ordinary course of business, as Salix reasonably may require in order to ensure compliance by Glenmark with the terms of this Agreement and Applicable Law.  
(b) Without prejudice to Glenmark’s obligations pursuant to Section 2.19(a), Glenmark shall diligently complete the master batch record for the Compound during the Manufacture of such Compound.  
(c) All materials, samples, records and other items referred to in Sections 2.19(a) and 2.19(b) shall be retained by Glenmark for the longer of (i) such period as may be [\*] and [\*] and (ii) [\*] years.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 18  
2.20 No Other Supply. Glenmark shall not, and Glenmark shall cause its Affiliates not to, Manufacture or supply the Compound to or for any Person other than (a) Salix and its Affiliates under and pursuant to this Agreement, (b) [\*] under and pursuant to the [\*]Glenmark Agreement, and (c) [\*] as permitted under the [\*]Glenmark Agreement.  
2.21 Shortages. In the event that the amount of Compound which Glenmark Manufactures is less than the amount required to meet the requirements of all Persons to be supplied by Glenmark pursuant to Section 2.20, the total supply Manufactured by Glenmark shall be apportioned as follows: first, to those Persons with pending or approved Marketing Authorizations, pro rata on the basis of each such Person’s good faith anticipated volume requirements of the Compound for the next [\*] months for itself and its Affiliates, licensees and sublicensees in respect of those countries or jurisdictions where such Person (or its Affiliates, licensees or sublicensees) has a pending or approved Marketing Authorization; second, to those Persons who paid for the Compound Equipment, pro rata on the basis of each such Person’s good faith anticipated volume requirements of the Compound for the next [\*] months; and third, as agreed by the Parties in good faith.  
2.22 Second Source. Notwithstanding anything to the contrary herein, Salix shall have the right, at its own expense, to secure a Third Party Manufacturer to Manufacture Compound for supply to Salix; provided, however, that no such Third Party Manufacturer shall be located in any country that is included in the Glenmark Territory. Glenmark shall use its commercially reasonable efforts to assist Salix to qualify such Third Party Manufacturer designated by Salix to Manufacture such Compound, and provide, to such Third Party Manufacturer such technical assistance, as Salix may reasonably request and such Third Party Manufacturer may reasonably require in order to Manufacture the Compound at Salix’s sole cost and expense, provided that the technical assistance is for no more than [\*] (equal to [\*] work hours each). [\*] shall also promptly grant to such Third Party Manufacturer a Third Party Manufacturer License, provided that Salix shall compensate [\*] in the manner set forth in Schedule 2.5(d), subject to all of the limitations set forth in such Schedule including the limitation with respect to the [\*] year duration of such obligations and Schedule 1.31, Section III.  
ARTICLE III. GLOBAL COORDINATION  
3.1 Global Cooperation and Coordination. Each of the Parties holds certain licenses from Napo permitting it to Exploit the Product in certain fields of use in certain territories. Accordingly, each of the Parties has an interest in enhancing the development and commercialization of the Product in those fields and territories to which its licenses extend. Each Party hereby acknowledges that the maximum commercial potential of the Product in its field of use and territories will be achieved through the coordinated global development and commercialization. To that end, each of the Parties hereby agrees to cooperate and coordinate with the other Party to support the global development,  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 19  
approval by Regulatory Authorities, commercialization and other Exploitation of the Product.  
3.2 Consultation. The Parties shall consult with each other on a regular basis, either in writing, by telephone, or through face-to-face meetings, as the Parties may deem most expedient, with regard to all aspects of the development and commercialization of the Product. Without limiting the foregoing, each Party shall designate by written notice to the other Party a single senior executive of such Party to serve as the principal contact with such other Party for purposes of the cooperation and coordination contemplated by this Article 3. Each Party shall ensure that at all times during the Term it has designated such a senior executive for such purpose.  
3.3 Regulatory Matters.  
(a) Rights of Reference. Each Party hereby grants to the other Party rights of reference in and to all Regulatory Documentation filed by such Party with any Regulatory Authority. The Parties shall negotiate in good faith and implement appropriate provisions, consistent with Applicable Law, in respect of mutual adverse event reporting and mutual access to, and mutual exchange between the Parties of, information necessary for each Party to adhere to regulatory requirements. Without limiting the foregoing, each Party shall have the right to cross reference, file or incorporate by reference any regulatory submission or Drug Master File (and any data contained therein) for the Product, or any component thereof (including any Regulatory Approvals), in order to support regulatory submissions that such Party has the right to make.  
(b) Regulatory Inspections. If any governmental or Regulatory Authority takes, or gives notice of its intent to take, any other regulatory action alleging improper or inadequate Manufacturing practices (including the issuance of a “Notice of Inspectional Observations,” “Warning Letter” or the equivalent) with respect to those portions of the Facility where Manufacture of the Compound takes place, such Party shall notify the other Party by telephone within twenty-four (24) hours, and in writing within one (1) business day of such contact or notice, or sooner if necessary to permit such other Party to be present at, or otherwise participate in, any such inspection or regulatory action with respect to the Compound and shall supply such other Party with all information pertinent thereto. Such other Party shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Compound. The inspected Party shall provide the other Party with copies of all documentation issued or inspected by any governmental or Regulatory Authority in connection with such inspection or regulatory action and any response thereto proposed by the inspected Party. No such responses shall contain any false or misleading information, or omit any information necessary to make such response not false or misleading, with respect to the Compound.  
(c) Access to Data. Each Party shall provide the other Party on a timely basis with access to all material pre-clinical data and clinical data compiled in support of a an application for Regulatory Approval or other regulatory filings with  
 20  
respect to the Product, when and as such pre-clinical data or clinical data become available. Each Party shall provide the other Party with Regulatory Documentation within a reasonable timeframe of receipt or production thereof and, to the extent applicable, within the timeframe as is necessary for the responsible Party to take action or comply with any requirement of any Regulatory Authority applicable to the responsible Party.  
(d) Communications with Regulatory Authorities. As between Salix and Glenmark, Salix shall have sole responsibility and authority to communicate with Regulatory Authorities with respect to the Drug Master File for the Compound; provided that, from and after the date that such Drug Master File is transferred to Glenmark, then Glenmark shall have the sole responsibility and authority to communicate with Regulatory Authorities with respect to such Drug Master File. Subject to the foregoing, (i) Glenmark shall have the sole responsibility and authority to communicate with Regulatory Authorities during the term of the Napo-Glenmark Agreement in relation to the Product in the Glenmark Territory and for the fields of use exclusively granted Glenmark in the Glenmark Territory and (ii) in relation to the Product outside the Glenmark Territory and outside the fields of use exclusively granted to Glenmark in the Glenmark Territory, either Napo or Salix shall have sole responsibility and authority to communicate with Regulatory Authorities with respect to such Product.  
(e) Conduct of Recalls. As between Salix and Glenmark, Salix shall have the sole responsibility and authority to conduct, and shall have the final decision whether to implement, all voluntary and involuntary recalls, stop sales, field corrections or other related actions (collectively, “Recalls”) of the Product in and with respect to all fields of use in all countries worldwide, except for those countries included in the General Territory (as defined in the Napo-Glenmark Agreement), but only in the field of use relating to HIV/AIDS-related diarrhea and pediatric diarrhea, and those countries included in the AAID Specific Territory (as defined in the Napo-Glenmark Agreement), but only in the field of use relating to adult acute infectious diarrhea, with respect to which fields of use in the specified countries Glenmark shall have sole responsibility and authority to conduct or implement Recalls during the term of the Napo-Glenmark Agreement. Glenmark and Salix shall cooperate and each shall provide such assistance to the other in respect of Recalls of the Product as the other may reasonably request.  
3.4 Trademarks. The Parties shall cooperate in all respects for the purpose of achieving appropriate coordination and harmonization of the use and manner of use of trademarks, trade dress, and trade names in respect of the Product on a global basis.  
ARTICLE IV. INTELLECTUAL PROPERTY  
4.1 Ownership.  
(a) Salix shall own all right, title and interest in and to (i) the Specifications and the Salix Information and (ii) any and all Compound Inventions.  
 21  
Salix hereby grants to Glenmark and its Affiliates the right to use the Compound Inventions on the same terms and conditions set forth in Section 2.1 of the Napo-Glenmark Agreement, as such agreement is in effect as of the Effective Date. Glenmark shall, and shall cause its Affiliates to, promptly disclose in writing to Salix the discovery, development, making, conception or reduction to practice of any Compound Invention and shall and does hereby, and shall cause its Affiliates to, assign to Salix any and all right, title or interest Glenmark or its Affiliates may have in or to any Compound Invention. Glenmark shall execute any documents and perform such other acts as may be reasonably requested by Salix in order to secure, perfect, confirm, exercise or enforce Salix’s foregoing rights.  
(b) Glenmark shall own all right, title and interest in and to any manufacturing technique or process that is not derived from or based on the Specifications, any Salix Information or any Compound Invention that is conceived, discovered, developed or otherwise made, solely by or on behalf of Glenmark as a result of Glenmark’s performance of its obligations hereunder (the “Glenmark Inventions”). Glenmark shall, and shall cause its Affiliates to, promptly disclose in writing to Salix the discovery, development, making, conception or reduction to practice of any Glenmark Invention. Subject to Schedule 1.31, Section III, Glenmark shall, and does hereby, grant to Salix a non-exclusive license to Glenmark Inventions and Glenmark Invention Patents to Exploit the Compound and Products in all fields of use in all countries worldwide, except for (i) those countries included in the General Territory (as such term is defined in the Napo-Glenmark Agreement as such agreement is in effect as of the Effective Date), but only in the field of use relating to HIV/AIDS-related diarrhea and pediatric diarrhea, and (ii) those countries included in the AAID Specific Territory (as such term is defined in the Napo-Glenmark Agreement as such agreement is in effect as of the Effective Date), but only in the field of use relating to adult acute infectious diarrhea.  
(c) Glenmark and Salix shall jointly own all right, title and interest in and to any and all Joint Inventions. Each of Glenmark and Salix shall, and shall cause its respective Affiliates to, promptly disclose in writing to the other Party the discovery, development, making, conception or reduction to practice of any Joint Invention. For those countries in the Territory where a specific license is required to be granted by a Joint Invention owner to the other Joint Invention owner in order for the other Joint Invention owner to practice such Joint Inventions in such countries in the Territory, Glenmark shall, and does hereby, grant to Salix a non-exclusive fully paid up license to Glenmark’s interest in all Joint Inventions to Exploit the Compound and Products in all fields of use in all countries worldwide, except for (i) those countries included in the General Territory, but only in the field of use relating to HIV/AIDS-related diarrhea and pediatric diarrhea, and (ii) those countries included in the AAID Specific Territory, but only in the field of use relating to adult acute infectious diarrhea. For those countries in the Territory where a specific license is required to be granted by a Joint Invention owner to the other Joint Invention owner in order for the other Joint Invention owner to practice such Joint Inventions in such countries in the Territory, Salix shall, and does hereby, grant to Glenmark a non-exclusive fully paid-up license to Salix’s interest in all Joint Inventions to Exploit the Compound and Products in  
 22  
(i) those countries included in the General Territory, but only in the field of use relating to HIV/AIDS-related diarrhea and pediatric diarrhea, and (ii) those countries included in the AAID Specific Territory, but only in the field of use relating to adult acute infectious diarrhea.  
(d) Without limiting the provisions of Article VI, Glenmark shall use the Specifications and Salix Information solely for purposes of performing its supply obligations hereunder.  
4.2 Patent Maintenance and Prosecution.  
(a) Compound Invention Patents.  
(i) [\*] shall have sole discretion and responsibility to prepare, file, prosecute and maintain all patent applications and patents covering Compound Inventions (collectively, the “Compound Invention Patents”, and each, a “Compound Invention Patent”) and shall be responsible for related interference and opposition proceedings; provided, however, that if [\*] plans to abandon any Compound Invention Patent, [\*] shall notify [\*] in writing at least [\*] days in advance of the due date of any payment or other administrative action that is required to maintain such Compound Invention Patent (i.e., an administrative action that involves routine and customary filings, it being understood that interference, opposition, reissue and re-examination proceedings, prosecution or defense of infringement actions, and the like, shall not be considered administrative actions), and Glenmark may elect, upon written notice within such [\*]-day period to [\*], to make such payment or take such administrative action, on behalf of [\*]. Except as expressly permitted in this Section 4.2(a)(i), [\*] shall have no right to prepare, file, prosecute or maintain any Compound Invention Patents.  
(ii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue and re-examination proceedings) Compound Invention Patents as contemplated by Section 4.2(a)(i) shall be borne by the [\*] such filing, prosecution and maintenance.  
(b) Glenmark Invention Patents.  
(i) [\*] shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all patent applications and patents covering Glenmark Inventions (collectively, the “Glenmark Invention Patents”, and each, a “Glenmark Invention Patent”) and shall be responsible for related interference and opposition proceedings; provided, however, that if [\*] plans to abandon any Glenmark Invention Patent, [\*] shall notify [\*] in writing at least [\*] days in advance of the due date of any payment or other administrative action that is required to maintain such Glenmark Invention Patent (i.e., an administrative action that involves routine and customary filings, it being understood that interference, opposition, reissue and re-examination proceedings, prosecution or defense of infringement actions, and the like, shall not be  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 23  
considered administrative actions), and [\*] may elect, upon written notice within such [\*]-day period to [\*], to make such payment or take such administrative action, on behalf of [\*]. Except as expressly permitted in this Section 4.2(b)(i), [\*] shall have no right to prepare, file, prosecute or maintain any Glenmark Invention Patents.  
(ii) If [\*] does not wish to file, prosecute or maintain any Glenmark Invention Patent or maintain or defend such Glenmark Invention Patent in a particular country, it shall notify [\*] in writing and, if [\*] elects to maintain such Glenmark Invention Patent as contemplated by Section 4.2(b)(i), [\*] shall, and shall cause its Affiliates, as applicable, to (A) reasonably cooperate with [\*] in this regard and, (B) upon [\*] request, promptly release or assign to [\*], without compensation, all right, title and interest in and to such invention in such country. In the event of such assignment, [\*] hereby grants to [\*] a non-exclusive, [\*] license under the relevant Glenmark Invention Patent to use for any purpose in the Territory.  
(iii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue and re-examination proceedings) Glenmark Invention Patents as contemplated by Section 4.2(b)(i) and (ii) shall be borne by the [\*] such filing, prosecution and maintenance.  
(c) Joint Invention Patents.  
(i) Salix and Glenmark shall collaborate to determine which Party shall be responsible for preparing, filing, prosecuting and maintaining all patent applications and patents covering Joint Inventions (collectively, the “Joint Invention Patents”, and each, a “Joint Invention Patent”) and for related interference and opposition proceedings on behalf of both Parties based on a good faith determination of the relative contributions of the Parties to the invention(s) claimed or covered by such Joint Invention Patent and the relative level of interest of the Parties in such invention(s). At least [\*] business days prior to the contemplated filing with respect to a Joint Invention Patent, the [\*] for such activities for such Joint Invention Patent shall submit a substantially completed draft of such Joint Invention Patent to the other Party for its review and approval, and shall incorporate any reasonable comments provided by the other Party. If the [\*] does not wish to file, prosecute or maintain any Joint Invention Patent or maintain or defend such Joint Invention Patent in a particular country, it shall notify the other Party in writing and, if the other Party elects to maintain such Joint Invention Patent, such first Party shall, and shall cause its Affiliates, as applicable, to (A) reasonably cooperate with such first Party in this regard and (B) upon such first Party’s request, promptly release or assign to such first Party, without compensation, all right, title and interest in and to such invention in such country (whereupon such Joint Invention Patent shall cease to be a Joint Invention Patent and thereafter shall be deemed to be a [\*] or a Compound Invention Patent, as applicable, for purposes of this Article IV).  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 24  
(ii) Costs and expenses of filing, prosecuting and maintaining (including costs and expenses of patent interference, opposition, reissue and re-examination proceedings) Joint Invention Patents as contemplated by Section 4.2(c)(i) shall be shall be borne by the [\*] such filing, prosecution and maintenance.  
(d) Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in Sections 4.2(a), 4.2(b) and 4.2(c). Each Party shall keep the other Party currently informed of all steps to be taken in the preparation and prosecution of all applications filed by it according to this Section 4.2 and shall furnish such other Party with copies of such applications for Patents, amendments thereto and other related correspondence to and from patent offices, and, to the extent reasonably practicable, permit such other Party an opportunity to offer its comments thereon before making a submission to a patent office which could materially affect the scope or validity of the patent coverage that may result. Such other Party shall offer its comments, if any, promptly.  
(e) With respect to Patents filed in any country other than those countries included in the Glenmark Territory, [\*] shall be responsible for making decisions regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, for such Patents. With respect to Patents filed in any country included in the Glenmark Territory, the Parties shall cooperate in making decisions regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, for such Patents. Notwithstanding the foregoing, the Parties shall coordinate their activities with respect to any patent term extension with respect to all Patents in order to secure the optimal protection for the Product available under Applicable Law.  
4.3 Enforcement of Patents.  
(a) If any Patent is allegedly or actually infringed by any Person in a manner relating to the Product, the Party first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail.  
(b) As between the Parties, [\*] shall have the first right, but not the obligation, to control the prosecution of any infringement described in this Section 4.3(a). [\*] shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If [\*] does not initiate an infringement action within [\*] days (or [\*] days in the case of an action brought under the Xxxxx-Xxxxxx Act or within the timeframe of any other relevant regulatory or statutory framework that may govern) of learning of the infringement, [\*] shall have the right, but not the obligation, to bring such an action solely (i) with respect to any Glenmark Invention Patent or  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 25  
Joint Invention Patent in any country included in the Glenmark Territory and, (ii) subject to the prior written consent of [\*], with respect to any Glenmark Invention Patent or Joint Invention Patent in countries outside the Glenmark Territory; provided that, if the Patent at issue is the only patent protecting the Product, [\*] shall in any event consult with [\*] with respect to any such action and shall obtain [\*]’s written consent prior to taking any steps in respect of such action. [\*] shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.  
(c) In the event that a Party entitled to bring an infringement action does so in accordance with this Section 4.3(a), the other Party shall cooperate fully, including furnishing of a power of attorney, being joined as a party plaintiff or indispensable party in such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. If a Party pursues an action against such alleged infringement, it shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken to preclude such infringement.  
(d) Any costs and expenses relating to any enforcement action commenced pursuant to this Section 4.3 by [\*] shall be borne by [\*]. Any costs and expenses relating to any enforcement action commenced pursuant to this Section 4.3 by [\*] shall be borne by [\*]. Any damages or other amounts collected shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be [\*]; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales or profits with respect to the Product, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to the Product.  
4.4 Third Person Litigation.  
(a) If any Person institutes against Glenmark any action that alleges that the Manufacture of Compound hereunder in accordance with the terms hereof infringes the intellectual property rights held by such Person, then, as between Glenmark and Salix, [\*] shall have the first right, but not the obligation, to contest, and assume direction and control of the defense of, such action, including the right to settle such action; provided that, prior to any such settlement, [\*] provides its written consent (such consent not to be unreasonably withheld, conditioned or delayed). If [\*] determines not to defend against such action, [\*] shall, at its sole cost and expense, have the right but not the obligation to control the defense of such action solely (i) with respect to any [\*] in any country included in the [\*] and, (ii) subject to the prior written consent of [\*], with respect to any [\*] or [\*] in countries outside the [\*]; provided that, if the Patent at issue is the only patent protecting the Product, [\*] shall in any event  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 26  
consult with [\*] with respect to any such action and shall obtain [\*]’s written consent prior to taking any steps in respect of such action. [\*] shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.  
(b) Any costs and expenses relating to any enforcement action commenced pursuant to this Section 4.4 shall be borne by the [\*] the defense of such action. Any damages or other amounts collected shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to control the defense of the action.  
(c) In the event that a Party entitled to defend an infringement action does so in accordance with this Section 4.4, the other Party shall cooperate fully, including providing access to relevant documents and other evidence and making its employees available at reasonable business hours. If a Party pursues the defense of such an infringement action, it shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken to preclude such infringement.  
4.5 Third Party Licenses. If, in the absence of a license from a Person, the Manufacture of the Compound hereunder in accordance with the terms hereof infringes or misappropriates any patent or any intellectual property right of such Person, such that Glenmark or any of its Affiliates cannot Manufacture such Compound without infringing the patent or intellectual property rights of such Person, then [\*] shall have the first right to take the lead on negotiating the terms of each such license; provided that if [\*] does not take such lead, then [\*] may do so; provided further that the negotiating Party shall obtain the written consent of the other Party prior to entering into any such license, such consent not to be unreasonably withheld, conditioned, or delayed. The Parties shall negotiate in good faith an appropriate allocation of any royalties or other payments to be made pursuant to any such license so as to reflect the economic interests of the Parties under this Agreement with respect to the Product.  
ARTICLE V. REPRESENTATIONS AND WARRANTIES; COVENANTS  
5.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:  
(a) Such Party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 27  
terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.  
(b) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.  
(c) The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (i) do not and will not conflict with or violate any requirement of applicable law or any provision of the articles of incorporation, bylaws, limited partnership agreement or other similar documents of such Party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.  
5.2 Additional Warranties and Covenants of Glenmark. Glenmark hereby represents, warrants and covenants to Salix that (a) neither Glenmark nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or any similar law in any country in the Specified Territory or listed on either Excluded List or any similar list in any country in the Specified Territory and (b) neither Glenmark nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or any similar law in any country in the Specified Territory, or who is the subject of a conviction described in such section, or listed on either Excluded List; provided that, in each case ((a) and (b)), with respect to any such similar laws or lists in any country in the Specified Territory other than the United States, Salix has identified for Glenmark with specificity such law or list. Glenmark shall inform Salix in writing immediately if it or, to its knowledge, any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA or any similar law in any country in the Specified Territory or listed on either Excluded List, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or is threatened, relating to the debarment or conviction under Section 306 of the FFDCA or any similar law in any country in the Specified Territory, or listing on either Excluded List, of Glenmark or, to Glenmark’s knowledge, any other Person performing services hereunder; provided that, with respect to any such similar laws or lists in any country in the Specified Territory other than the United States, Salix has identified for Glenmark with specificity such law or list.  
5.3 Disclaimer of Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR  
 28  
IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY.  
ARTICLE VI. CONFIDENTIALITY  
6.1 Confidential Information. Subject to the provisions of Sections 6.2 and 6.3, at all times during the Term and for [\*] years following the expiration or termination of this Agreement, the Receiving Party (a) shall keep completely confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party’s employees, Affiliates, or consultants who have a need to know such information to perform such Party’s obligations hereunder (and who shall be advised of the Receiving Party’s obligations hereunder and who are bound by confidentiality obligations with respect to such Confidential Information no less onerous than those set forth in this Agreement) (collectively, “Recipients”) and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. The Receiving Party shall be jointly and severally liable for any breach by any of its Recipients of the restrictions set forth in this Agreement.  
6.2 Exceptions to Confidentiality. The Receiving Party’s obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:  
(a) that is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of a Receiving Party or its Recipients;  
(b) that is received from a third party without restriction and without breach of any agreement between such third party and the Disclosing Party;  
(c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party; provided, however, that this exception shall not apply with respect to any information or materials regarding the Compound that are provided to Glenmark by Salix under this Agreement;  
(d) that is generally made available to third parties by the Disclosing Party without restriction on disclosure; or  
(e) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 29  
6.3 Disclosure.  
(a) Each Party may disclose Confidential Information to the extent that such disclosure is:  
(i) made in response to a valid order of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in such response to such court or governmental order; or  
(ii) otherwise required by law or regulation, in the opinion of counsel to the Receiving Party.  
(b) Salix may disclose Confidential Information to the extent that such disclosure is made to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.  
6.4 Notification. The Receiving Party shall notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party’s discovery of any loss or compromise of the Disclosing Party’s Confidential Information.  
6.5 Remedies. Each Party agrees that the unauthorized use or disclosure of any information by the Receiving Party in violation of this Agreement will cause severe and irreparable damage to the Disclosing Party. In the event of any violation of this Article V, the Receiving Party agrees that the Disclosing Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, without the necessity of proving irreparable harm or monetary damages, as well as any other relief permitted by Applicable Law. The Receiving Party agrees to waive any requirement that the Disclosing Party post bond as a condition for obtaining any such relief.  
6.6 Use of Names. Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 6.6 shall not prohibit either Party from making any disclosure identifying the other Party that is required by applicable law;  
 30  
provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.  
6.7 Press Releases. Except as expressly provided in Section 6.3, neither Party shall make a press release or other public announcement regarding this Agreement, the terms hereof or the transactions contemplated hereby without the prior written approval of the other Party. Each Party shall provide the other with the proposed text of any such press release or public announcement for review and approval, which approval shall not be unreasonably withheld, conditioned or delayed, as early as possible, but in no event less than four (4) business days in advance of the publication, communication or dissemination thereof; provided, however, that the receiving Party shall be deemed to have approved any such press release or public announcement if it fails to notify the proposing Party in writing of any objections to such press release or public announcement within three (3) business days after receipt by the receiving Party of the text of such public announcement.  
ARTICLE VII. TERM AND TERMINATION  
7.1 Term. This Agreement shall commence as of the Effective Date and, unless earlier terminated in accordance with the terms hereof, shall expire on the tenth (10th) anniversary of the Effective Date, unless extended for additional two (2) year periods, at Salix’s option, upon written notice given by Salix to Glenmark not less than six (6) months prior to the expiration of the then-current term (the “Term”).  
7.2 Termination. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:  
(a) Salix may terminate this Agreement immediately upon notice to Glenmark in the event that Regulatory Authorities cause the withdrawal of any Product from any national market in the Territory.  
(b) Upon the termination of the Napo-Glenmark Agreement, Glenmark may terminate this Agreement upon eighteen (18) months’ prior written notice to Salix.  
(c) This Agreement may be terminated by either Party:  
(i) immediately upon written notice if the other Party shall (a) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) propose a written agreement of composition or extension of its debts, (c) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, (d) propose or be a party to any dissolution or liquidation, (e) make makes an assignment for the benefit of its creditors, or (f) admit in writing its inability generally to pay its debts as they fall due in the general course;  
 31  
(ii) immediately upon written notice in the event of any material breach by the other Party in the performance of any of its obligations herein contained that has not been cured by the defaulting Party within thirty (30) days after receiving written notice thereof from the non-breaching Party;  
(iii) upon at least thirty (30) days’ prior written notice to the other Party in the event that any Person sells, offers for sale, or distributes an unauthorized generic version of the Compound or any Product in any national market in the Territory (such event, an “Other Product Entry”), which notice of termination, if given, must be given within thirty (30) days after the Other Product Entry; or  
(iv) immediately upon written notice in the event that, as a result of an order of government or any other official authority, the continued operation of this Agreement in its entirety or in substantial part is prevented or delayed for an unspecified and indeterminate period.  
7.3 Effect of Expiration or Termination.  
(a) The expiration or earlier termination of this Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such termination, and the provisions of Section 4.1, Articles VI, VIII and IX, and this Section 7.2(c)(i) shall survive the expiration or termination of this Agreement. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available at law or in equity.  
(b) Upon expiration or earlier termination of this Agreement, each Party, at the request of the other, shall return all data, files, records and other materials in its possession or control containing or comprising the other Party’s Confidential Information except that the legal department of such Party may retain one copy for archival purposes.  
(c) Upon expiration or earlier termination of this Agreement, other than pursuant to Section 7.2(b)(i), at Salix’s option and sole cost and expense, Glenmark shall use its commercially reasonable efforts promptly to assist Salix to qualify such Third Party Manufacturer designated by Salix to Manufacture such Compound, and provide, to such Third Party Manufacturer such technical assistance, as Salix may reasonably request and such Third Party Manufacturer may reasonably require in order to Manufacture the Compound provided that the technical assistance is for no more than [\*] (equal to [\*] work hours each). [\*] shall also promptly grant to such Third Party Manufacturer a Third Party Manufacturer License, provided that Salix shall compensate [\*] in the manner set forth in Schedule 2.5(d), subject to all of the limitations set forth in such Schedule including the limitation with respect to the [\*] year duration of such obligations and Schedule 1.31, Section III.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 32  
(d) Subject to Section 7.3(f), upon termination of this Agreement for any reason, (i) Glenmark immediately shall cease all Manufacturing of the Compound pursuant to this Agreement, (ii) all submitted but unfilled Purchase Orders automatically shall be cancelled, and (iii) Glenmark promptly shall return any remaining Salix-Supplied Material to Salix or its designee.  
(e) Subject to Glenmark’s continuing right to make Compound and use the Compound Equipment, in the event of termination of this Agreement by Glenmark pursuant to 7.2(b), Glenmark shall continue to supply Compound to Salix pursuant to the terms of this Agreement for [\*] months following the date of notice of termination; provided that, notwithstanding Section 2.2, Salix shall have the right to submit a revised Forecast promptly after the date Salix receives notice of such termination from Glenmark; provided further that Salix may elect, upon [\*] months’ prior written notice to Glenmark, to extend such period for [\*] periods, and shall have the right, notwithstanding Section 2.2, to submit a revised Forecast together with such notice. Thereafter, upon the mutual written agreement of the Parties, such period may be extended for an additional [\*] months. In addition, if there is no Third Party Manufacturer that has been approved by the FDA and is referenced in Salix’s Regulatory Documentation in respect of the Product that is supplying Compound to Salix as of the date of notice of such termination, then (i) Salix shall use commercially reasonable efforts to qualify a Third Party Manufacturer and (ii) Glenmark shall use commercially reasonable efforts to assist Salix in qualifying a Third Party Manufacturer in accordance with Section 2.22, in each case ((i) and (ii)), within [\*] months of the date of notice of such termination.  
(f) For purposes of clarification, termination of this Agreement does not preclude Glenmark from manufacturing Compound for its own use and the use of its Affiliates and Glenmark may continue to use Compound Equipment so long as Glenmark continues to compensate Salix in accordance with Section 2.8(c); provided that Glenmark shall have the option, in its sole discretion, to purchase the Scale-Up Equipment from Salix at such Scale-Up Equipment’s fair market value as agreed by the Parties. If Glenmark does not exercise its option, (i) Salix shall have the first right to remove the Scale-Up Equipment from the Facility at Salix’s sole cost and expense; and (ii) if Salix does not remove the Scale-Up Equipment from the Facility, Glenmark may have the Scale-Up Equipment removed from the Facility at Salix’s sole cost and expense.  
ARTICLE VIII. INDEMNIFICATION  
8.1 Glenmark Indemnification. Glenmark shall indemnify Salix, its Affiliates and its and their respective directors, officers, employees and agents (the “Salix Indemnified Parties”), and defend and hold each of them harmless, from and against any and all Third Party claims, lawsuits, losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys’ fees and disbursements) (collectively, “Losses”) incurred by any of them in connection with, arising from or occurring as a result of Glenmark’s gross negligence or willful misconduct in the performance of this  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 33  
Agreement, except, in each case, for those Losses for which Salix has an obligation to indemnify the Glenmark Indemnified Parties pursuant to Section 8.2, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.  
8.2 Salix Indemnification. Salix shall indemnify Glenmark, its Affiliates and its and their respective directors, officers, employees and agents (the “Glenmark Indemnified Parties”), and defend and save each of them harmless, from and against any and all Losses incurred by any of them in connection with, arising from or occurring as a result of (a) any Third Party Claim made by any Person that the Manufacture and supply of the Compound in accordance with the terms hereof infringes, misappropriates or otherwise violates the patent, trademark or other intellectual property rights of such Person, (b) any Third Party Claim made by any Person relating to or arising out of death, personal injury, or other product liability, related to the marketing, sale, distribution or use of the Compound or the Product, and (c) the gross negligence or willful misconduct of Salix or its subcontractors or agents, except, in each case, for those Losses for which Glenmark has an obligation to indemnify the Salix Indemnified Parties pursuant to Section 8.1, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.  
8.3 Indemnification Procedure.  
(a) Notice of Claim. The indemnified party (the “Indemnified Party”) shall give the indemnifying Party (the “Indemnifying Party”) prompt written notice (an “Indemnification Claim Notice”) of any Losses or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 8.1 or 8.2, but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.  
(b) Third Party Claims. The obligations of an Indemnifying Party under this Article VIII with respect to Losses arising from claims of any third Person that are subject to indemnification as provided for in Section 8.1 or 8.2 (a “Third Party Claim”) shall be governed by and be contingent upon the following additional terms and conditions:  
(i) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party’s claim for indemnification. Upon assuming  
 34  
the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party, which shall be reasonably acceptable to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Third Party Claim. Subject to Section 8.3(b)(ii), if the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless a Salix Indemnified Party or Glenmark Indemnified Party, as applicable, from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including attorneys’ fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim with respect to such Salix Indemnified Party or Glenmark Indemnified Party, as applicable.  
(ii) Right to Participate in Defense. Without limiting Section 8.3(b)(i), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party’s own expense unless (A) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (B) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 8.3(b)(i) (in which case the Indemnified Party shall control the defense), or (C) the interests of the Indemnified Party and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under applicable law, ethical rules or equitable principles.  
(iii) Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party’s becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 8.3(b)(i), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any  
 35  
Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).  
(iv) Cooperation. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.  
(v) Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a calendar quarter basis in arrears by the Indemnifying Party, without prejudice to the Indemnifying Party’s right to contest the Indemnified Party’s right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.  
8.4 Insurance.  
(a) Salix shall maintain (i) comprehensive general liability insurance written on an occurrence basis with a combined single limit for bodily injury and property damage of not less than [\*] United States Dollars ($[\*]) and (ii) product liability/completed operations coverage with a per claim limit of not less than [\*] United States Dollars ($[\*]) (together, the “Salix Policies”).  
(b) Glenmark shall maintain (i) comprehensive general liability insurance in the amount of [\*] United States Dollars ($[\*]) and (ii) public liability insurance in the amount of [\*] United States Dollars ($[\*]) (collectively, the “Glenmark Policies”).  
(c) The Policies shall (i) be provided by an insurance carrier(s) acceptable to the other Party and (ii) show the other Party as additional named insured and loss payee, as its interests may appear. Certificates of insurance for the Policies shall be furnished to the other Party within ten (10) days after the Effective Date. The Policies shall remain in effect throughout the Term of this Agreement and shall not be canceled or  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 36  
subject to a reduction of coverage or any other modification without the prior written authorization of the other Party.  
8.5 Limitation on Damages.  
(a) EXCEPT WITH RESPECT TO THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF A PARTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION OR LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE.  
(b) EXCEPT FOR EACH PARTY’S RESPECTIVE INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTIONS 8.1 AND 8.2, EACH PARTY’S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE TOTAL FEES PAID BY SALIX TO GLENMARK DURING THE TERM OF THIS AGREEMENT; PROVIDED, HOWEVER, THAT GLENMARK’S LIABILITY FOR RECALLS PURSUANT TO SECTION 2.17 SHALL IN NO EVENT EXCEED THE PURCHASE PRICE RECEIVED BY GLENMARK FOR THE BATCH(ES) GIVING RISE TO SUCH LIABILITY.  
ARTICLE IX. MISCELLANEOUS  
9.1 Notices. All notices, requests and other communications hereunder must be in writing, specifically reference this Agreement in a prominent manner, and be delivered personally, by electronic mail (i.e., E-mail) with delivery receipt requested or by recognized international courier, to the Parties at the following addresses or E-mail addresses:  
If to Salix to:  
Salix Pharmaceuticals, Inc.  
0000 Xxxxxxxxx Xxxx Xxxxx  
Xxxxxxxxxxx, Xxxxx Xxxxxxxx 00000  
Attention: AVP, Pharmaceutical Development and Manufacturing  
E-mail: Xxxxxx.Xxxxxxxx@Xxxxx.xxx  
with copies (which will not constitute notice) to:  
Salix Pharmaceuticals, Inc.  
0000 Xxxxxxxxx Xxxx Xxxxx  
Xxxxxxxxxxx, Xxxxx Xxxxxxxx 00000  
Attention: General Counsel  
E-mail: Xxxx.Xxxxx@Xxxxx.xxx  
and  
 37  
Xxxxxxxxx & Xxxxxxx LLP  
0000 Xxxxxxxxxxxx Xxxxxx, X.X.  
Washington, D. C. 20004  
Attention: Xxxxxx X. Xxxxxxx, Esq.  
E-mail: xxxxxxxx@xxx.xxx  
If to Glenmark to:  
Glenmark Pharmaceuticals Ltd.  
B/2, Xxxxxxxxx Xxxxxxxx  
00, Xxxxxxxxx Xxxxx Xxxx  
Xxxxxx-000 000  
Xxxxx  
Attention: Xxxxx Xxxxxxxx  
E-mail: xxxxx\_xxxxxxxx@xxxxxxxxxxxxxx.xxx  
with a copy (which will not constitute notice) to:  
Glenmark Pharmaceuticals Ltd.  
B/2, Xxxxxxxxx Xxxxxxxx  
00, Xxxxxxxxx Xxxxx Xxxx  
Xxxxxx-000 000  
Xxxxx  
Attention: Xxxxxx Xxxxx  
E-mail: xxxxxx\_xxxxx@xxxxxxxxxxxxxx.xxx  
All such notices, requests and other communications will (a) if delivered personally to the address as provided in this Section, be deemed given upon receipt, (b) if delivered by electronic mail to the E-mail address as provided in this Section 9.1, be deemed given on the next regular business day in the jurisdiction of receipt, and (c) if delivered by courier to the address as provided in this Section 9.1, be deemed given upon receipt. Any Party from time to time may change its address, E-mail address or other information for the purpose of notices to that Party by giving notice specifying such change to the other Party hereto.  
9.2 Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance in whole or in part (other than a failure to pay any amount due hereunder), nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 9.2, where delivery or performance has been affected by a condition beyond such Party’s reasonable control, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority; provided that the Party affected by such a condition shall, within ten (10) days of its occurrence, give notice to the other Party stating the nature of the  
 38  
condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its commercially reasonable efforts to remedy its inability to perform. Notwithstanding the foregoing, in the event the suspension of performance continues for [\*] days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the non-affected Party may terminate this Agreement immediately by written notice to the affected Party.  
9.3 Entire Agreement; Amendment. This Agreement, together with the Schedules and Exhibits attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.  
9.4 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.  
9.5 Successors and Assigns. The terms and provisions hereof shall inure to the benefit of, and be binding upon, Salix, Glenmark and their respective successors and permitted assigns.  
9.6 Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement or the breach, termination or validity thereof (each, a “Dispute”), shall be referred to a senior executive of each Party; provided that each such senior executive is not involved in such Dispute. Such senior executives shall meet for attempted resolution of such Dispute by good faith negotiations within thirty (30) days after such Dispute is referred to such senior management employees. In the event such senior management employees are not able to resolve such Dispute within such thirty (30) day period, then, at the election of either Party, such Dispute shall be decided by litigation. Any such litigation shall be pursued in accordance with Section 9.7; provided that any dispute regarding the validity, scope, enforceability, inventorship or ownership of intellectual property rights shall be submitted by either Party to a court of competent jurisdiction in the country in which such rights apply.  
9.7 Governing Law; Jurisdiction; Venue; Service.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 39  
(a) This Agreement shall be governed and interpreted in accordance with the law of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.  
(b) Subject to Section 9.6, each Party irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of general jurisdiction of the State of New York and the United States District Court for the Southern District of New York sitting in the Borough of Manhattan (collectively, the “Courts”) for any action, suit or proceeding (other than appeals therefrom) concerning any matter arising out of or relating to this Agreement, and agrees not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such Courts.  
(c) Each Party hereto further hereby irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the Courts and hereby further irrevocably and unconditionally agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of such Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party.  
(d) Each Party hereto further agrees that, to the maximum extent permitted by Applicable Law, service of any process, summons, notice or document by registered mail to its address and contact person for notices provided for in Section 9.1 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any of the Courts.  
9.8 Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any person, firm, corporation or other entity, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.  
9.9 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.  
9.10 Assignment. Except as expressly provided herein, neither Party may, without the prior written consent of the other Party, sell, transfer, assign, delegate,  
 40  
pledge, subcontract or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, (a) Salix may, without the prior written consent of Glenmark, assign this Agreement and its rights and obligations hereunder to the purchaser or sublicensee of Salix’s rights in and to the Compound or any Product and (b) either Party may, without the prior written consent of the other Party, assign this Agreement and its rights and obligations hereunder to any of its Affiliates or the purchaser of all or substantially all of its assets or to any successor entity or acquirer in the event of a merger, consolidation or change in control of such Party. Any attempt to assign, transfer, subcontract or delegate any portion of this Agreement in violation of this Section shall be null and void. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Salix or Glenmark, as the case may be. In the event either Party assigns or delegates its rights or obligations to another Person in accordance with the terms hereof, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement and the assignor or transferor shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement from and after the effective date of such assignment. Notwithstanding the foregoing, no such assignment or delegation shall relieve the assignor or transferor of any of its obligations hereunder. Notwithstanding anything to the contrary herein, Glenmark may not subcontract or delegate any of its obligations under this Agreement to any Person without the prior written consent of Salix, which consent shall not be unreasonably withheld, conditioned or delayed.  
9.11 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.  
9.12 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.  
9.13 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer, employee, or joint venture  
 41  
relationship between the Parties. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority.  
9.14 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms “hereof,” “herein,” “hereby” and derivative or similar words refer to this entire Agreement; (d) the terms “Article,” “Section,” “Schedule,” “Exhibit” or “clause” refer to the specified Article, Section, Schedule, Exhibit or clause of this Agreement; (e) the term “or” has, except where otherwise indicated, the inclusive meaning represented by the phrase “and/or”; (f) the term “including” or “includes” means “including without limitation” or “includes without limitation”; and (g) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.  
9.15 Remedies. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable law or otherwise available except as expressly set forth herein.  
9.16 Counterparts; Facsimile Execution. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement (and each amendment, modification and waiver in respect of it) by facsimile or other electronic transmission shall be as effective as delivery of a manually executed original counterpart of each such instrument.  
9.17 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.  
 42  
9.18 Attorneys’ Fees. If a Party is determined to be in breach of this Agreement by a court of competent jurisdiction, such Party shall be responsible to the prevailing Party for any and all reasonable out-of-pocket expenses, including attorneys’ fees and court costs actually incurred by the prevailing Party by reason of its enforcement and protection of its rights under this Agreement, as determined by such court.  
[The remainder of this page has been intentionally left blank.]  
 43  
IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the day and year first above written.  
 SALIX PHARMACEUTICALS, INC. GLENMARK PHARMACEUTICALS LTD  
By: /s/ Xxxxxxx X. Xxxxx By: /s/ Xxxxxx Xxxxx  
Name: Xxxxxxx X. Xxxxx Name: Xxxxxx Xxxxx  
Title: President and CEO Title: Director Finance & Legal  
Napo hereby acknowledges and consents to this Agreement.  
 NAPO PHARMACEUTICALS, INC.  
By: /s/ Xxxx Xxxxx  
Name: Xxxx Xxxxx  
Title: CEO  
Schedule 1.6  
Capped Price  
$ [\*]/gram  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 2  
Schedule 1.17  
Current Capacity  
Glenmark’s Current Capacity is based on a [\*] for purification and fractionation of the Compound.  
The Current Capacity permits up to [\*] cycles per month to be run that produce [\*] kg of Compound per cycle, or [\*] kg per year.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
Schedule 1.31  
Fully-Allocated Manufacturing Costs  
As used in this Agreement, “Fully-Allocated Manufacturing Costs” (“FAMC”) means:  
I. FAMC includes the costs of all direct materials, direct labor and manufacturing overhead consumed, provided or procured by a manufacturing facility in the manufacture of the Compound, together with appropriate: (i) allowances for manufacturing variances, (ii) inventory carrying charges, and (iii) adjustments for inventory valuations as calculated using International Financial Reporting Standards (“IFRS”). To the extent calculation under IFRS is limited due to Glenmark’s current books and records, Glenmark agrees to use Glenmark’s then current standard procedures and methodology for such calculation, consistently applied. Further, Glenmark agrees to use commercially reasonable efforts to apply IFRS calculation as soon as practicable. Costs associated with unused capacity or downtime shall not be included in determining FAMC, and FAMC shall not include [\*] and other [\*] or [\*] or [\*] or [\*]. Also not included in the FAMC costs is the [\*] (defined above).  
For such purposes:  
A. Direct material costs include:  
1. The cost of [\*] (i.e., [\*], etc. to the extent [\*] and [\*] and more appropriately captured by Item I.C.2. (below), [\*] and other [\*] used in the production of a Compound.  
2. [\*] and [\*] (exclusive of [\*] in excess of [\*] for Compound.)  
B. Direct labor costs include:  
1. [\*] and [\*] for [\*].  
C. Manufacturing overhead is limited to costs that can be identified in a practical manner with specific units of production in accordance with IFRS but cannot be included in specific direct material or direct labor costs. Such overhead costs may include:  
1. [\*], including, but not limited to, [\*] (e.g., [\*] and [\*] (e.g., [\*] and [\*] and [\*] and [\*] (excluding [\*]) and [\*] with respect to the Compound at the Facility.  
2. [\*] which reflects on a [\*] in the manufacture of the Compound at the Facility.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
3. [\*], including [\*], including [\*] and [\*] (including [\*] and [\*] relating to [\*] and [\*]), [\*], and other [\*] in connection with the Manufacture of the Compound at the Facility.  
4. [\*] and other [\*] or [\*] to Manufacture the Compound at the Facility.  
D. Allowances for manufacturing variances, including yield variances within GMP tolerances.  
E. Allowances for adjustments to inventory, valuation, including reasonable charges for spoilage, expiration of shelf life and like charges related to the Compound Manufactured at the Facility.  
F. Property and sales taxes on shipment and warehousing related to finished goods.  
II. FAMC does not include:  
A. [\*]  
B. [\*]  
C. [\*]  
C. [\*]  
D. Costs associated with the [\*] and the [\*], including, without limitation, the costs of [\*] and other [\*].  
E. [\*]  
F. [\*]  
G. [\*]  
III. Adjustments for Glenmark Inventions  
In the event that (a) any Glenmark Inventions come into existence during the Term, (b) such Glenmark Inventions result in a reduction of the then-current FAMC, and (c) Salix has the Compound Manufactured using such Glenmark Inventions, then the FAMC shall be increased by an amount equal to [\*] percent ([\*]%) of the amount of any such reduction in FAMC (the “Markup Amount”) if such Manufacture is performed by Glenmark. If such Manufacture is performed by a Third Party Manufacturer pursuant to a Third Party Manufacturer License,  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 2  
then the markup set forth in Section (B) of Schedule 2.5(d) shall be increased by the [\*].  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
Schedule 1.40  
Glenmark Territory  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
Schedule 1.81  
Specifications  
Compound-Related Specifications  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
CPL-Related Specifications  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
Schedule 1.88  
Third Party Manufacturer License  
A Third Party Manufacturer License shall be a non-exclusive license to use the Glenmark Inventions and the Glenmark Information solely for the purpose to Manufacture the Compound for supply to Salix.  
Schedule 2.2(c)  
Full Production Lot Sizes  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
Schedule 2.5(c)  
Fixed Price  
$[\*]/gram  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
Schedule 2.5(d)  
Compensation to Glenmark for Use of  
Third Party Manufacturer  
In the event that Salix uses a Third Party Manufacturer at any time during the Term of this Agreement from the Effective Date until the [\*] anniversary thereof, Salix shall compensate Glenmark for any such use as follows:  
(A) So long as Glenmark is ready, willing and able to supply Salix’s full requirement for Compound, Salix may purchase Compound from a Third Party Manufacturer without any markup so long as Salix purchases no more than [\*] ([\*]%) of its total requirements for Compound from the Third Party Manufacturer;  
(B) If Glenmark is ready, willing and able to supply Salix’s full requirements for Compound and Salix purchases Compound from a Third Party Manufacturer for more than [\*] ([\*]%) of its total requirements for Compound from the Third Party Manufacturer, Salix shall pay Glenmark a markup of [\*] ([\*]%) of the purchase price paid to the Third Party Manufacturer for the quantities in excess of [\*] percent ([\*]%);  
(C) If Glenmark is unable to supply Compound to Salix, Salix may purchase any quantities of Compound from a Third Party Manufacturer such quantities of Compound that Glenmark is unable to supply to Salix without any markup, so long as Glenmark’s inability to supply is not the direct result of Salix’s breach of its obligations under this Agreement or Salix’s willful misconduct. In such event, Glenmark may resume supply of Compound to Salix for at least [\*] percent ([\*]%) of Salix’s full requirements of Compound, if Glenmark provides Salix’s with [\*] months’ prior written notice of its intention to resume supply of Compound from Glenmark for at least [\*] percent ([\*]%) of Salix’s full requirements of Compound. Salix shall resume its relationship with Glenmark in such capacity as soon as practicable; provided that Salix has fulfilled its purchase requirement to its Third Party Manufacturer, which in no event shall be more than [\*] months from receipt of such notice by Salix from Glenmark.  
(D) If Glenmark’s inability to supply is the result of Salix’s breach of its obligations under this Agreement or Glenmark’s willful misconduct, then Salix is obligated to pay a markup in accordance with the terms of Section (B) above.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
 Exhibit A – Page 2 of 2  
Schedule 2.8(c)  
Compound Equipment Usage  
Costs for usage of the Compound Equipment shall be based on depreciation of the Compound Equipment on a pro rata basis over the reasonably estimated life of the Compound Equipment and use of the Compound Equipment in the Manufacture of Compound for the performance of the Glenmark Activities.  
Exhibit A  
Example of Scale-Up Plan  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
CROFELEMER SCALE-UP KEY EQUIPMENT ESTIMATES (EXAMPLE)  
[\*]  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.