Exhibit 10.68  
\*Portions of this document marked [\*] are requested to be treated confidentially.  
EXECUTION COPY  
RIFAXIMIN  
MANUFACTURING AND SUPPLY AGREEMENT  
between  
SALIX PHARMACEUTICALS, INC.  
and  
LUPIN LTD.  
Dated as of September 30, 2009  
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This RIFAXIMIN MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”), dated as of September 30, 2009 (the “Effective Date”), is made by and between Salix Pharmaceuticals, Inc., a California corporation (“Salix”), and Lupin Ltd., a corporation organized under the laws of India (“Lupin”). Salix and Lupin 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 Lupin manufacture and supply the Compound (as defined below) for Salix, and Lupin wishes to manufacture and supply 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 “Adverse Event” means (a) any finding from tests in laboratory animals or in vitro that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity, (b) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use, or occurring following application of a Product to humans, whether expected and whether considered related to or caused by such Product, including such an event or experience as occurs in the course of the use of such Product in professional practice, in a clinical trial, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected therapeutic action of such Product, and (c) those events or experiences that are required to be reported to the Regulatory Authorities under corresponding Applicable Law.  
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 the Regulatory Authorities, that may be in effect from time to time.  
1.5 [\*]  
\* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
1.6 “Calendar Quarter” means each period of three consecutive months commencing on January 1, April 1, July 1, and October 1.  
1.7 “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, 2009, 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.  
1.8 “Capacity” means the capacity of Lupin’s plant, equipment and process to conduct the Manufacturing process and, having due regard for Lupin’s own requirements of Compound and for any commitments that it may have made to supply Compound to other Persons, to supply Compound to Salix in accordance with the terms hereof.  
1.9 “Certificate of Analysis” has the meaning set forth in the Quality Agreement.  
1.10 “Certificate of Compliance” has the meaning set forth in the Quality Agreement.  
1.11 “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.  
1.12 “Compound” means the active pharmaceutical entity rifaximin, which is [\*], and all complexes, mixtures and other combinations, prodrugs, metabolites, enantiomers, polymorphs, salt forms, racemates, and isomers thereof, or any derivatives of any of the foregoing.  
1.13 “Compound Inventions” has the meaning set forth in Section 3.1.  
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 (including by a third 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.  
1.15 “Corporate Names” means such Trademarks and corporate names and logos Controlled (as defined in the License Agreement) by Lupin as Lupin may designate in writing from time to time, together with any variations and derivatives thereof.  
1.16 “Courts” has the meaning set forth in Section 8.7(b).  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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1.17 “Covered Quarter” has the meaning set forth in Section 2.1(b).  
1.18 “Current Capacity” has the meaning set forth in Section 2.9(a).  
1.19 “Disclosing Party” means the Party disclosing Confidential Information.  
1.20 “Dispute” has the meaning set forth in Section 8.6.  
1.21 “Drug Master File” means any drug master file filed with the FDA with respect to the Compound.  
1.22 “Effective Date” has the meaning set forth in the preamble hereto.  
1.23 “Excluded Lists” means the 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 Lupin located at [\*].  
1.26 “FDA” means the United States Food and Drug Administration and any successor agency thereto.  
1.27 “FFDCA” has the meaning set forth in Section 2.6.  
1.28 “Firm Forecast” has the meaning set forth in Section 2.2(b).  
1.29 “Forecast” has the meaning set forth in Section 2.2(b).  
1.30 “GMP” means the current good manufacturing practices applicable from time to time to the Manufacturing of Compound pursuant to Applicable Law.  
1.31 “Indemnification Claim Notice” has the meaning set forth in Section 7.3(a).  
1.32 “Indemnified Party” has the meaning set forth in Section 7.3(a).  
1.33 “Indemnifying Party” has the meaning set forth in Section 7.3(a).  
1.34 “Informational Forecast” has the meaning set forth in Section 2.2(a).  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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1.35 “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.  
1.36 “Joint Invention” means any Invention 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.  
1.37 “Joint Invention Patent” has the meaning set forth in Section 3.2.  
1.38 “Launch Date” means the first date on which Salix anticipates requiring commercial supply of Compound hereunder.  
1.39 “License Agreement” means that certain Development, Commercialization and License Agreement between the Parties of even date herewith.  
1.40 “Losses” has the meaning set forth in Section 7.1.  
1.41 “Lupin” has the meaning set forth in the preamble hereto.  
1.42 “Lupin Indemnified Parties” has the meaning set forth in Section 7.2.  
1.43 “Manufacture” and “Manufacturing” means the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of a pharmaceutical product or compound.  
1.44 “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.  
1.45 “Material(s)” means all ingredients, raw materials, packaging and labeling components, and all other supplies of any kind, required or used in connection with the Manufacturing of the Compound.  
1.46 “Other Product Entry” means the commercial sale or distribution by any Person other than Salix or an Affiliate thereof of an unauthorized generic version of any Product in the Territory (which generic version is not subject to any restraining order or other injunction which would prevent it from being sold or distributed in the Territory).  
1.47 “Party” and “Parties” has the meaning set forth in the preamble hereto.  
1.48 “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  
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organization, including a government or political subdivision, department or agency of a government.  
1.49 “Policies” has the meaning set forth in Section 7.4(a).  
1.50 “Products” means (a) Salix’s XIFAXAN® product as currently marketed by Salix in the Territory, (b) any new immediate release dosage forms thereof that may receive Regulatory Approval in respect of the Territory during the Term and (c) any generic product in respect of any of the foregoing that may be authorized by Salix during the Term.  
1.51 “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 Lupin to Salix and (b) the required delivery dates therefor.  
1.52 “Purchase Price” has the meaning set forth in Section 2.5(a).  
1.53 “Quality Agreement” means the quality assurance agreement to be agreed between the Parties relating to the Manufacture of the Compound in accordance with Section 2.12, as such agreement shall be amended from time to time.  
1.54 “Receiving Party” means the Party receiving Confidential Information.  
1.55 “Recipients” has the meaning set forth in Section 5.1.  
1.56 “Regulatory Approval” means, with respect to any particular country or other jurisdiction, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the Exploitation of a Product in such country or jurisdiction, including, where applicable, (a) approval of a Product in such country or jurisdiction, 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.  
1.57 “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 other jurisdiction.  
1.58 “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, 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 and (b) any minutes or contact logs with respect to any telephone conferences or in-person meetings conducted with any Regulatory Authority relating to the subject matter described in clause (a) of this sentence.  
1.59 “Salix” has the meaning set forth in the preamble hereto.  
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1.60 “Salix Indemnified Parties” has the meaning set forth in Section 7.1.  
1.61 “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 in the Manufacture of the Compound (including information received from a third party).  
1.62 “Salix Purchase Commitment” in respect of a given Calendar Quarter means fifty percent (50%) of Salix’s requirements for Compound in such Calendar Quarter for the manufacture of Products for sale in the Territory.  
1.63 “Scale-Up Plans” has the meaning set forth in Section 2.9(c).  
1.64 “Specifications” means the specifications for the Compound to be reasonably agreed upon between the Parties, as the same may be amended from time to time in accordance with the terms hereof.  
1.65 “Term” has the meaning set forth in Section 6.1.  
1.66 “Territory” means the United States.  
1.67 “Testing Laboratory” has the meaning set forth in Section 2.7(e).  
1.68 “Third Party Claim” has the meaning set forth in Section 7.3(b).  
1.69 “Trademark” shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand xxxx, service xxxx, trade name, brand name, logo or business symbol, whether or not registered.  
1.70 “United States” means the United States of America, its territories and possessions (including Puerto Rico).  
ARTICLE II. MANUFACTURING AND SUPPLY  
2.1 Purchase and Supply Obligations.  
(a) Subject to the terms and conditions hereof, Lupin shall Manufacture and supply to Salix such quantities of Compound as Salix may order in accordance with the terms hereof from time to time during the Term.  
(b) Salix hereby covenants and agrees that, during the Term, it shall purchase from Lupin the Salix Purchase Commitment. Salix shall provide, within thirty (30) days of the end of each Calendar Quarter, a certification that it has purchased its Salix Purchase Commitment for such Calendar Quarter, along with sufficient backup documentation of such fact. Lupin shall have the right to audit Salix’s records to confirm that Salix has purchased the Salix Purchase Commitment, pursuant to Section 8.8. In the  
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event that as of the end of any Calendar Quarter during the Term commencing on or after January 1, 2010 (a “Covered Quarter”), Salix’s purchases of Compound pursuant to this Agreement during such Calendar Quarter are less than the Salix Purchase Commitment in such Calendar Quarter, then Salix shall, within thirty (30) days following the end of such Calendar Quarter, pay to Lupin an amount equal to the product obtained by multiplying (i) the difference between the Salix Purchase Commitment and Salix’s purchases of Compound pursuant to this Agreement during such Calendar Quarter by (ii) the Purchase Price. With respect to the Calendar Quarter ending December 31, 2009, Salix shall, within thirty (30) days following the end of such Calendar Quarter, pay to Lupin an amount equal to (a)(i) Salix’s requirements for Compound in 2009 for the manufacture of Products for sale in the Territory divided by (ii) eight (8) multiplied by (b) the Purchase Price; provided, that Salix may, at its election, make such payment prior to December 31, 2009 based on its reasonable estimate of its requirements for 2009, so long as within thirty (30) days following the end of such Calendar Quarter it makes Lupin whole for any difference between such estimated requirements and Salix’s actual requirements for 2009.  
(c) Lupin shall have the right, pursuant to and in accordance with Section 8.8, to audit Salix’s records to confirm that Salix has made all payments required to be made by it by the provisions of clause (b).  
(d) Notwithstanding anything in this Section 2.1 to the contrary, during the [\*] ([\*])[\*] prior to the Launch Date, Salix may at any time submit Purchase Orders for Compound solely for the purpose of qualifying then-existing Salix Products and Lupin shall use its commercially reasonable efforts to fulfill such orders. Any such Purchase Orders shall be subject to the pricing set forth in Section 2.5 but shall not be subject to the forecasting requirements set forth in Section 2.2.  
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 Lupin a written good faith forecast estimating, on a quarterly basis, the quantities of Compound that Salix expects to purchase from Lupin during such Calendar Year (each, an “Informational Forecast”); provided that in the event that the Launch Date is anticipated to occur in Calendar Year 2009, Salix shall deliver to Lupin the Informational Forecast in respect of Calendar Year 2009 on a date reasonably agreed by the Parties. Each Informational Forecast shall be non-binding and shall be used by Lupin for planning purposes only.  
(b) Commencing with a month that is at least [\*] ([\*]) months prior to the month in which the Launch Date is anticipated to occur, on the fifteenth (15th) day of each month (or, at Salix’s discretion, at any time from the eighth (8th) day of such month up to and including the twenty-second (22nd ) day of such month), Salix shall deliver to Lupin a written good faith forecast estimating the quantities of Compound that Salix  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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expects to purchase from Lupin for each month during the following [\*] ([\*]) months (each, a “Forecast”). The first [\*] ([\*]) months of each Forecast shall be a “Firm Forecast”. Except as provided in clause (c) below, each Forecast shall be non-binding and shall be used by Lupin 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 delivered to Salix during each of the first [\*] ([\*]) 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, such full production lot sizes to be mutually agreed following determination of the Specifications, (ii) shall not be more than [\*] percent ([\*]%) of the quantities specified in the most recent Firm Forecast applicable to such month, and (iii) shall, unless otherwise agreed by Lupin in writing, be consistent with Lupin’s Current Capacity (or any increased capacity available to Lupin as of the Launch Date or as subsequently agreed pursuant to a Scale-Up Plan).  
(d) With respect to each Purchase Order, Salix shall be obligated to purchase, and Lupin shall be obligated to deliver, by the required delivery date set forth therein such quantities of Compound as are set forth therein. In the event that the terms of any Purchase Order are not consistent with or are in addition to the teens of this Agreement, the terms of this Agreement shall prevail.  
(e) Lupin shall deliver the quantities of Compound set forth in each Purchase Order by the required delivery date set forth in such Purchase Order [\*] (as defined in Incoterms 2000) the port of entry designated by Salix; provided, however, that (i) Lupin 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) [\*] 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, Lupin, 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 [\*].  
(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 export of the Compound.  
2.3 Materials.  
(a) Lupin shall maintain an inventory of Materials in sufficient quantities, and shall use commercially reasonable efforts to supply Salix with quantities  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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of Compound that are up to [\*] percent ([\*]%) of the quantities specified in each Firm Forecast.  
(b) Lupin shall be responsible for auditing and qualifying its supplier(s) of Materials and obtaining supplies of Materials in accordance with the Specifications. All Materials shall conform to the applicable specifications or Drug Master File, as further referenced in Regulatory Documentation owned or filed by or on behalf of Salix in respect of any Product.  
2.4 Invoice and Payment. Lupin promptly shall invoice Salix for all quantities of Compound delivered in accordance herewith. Payment with respect to Compound delivered shall be due [\*] ([\*]) days after delivery to Salix of the invoice with respect thereto (which shall be deemed to be delivered as of the date of shipment, if delivered prior to shipment, and shall be sent in electronic form contemporaneously with such delivery); 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 Laboratory 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 that if Salix disputes any portion of an invoice, it shall pay the undisputed portion and shall provide Lupin 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 Lupin 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 (the “Purchase Price”) for all Compound to be delivered hereunder shall be determined as set forth in this Section 2.5.  
(b) Beginning with Salix’s delivery of its first Forecast pursuant to Section 2.2(b) and continuing thereafter, the Purchase Price shall equal [\*] United States Dollars ($[\*]) per kilogram of Compound.  
2.6 Warranty. In connection with each delivery of Compound to Salix hereunder, Lupin 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 in facilities that  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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are in compliance with all Applicable Law at the time of such Manufacture (including applicable 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 for Compound as defined in the specifications set forth in Lupin’s Drug Master File for the Compound as of the Effective Date or, with respect to Compound for which the Specifications have been amended, such period of time reasonably agreed to by the Parties after the date of delivery thereof (or, in either case, such longer period after the date of delivery thereof as may be supported by ongoing stability studies); (f) such Compound has not been adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act, as amended (the “FFDCA”), and similar provisions of other Applicable Law; (g) such Compound may be introduced into interstate commerce pursuant to the FFDCA and similar provisions of other Applicable Law; and (h) neither Lupin nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or listed on either Excluded List.  
2.7 Failure or Inability to Supply Compound.  
(a) In the event that Lupin, 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 warranty set forth in Section 2.6 (whether by reason of force majeure or otherwise), Lupin shall, as promptly as possible, notify Salix thereof (and, in any event, shall use commercially reasonable efforts to provide at least [\*] ([\*]) days’ advance notice thereof to Salix). Promptly thereafter, the Parties shall meet to discuss how Salix shall obtain such full quantity of conforming Compound. Compliance by Lupin with this Section 2.7(a) shall not relieve Lupin of any other obligation or liability under this Agreement, including any obligation or liability under Section 2.7(b), (c), or (d).  
(b) If Lupin 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.  
(c) If Lupin 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, in which event the Purchase Price otherwise payable by Salix with respect to all Compound accepted by Salix under such Purchase Order shall be reduced by [\*] percent ([\*]%).  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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(d) If Lupin 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, in which event the Purchase Price otherwise payable by Salix with respect to all Compound accepted by Salix under such Purchase Order shall be reduced by [\*] percent ([\*]%) or (ii) provide written notice to Lupin of its intention to qualify a third party manufacturer for the Compound, in which event Lupin shall use its commercially reasonable efforts promptly to assist Salix to qualify such third party manufacturer designated by Salix to Manufacture the Compound, and shall promptly grant to such third party manufacturer, on a royalty-free, non-exclusive basis, such licenses, and provide to such third party manufacturer, free of charge, such technical assistance, as such third party manufacturer may require in order to Manufacture the Compound to the then-current Specifications in accordance with the then-current Manufacturing process for the Compound, including full technology transfer of the then-current Manufacturing process for the Compound, in all cases solely for the purposes of Salix’s production of Products.  
(e) In the event that Salix determines, within [\*] ([\*]) days after delivery thereof by Lupin (or within [\*] ([\*]) days after discovery of any nonconformity that could not reasonably have been detected by a customary inspection on delivery), that any Compound supplied by Lupin does not conform to the warranty set forth in Section 2.6, Salix shall give Lupin notice thereof (including a sample of such Compound, if applicable). Lupin shall undertake appropriate evaluation of such sample and shall notify Salix whether it has confirmed such nonconformity within [\*] ([\*]) days after receipt of such notice from Salix. If Lupin notifies Salix that it has not confirmed such nonconformity, the Parties shall submit the dispute to an independent testing laboratory or other appropriate expert mutually acceptable to the Parties (the “Testing Laboratory”) for evaluation. Both Parties shall cooperate with the Testing Laboratory’s reasonable requests for assistance in connection with its evaluation hereunder. The findings of the Testing Laboratory shall be binding on the Parties, absent manifest error. The expenses of the Testing Laboratory shall be borne by Lupin if the testing confirms the nonconformity and otherwise by Salix. If the Testing Laboratory or Lupin confirms that a lot of Compound does not conform to the warranty set forth in Section 2.6, Lupin, at Salix’s option, promptly shall (i) supply Salix with a conforming quantity of Compound at Lupin’s expense or (ii) reimburse Salix for the Purchase Price paid by Salix with respect to such nonconforming Compound if already paid. In addition, Lupin promptly shall reimburse Salix for all costs incurred by Salix with respect to such nonconforming Compound. Salix shall have the right to offset any such costs against any payments owed by Salix to Lupin under this Agreement. Lupin immediately shall notify Salix if at any time it discovers that any Compound delivered hereunder does not conform to the warranty set forth in Section 2.6.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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(f) For purposes of this Section 2.7, delivery of [\*] percent ([\*]%) or more of the Compound ordered pursuant to any Purchase Order shall constitute “full delivery.”  
2.8 Inventory Warehousing. Following delivery by Lupin, Salix agrees to maintain the Compound at a facility that is temperature and humidity controlled. Salix agrees to inspect the facility where the Compound is held or stored, and keep records of such inspection in accordance with Salix’s standard operating procedures, which records may be requested by Lupin for cause.  
2.9 Current Capacity and Scale-Up Plans.  
(a) Lupin represents and warrants to Salix that Lupin’s Capacity as of the Effective Date (based on the specifications for the Compound set forth in Lupin’s Drug Master File as of the Effective Date) is as set forth on Schedule 2.9(a) (the “Current Capacity”).  
(b) Lupin agrees that at all times during the Term it will not, unless otherwise agreed in writing by Salix, allow its Capacity to be less than the Current Capacity (or any increased capacity, to the extent Lupin has determined in its sole discretion to make it available as of the Launch Date, or as subsequently agreed pursuant to any Scale-Up Plans). Without limiting the foregoing sentence, Lupin agrees that it will not at any time during the Term enter into any commitment to sell or otherwise supply Compound (or product containing Compound) to any third party that would cause its Capacity to be less than the Current Capacity (or any increased capacity, to the extent Lupin has determined in its sole discretion to make it available as of the Launch Date, or as subsequently agreed pursuant to any Scale-Up Plans).  
(c) In the event that at any time during the Term Salix contemplates that its annual requirements of the Compound are likely to exceed the Current Capacity (or any increased Capacity as of such date), Salix shall promptly notify Lupin of that fact and the Parties shall thereafter discuss in good faith plans to increase Lupin’s Capacity in respect of the Compound so as to meet Salix’s anticipated needs (as mutually agreed upon in writing, the “Scale-Up Plans”). Lupin agrees to implement any mutually agreed upon Scale-Up Plan as promptly as possible.  
(d) As of [\*] ([\*])[\*] prior to the Launch Date, Lupin shall provide Salix with a certificate that, to the best of its knowledge, it will have sufficient Capacity as of the Launch Date to fulfill its supply obligations hereunder.  
2.10 Costs and Expenses. Except as otherwise explicitly set forth herein, Lupin 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 Materials.  
2.11 Amendment of Specifications.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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(a) Salix may amend, modify or supplement the Specifications, the Manufacturing process, or the test methods for the Compound as determined by Salix, unilaterally and in its sole discretion, to be necessary or appropriate in order to comply with any Regulatory Approval, GMP and all other Applicable Law and compendia. Salix may not amend, modify or supplement the Specifications, the Manufacturing process, or the test methods for the Compound for any other purpose without Lupin’s written consent, not to be unreasonably withheld. Salix promptly shall provide Lupin with appropriate documentation relating to any such changes to the Specifications or Manufacturing process to the extent that such changes affect Lupin’s Manufacturing of the Compound hereunder.  
(b) Lupin shall not 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, not to be unreasonably withheld.  
(c) In the event that any amendment to the Specifications, the Manufacturing process, or the test methods for the Compound adversely affects Lupin’s ability to maintain its Capacity at the Current Capacity (or any increased capacity available to Lupin as of the Launch Date or as subsequently agreed pursuant to a Scale-Up Plan) the Parties shall discuss in good faith a Scale-Up Plan to address such shortfall in Capacity and Lupin shall implement any mutually agreed Scale-Up Plan as promptly as possible.  
(d) [\*] shall reimburse [\*] for reasonable expenses that are actually incurred by [\*] in connection with any material amendment of the Specifications or the Manufacturing process for the Compound required by [\*] pursuant to Section 2.11(a), 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 [\*] or any of its Affiliates; provided, however, that [\*] liability for such reimbursement shall be limited to levels of inventory that are consistent with the most recent Firm Forecast; and further provided, that Salix and Lupin shall engage in good faith discussions regarding the amount of such expenses.  
(e) [\*] shall be solely responsible for any and all increased costs or expenses incurred by it or [\*] as a result of any amendment of the Specifications or the Manufacturing process for the Compound (i) requested by [\*] and consented to in writing by [\*] or (ii) required by [\*] as a result of [\*] failure to Manufacture the Compound in conformity with the warranty set forth in Section 2.6.  
2.12 Quality Agreement. Within [\*] ([\*]) days after the Effective Date, and in any event, prior to any commercial sale of the Compound, Salix and Lupin shall prepare and enter into a reasonable and customary quality assurance agreement that shall set forth the terms and conditions upon which Lupin will conduct its quality activities in connection with this  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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Agreement (the “Quality Agreement”). Each Party shall duly and punctually perform all of its obligations under the Quality Agreement.  
2.13 Quality Control Analyses and Release. Lupin shall be responsible for all quality control analyses of the Compound and all Compound shall be released by Lupin, in each case in accordance with the terms of the Quality Agreement.  
2.14 Maintenance of Facility.  
(a) Except as otherwise approved in writing by Salix, Lupin shall Manufacture the Compound exclusively at the Facility.  
(b) Lupin shall ensure that any and all licenses, registrations, and Regulatory Authority approvals required by Applicable Law to be obtained in connection with the Facility and equipment used in connection with the Manufacture of the Compound by Lupin so as to permit Lupin to Manufacture Compound and supply it to Salix as contemplated hereunder have been obtained and are in all respects current and in full force and effect.  
(c) Lupin shall at all times during the Term 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) Lupin shall maintain in the Facility adequate and segregated holding accommodations for the Compound manufactured for Salix hereunder as and to the extent required by the Specifications, the Regulatory Approvals, GMP and all other Applicable Law.  
(e) Lupin shall only use disposal services or sites that have appropriate environmental permits and are in compliance with Applicable Law.  
2.15 Regulatory Cooperation of Lupin. Lupin shall cooperate with any reasonable requests for assistance from Salix with respect to obtaining and maintaining any and all Regulatory Approvals required in connection with the sourcing of Compound by Salix hereunder and the sale of Products in the Territory, including by:  
(a) [\*] making [\*] employees, consultants and other staff available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning the Compound and Products;  
(b) [\*] disclosing and making available to Salix, in whatever form Salix may reasonably request, all Manufacturing and quality control data, CMC Data and other information related to the Compound and the Manufacturing process therefor as is reasonably necessary or desirable to prepare, file, obtain and maintain any Regulatory  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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Approval required in connection with the sourcing of Compound by Salix hereunder and the sale of Products in the Territory; and  
(c) [\*] (i) preparing, in accordance with Applicable Law, a Drug Master File in respect of the Compound and filing each such Drug Master File with the FDA and those Regulatory Authorities (other than the FDA) designated by Salix, as applicable, and (ii) providing to Salix a copy of the open portion of each such Drug Master File.  
2.16 Inspection by Salix. Lupin agrees that Salix and its agents (so long as such agents have entered into binding confidentiality agreements with Salix providing for obligations no less strict than Salix’s confidentiality obligations to Lupin hereunder) shall have the right, as required by Applicable Law or otherwise [\*] each Calendar Year, or otherwise for cause, upon reasonable prior notice to Lupin and during normal business hours, to inspect the Facility 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 (to the extent they relate to the Compound). Following such audit, Salix shall discuss its observations and conclusions with Lupin and Lupin shall implement such corrective actions as may be reasonably determined by Salix within [\*] ([\*]) days after notification thereof by Salix or such longer period as may be agreed by the Parties.  
2.17 Notification of Regulatory Inspections; Communications. Lupin shall notify Salix by telephone within twenty-four (24) hours, and in writing within two (2) business days, after learning of any proposed visit to, or inspection of, the Facility by any Regulatory Authority and immediately by telephone after learning of any unannounced visit to, or inspection of, the Facility by any Regulatory Authority, in each case relating to the Compound or any equipment or Manufacturing process used in connection with the Manufacture of the Compound. Lupin shall [\*] any report and other written communications received from such Regulatory Authority in connection with such visit or inspection, in each case relating to the Compound or any equipment or Manufacturing process used in connection with the Manufacture of the Compound, within [\*] ([\*]) business days after receipt thereof and shall consult with Salix concerning the response of Lupin to each such communication. Lupin shall [\*] as soon as reasonably practicable. The Parties acknowledge and agree that [\*] has the sole right to determine the contents and form of any communication with, or response to, FDA. Lupin covenants that such communications with, and responses to, FDA shall not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make such communication or response not misleading.  
2.18 Adverse Events. Salix shall promptly notify Lupin of any information that comes to Salix’s attention concerning any Adverse Event, including any serious or unexpected symptoms (e.g. nausea, chest pain), signs (e.g., tachycardia, enlarged liver) or the abnormal results of an investigation (e.g., laboratory findings, electrocardiogram), including any unfavorable side effect, injury, toxicity or sensitivity reaction, or any unexpected incidence, and the severity thereof, associated with the clinical uses, studies, investigations, tests and marketing of the Compound or a Product.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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2.19 Recalls and Withdrawals. Lupin promptly shall reimburse Salix for all costs incurred by Salix in connection with recalls, market withdrawals, and returns and destruction of Product containing any nonconforming Compound (as determined pursuant to Section 2.7(e)) as and to the extent such recalls, market withdrawals, and returns and destruction of Product result from Lupin’s breach of its obligations under this Agreement or negligence or willful misconduct. Salix shall have the right to offset any such costs against any payments owed by Salix to Lupin under this Agreement.  
2.20 Compliance with Applicable Laws. Lupin shall strictly comply, and shall cause each of its Materials suppliers to strictly 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, including those relating to environmental matters, public health, wages, hours and conditions of employment, subcontractor selection, discrimination and occupational health/safety. Without limiting the foregoing, Lupin covenants that neither Lupin nor any of its permitted subcontractors shall utilize child, or any form of forced or involuntary, labor in the Manufacture of the Compound or services under this Agreement. Upon Salix’s request, Lupin shall certify in writing its compliance with this Section 2.20 and shall provide all permits, certificates and licenses that may be required for its performance under this Agreement.  
2.21 Retention of Manufacturing Records and Samples.  
(a) Lupin shall generate (as and to the extent required by Applicable Law), retain and maintain, both during the Term and thereafter:  
(i) all records necessary to comply with GMP and all other Applicable Law relating to the Manufacture of the Compound;  
(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 as Salix reasonably may require in order to ensure compliance by Lupin with the terms of this Agreement and Applicable Law.  
(a) Without prejudice to Lupin’s obligations pursuant to Section 2.21(a), Lupin shall diligently complete the master batch record for the Compound during the Manufacture of such Compound.  
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(b) All materials, samples, records and other items referred to in Sections 2.21(a) and 2.21(b) shall be retained by Lupin for the longer of (i) such period as may be required by GMP and all other Applicable Law and (ii) [\*] ([\*]) years.  
2.22 Exclusive Supply Arrangement in Respect of the Territory.  
(a) To the maximum extent permitted by Applicable Law, except pursuant to [\*], Lupin shall not, and Lupin shall cause its Affiliates not to, distribute, market, promote, offer for sale, sell or otherwise supply the Compound, directly or indirectly, whether alone or in combination with other molecules or compounds, whether as a raw material or as a finished product, and whether at wholesale or retail, to:  
(i) any Person in the Territory other than Salix or its Affiliates for use in humans; or  
(ii) any Person outside the Territory that Lupin or its Affiliates, as applicable, (A) reasonably suspects is likely to directly or indirectly distribute, market, promote, offer for sale, sell or otherwise supply the Compound to any Person in the Territory other than Salix or its Affiliates or assist another Person to do so or (B) knows has directly or indirectly distributed, marketed, promoted, offered for sale, sold or otherwise supplied the Compound to any Person in the Territory other than Salix or its Affiliates for use in humans, or assisted another Person to do so.  
(b) The provisions of Section 2.22(a) shall terminate as of the end of the Term.  
2.23 Shortages. In the event that the amount of Compound which Lupin Manufactures is less than the amount required to meet the requirements of all Persons permitted to be supplied by Lupin after giving effect to the provisions of Section 2.22, the total supply Manufactured by Lupin shall be apportioned first to Salix and its Affiliates, to the extent of their documented requirements during the relevant Manufacturing period, with any remainder to be allocated by Lupin among such Persons as are permitted to be supplied by Lupin after giving effect to the provisions of Section 2.22.  
2.24 Second Source. Salix shall have the right to secure a second source of the Compound, and Lupin shall promptly grant to such third party manufacturer as may be designated by Salix as a second source of the Compound, on a royalty-free, non-exclusive basis, such licenses, and provide to such third party manufacturer, free of charge, such technical assistance, as such third party manufacturer may require in order to Manufacture the Compound, solely for use by Salix in its production of the Products, to the then-current Manufacturing process for the Compound.  
ARTICLE III. INTELLECTUAL PROPERTY  
3.1 Ownership of Inventions.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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(a) Except as otherwise expressly provided in this Article III, each Party shall own all right, title and interest in and to any Inventions that are conceived, discovered, developed or otherwise made exclusively by or on behalf of such Party or its Affiliates, employees or contractors in performing such Party’s obligations hereunder or in respect of such Party’s activities in respect hereof. Salix hereby grants to Lupin a [\*], non-exclusive license to use all such right, title and interest in and to any such Inventions that Salix may develop for the sole purpose of performing Lupin’s obligations hereunder or exercising Lupin’s rights hereunder. Lupin hereby grants to Salix an irrevocable, perpetual, fully paid-up, royalty-free, non-exclusive license in the Territory, with the right to enforce and to grant sublicenses through multiple tiers, to use all such right, title and interest in and to any such Inventions that Lupin may develop relating to the Compound (“Compound Inventions”).  
(b) Salix and Lupin shall jointly own all right, title and interest in and to any Joint Inventions; provided that (i) Lupin shall, and does hereby, grant to Salix an irrevocable, perpetual, fully paid-up, royalty-free, non-exclusive license, with the right to grant sublicenses through multiple tiers, under all of Lupin’s right, title and interest in and to all Joint Inventions to Exploit the Compound and Products, solely for use in the Territory, and (ii) Salix shall, and does hereby, grant to Lupin a worldwide (other than in the Territory), irrevocable, perpetual, [\*], non-exclusive license, with the right to grant sublicenses through multiple tiers, under all of Salix’s right, title and interest in and to all Joint Inventions to Exploit the Compound and Products, solely for use outside the Territory. Each of Salix and Lupin 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.  
3.2 Prosecution of Invention Patents. Salix shall have the first right, but not the obligation, to prepare, file, prosecute and maintain any patent applications and patents covering Joint Inventions and Compound Patents (collectively, the “Invention Patents,” and each, an “Invention Patent”) and shall be responsible for related interference, re-issuance, re-examination and opposition proceedings; provided, however, that if Salix plans to abandon an Invention Patent, Salix shall notify Lupin in writing at least [\*] ([\*]) days in advance of the due date of any payment or other action that is required to prepare, file, prosecute or maintain such Invention Patent, and Lupin may elect, upon written notice within such [\*] ([\*]) day period to Salix, to make such payment or take such action, at Lupin’s expense, and thereafter to become the sole owner of such Invention Patent. In such event, Salix shall cooperate, without additional consideration, to assign and transfer all of its right, title and interest in and to such Invention Patent to Lupin as the sole owner.  
3.3 United States Law. The determination of whether Inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable law in the United States. In the event that United States law does not apply to the conception, discovery, development or making of any Invention hereunder, each Party shall, and does hereby, assign, and shall cause its  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions, as well as any intellectual property rights with respect thereto, as necessary to fully effect ownership as contemplated by Section 3.1.  
3.4 Corporate Names. Lupin shall, and does hereby, grant to Salix a non-exclusive, royalty-free license, with the right to grant sublicenses through multiple tiers, to use such Corporate Names of Lupin or its Affiliates, solely as may be required by Applicable Law, in connection with its sale or documentation of the chain of custody of Products in the Territory.  
ARTICLE IV. REPRESENTATIONS AND WARRANTIES; COVENANTS  
4.1 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 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 in 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.  
(d) Neither such Party nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or listed on either Excluded List.  
(e) Neither such Party 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 who is the subject of a conviction described in such section, or listed on either Excluded List.  
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(f) Each Party will inform the other Party in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA or listed on either Excluded List, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party’s knowledge, is threatened, relating to the debarment or conviction under Section 306 of the FFDCA, or listing on either Excluded List, of such Party or any Person performing services hereunder.  
4.2 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 IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY.  
ARTICLE V. CONFIDENTIALITY  
5.1 Confidential Information. Subject to the provisions of Sections 5.2 and 5.3, 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.  
5.2 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;  
(d) that is generally made available to third parties by the Disclosing Party without restriction on disclosure; or  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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(e) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party.  
5.3 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;  
(ii) made pursuant to Section 2.24; or  
(iii) otherwise required by law or regulation, in the opinion of legal 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.  
(c) To the extent, if any, that a Party concludes in good faith that it is required by applicable laws or regulations to file or register this Agreement or a notification thereof with any governmental authority, including the U.S. Securities and Exchange Commission, such Party may do so, and the other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. In such situation, the filing Party shall request confidential treatment of sensitive provisions of the Agreement, to the extent permitted by Applicable Law and in consultation with the other Party. The Parties shall promptly inform each other as to the activities or inquiries of any such governmental authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.  
5.4 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.  
5.5 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  
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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.  
5.6 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 5.6 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.  
5.7 Press Releases. Except as expressly provided in Section 5.3, 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 [\*] ([\*]) 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 [\*] ([\*]) business days after receipt by the receiving Party of the text of such public announcement.  
ARTICLE VI. TERM AND TERMINATION  
6.1 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 Launch Date, unless extended for additional [\*] ([\*]) year periods, at Salix’s option, upon written notice given by Salix to Lupin not less than [\*] ([\*]) months prior to the expiration of the then-current term (the “Term”).  
6.2 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 Lupin in the event that Regulatory Authorities require or cause the withdrawal of any Product from the Territory.  
(b) Any time after the earlier of (a) an Other Product Entry and (b) the [\*] anniversary of the Effective Date, Salix may terminate this Agreement for any reason or no reason upon not less than [\*] ([\*]) days’ prior written notice to Lupin (which may be provided prior to such [\*] anniversary).  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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(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 [\*] ([\*]) 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;  
(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 (if curable) has not been cured by the defaulting Party within [\*] ([\*]) days after receiving written notice thereof from the nonbreaching Party;  
(iii) 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 prohibited or prevented or delayed for an unspecified and indeterminate period; or  
(iv) as provided in Section 8.2.  
6.3 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 Sections 2.4, 2.6, 2.8, 2.13, 2.18, 2.19, 2.21, Articles III, IV and V, this Article VI, Article VII and Article VIII, 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  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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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 of this Agreement or any earlier termination of this Agreement by Salix pursuant to Section 6.2(c), then, at Salix’s option, Lupin shall, for [\*] from such expiration or termination, use its commercially reasonable efforts promptly to assist Salix to qualify a third party manufacturer designated by Salix to Manufacture Compound to meet Salix’s requirements, in which event Lupin shall use its commercially reasonable efforts promptly to assist Salix to qualify such third party manufacturer to Manufacture Compound, and shall promptly grant to such third party manufacturer, on a royalty-free, non-exclusive basis, such licenses, and provide to such third party manufacturer, free of charge in the event of a termination of this Agreement by Salix pursuant to Section 6.2(c) and at Lupin’s standard time and materials cost in the event of an expiration of this Agreement, such technical assistance, as such third party manufacturer may require in order to Manufacture the Compound to the then-current Specifications in accordance with the then-current Manufacturing process for the Compound, in all cases solely for the purposes of Salix’s production of Products.  
(d) Upon any termination of this Agreement by Salix pursuant to Section 6.2(a) or 6.2(b) or by Lupin pursuant to Section 6.2(c), Salix shall [\*] at the time of such termination. Salix shall in addition [\*] in accordance with this Agreement. Salix shall [\*].  
(e) Except as and to the extent contemplated by clause (d), upon expiration of this Agreement or any earlier termination of this Agreement, Lupin immediately shall cease all Manufacturing of the Compound pursuant to this Agreement.  
(f) Following expiration or termination of this Agreement, Lupin shall provide such reasonable cooperation and support with respect to regulatory matters as Salix may require in order to dispose of previously purchased Compound.  
ARTICLE VII. INDEMNIFICATION  
7.1 Lupin Indemnification. Lupin 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 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 (a) the breach by Lupin of any of its representations or warranties set forth in this Agreement, (b) Lupin’s material breach of this Agreement; (c) Lupin’s negligence or willful misconduct in the performance of this Agreement, (d) the storage, release, or disposal of any hazardous or regulated material or any waste by Lupin, and (e) the enforcement by Salix of its rights under this Section 7.1, except, in each case, for those Losses for which Salix has an obligation to indemnify the Lupin Indemnified Parties pursuant to Section 7.2, as to which  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.  
7.2 Salix Indemnification. Salix shall indemnify Lupin, its Affiliates and its and their respective directors, officers, employees and agents (the “Lupin Indemnified Parties”), and defend and hold 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) the breach by Salix of any of its representations or warranties set forth in this Agreement, (b) Salix’s material breach of this Agreement, (c) 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, (d) 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 Product and caused by the negligence of Salix or its subcontractors or agents and (e) the enforcement by Lupin of its rights under this Section 7.2, except, in each case, for those Losses for which Lupin has an obligation to indemnify the Salix Indemnified Parties pursuant to Section 7.1, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.  
7.3 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 7.1 or 7.2, 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 VII with respect to Losses arising from claims of any third Person that are subject to indemnification as provided for in Section 7.1 or 7.2 (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 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  
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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 clause (ii) below, 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 Lupin 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 reasonable 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 Lupin Indemnified Party, as applicable.  
(ii) Right to Participate in Defense. Without limiting Section 7.3(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 7.3(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 7.3(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 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).  
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(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.  
7.4 Insurance.  
(a) Each Party shall maintain (i) comprehensive general liability insurance 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 ($[\*]) (collectively, the “Policies”). If any Policy is written on a claims-made basis, the retroactive date, if any, shall not be later than the Effective Date of this Agreement. In addition, such coverage shall be continued in full force throughout the Term of this Agreement and for a period of [\*] ([\*]) years thereafter and neither Party’s Policies shall be canceled or subject to a reduction of coverage or any other modification without written notice to the other Party.  
(b) Each Party shall furnish certificates of insurance for its Policies to the other Party within ten (10) days after the Effective Date.  
7.5 Limitation on Damages. EXCEPT WITH RESPECT TO THE [\*] OR INTENTIONAL MISCONDUCT OF A PARTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION OR LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE; PROVIDED, HOWEVER, THAT THIS EXCLUSION IS NOT INTENDED TO, NOR SHALL IT, EXCLUDE DAMAGES OWED TO THIRD PARTIES.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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ARTICLE VIII. MISCELLANEOUS  
8.1 Notices. All notices, requests and other communications hereunder must be in writing, specifically reference this Agreement in a prominent manner, and be delivered personally or by recognized international courier to the Parties at the following addresses:  
If to Salix to:  
Salix Pharmaceuticals, Inc.  
0000 Xxxxxxxxx Xxxx Xxxxx  
Xxxxxxxxxxx, Xxxxx Xxxxxxxx 00000  
Attention: AVP, Pharmaceutical Development and Manufacturing  
with copies (which shall not constitute notice) to:  
Salix Pharmaceuticals, Inc.  
0000 Xxxxxxxxx Xxxx Xxxxx  
Xxxxxxxxxxx, Xxxxx Xxxxxxxx 00000  
Attention: General Counsel  
and  
Xxxxxxxxx & Xxxxxxx LLP  
0000 Xxxxxxxxxxxx Xxxxxx, X.X.  
Xxxxxxxxxx, X.X. 00000  
Attention: Xxxxxx X. Xxxxxxx, Esq.  
If to Lupin to:  
Lupin Limited  
“B” Wing, Fifth Floor  
Xxxxxx Xxxxx Xxxxxxx  
Xxxxxx - 000 000, Xxxxx  
Attention: Managing Director  
with a copy to:  
Lupin Pharmaceuticals, Inc.  
Harborplace Tower  
000 X. Xxxxxxx Xxxxxx, 00xx Xxxxx  
Xxxxxxxxx, XX 00000  
Attention: Xxxxxx Xxxxx  
with a copy (which shall not constitute notice) to:  
 28  
DLA Piper LLP (US)  
The Marbury Building  
0000 Xxxxx Xxxxxx  
Xxxxxxxxx, XX 00000  
Attention: Xxxxxx X. Xxxxxxxx, Esq.  
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, and (b) if delivered by courier to the address as provided in this Section 8.1, be deemed given upon receipt. Any Party from time to time may change its address or other information for the purpose of notices to that Party by giving notice specifying such change to the other Party hereto.  
8.2 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 8.2, 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 [\*] ([\*]) days of its occurrence, give notice to the other Party stating the nature of the 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 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 nonaffected Party may terminate this Agreement immediately by written notice to the affected Party.  
8.3 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.  
8.4 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.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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8.5 Successors and Assigns. The terms and provisions hereof shall inure to the benefit of, and be binding upon, Salix, Lupin and their respective successors and permitted assigns.  
8.6 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 executives. If the Dispute remains unresolved after such thirty (30)-day negotiation 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 8.7; 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.  
8.7 Governing Law; Jurisdiction; Venue; Service.  
(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 8.6, 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 United States registered mail to its address and contact person for notices provided for in  
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Section 8.1 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any of the Courts.  
(e) Lupin hereby designates, appoints and empowers Lupin Pharmaceuticals, Inc., with an office located at Harborplace Tower, 000 X. Xxxxxxx Xxxxxx, 00xx Xxxxx, Xxxxxxxxx, XX 00000, U.S.A., as its designee, appointee and agent to receive, accept and forward for and on its behalf, and it properties, assets and revenues, service of any and all legal process, summons, notices and documents which may be served in any action, suit or proceeding arising out of or relating to this Agreement or any of the transactions or services contemplated hereunder that is brought in the Courts which may be made on any designee, appointee and agent in accordance with legal procedures prescribed in such Courts. If for any reason such designee, appointee and agent hereunder shall not be available to act as such, then Lupin agrees to designate a new designee, appointee or agent in the City of New York on the terms and for the purposes of this paragraph (e). Lupin further hereby consents and agrees to the service of any and all legal process, summons, notices and documents out of any of the Courts in any such action, suit or proceeding by serving a copy thereof upon the agent for service of process referred to in this paragraph (e) (whether or not the appointment of such agent shall for any reason prove to be ineffective or such agent shall accept or acknowledge such service) coupled with mailing of copies thereof in accordance with paragraph (d), above. Lupin agrees that the failure of any such designee, appointee or agent to give any notice of such service to it shall not impair or affect in any way the validity of such service or any judgment rendered in any action or proceeding based thereon.  
8.8 Audit; Late Payments.  
(a) Each Party shall have the right to have an independent certified public accounting film of internationally recognized standing, and reasonably acceptable to the other Party, provided with access by such other Party during normal business hours, and upon reasonable prior written notice, to examine only those records of such other Party (and its Affiliates and Sublicensees) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than [\*] ([\*]) years prior to the auditing Party’s request, the correctness or completeness of any payment made or statement submitted under this Agreement. Such examinations may not (i) be conducted more than once in any [\*] ([\*]) month period (unless a previous audit during such [\*] ([\*]) month period revealed an underpayment with respect to such period or an incorrect statement submitted by the audited Party in respect of such period or the audited Party restates or revises such books and records for such period) or (ii) be repeated for any Calendar Year. Results of such audit shall (i) be (A) limited to information relating to the Compound and Products, (B) made available to both Parties in writing, and (C) subject to Article V and (ii) not reveal any specific information of the audited Party to the auditing Party other than (A) whether the audited Party is in compliance with its payment obligations under this Agreement or whether statements submitted by the audited Party under this Agreement are true and correct, as the case may be, and (B) the amount of any additional payment owed to the auditing Party or excess payment reimbursable to the  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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audited Party or any correction to statements submitted by the audited Party under this Agreement, as the case may be. Except as provided below, the cost of this examination shall be borne by the auditing Party, unless the audit reveals a variance of more than five percent (5%) from the reported amounts, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 8.8(b), if such audit concludes that additional payments were owed or that excess payments were made during such period, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.8(c), or the auditing Party shall reimburse such excess payments, with interest from the date of original payment as provided in Section 8.8(c), within sixty (60) days after the date on which such auditor’s written report is delivered to the Parties.  
(b) In the event of a Dispute of any audit under Section 8.8, Lupin and Salix shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such Dispute within thirty (30) days, the Dispute shall be resolved in accordance with Section 8.6.  
(c) If any payment due to a Party under this Agreement is not paid when due, then the owing Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) equal to the lesser of (a) the prime rate as reported on the first business day of each month such payment is overdue in The Wall Street Journal, Eastern Edition, plus [\*] ([\*]) percentage points, and (b) the maximum rate permitted by Applicable Law. Interest payable under this Section 8.8(c) shall run from the date upon which payment of the relevant principal sum became due through the date of payment thereof in full together with such interest.  
8.9 Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, 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.  
8.10 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.  
8.11 Assignment. Except as expressly provided herein, neither Party may, without the prior written consent of the other Party, sell, transfer, assign, delegate, 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, that (a) Salix may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate or to the purchaser or sublicensee of Salix’s rights in and to the Compound or any  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.  
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Product, (b) Lupin may, without such consent, assign this Agreement and its rights and obligations hereunder to one or more Affiliates, and (c) either Party may, without such consent, assign this Agreement and its rights and obligations hereunder to 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 Lupin, 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. No such assignment or delegation shall relieve the assignor or transferor of any of its obligations hereunder. Notwithstanding the foregoing, Lupin shall have the right, from time to time and without the necessity of providing notice to or obtaining the consent of Salix, to delegate, assign, or subcontract to any Affiliate, certain of Lupin’s rights or responsibilities under this Agreement. In all cases, Lupin shall remain the contract Party under this Agreement and shall remain responsible to Salix for the performance of all such obligations under this Agreement.  
8.12 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.  
8.13 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.  
8.14 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 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.  
8.15 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”  
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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.  
8.16 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.  
8.17 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.  
8.18 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.  
[The remainder of this page has been intentionally left blank.]  
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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement to be effective as of the Effective Date.  
 SALIX PHARMACEUTICALS, INC. LUPIN LTD.  
By:   
/s/ Xxxxxxx X. Xxxxx  
 By:   
/s/ Xxxxxx Xxxxx  
Name:   
Xxxxxxx X. Xxxxx  
 Name:   
Xxxxxx Xxxxx  
Title   
President and CEO  
 Title:   
Group President  
Schedule 2.9(a)  
Current Capacity  
Manufacture and supply in accordance with the terms of this Agreement of not less than [\*] of Compound per Calendar Year.  
 \* Confidential treatment requested; certain information omitted and filed separately with the SEC.