EX-10.2 3 dex102.htm MANUFACTURING AND CLINICAL SUPPLY AGREEMENT  
Exhibit 10.2  
\*\* CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND WILL BE FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A  
CONFIDENTIAL TREATMENT REQUEST.  
Manufacturing and Clinical Supply Agreement  
THIS AGREEMENT is effective as of the 17th day of January, 2006 (“Effective Date”).  
BY AND BETWEEN:  
AUXILIUM PHARMACEUTICALS, INC., a Delaware corporation, with its principal offices located at 00 Xxxxxx Xxxxxx Xxxxxxx, Xxxxxxx, XX 00000 (hereinafter referred to as “CLIENT”)  
AND:  
XXXXXX TECHNOLOGIES, INC., a Delaware corporation, with a place of business located at 00000 Xxxxxxx Xxxxxx, Xxx Xxxxx, XX 00000 (hereinafter referred to as “XXXXXX”);  
WHEREAS CLIENT has formulations and/or know-how related to each Drug Product, as defined below;  
WHEREAS XXXXXX has the expertise and the manufacturing facility suitable for the Production of Drug Product;  
WHEREAS, CLIENT wishes to have XXXXXX Produce Drug Product and XXXXXX wishes to Produce Drug Product for CLIENT;  
NOW, THEREFORE, in consideration of the premises and the undertakings, terms, conditions and covenants set forth below, the parties hereto agree as follows:  
Article 1, DEFINITIONS.  
 1.1 AFFILIATE of a party hereto shall mean any entity that controls or is controlled by such party, or is under common control with such party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable interest for an entity other than a corporation).  
 1.2 BATCH shall mean a specific quantity of a Drug Product comprising a number of units mutually agreed upon between CLIENT and XXXXXX, and that (a) is intended to have uniform character and quality within specified limits, and (b) is produced according to a single manufacturing order during the same cycle of manufacture.  
 1.3 BULK DRUG SUBSTANCE shall mean the active compound, as set forth in the Project Plan, to be supplied by CLIENT for use in Production of Drug Product.  
 XXXXXX CONFIDENTIAL 1  
 1.4 cGMP shall mean current Good Manufacturing Practices as defined in the FDA rules and regulations, 21 CFR Parts 210-211.  
 1.5 CANCELLATION FEES shall mean the fees payable by CLIENT in the event that CLIENT cancels the Production of any Batch of Drug Product set forth in the Project Plan, except in the event of a default by XXXXXX as set forth in Section 3.3.  
 1.6 COMPONENTS shall mean all Components used by XXXXXX in Production of Drug Product under this Agreement. Components are listed in the Project Plan, such Components identified as Components supplied by CLIENT (“CLIENT Supplied Components”) and Components supplied by XXXXXX (“XXXXXX Supplied Components”).  
 1.7 CONFIDENTIAL INFORMATION shall mean all information and data provided by one party to the other party except any portion of such information and data which:  
 (i) is known to the recipient as evidenced by its written records before receipt thereof from the disclosing party;  
 (ii) is disclosed to the recipient by a third person who has the right to make such disclosure;  
 (iii) is or becomes part of the public domain through no fault of the recipient; or  
 (iv) the recipient can reasonably establish is independently developed by recipient without use of the information disclosed by the disclosing party.  
 1.8 XXXXXX SOPs shall mean ALTHEA’s Standard Operating Procedures which shall be deemed reviewed and approved by CLIENT prior to entering into each Project Plan.  
 1.9 DEVELOPMENT shall mean studies, if any, conducted by XXXXXX to develop a process to Produce Drug Product, in accordance with the Specifications and cGMP. Development activities, if any, shall be identified in the Development & Regulatory Plan.  
 1.10 DRUG PRODUCT shall mean each pharmaceutical product set forth in a Project Plan to be Produced by XXXXXX in bulk or finished dosage form for development and/or clinical use only.  
 1.11 FDA shall mean the United States Food and Drug Administration or any successor entity thereto.  
 1.12 FD&C ACT shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.  
 1.13 IND shall mean an Investigational New Drug Exemption Application for Drug Product, as defined in the United States Food and Drug Administration (FDA) rules and regulations, 21 CFR.  
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 1.14 LABELING shall mean all labels and other written, printed, or graphic matter upon: (i) Drug Product or any container, carton, or wrapper utilized with Drug Product or (ii) any written material accompanying Drug Product.  
 1.15 MASTER BATCH RECORD (MBR) shall mean the formal set of instructions for Production of Drug Product. The MBR shall be developed and maintained in ALTHEA’s standard format by XXXXXX, using CLIENT’s master formula and technical support.  
 1.16 PRODUCTION or PRODUCE shall mean the formulation (if any), filling, lyophilization, packaging, inspection, labeling, and testing of Drug Product by XXXXXX.  
 1.17 PRODUCT SPECIFICATION SHEET shall mean a listing of the analytical testing and corresponding Specifications, to be performed on the Bulk Drug Substance and Drug Product in connection with the stability program.  
 1.18 PROJECT PLAN shall mean the document containing the parameters for Production of Drug Product which shall be developed by XXXXXX and agreed to in writing by CLIENT for each Drug Product under this Agreement. Prior to commencing Production of any Drug Product, XXXXXX shall deliver two (2) signed originals of the Project Plan to CLIENT. CLIENT shall sign both originals of the Project Plan and return one (1) fully executed original to XXXXXX. Each fully executed Project Plan shall be incorporated by reference and made a part of this Agreement. XXXXXX shall have no obligation for Production of a Drug Product until CLIENT has executed and returned the Project Plan for such Drug Product to XXXXXX.  
 1.19 PURCHASE PRICE shall mean the amount to be paid by CLIENT as specified in each Project Plan.  
 1.20 REGULATORY AUTHORITY shall mean those agencies or authorities responsible for regulation of Drug Product in the United States and overseas. XXXXXX shall have no obligation to Produce Drug Product in compliance with the requirements of a Regulatory Authority not specified in the applicable Project Plan.  
 1.21 RELEASED EXECUTED BATCH RECORD shall mean the completed Batch record and associated deviation reports, investigation reports, and Certificates of Analysis created for each Batch of Drug Product produced according to the applicable Project Plan.  
 1.22 SPECIFICATIONS shall mean those specifications set forth in Product Specification Sheet and the Master Batch Record for Drug Product, and to the extent that XXXXXX is required to test the Bulk Drug Substance, for the Bulk Drug Substance.  
Article 2, PRODUCTION OF DRUG PRODUCT.  
 2.1 Initiation: Upon execution of this Agreement and the corresponding Project Plan for each Drug Product, XXXXXX shall commence Production of such Drug Product pursuant to the Project Plan.  
 XXXXXX CONFIDENTIAL 3  
 2.2 Documentation: The Master Batch Record shall be reviewed and approved by XXXXXX and by CLIENT prior to commencement of Production. Any material change to an approved Master Batch Record will be reviewed and approved by XXXXXX and by CLIENT prior to said change being implemented. Each Batch of Drug Product shall be Produced by using a copy of the Master Batch Record. Each copy of the Master Batch Record for such Batch of Drug Product shall be assigned a unique batch number. Any deviation from the manufacturing process specified in the Master Batch Record must be documented in the copy of the Master Batch Record for that Batch. XXXXXX shall provide CLIENT with required supporting Development and Production documentation in a form reasonably suitable and sufficient for CLIENT’s submission to the FDA.  
 2.3 Bulk Drug Substance and Components Supply: CLIENT, at its sole cost and expense (including, without limitation, shipping costs), shall supply to XXXXXX, in a timely manner, (a) all Bulk Drug Substance required to satisfy the terms of this Agreement and (b) all other CLIENT Supplied Components, all to be delivered to XXXXXX as set forth in the applicable Project Plan for Production of such Drug Product. Except as may otherwise be set forth specifically in the Project Plan, on receipt of the Bulk Drug Substance and CLIENT Supplied Components as set forth above, ALTHEA’s sole obligation with respect to evaluation of the Bulk Drug Substance and CLIENT Supplied Components shall be to review the accompanying certificate of analysis to confirm that the Bulk Drug Substance and CLIENT Supplied Components (if applicable) conform with the Specifications and component specifications, respectively.  
 2.4 Bulk Drug Substance and Component Delivery Delays: XXXXXX shall have no responsibility for delays in delivery of Drug Product caused by delays in receipt of Bulk Drug Substance or CLIENT Components. Notwithstanding anything in this Agreement to the contrary, in the event that XXXXXX receives the Bulk Drug Substance for Production of Drug Product from CLIENT with less time than requested in the applicable Project Plan prior to the scheduled date of Production of such Drug Product, but within sufficient time to Produce such Drug Product on such scheduled date, as determined in good faith by XXXXXX, XXXXXX shall Produce such Drug Product as per the original schedule and CLIENT shall be responsible for any additional costs incurred by XXXXXX as a result of such situation, such additional costs not to exceed Five Thousand Dollars ($5000.00). Notwithstanding anything in this Agreement to the contrary, in the event that XXXXXX receives the Bulk Drug Substance for Production of Drug Product from CLIENT with less time than requested in the applicable Project Plan prior to the scheduled date of Production of such Drug Product, but without sufficient time to Produce such Drug Product on the scheduled date, as determined in good faith by XXXXXX, XXXXXX shall reschedule Production of such Drug Product and shall charge CLIENT the applicable Cancellation Fee.  
 2.5 Importer of Record: In the event any material or equipment to be supplied by CLIENT, including without limitation CLIENT Supplied Components and Bulk Drug Substance, is imported into the United States for delivery to XXXXXX (“Imported Goods”), CLIENT shall be the “Importer of Record” of such Imported Goods. As the Importer of Record, CLIENT shall be responsible for all aspects of the Imported Goods including, without limitation (a) customs and other regulatory clearance of Imported Goods, (b) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Imported Goods, and (c) keeping all records, documents,  
 XXXXXX CONFIDENTIAL 4  
correspondence and tracking information required by applicable laws, rules and regulations arising out of or in connection with the importation or delivery of the Imported Goods.  
 2.6 Material Safety Data Sheet: CLIENT shall provide XXXXXX a Material Safety Data Sheet for Bulk Drug Substance and for each Drug Product. XXXXXX shall immediately notify CLIENT of any unusual health or environmental occurrence relating to Drug Product, including, but not limited to any claim or complaint by any employee of XXXXXX or any of its Affiliates or third party that the operations of XXXXXX pursuant to this Agreement have resulted in any adverse health or safety effect on an employee or third party. XXXXXX agrees to advise CLIENT immediately of any safety or toxicity problems of which it becomes aware regarding the Drug Product.  
 2.7 Vendor and Supplier Audit and Certification: CLIENT shall certify and audit all Drug Product-related vendors and suppliers, or approve ALTHEA’S selection of vendors and suppliers by way of signing this agreement.  
 2.8 Delivery Terms: XXXXXX shall ship all Drug Product to CLIENT or to CLIENT’s designated consignee. All shipments shall be shipped FOB XXXXXX, by a common carrier designated by CLIENT, at CLIENT’s expense; provided, however, XXXXXX shall be responsible for the loading of the Drug Product on departure and shall bear risk of loss and all costs of such loading. CLIENT shall procure, at its cost, insurance covering damage or loss of Drug Product during shipping. All shipping instructions of CLIENT shall be accompanied by the name and address of the recipient and the shipping date.  
 2.9 Exporter of Record: CLIENT shall be the exporter of record for any Product shipped out of the United States, as CLIENT remains the owner of the Product. CLIENT warrants that all shipments of Product exported from the United States will be made in compliance with all applicable United States export laws and regulations and all applicable import laws and regulations into the country of deportation.  
CLIENT shall be responsible for obtaining and paying for any licenses or other governmental authorization(s) necessary for the exportation from the United States. CLIENT shall select and pay the freight forwarder who shall solely be CLIENT’s agent. CLIENT and its freight forwarder shall be solely responsible for preparing and filing the Shipper’s Export Declaration and any other documentation required for the export.  
 2.10 Foreign Corrupt Practices Act. Each party to this Agreement represents and warrants that it has not paid, and covenants that it will not pay, anything of value to any government employee in connection with the production or resale of the Product.  
 2.11 Deposits and Payment for Drug Product and Development: Promptly upon signing of each Project Plan and receipt of an invoice by XXXXXX, CLIENT shall pay to XXXXXX fifty percent (50%) of the total fees of this agreement. Thereafter XXXXXX will invoice CLIENT monthly, based on the specific services completed during the month. The final invoice for the Drug Product will be issued upon the delivery of released Drug Product to CLIENT by XXXXXX. CLIENT shall pay all invoices within thirty (30) days of the invoice date therefore. Any payment due under this Agreement not received within the times noted above shall bear interest at the lesser of (a) the maximum rate permitted by law, and (b) 1.5% per month on the outstanding balance compounded monthly.  
 XXXXXX CONFIDENTIAL 5  
 2.12 Default in Payment Obligations: In addition to all other remedies available to XXXXXX in the event of a CLIENT default, if CLIENT fails to make payments as required hereunder, XXXXXX may take appropriate measures to assure prompt and full payment, including refuse to Produce any Drug Product until CLIENT’s account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of Drug Product until CLIENT provides assurance of performance reasonably satisfactory to XXXXXX, and/or take other reasonable means as XXXXXX may determine.  
Article 3, TERM AND TERMINATION.  
 3.1 Term: This Agreement shall commence on the date first above written and will continue until the Production activities, as described in the Project Plan, have been completed, unless sooner terminated pursuant to Section 3.2 herein (the “Term”).  
 3.2 Termination: This Agreement may be terminated at any time upon the occurrence of any of the following events:  
 3.2.1 Termination for Breach: Either party may terminate this Agreement upon the breach of any provision of this Agreement by the other party if such breach is not cured by the breaching party within thirty (30) calendar days (or such additional time reasonably necessary to cure such default provided the breaching party has commenced a cure within the thirty (30) day period and is diligently pursuing completion of such cure) after receipt by the breaching party of written notice of such default. At the option of the non-breaching party, such termination may be with respect to the entire Agreement, or only with respect to the Drug Product that is subject to the breach.  
 3.2.2 Termination for Financial Matters: This Agreement may be terminated immediately by either party by giving the other party written notice thereof in the event such other party makes a general assignment for the benefit of its creditors, or proceedings of a case are commenced in any court of competent jurisdiction by or against such party seeking (a) such party’s reorganization, liquidation, dissolution, arrangement or winding up, or the composition or readjustment of its debts, (b) the appointment of a receiver or trustee for or over such party’s property, or (c) similar relief in respect of such party under any law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, and such proceedings shall continue undismissed, or an order with respect to the foregoing shall be entered and continue unstated, for a period of more than sixty (60) days.  
 3.2.3 Termination for Safety/Regulatory Reasons. CLIENT may terminate this Agreement at any time upon written notice to XXXXXX for reasons related to patient safety, efficacy of Drug Product or any request, requirement or advice from the FDA and other regulatory authority.  
 XXXXXX CONFIDENTIAL 6  
 3.3 Payment on Termination: In the event of the termination of this Agreement by CLIENT, CLIENT shall reimburse XXXXXX for (a) all Components ordered according to the Project Plan prior to termination and not cancelable at no cost to XXXXXX, (b) all work-in-process commenced by XXXXXX, (c) all completed testing and (d) all finished Drug Product. In the event of cancellation by CLIENT of the Production of any Batch set forth in a Project Plan or in the event of termination of this Agreement, except for termination in the event of a default by XXXXXX pursuant to Section 3.2.1, CLIENT shall pay the Cancellation Fees as hereinafter set forth: (i) CLIENT is subject to a 20% charge if the Batch is canceled less than nine (9) weeks from the scheduled fill date, (ii) a 30% charge if the Batch is canceled less than six (6) weeks from the scheduled fill date, and (iii) a 50% charge if the Batch is canceled less than three (3) weeks from the scheduled fill date. In addition, CLIENT must compensate XXXXXX for any materials ordered or testing completed. For purposes of the foregoing, one (1) week is equivalent to seven (7) days. Following expiration or termination, XXXXXX shall ship such materials to CLIENT at CLIENT’s cost and per CLIENT’s instructions. CLIENT shall make payment for all expenses described in Section 3.3 thirty (30) days from the invoice date.  
 3.4 Technical Transfer: In the event either Party terminates this Agreement before completion of the Development and Production as described in the Project Plan, XXXXXX shall upon CLIENT’S request provide CLIENT with technology transfer assistance to a third party from XXXXXX personnel skilled in providing the Services to assist in completion of the Development and Production underway. Such technology transfer shall include all technical information necessary for the performance of the Services, including, without limitation, (i) chemical and other scientific data, (ii) processes and analytic methodology used in validation, stability testing and other testing or analysis, and (iii) all other data, and information necessary to continue performance of the services. Any disclosure or use of such technical information by a third party will be subject to appropriate confidentiality and use restrictions. CLIENT will bear the costs associated with such technology transfer if CLIENT terminates this Agreement pursuant to Section 3.2.3 or if XXXXXX terminates the Agreement pursuant to Section 3.2.1 or 3.2.2. XXXXXX will bear the costs associated with such technology transfer if CLIENT terminates the Agreement pursuant to Section 3.2.1 or 3.2.2.  
 3.5 Survival: Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason, except as set forth in Section 12.1, shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any of the provisions of this Agreement. The provisions of Sections 3.3, 3.4 6, 9, 10, 11, 12, 13, 14, and 15 hereof shall survive expiration or termination of this Agreement.  
Article 4, CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE.  
 4.1 Certificates of Analysis: At CLIENT’s cost and expense, XXXXXX shall test, or cause to be tested by third parties, in accordance with the Specifications, each Batch of Drug Product Produced pursuant to this Agreement before delivery to CLIENT. A certificate of analysis for each Batch delivered shall set forth the items tested, Specifications, and test results. XXXXXX shall also indicate on the final page of the Executed Batch Record that all batch Production and control records have been reviewed and approved by the appropriate quality  
 XXXXXX CONFIDENTIAL 7  
control unit. XXXXXX shall send, or cause to be sent, such certificates to CLIENT prior to the shipment of Drug Product (unless Drug Product is shipped under quarantine). CLIENT shall test, or cause to be tested, for final release, each Batch of Drug Product as meeting the Specifications. As required by the FDA (see Section 5.2 below), CLIENT assumes full responsibility for final release of each Batch of Drug Product.  
 4.2 Manufacturing Compliance: XXXXXX shall advise CLIENT immediately if it receives a Notice of Inspection from any regulatory authority or an authorized agent of any regulatory authority visits ALTHEA’s manufacturing facility and makes an inquiry regarding such facility or regarding or affecting ALTHEA’s Production of Drug Product for CLIENT. In addition, XXXXXX shall keep CLIENT informed of the progress of the inspection and provide to CLIENT a copy of any documents produced to the regulatory authority pursuant to such Notice of Inspection unless prohibited from doing so by the relevant regulatory authority.  
 4.3 Reserve Samples: CLIENT shall be responsible for obtaining and maintaining sufficient quantities of Bulk Drug Substance and Drug Product reserve samples pursuant to cGMP.  
 4.4 Annual Quality Review: CLIENT shall be responsible for evaluating, at least annually, the quality standards of Drug Product to determine the need for changes in Specifications, manufacturing processes, and/or controlled documents. CLIENT shall supply XXXXXX a copy of the evaluation and recommendations, if any.  
 4.5 Distribution Records: XXXXXX shall maintain distribution records that contain all of the appropriate information as specified in cGMP.  
 4.6 Customer Complaints: CLIENT, as required by cGMP, shall maintain complaint files. All specific CLIENT Drug Product-related complaints received by XXXXXX shall be forwarded to CLIENT. CLIENT shall be responsible for the review of the complaint to determine the need for an investigation or the need to report to the FDA as required by cGMP. CLIENT shall send to XXXXXX all Drug Product performance or manufacturing-related complaints which require investigation. XXXXXX shall conduct an investigation for each Drug Product performance or manufacturing-related complaint and shall report findings and follow-up of each investigation to CLIENT. CLIENT shall make these complaint files available to XXXXXX in the event they are required during an FDA inspection.  
 4.7 Inspections/Audits: CLIENT, upon prior written notice and during normal business hours, shall have the right to audit, once annually for not more than two (2) days, XXXXXX batch records and the portions of ALTHEA’s facility used for Production of Drug Product. If CLIENT chooses to audit XXXXXX more than one (1) time in a calendar year or for more than two (2) days, CLIENT agrees to reimburse XXXXXX for ALTHEA’s reasonable expenses incurred in hosting the audit. All audited data will be treated as Confidential Information of XXXXXX and CLIENT shall not be permitted to remove or copy data without ALTHEA’s prior consent. In addition, CLIENT’s authorized personnel may visit ALTHEA’s manufacturing facilities at reasonable times and with reasonable frequency during normal business hours and upon reasonable advance written notice to observe the progress of any services being performed under this Agreement.  
 XXXXXX CONFIDENTIAL 8  
 4.8 Regulatory Compliance: Unless otherwise stated, XXXXXX is responsible for compliance with all Federal, State and local laws and regulations (“Regulations”) as they apply generally to Production of pharmaceutical products. CLIENT shall be responsible for compliance with all Regulations as they apply to all other aspects of the Production, use, and sale of Drug Product, which responsibility shall include, without limitation, all contact with the FDA regarding the foregoing.  
Article 5, ACCEPTANCE OF DRUG PRODUCT.  
 5.1 Non-Conforming Drug Product: Within fifteen (15) calendar days from the date of Production of any Batch pursuant to the Project Plan, XXXXXX shall promptly forward to CLIENT, or CLIENT’s designee, samples of such Batch. Within thirty (30) calendar days after receipt by CLIENT of the samples or fifteen (15) calendar days after receipt by CLIENT of the Released Executed Batch Record, whichever is later, CLIENT shall determine whether Drug Product conforms to CLIENT’s Drug Product Specifications, Master Batch Record, ALTHEA’s current SOPs, and the Project Plan (collectively the “Product Requirements”).  
 5.1.1 If (a) any Batch of Drug Product conforms to the Product Requirements, or (b) CLIENT fails to notify XXXXXX within the applicable time period that any Batch of Drug Product does not conform to the Product Requirements, then CLIENT shall be deemed to have accepted the Drug Product and waived its right to revoke acceptance.  
 5.1.2 If CLIENT believes any Batch of Drug Product does not conform to the Product Requirements, it shall notify XXXXXX by telephone, including a detailed explanation of the non-conformity, and shall confirm such notice in writing via overnight delivery to XXXXXX. Upon receipt of such notice, XXXXXX will investigate such alleged non-conformity, and (i) if XXXXXX agrees such Drug Product is non-conforming, deliver to CLIENT a corrective action plan within thirty (30) calendar days after receipt of CLIENT’s written notice of non-conformity, or such additional time as is reasonably required if such investigation or plan requires data from sources other than CLIENT or XXXXXX, or (ii) if XXXXXX disagrees with CLIENT’s determination that the Batch of Drug Product is non-conforming, XXXXXX shall so notify CLIENT by telephone within the thirty (30) calendar day period and confirm such notice in writing by overnight delivery.  
 5.1.3 If the parties dispute whether Batch of Drug Product is conforming or non-conforming, samples of the Batch of Drug Product will be submitted to a mutually acceptable laboratory or consultant for resolution, whose determination of conformity or non-conformity, and the cause thereof if non-conforming, shall be binding upon the parties. CLIENT shall bear the costs of such laboratory or consultant, except as set forth in Section 5.2.  
 5.1.4 Manufacturing deviations and investigations which occur during Production of Drug Product and which do not cause the Production to be non-compliant with cGMP, shall not be deemed to cause such Drug Product to be non-conforming.  
 XXXXXX CONFIDENTIAL 9  
 5.2 Remedies for Non Conforming Product: In the event XXXXXX agrees that the Batch of Drug Product is non-conforming as a result of the negligence, willful misconduct, or breach of this agreement by XXXXXX or the laboratory determines that the shipment of Drug Product is non-conforming as a result of the negligence, willful misconduct, or breach of this Agreement by XXXXXX, then XXXXXX, at CLIENT’S option, and at ALTHEA’S sole cost and expense shall either (i) replace such non-conforming Drug Product within sixty (60) calendar days from receipt of replacement Bulk Drug Substance from CLIENT and reimburse CLIENT for reasonable costs of replacing Bulk Drug Substance, or (ii) refund the Purchase Price of the non-conforming Drug Product and reimburse CLIENT for the reasonable costs of replacing Bulk Drug Substance. XXXXXX will obtain specific insurance coverage in order to reimburse the client for replacing Bulk Drug Substance during the period of performance and the cost of this supplemental insurance shall be at the CLIENT’S expense. In no event will ALTHEA’S liability for the replacement costs of Bulk Drug Substance exceed $[\*\*\*\*\*\*].  
 5.3 Non-conforming Bulk Drug Substance: If Drug Product is rejected by CLIENT, and such Drug Product’s failure to meet the Product Requirements is the result of non-conforming Bulk Drug Substance, then such non-conformity shall be deemed not to be non-conforming solely as a result of the negligence of XXXXXX.  
Article 6, DRUG PRODUCT RECALLS.  
 6.1 Drug Product Recalls: In the event CLIENT shall be required to recall any Drug Product because such Drug Product may violate local, state or federal laws or regulations, the laws or regulations of any applicable foreign government or agency or the Drug Product Specifications, or in the event that CLIENT elects to institute a voluntary recall, CLIENT shall be responsible for coordinating such recall. CLIENT promptly shall notify XXXXXX if any Drug Product is the subject of a recall and provide XXXXXX with a copy of all documents relating to such recall. XXXXXX shall cooperate with CLIENT in connection with any recall, at CLIENT’s expense. CLIENT shall be responsible for all of the costs and expenses of such recall.  
Article 7, FORCE MAJEURE; FAILURE TO SUPPLY.  
 7.1 Force Majeure Events: Failure of either party to perform under this Agreement (except the obligation to make payments) shall not subject such party to any liability to the other if such failure is caused by acts of God, acts of terrorism, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, compliance with any order or regulation of any government entity, or by any cause beyond the reasonable control of the affected party, whether or not foreseeable, provided that written notice of such event is promptly given to the other party.  
 7.2 Failure to Supply: If XXXXXX fails to supply all or any material part of Drug Product ordered by CLIENT, CLIENT may require XXXXXX to supply the undelivered Drug Product or a lesser quantity at a future date agreed upon by XXXXXX and CLIENT. The provisions of this Section 7.2 shall be without prejudice to CLIENT’s rights under Section 3.2 and remedies provided for thereunder.  
 XXXXXX CONFIDENTIAL 10  
Article 8, CHANGES IN PRODUCTION.  
 8.1 Changes to Master Batch Records and Product Specifications: XXXXXX agrees to inform CLIENT within fifteen (15) days of the result of any regulatory development or changes to Drug Product-specific SOPs that materially affect the Production of Drug Product. XXXXXX shall notify CLIENT of and require written approval from CLIENT for changes to Master Batch Records and Drug Product Specifications prior to the Production of subsequent Batches of Drug Product.  
 8.2 Product-Specific Changes: If facility, equipment, process or system changes are required of XXXXXX as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply primarily to the Production and supply of one or more Drug Products, then CLIENT and XXXXXX will review such requirements and agree in writing to such regulatory changes, and CLIENT shall bear 100% of the reasonable costs thereof.  
 8.3 General Changes: If such regulatory changes apply generally to one or more Drug Products as well as to other products Produced by XXXXXX for itself or for third parties, then CLIENT shall pay a pro rata amount of the reasonable cost of such regulatory changes based upon the proportion of time that such facility is dedicated to the Production of Drug Products relative to the Production of such other products.  
Article 9, CONFIDENTIALITY.  
 9.1 Confidentiality: It is contemplated that in the course of the performance of this Agreement each party may, from time to time, disclose Confidential Information to the other. Each party agrees to take all reasonable steps to prevent disclosure of Confidential Information to third parties. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any governmental agency necessary approvals or licenses or to obtain patents with respect to the Drug Product.  
 9.2 Prior Confidentiality Agreement: This Agreement, by reference, incorporates the Confidentiality Agreement signed by CLIENT and XXXXXX on February 9, 2005, and is made a part hereof as though fully set forth herein.  
 9.3 Third Party Disclosure: XXXXXX shall be permitted to disclose Drug Product information to third party developmental and analytical service providers in connection with performance of its obligations hereunder provided such providers shall be subject to confidentiality agreements that would protect CLIENT’S Confidential Information. Either party may disclose Confidential Information of the disclosing party to those Affiliates, agents and consultants who need to know such information to accomplish the purposes of this Agreement (collectively, “Permitted Recipients”); provided such Permitted Recipients are bound to maintain such Confidential Information in confidence.  
 XXXXXX CONFIDENTIAL 11  
 9.4 Litigation and Governmental Disclosure: Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party’s Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.  
 9.5 Limitation of Disclosure: The parties agree that, except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission, and except as may be authorized in Section 9.4, no information concerning this Agreement and the transactions contemplated herein shall be made public by either party without the prior written consent of the other.  
 9.6 Publicity and SEC Filings. The parties agree that the public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the parties. The failure of a party to return a draft of a press release with its proposed amendments or modifications to such press release to the other party within five (5) days of such party’s receipt of such press release shall be deemed as such party’s approval of such press release as received by such party. Each party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either party included in any such disclosure.  
 9.7 Duration of Confidentiality: All obligations of confidentiality and non-use imposed upon the parties under this Agreement shall expire ten (10) years after the expiration or earlier termination of this Agreement; provided, however, that Confidential Information which constitutes the trade secrets of a party shall be kept confidential indefinitely, subject to the limitations set forth in Sections 9.4 through 9.5.  
Article 10, INVENTIONS.  
 10.1 If at any time or times as a result of performing the Services pursuant to this Agreement, XXXXXX shall (either alone or with others), make, conceive, create, discover, invent or reduce to practice any invention, modification, discovery, design, development, improvement, process, software program, work of authorship, documentation, formula or data (collectively, “Developments”), whether or not patentable or registrable under any patent, copyright, trademark or similar statutes or subject to analogous protection (collectively, “Legal Protection”) that (a) specifically relate to ALTHEA’s development or production support of CLIENT’s projects (including, without limitation, any of the products or services being or to be developed, manufactured or sold by CLIENT), (b) result from the performance of the  
 XXXXXX CONFIDENTIAL 12  
Services, (c) result from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by CLIENT, or (d) result from or are based on Confidential Information of CLIENT, such Developments, and any rights that XXXXXX may have or acquire therein in any country throughout the world, and their resulting benefits (collectively, “Rights”) are and shall immediately become the sole and absolute property of CLIENT, as “work made for hire” or otherwise.  
 10.2 XXXXXX hereby assigns to CLIENT, without further compensation at any time, all of ALTHEA’s Rights with respect to the Developments. To ensure CLIENT’s ownership of the Developments, XXXXXX shall promptly:  
 (a) Disclose each Development to CLIENT (or any persons designated by it), and without disclosing the same to others, communicate to CLIENT all available information relating to the Developments (with all necessary plans and models); and  
 (b) Whether during or after the termination of this Agreement, at the reasonable request and cost of CLIENT, sign, execute, make and do all such deeds, documents, acts and things as AUXILIUM and its duly authorized agents may reasonably require to (i) apply for, obtain, register, vest, renew and restore, in the name of AUXILIUM alone (unless AUXILIUM otherwise directs), any Rights with respect to the Developments under Legal Protection in any country throughout the world; and (ii) enforce and defend at the CLIENT’S expense any judicial, opposition or other proceedings, petitions or applications in respect of such Legal Protection relating to a Development, or the revocation thereof.  
 10.3 CLIENT grants to XXXXXX a royalty free non-exclusive worldwide license to use any Developments and other intellectual property rights of CLIENT solely to enable XXXXXX to perform the Services.  
 10.4 Nothing in this Agreement shall affect any intellectual property rights owned by and/or licensed to XXXXXX as at the date of this Agreement or any intellectual property rights which XXXXXX may subsequently develop, acquire, own and/or have licensed to it which arise outside of and independently of the provision of Services.  
Article 11, REPRESENTATIONS AND WARRANTIES.  
 11.1 Mutual Representations: Each party hereby represents and warrants to the other party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.  
 11.2 XXXXXX Warranties: XXXXXX represents and warrants that services it performs in the Production of Drug Product shall be in accordance with all applicable laws and regulations, including, without limitation, the FD&C Act and cGMP and the standards and practices that  
 XXXXXX CONFIDENTIAL 13  
are generally accepted in the industry and exercised by other persons engaged in performing similar services. XXXXXX represents and warrants that it has obtained (or will obtain prior to Producing Drug Product), and will remain in compliance with during the term of this Agreement, all permits, licenses and other authorizations (the “Permits”) which are required under federal, state and local laws, rules and regulations applicable to the Production only of Drug Product as specified in the Project Plan; provided, however, XXXXXX shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of Bulk Drug Substance or Drug Product or with respect to the Labeling of Drug Product. XXXXXX makes no representation or warranty with respect to the sale, marketing, distribution or use of the Bulk Drug Substance or as to printed materials supplied by CLIENT or its consignee.  
XXXXXX further represents and warrants that it is not now and has never been (i) a corporation, partnership, or association that has been debarred by the FDA under 21 U.S.C. §335a (a) or (b), or by any other regulatory agency (a “Debarred Entity”), from submitting or assisting in the submission of an abbreviated new drug application, or (ii) an employer, employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity.  
XXXXXX further represents and warrants that it has not been convicted of or pled guilty or no contest to a crime or been sanctioned by a federal or state law enforcement, regulatory, or licensing agency.  
XXXXXX further represents and warrants that it has no knowledge of any circumstances which may affect the accuracy of the forgoing representations, and that it will immediately notify CLIENT in the event of any such debarment, conviction, threat or indictment occurring during the term of this Agreement.  
 11.3 Disclaimer of Warranties: Except for those warranties set forth in Sections 11.1 and 11.2 of this Agreement, XXXXXX makes no warranties, written, oral, express or implied, with respect to Drug Product or the Development and Production of Drug Product. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY XXXXXX. NO WARRANTIES OF XXXXXX MAY BE CHANGED BY ANY REPRESENTATIVES OF XXXXXX. CLIENT accepts Drug Product subject to the terms hereof.  
 11.4 CLIENT Warranties: CLIENT warrants that (a) it has the right to give XXXXXX any information provided by CLIENT hereunder, and that XXXXXX has the right to use such information for the Production of Drug Product, and (b) CLIENT has no knowledge of any (i) patents or other intellectual rights that would be infringed by ALTHEA’s Production of Drug Product under this Agreement, or (ii) proprietary rights of third parties which would be violated by ALTHEA’s performance hereunder. CLIENT further warrants that the Bulk Drug Substance provided to XXXXXX hereunder (1) conforms to the Bulk Drug Substance Specifications and (2) is not adulterated or misbranded within the meaning of the FD&C Act.  
 XXXXXX CONFIDENTIAL 14  
Article 12, LIMITATION OF LIABILITY AND WAIVER OF SUBROGATION.  
 12.1 Limitation of Liability: Except as is otherwise set forth in Section 5, ALTHEA’s liability to CLIENT for any breach of this Agreement is limited to the value of the contract, as reflected on the applicable Project Plan. Under no circumstances shall XXXXXX be liable for loss of use or profits or other collateral, special, consequential or other damages, losses, or expenses, including but not limited to the cost of cover (except as is otherwise set forth in Section 5) or the cost of a recall in connection with, or by reason of the Production and delivery of Drug Product under this Agreement whether such claims are founded in tort or contract. The foregoing constitutes the sole and exclusive remedy of CLIENT and the sole and exclusive liability of XXXXXX. All claims by CLIENT for breach or default under this Agreement shall be brought within one (1) year after the cause of action accrued or shall be deemed waived.  
 12.2 Waiver of Subrogation: All XXXXXX Supplied Components and equipment used by XXXXXX in the Production of Drug Product (collectively, “XXXXXX Property”) shall at all times remain the property of XXXXXX and XXXXXX assumes risk of loss for such property until delivery of Drug Product to a common carrier as specified under Section 2.8. XXXXXX hereby waives any and all rights of recovery against CLIENT and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to XXXXXX Property to the extent the loss or damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement). CLIENT assumes all risk of loss for all CLIENT Supplied Components, all Bulk Drug Substance supplied by CLIENT, and all Drug Product (collectively, “CLIENT Property”), unless the loss or damage occurs through no fault of CLIENT, as the result of hazard, accident or the negligence or willful malfeasance of XXXXXX, while such CLIENT Property is in the possession and control of XXXXXX. CLIENT hereby waives any and all rights of recovery against XXXXXX and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to the CLIENT Property to the extent the loss or damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement).  
Article 13, INDEMNIFICATION.  
 13.1 CLIENT Indemnification: CLIENT shall indemnify, defend and hold harmless XXXXXX and its Affiliates, and any of their respective directors, officers, employees, subcontractors and agents (collectively the “XXXXXX Indemnitees”) from and against any and all liabilities, obligations, penalties, claims, judgments, demands, actions, disbursements of any kind and nature, suits, losses, damages, costs and expenses (including, without limitation, reasonable attorney’s fees) arising out of or in connection with property damage or personal injury (including without limitation death) of third parties (collectively “Claims”) in connection with (a) CLIENT’s storage, promotion, labeling, marketing, distribution, use or sale of Bulk Drug Substance or Drug Product, (b) CLIENT’s negligence or willful misconduct, (c) CLIENT’s breach of this Agreement, or (d) any claim that the use, sale, Production, marketing or distribution of Bulk Drug Substance or Drug Product by XXXXXX or CLIENT violates the patent, trademark, copyright or other proprietary rights of any third party, except to the extent any of the foregoing (a) or (d) is caused by the negligence or willful misconduct of the Indemnified Parties or by the breach by XXXXXX of its obligations under this Agreement.  
 XXXXXX CONFIDENTIAL 15  
 13.2 XXXXXX Indemnification: XXXXXX shall indemnify, defend and hold harmless CLIENT and its Affiliates and any of their respective directors, officers, employees, subcontractors and agents (collectively the “CLIENT Indemnitees”) from and against any and all Claims arising out of the XXXXXX Indemnitees’ negligence, willful misconduct or breach of their obligations under this Agreement.  
 13.3 Indemnitee Obligations: A party (the “Indemnitee”) which intends to claim indemnification under this Article 13 shall promptly notify the other party (the “Indemnitor”) in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees, subcontractors, or agents, intend to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee shall permit, and shall cause its Affiliates, and their respective directors, officers, employees, subcontractors and agents to permit, the Indemnitor, at its discretion, to settle any such action, claim or other matter, and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the Indemnitee’s rights hereunder, or impose any obligations on the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee’s prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, which shall not be unreasonably withheld or delayed. The Indemnitee, its Affiliates, and their respective directors, officers, employees, subcontractors and agents shall fully cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Article 13. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.  
 13.4 Injunction: In the event that the Production or sale of a Drug Product is enjoined due to alleged infringement by either party of the proprietary rights of a third party, such action shall be deemed a breach of this Agreement by CLIENT and subject to the terms of Article 3.  
Article 14, INSURANCE.  
 14.1 CLIENT Insurance: CLIENT shall procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of Drug Product, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the “CLIENT Insurance”) of at least two million dollars ($2,000,000) combined single limit and shall be with an insurance carrier reasonably acceptable to XXXXXX. XXXXXX shall be named as an additional insured on the CLIENT Insurance and CLIENT promptly shall deliver a certificate of CLIENT Insurance and endorsement of additional insured to XXXXXX evidencing such coverage. If CLIENT fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement XXXXXX is notified of the cancellation or lapse of the CLIENT Insurance, and CLIENT fails to rectify the same within ten (10) calendar days after notice from XXXXXX, in addition to all other remedies available to XXXXXX hereunder, XXXXXX, at its option,  
 XXXXXX CONFIDENTIAL 16  
may obtain the CLIENT Insurance and CLIENT promptly shall reimburse XXXXXX for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of CLIENT.  
 14.2 XXXXXX Insurance: XXXXXX shall procure and maintain the following insurance:(a) during the Term of this Agreement and for a period of one (1) year beyond the expiration date of Drug Product, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage of at least two million dollars ($2,000,000) combined single limit and (b) insurance of at least $[\*\*\*\*\*\*] to cover the loss or destruction of CLIENT Property resulting from hazard, accident, or the negligence or willful malfeasance of XXXXXX while CLIENT PROPERTY is within ALTHEA’s possession and control (the “XXXXXX Insurance”). The XXXXXX Insurance shall be with an insurance carrier reasonably acceptable to CLIENT. CLIENT shall be named as an additional insured on the XXXXXX Insurance and XXXXXX promptly shall deliver a certificate of XXXXXX Insurance and endorsement of additional insured to CLIENT evidencing such coverage. If XXXXXX fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement CLIENT is notified of the cancellation or lapse of the XXXXXX Insurance, and XXXXXX fails to rectify the same within ten (10) calendar days after notice from CLIENT, in addition to all other remedies available to CLIENT hereunder, CLIENT, at its option, may obtain the XXXXXX Insurance and XXXXXX promptly shall reimburse CLIENT for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of XXXXXX.  
Article 15, GENERAL PROVISIONS.  
 15.1 Notices: All notices hereunder shall be delivered by facsimile (confirmed by overnight delivery), or by overnight delivery with a reputable overnight delivery service, to the following address of the respective parties:  
 If to CLIENT: Auxilium Pharmaceuticals, Inc.  
 00 Xxxxxx Xxxxxx Xxxxxxx  
 Xxxxxxx, XX 00000  
 Attn: General Counsel  
 Telephone: (000) 000-0000  
 Facsimile: (000) 000-0000  
If to XXXXXX: Xxxxxx Technologies, Inc.  
 00000 Xxxxxxx Xxxxxx  
 Xxx Xxxxx, XX 00000  
 Attn: W. Xxxx Xxxxx  
 Executive Vice President and Chief Business Officer  
 Telephone: (000) 000-0000  
 Facsimile: (000) 000-0000  
 XXXXXX CONFIDENTIAL 17  
For specific inquiries, the following XXXXXX responsible parties may be contacted directly:  
 Project Manager Xxxx Xxxxxxx  
Quality Control and   
Quality Assurance Manager Xxx Xxxxx  
Materials Manager Xxxxxxx Xxxxxxx  
Accounting Manager Xxxxxx Xxxxxx  
For specific inquiries, the following CLIENT responsible parties may be contacted directly:  
 Project Manager Xxxx Xxxxxxxx  
Quality Control and   
Quality Assurance Manager Xxxx Del Tito  
Materials Manager Xxx Xxxxx  
Accounting Contact Xxxx Xxxxxx  
Notices shall be effective on the day following the date of transmission if sent by facsimile, and on the second business day following the date of delivery to the overnight delivery service if sent by overnight delivery. A party may change its address listed above by notice to the other party given in accordance with this section.  
 15.2 Entire Agreement; Amendment: The parties hereto acknowledge that this Agreement sets forth the entire agreement and understanding of the parties and supercedes all prior written or oral agreements or understandings with respect to the subject matter hereof. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by an authorized agent or representative of both parties hereto. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.  
 15.3 Waiver: None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is agreed to, in writing, by authorized agents of both parties. The failure of a party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any rights of any party hereto.  
 15.4 Obligations to Third Parties: Each party warrants and represents that this Agreement is not inconsistent with any contractual obligations, expressed or implied, undertaken with any third party.  
 15.5 Assignment: This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the parties and may not be assigned or transferred by either party without the prior written consent of the other, which consent will not be unreasonably withheld or delayed, except that no consent shall be required in the case of a transfer to a wholly-owned subsidiary or transaction involving the merger, consolidation or sale of substantially all of the assets of the party seeking such assignment or transfer and  
 XXXXXX CONFIDENTIAL 18  
such transaction relates to the business covered by this Agreement and the resulting entity assumes all the obligations under this Agreement. XXXXXX may, without such consent, assign this Agreement to an Affiliate of XXXXXX, provided that the assignee assumes all obligations of XXXXXX under this Agreement. No assignment shall relieve any party of responsibility for the performance of its obligations hereunder.  
 15.6 Successors and Assigns: This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.  
 15.7 Taxes: CLIENT shall pay all national, state, municipal or other sales, use excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the sale of Drug Product to CLIENT pursuant to this Agreement or the sale or distribution of Drug Product by CLIENT (or at CLIENT’s sole expense, defend against the imposition of such taxes and expenses). XXXXXX shall notify CLIENT of any such taxes that any governmental authority is seeking to collect from XXXXXX, and CLIENT may assume the defense thereof in ALTHEA’s name, if necessary, and XXXXXX agrees to fully cooperate in such defense to the extent of the capacity of XXXXXX, at CLIENT’s expense. XXXXXX shall pay all national, state, municipal or other taxes on the income resulting from the sale by XXXXXX of the Drug Product to CLIENT under this Agreement, including but not limited to, gross income, adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.  
 15.8 Independent Contractor: XXXXXX shall act as an independent contractor for CLIENT in providing the services required hereunder and shall not be considered an agent of, or joint venturer with, CLIENT. Unless otherwise provided herein to the contrary, XXXXXX shall furnish all expertise, labor, supervision, machining and equipment necessary for performance hereunder and shall obtain and maintain all building and other permits and licenses required by public authorities.  
 15.9 Governing Law: This Agreement is being delivered and executed in the State of California. In any action brought regarding the validity, construction and enforcement of this Agreement, it shall be governed in all respects by the laws of the State of California, without regard to the principals of conflicts of laws. The courts of the States of California and Delaware shall have personal jurisdiction over the parties hereto in all matters arising hereunder, and venue for such suit(s) will be in a California or Delaware state or federal court.  
 15.10 Severability: In the event that any term or provision of this Agreement shall violate any applicable statute, ordinance, or rule of law in any jurisdiction in which it is used, or otherwise be unenforceable, such provision shall be ineffective to the extent of such violation without invalidating any other provision hereof.  
 15.11 Headings, Interpretation: The headings used in this Agreement are for convenience only and are not part of this Agreement.  
 XXXXXX CONFIDENTIAL 19  
IN WITNESS WHEREOF, the parties hereto have each caused this Drug Product Development and Clinical Supply Agreement to be executed by their duly-authorized representatives as of the Effective Date above written.  
 AUXILIUM PHARMACEUTICALS, INC. XXXXXX TECHNOLOGIES, INC  
By:   
/s/ Xxxxx Xxxxxxx  
 By:   
/s/ W. Xxxx Xxxxx  
Name: Xxxxx Xxxxxxx Name: W. Xxxx Xxxxx  
Title: Executive Vice President Title: Executive Vice President and CBO  
 XXXXXX CONFIDENTIAL 20  
Project Plan for Aseptic Filling  
and Lyophilization  
Prepared for:  
Xxxx Xxxxxxxx  
Auxilium Pharmaceuticals, Inc.  
00 Xxxxxx Xxxxxx Xxxxxxx  
Xxxxxxx, XX 00000  
Prepared by:  
Xxxxxx Technologies  
00000 Xxxxxxx Xxxxxx  
Xxx Xxxxx, XX 00000  
000-000-0000  
000-000-0000 (fax)  
 TABLE OF CONTENTS  
 1. Outline of Deliverables 1  
2. Pricing Summary 2  
3. Timing 4  
4. Sample Specifications 6  
5. Payment Schedule 9  
6. Authorizations 10  
XXXXXX CONFIDENTIAL  
1. Outline of Deliverables and Proposed Timeline  
A. Deliverables to Xxxxxx from Auxilium required for Initiation  
 1. Signed contract (insert date)  
 2. All API and Raw materials no later than 3 weeks prior to fill.  
B. Deliverables to Auxilium  
 1. Completed Batch Records  
 2. Satisfactory and timely closeout of any deviations, OOS or other non-conformance investigations  
 3. Completed Certificate of Analysis including all tests results  
 4. Final Filled Product Shipped to Auxilium  
 XXXXXX CONFIDENTIAL 1  
2. Pricing Summary  
A. Pricing Summary for development batch, cGMP  
 Service Description  
 Units Unit Price Total Price  
Custom fill and lyophilization of Auxilium’s AA4500 product (Development batch) [\*\*\*] vials $[\*\*\*\*\*\*\*] $[\*\*\*\*\*\*]  
Includes:  
 • Dilution with lactose  
 • Sterile filtration  
 • Pre-filtration bioburden  
 • In-process UV  
 • [\*\*\*\*\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*\*\*\*\*]  
 • Visual Inspection throughout  
 • Lyophilization according to protocol provided by Auxilium  
 • QC testing:  
 • Osmolarity  
 • Moisture  
 cGMP fill and lyophilization of Auxilium’s AA4500 product [\*\*\*] vials $[\*\*\*\*\*\*\*] $[\*\*\*\*\*\*]  
Includes:  
 • Custom Batch Records  
 • Dilution with lactose  
 • Sterile filtration  
 • Pre-filtration bioburden  
 • In-process UV  
 • [\*\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*\*]  
 • Visual Inspection throughout  
 • Lyophilization according to protocol provide by Auxilium  
 • QC Testing of lyophilized product  
 • Reconstitution Time  
 • pH  
 • Osmolarity  
 • Sterility  
 • Moisture  
 • LAL USP 26 <85>  
 • QA review and release  
 XXXXXX CONFIDENTIAL 2  
cGMP fill and lyophilization of Auxilium’s placebo   
Includes: [\*\*\*] vials $[ \*\*\*\*\*\*] $[ \*\*\*\*\*\*\*]  
• Custom Batch Records  
 • Sterile filtration  
 • Pre-filtration bioburden  
 • [\*\*\*\*\*\*\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*\*\*\*\*\*\*]  
 • Visual Inspection throughout  
 • Density  
 • Lyophilization according to protocol provide by Auxilium  
 • QC testing  
 • pH  
 • Sugar Content  
 • LAL USP 26 <85>  
 • Appearance  
 • Sterility  
 • Residual Moisture  
 • Osmolarity  
 • Protein Content by UV[\*\*\*\*\*]  
 • QA Review and Release  
 cGMP fill of Auxilium’s diluent  
 Includes: [\*\*\*] vials $[ \*\*\*\*\*\*] $[ \*\*\*\*\*\*]  
Formulation  
 Documentation fee  
 2 – in-line filters  
 Pre-filtration bioburden  
 3 ml fill in 5 ml vials  
 Labeling  
 Terminal Sterilization  
 Batch Records  
 QC testing and release  
 • Sterility USP 26 <71> and B&F  
 • [\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*]  
 • [\*\*\*\*\*\*\*\*]  
 • LAL USP 26 <85>  
 • Conductivity  
 • pH  
 • QA Review and Release  
 • Certificate of Analysis  
 XXXXXX CONFIDENTIAL 3  
3. TIMING  
 Activity  
 Completion Date  
Receive and Release Raw Materials & Components for development batch  
 [\*\*\*\*\*]  
Development Batch Production  
 [\*\*\*\*\*]  
Ship development batch to Auxilium  
 [\*\*\*\*\*]  
Master Batch Record for AA4500 Sent to Auxilium QA for Review  
 [\*\*\*\*\*]  
Master Batch Record for AA4500 Approval by Auxilium QA  
 [\*\*\*\*\*]  
Receive and Release Raw Materials & Components for AA4500 production  
 [\*\*\*\*\*]  
Receive AA4500 Drug Substance from Auxilium  
 [\*\*\*\*\*]  
AA4500 Product Fill  
 [\*\*\*\*\*]  
AA4500 Product Lyophilization  
 [\*\*\*\*\*]  
Begin Xxxxxx QC Final Fill Testing AA4500  
 [\*\*\*\*\*]  
Ship AA4500 Vials to Auxilium  
 [\*\*\*\*\*]  
Fully Released Product and Completed AA4500 Master Batch Record sent to Auxilium  
 [\*\*\*\*\*]  
Master Batch Record for placebo Sent to Auxilium QA for Review  
 [\*\*\*\*\*]  
Master Batch Record for placebo Approval by Auxilium QA  
 [\*\*\*\*\*]  
Receive and Release Raw Materials & Components for placebo production  
 [\*\*\*\*\*]  
Receive Placebo from Auxilium  
 [\*\*\*\*\*]  
Placebo Fill  
 [\*\*\*\*\*]  
Placebo Lyophilization  
 [\*\*\*\*\*]  
Begin Xxxxxx QC Final Fill Testing Placebo  
 [\*\*\*\*\*]  
 XXXXXX CONFIDENTIAL 4  
Ship Placebo Vials to Auxilium  
 [\*\*\*\*\*]  
Fully Released Product and Completed Placebo Master Batch Record sent to Auxilium  
 [\*\*\*\*\*]  
Master Batch Record for diluent Sent to Auxilium QA for Review  
 [\*\*\*\*\*]  
Master Batch Record for diluent Approval by Auxilium QA  
 [\*\*\*\*\*]  
Receive and Release Raw Materials & Components for diluent production  
 [\*\*\*\*\*]  
Receive diluent from Auxilium  
 [\*\*\*\*\*]  
Diluent Fill  
 [\*\*\*\*\*]  
Begin Xxxxxx QC Final Fill Testing diluent  
 [\*\*\*\*\*]  
Ship Diluent Vials to Auxilium  
 [\*\*\*\*\*]  
Fully Released Product and Completed diluent Master Batch Record sent to Auxilium  
 [\*\*\*\*\*]  
 XXXXXX CONFIDENTIAL 5  
4. SPECIFICATIONS  
Development Lot Specifications  
 Test Article  
 Test  
 Specification  
Bulk  
 Prefiltration Bioburden  
 In-Process  
 Conc by UV  
 [\*\*\*\*\*]  
Final Fill/lyo  
 100% Visual Inspection  
 [\*\*\*\*\*]  
AA4500 Lot Specifications  
 Test Article  
 Test  
 Specification  
Bulk Prefiltration Bioburden   
In-Process Conc by UV   
[\*\*\*\*\*]  
Final Lyophilized Product   
Appearance before reconstitution  
 Appearance after reconstitution  
 Sterility USP 26 <71>  
 Protein Content by UV[\*\*\*\*]  
 LAL USP 26 <85>  
 Osmolality  
 Moisture  
 pH  
 Reconstitution Time  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 XXXXXX CONFIDENTIAL 6  
Placebo Lot Specifications  
 Test Article  
 Test  
 Specification  
Bulk   
Prefiltration Bioburden  
 Final Lyophilized  
Product  
 Appearance before reconstitution  
 Appearance after reconstitution  
 100% Visual Inspection Container/Closure Integrity  
 pH  
 Sugar Content  
 Protein Content by UV [\*\*\*\*]  
 LAL USP 26 <85>  
 Sterility  
 Residual Moisture  
 Osmolarity  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 XXXXXX CONFIDENTIAL 7  
Diluent Lot Specifications  
 Test Article  
 Test  
 Specification  
Bulk   
Prefiltration Bioburden  
 Final Product   
100% Visual Inspection  
 Container/Closure Integrity, visual inspection  
 Sterility USP 26 <71> and B&F  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 LAL USP 26 <85>  
 Conductivity  
 pH  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 XXXXXX CONFIDENTIAL 8  
5. Payment Schedule\*  
Payment Schedule  
 Activity  
 Activity Total Invoice Amount Estimated Invoice Date\*  
Prepayment- 50%  
 $ 348,000.00 $ 174,000.00 Jan. 2006  
Development lot  
 $ [\*\*\*] $ [\*\*\*] [\*\*\*]  
Completion of Development lot  
 $ [\*\*\*] [\*\*\*]  
cGMP AA4500 fill and lyophilization of AA4500  
 $ [\*\*\*]   
• Prepayment  
 $ [\*\*\*] [\*\*\*]  
• Batch record preparation  
 $ [\*\*\*] [\*\*\*]  
• Final Lyophilized Product Release  
 $ [\*\*\*] [\*\*\*]  
cGMP fill and lyophilization of Auxilium’s placebo  
 $ [\*\*\*]   
• Prepayment  
 $ [\*\*\*] [\*\*\*]  
• Batch record preparation  
 $ [\*\*\*] [\*\*\*]  
• Final Lyophilized Product Release  
 $ [\*\*\*] [\*\*\*]  
cGMP fill of Auxilium’s diluent  
 $ [\*\*\*]   
• Prepayment  
 $ [\*\*\*] [\*\*\*]  
• Batch record preparation  
 $ [\*\*\*] [\*\*\*]  
• Final Product Release  
 $ [\*\*\*] [\*\*\*]  
\* - Estimated invoice dates are based on proposed schedules. Invoices will be issued as work is performed.  
Note: Release of bulk and lyophilized material is approximately 6 weeks post production.  
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6. Authorizations  
IN WITNESS WHEREOF, the parties hereto have each caused this Project Plan to be executed by their duly-authorized representatives as of.  
 AUXILLIUM PHARMACEUTICAL, INC XXXXXX TECHNOLOGIES, INC  
By:   
/s/ Xxxx Xxxxxxxx /s/ Xxxxxxx Xxxxxx  
 By:   
/s/ Xxxx Xxxxxxx  
By: Xxxx Xxxxxxxx Xxxxxxx Xxxxxx By: Xxxx Xxxxxxx  
Title: Biotechnology Manager / VP Manufacturing Title: C.O.O.  
.  
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