Exhibit 10.48  
Non-Confidential Exhibit A  
MANUFACTURING AND SUPPLY AGREEMENT  
 THIS MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”) is dated as of December 6, 2007 and is between ANIP ACQUISITION COMPANY, d/b/a ANI PHARMACEUTICALS, INC. (“ANI”), a Delaware corporation and JDS Pharmaceuticals, LLC, a New York limited liability company, (“JDS”).  
 The parties wish to set forth the terms and conditions under which ANI will manufacture for and supply to JDS the Products described herein. Accordingly, in consideration of the mutual promises and undertakings contained herein and intending to be legally bound hereby, the parties hereto agree as follows:  
ARTICLE I  
DEFINITIONS  
When used in this Agreement, the following terms shall have the meanings set forth below:  
“Act” shall mean the Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated there under from time to time.  
“Affiliate” shall mean any person or legal entity controlling, controlled by or under common control with the person with respect to whom such status is at issue and shall include, without limitation, any corporation 50% or more of the voting power of which (or other comparable ownership interest for an entity other than a corporation) is owned, directly or indirectly, by a party hereto or any corporation, person or entity which owns 50% or more of such voting power of a party hereto.  
“Agreement” shall have the meaning given to that term in the introductory paragraph hereof.  
“ANI ’s Shipping Point” shall mean ANI’s facility in Baudette, Minnesota  
“cGMP” means the current Good Manufacturing Practice regulations applicable to the manufacture of the Products hereunder.  
“Claims” shall have the meaning given to that term in Section 5.1 hereof.  
“Confidential Information” shall have the meaning given to that term in Section 7.1 hereof.  
“Contract Quarter” shall mean (i) the period from the date of this Agreement through and including September 30, 2007, and (ii) thereafter, each period of three (3) successive calendar months during each Contract Year.  
“Contract Year” shall mean (i) the period from the date of this Agreement through and including December 31, 2007, and (ii) thereafter, January 1 through December 31 of each succeeding calendar year, unless terminated before such later date as provided herein.  
“FDA” shall mean the United States Food and Drug Administration and any successor agency.  
“Firm Commitment” shall have the meaning of a no cancellation clause on forecast product requirements in the Contract Quarter.  
“Force Majeure Event” shall have the meaning given to that term in Section 9.1 hereof.  
“Form” shall have the meaning given to that term in Section 2.3 hereof.  
“Indemnitee” shall have the meaning given to that term in Section 5.3 hereof.  
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 “Indemnitor” shall have the meaning given to that term in Section 5.3 hereof.  
“Labeling” shall mean all unit Products labels, package inserts, carton imprints, tablet debossing/embossing and/or imprinting and all other markings on packaging for, or other similar materials related to, the Products that are defined as labels or labeling under any applicable law or regulation.  
“Labeling Specifications” shall mean the labeling and packaging specifications for the Products attached here to as Exhibit B and made a part hereof, as such specifications may be amended from time to time by mutual agreement in writing of the Parties.  
“Latent Defects’ shall have the meaning given to that term in Section 2.7 (c)  
“Law” means any applicable statute, law, ordinance, rule, regulation, order, judgment, ruling or decree enacted, adopted, issued or promulgated by any Regulatory Authority.  
“Manufacturing Authorization” means any authorization necessary to manufacture the Products as granted by the applicable Regulatory Authority.  
“Manufacturing Standards” shall mean all U.S. Laws applicable to the manufacture of the Products.  
“Net Sales” shall have the meaning given to that term in Section 2.4(b) (iii) hereof  
“NDC” shall mean the national drug code assigned to each Product by the FDA.  
“Nonconformance” shall have the meaning given to that term in Section 2.7(c) hereof.  
“PPI” shall have the meaning given to that term in Section 2.4(b) hereof.  
“Products” shall mean the pharmaceutical dosage form consisting of: Lithium Carbonate as an active ingredient in the presentations specified in Exhibit A hereto and incorporated herein by reference, including, without limitation, bulk form, whether to be ultimately sold by JDS under the LITHOBID® (Lithium Carbonate, USP, Slow-Release Tablets) trademark or in generic form.  
“Product Specifications” shall mean the specifications for the Products attached hereto as Exhibit C, incorporated by reference herein, the Products specifications and methods set forth as of the date hereof in the manufacturing and control sections of the new drug application heretofore submitted to and approved by the FDA for the Products (including any Labeling requirements specified therein) and any amendments to such specifications that may be mutually agreed upon by the parties in writing.  
“Regulatory Authority” shall mean any U.S. governmental regulatory authority involved in granting approvals for the manufacture, marketing, sale, reimbursement and/or pricing of Products in the U.S., including, without limitation, the FDA and any judicial or administrative decisions relating thereto.  
“Regulatory Change” shall have the meaning given to that term in Section 9.2 hereof.  
“Regulatory Standards” shall mean all laws, rules, regulations and Regulatory Authority advisory opinions or orders applicable to the manufacturing, marketing, sale, reimbursement and/or pricing of any Products.  
“Specifications” shall mean the Products Specifications and the Labeling Specifications.  
“Standard Cost” shall have the meaning given to that term in Section 2.4(b) hereof.  
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 ARTICLE II  
SUPPLY  
2.1 Generally. Subject to the terms and conditions of this Agreement, ANI shall supply to JDS and JDS shall purchase from ANI the Products in such quantities as JDS may order hereunder from time to time for its worldwide requirements. Except for such quantities of the Product as JDS may order in bulk in accordance with the terms hereof, ANI shall supply the Product in finished, packaged form and tested in accordance with the Specifications and Manufacturing Standards. ANI will not implement any change in materials, components, processes or test methods without consulting with and receiving the prior written approval of JDS. ANI will utilize its change control processes in this regard. In addition, a Quality Agreement will be developed for quality governance substantially in the form attached hereto as Exhibit D.  
2.2 Forecasts.  
(a) Initial Forecast Within fifteen (15) business days of the signing of this Agreement, JDS shall submit to ANI a written forecast of its requirements for the Products for the first Contract Year, the first Contract Quarter of which shall constitute a Firm Commitment of JDS.  
(b) Subsequent Forecasts JDS shall submit to ANI by the first day of each successive Contract Quarter a 12-month rolling forecast, by Contract Quarter, of its requirements for the Products, the first quarter of which shall constitute a Firm Commitment of JDS.  
(c) ANI shall base its production planning on the forecasts provided to ANI by JDS pursuant Sections 2.2(a) and 2.2(b), with the option to manufacture successive batches to three (3) batches] of JDS’s forecast requirements for the Contract Quarter. ANI shall have the right at any time, to order materials and supplies to manufacture one hundred percent (100%) of those amounts of Product ordered by JDS under Section 2.2(a) and 2.2(b). In addition, to the extent any materials necessary to the manufacture of the Product require a longer lead time, ANI shall be entitled to order such materials as it deems appropriate to fulfill its obligations hereunder and consistent with normal production practices in the pharmaceutical industry, and considering the term of this Agreement. If any such materials or any work in process become unusable due to a change in the Product Specifications or orders lower than forecasts, ANI shall have the right to invoice JDS for the full cost of unusable materials or work in process and JDS shall promptly pay such invoice. JDS shall have full rights and title to such obsolete materials (and work in process). At JDS’s election, such materials (and work in process) shall be (i) destroyed by ANI, at JDS’s expense or (ii) transferred by ANI to JDS at JDS’s expense.  
2.3 Purchase Orders. Within thirty (30) days of the signing of this Agreement, JDS shall place its initial purchase order for the first quarter which is the Firm Commitment period described in Section 2.2(a). JDS shall place orders for Products only in whole number multiples of specified-size lots. JDS shall place each subsequent order for Products by delivering to ANI a written purchase order specifying the quantity and delivery date (which delivery date shall not be less than ninety (90) days after the date such purchase order is delivered to ANI unless otherwise agreed). Unless the parties otherwise agree, quantities specified in purchase orders for each Product for the second and subsequent Contract Quarters may not be less than 80% nor more than 120% of those set forth for such quarter in the most recent forecast submitted to ANI hereunder; provided, however, that ANI will use commercially reasonable  
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 efforts to fill any orders for quantities in excess of such maximum amount. ANI shall acknowledge and accept each purchase order received from JDS which complies with the forecast and order procedures set forth herein, within four (4) business days after receipt.  
2.4 Pricing and Payment.  
(a) General Price. The purchase price of Products supplied to JDS hereunder shall be \*\*\* plus any applicable sales or use taxes, duties and other similar taxes, unless JDS provides ANI with a valid resale certificate or other proof of exemption.  
(b) Price Changes. \*\*\*  
(c) Other Increases and/or Payments. \*\*\*  
(d) Invoicing and Payment. ANI shall invoice JDS for each shipment of the Product simultaneously with ANI’s actual shipment of Products and delivery to JDS of a certificate of analysis relating to such shipment. Payment shall be due within thirty (30) days from invoice date. Past due balances shall be subject to a service charge of 12% per annum, but in no event shall such charge exceed the maximum rate permitted by law. All payments shall be made in U.S. dollars.  
(e) Books and Records. ANI shall maintain accurate books and records of Standard Cost and other costs for which JDS is responsible pursuant to Section 2.4 which shall, from the date hereof until twelve (12) months following the expiration date of the last batch of Product manufactured hereunder, be made available for inspection and audit by JDS at least once per year solely for the purpose of verifying price increases pursuant to this Section 2.4 and other costs for which JDS is responsible. JDS shall be responsible for the costs of any such inspection and audit, provided that if it is determined that JDS has paid costs which exceed the costs as to which JDS is responsible pursuant to Section 2.4 by more than 5%, ANI shall be responsible for the reasonable costs of such audit, as well as for refunding the amount of the JDS overpayment.  
2.5 Delivery.  
(a) Generally. All Products sold to JDS hereunder shall be delivered to JDS FOB ANI’s Shipping Point. All risk of loss shall pass to JDS when ANI so delivers Products to a carrier for JDS. JDS shall designate a carrier and mode of shipment on each purchase order submitted to ANI provided, however, that should JDS fail to designate a carrier on its purchase order, ANI shall use the common carrier designated by JDS as its default carrier, or if JDS shall fail to designate a default carrier, ANI may select a common carrier for the account and risk of JDS.  
(b) Deviation from Agreed Delivery Time. ANI shall use commercially reasonable efforts to fill each purchase order submitted hereunder by the specified shipment date. Originally agreed times for delivery to JDS’s carrier are not to be deemed of the essence of an accepted order, and reasonable deviations from originally agreed times will be accepted by JDS. Deviations of more than \*\*\* shall be deemed unreasonable, unless JDS has on hand an inventory of Products sufficient to meet JDS’s requirements (based on its forecasts delivered to ANI under Section 2.2) for \*\*\* in which case deviations of more than \*\*\* will be deemed unreasonable.  
(c) Delay in Delivery. JDS recognizes the inherent difficulty in producing the Product and also recognizes that delays in shipment, while non-routine, may occur from time to time. ANI shall notify JDS promptly of any circumstance that may cause a delay in making Products available for shipment FOB ANI’s Shipping Point, stating the estimated period of delay and the reasons  
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 therefore. ANI shall use commercially reasonable efforts to avoid or minimize the delay, including, when necessary or at JDS’s request, the expenditure of premium time and shipping via air or other expedited routing. Any additional cost caused by such requirements shall be borne by the party causing the delay to the extent of any culpability. If no culpability can be assigned to either party, such additional costs for premium time and air shipment requested by JDS shall be borne solely by JDS. Nothing herein may be construed to prejudice any of the express rights or remedies provided to either party in this Agreement. In addition to any such rights JDS may have hereunder, JDS shall have the right to cancel any order which is not made available for shipment FOB ANI’s Shipping Point for more than \*\*\* after its agreed shipment date for causes other than Force Majeure Events or Regulatory Changes so long as such delay has arisen through no fault or negligence of JDS. Notwithstanding the foregoing, ANI shall not be liable in any way (including, without limitation, for the additional costs caused by the requirements set forth above in this section) for any delay excused under Article IX hereof.  
(d) Priority of Supply. If for any reason (including without limitation, a back order situation, a Force Majeure Event or a Regulatory Change) ANI is unable to supply JDS’s demand for Products and the demands of ANI’s other customers (including ANI and ANI’s Affiliates), ANI shall give JDS’s demand at least equal priority to those of ANI’s other customers (including ANI and ANI’s Affiliates).  
2.6 Labeling and Packaging.  
(a) Generally. JDS shall provide to ANI and shall bear the sole responsibility for ensuring the accuracy of the information contained in all Labeling Specifications and for compliance thereof with all Regulatory Standards. ANI shall be responsible for procuring all Labeling, which shall be created in accordance with the Labeling Specifications. With respect to all Products to be supplied in finished, packaged form, ANI shall procure sufficient Labeling to cover quantities of the Products as to which JDS’s forecasts under Section 2.2 hereof constitute a firm commitment. Acquisition of additional inventory of Labeling components beyond the three (3) month commitment shall be made only with advance consultation of JDS.  
(b) Changes. Should JDS desire or be required to change any component of Labeling or to introduce a new packaging component to which Labeling will be affixed, JDS shall so inform ANI and shall be responsible for updating the artwork or text, as applicable, and providing it to ANI in camera-ready or electronic form and in compliance with the Labeling Specifications. ANI shall make all necessary arrangements for such Labeling to be printed and shall provide to JDS printer’s proofs of all Labeling for JDS’s review.Within fifteen (15) business days of its receipt of such proofs, JDS shall either provide to ANI any necessary corrections thereto or notify ANI of its approval of such proofs. Upon JDS’s acceptance thereof, ANI shall return all artwork provided by JDS. ANI shall be entitled to directly charge JDS, amounts to take account of only those costs incurred in making changes to Labeling and/or packaging as provided for in this Section 2.6(b). Allowable transition cost charges include, without limitation, the costs of acquiring new Labeling in a timely manner to meet JDS’s pending purchase orders and forecast demand and the acquisition and disposal costs associated with obsolete inventory of Labeling, films, plates and packaging. ANI will charge JDS direct, out-of-pocket expenses in a one-time charge after completion of the Labeling transition.  
2.7 Stability Testing and Inspection of Products.  
(a) Stability Testing. ANI shall provide stability testing for Products manufactured hereunder, and shall provide all stability results to JDS in a timely fashion. ANI and JDS shall agree to a work outline to accomplish an acceptable stability program. ANI shall retain a suitable quantity  
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 of retained samples until twelve (12) months after the stated expiration date for the tested Product. ANI shall promptly notify JDS of any costs associated with the agreed upon stability testing program for the Products beyond those which ANI customarily and routinely incurs in connection with stability testing and such additional costs shall be charged to and shall be the sole responsibility of JDS (through an adjustment to the Standard Cost). ANI will notify JDS of stability failures within 48 hours of ANI’s s becoming aware of any such failure.  
(b) Certificate of Analysis. ANI will provide JDS with a certificate of analysis for all batches of Products shipped to JDS which shall include, without limitation, the expiry date. Such certificate of analysis shall be delivered to JDS at the time of shipment of the Products. Delivery of any Products by ANI to JDS shall constitute a certification by ANI that at the time of delivery the Products conforms to the certificate of analysis provided therewith and the Product Specifications and was manufactured in accordance with the Manufacturing Standards. JDS shall store all Products in conditions as specified in the Product Specifications. All Products delivered to JDS shall have a remaining expiry period of no more than three months less than the total initial labeled expiry period. To avoid confusion, and as an example: for Product that has an initial labeled expiry period of 24 months the Product delivered must have at least 21 months remaining expiry period upon receipt by JDS.  
(c) Nonconformance. Within thirty (30) days after its receipt of each shipment of Products at the destination specified in the shipping instructions, JDS shall inspect such shipment for material nonconformance with the applicable purchase order, the applicable Specifications or the representations and warranties of ANI set forth herein (“Nonconformance”). If, upon such inspection, JDS discovers any Nonconformance, JDS may reject the nonconforming portion of such shipment by giving prompt written notice to ANI Such notice shall include a copy of JDS’s test results and specify the precise Nonconformance upon which such rejection is based. Absent such notification, JDS shall be deemed to have accepted the shipment, except as to latent defects that could not have been detected in such 30-day period (“Latent Defects”). In no event shall ANI be liable for any Non-conformance arising out of the shipment, storage, use or handling of the Products following its delivery FOB ANI’s Shipping Point.  
(d) Procedure. Upon notifying ANI of any Nonconformance, or upon notifying ANI of any Latent Defects, JDS shall afford ANI a reasonable opportunity to inspect the shipment in question and make any appropriate adjustment or replacement. The parties shall submit any dispute regarding the proper rejection of a shipment to a mutually selected independent laboratory, the determination of which shall be binding on the parties and the costs of which shall be borne by the party against whom such determination is rendered. If such laboratory confirms a Nonconformance or Latent Defect in the shipment in question (or any part of it) at the time of delivery to the carrier, or if the parties agree that there is a shortage or a Nonconformance or Latent Defect, then ANI shall use commercially reasonable efforts to make up the shortage or replace any nonconforming Products, as the case may be, with such new Products to be shipped at ANI’s expense to the same destination as the original shipment. If ANI is unable to make up the shortage or replace any nonconforming Products, it shall promptly refund any money paid by JDS with respect to such undelivered or nonconforming Products and reimburse JDS for the costs of shipping such Products. ANI may, at its sole option, either direct JDS to return nonconforming Products to ANI or have it destroyed by JDS, and certify such destruction to ANI, all at ANI’s expense. ANI’s supply of substitute Products which conform to the applicable Specifications or, as the case may be, payment of the refund and reimbursement provided for herein, shall satisfy and discharge all claims or potential claims which JDS may have against ANI with respect to undelivered or nonconforming Products in that shipment, provided replacement Products is available to JDS within thirty (30) days of the identified shortage.  
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 2.8 Inspection of Facility. JDS or its designees may, at its sole expense, inspect the facilities being used by ANI to manufacture, package, store or ship the Products to assure compliance with Manufacturing Standards. Each such inspection shall be conducted upon reasonable advance notice, at mutually agreed times during regular business hours and in a manner which minimizes disruption of ANI’s business operations. JDS may conduct such inspections no more than twice each Contract Year unless it has a good faith reason to believe such facility is not materially in compliance with Manufacturing Standards.  
2.9 Recalls. If any Regulatory Authority with applicable jurisdiction shall order, or it shall otherwise become necessary to perform, any corrective action or market action with respect to any Products manufactured by ANI (including, without limitation, any recall, field correction, market withdrawal, stock recovery, customer notice or restriction), JDS shall have the exclusive responsibility to appropriately manage such action. If such corrective action or market action is caused by the action of or necessitated by the breach by one of the parties of any of its warranties, representations, obligations, covenants or agreements contained herein, or in any Manufacturing Authorization, then such party shall be liable, and shall reimburse the other party, for all reasonable costs incurred by the non-breaching party in connection with such action (including, without limitation, reasonable attorney’s fees and expenses). If each of the parties is partly responsible for such corrective action or market action, then each party shall be responsible for its proportionate share of such costs. If neither party is responsible for such corrective action or market action, then JDS shall be responsible for such costs. JDS shall also be exclusively responsible for handling all customer complaints, inquiries and the like, and ANI shall appropriately cooperate with JDS, including the completion of an investigation and the preparation and submission of a complaint report to JDS or its designees.  
2.10 Process Improvements and Development Activities. \*\*\*  
ARTICLE III  
REPRESENTATIONS AND WARRANTIES  
3.1 Representations and Warranties of ANI. ANI represents and warrants to JDS as follows:  
Conformance of Products. Subject to JDS’s obligations with respect to supplies of the Labeling Specifications under Section 2.6 hereof, each certification by ANI pursuant to Section 2.7(b) shall be deemed a representation and warranty hereunder, any breach of which representation and warranty being subject to the provisions of Section 5.1, Section 2.7(c) and Section 2.7(d) and the limitations contained in Section 3.3.  
Adulteration; Misbranding. Subject to JDS’s obligations with respect to supplies of the Labeling Specifications under Section 2.6 hereof, no Products supplied by ANI to JDS under this Agreement shall, at the time of delivery to the carrier FOB ANI’s Shipping Point, be adulterated or misbranded within the ANI of the Act or be an article which may not be introduced into interstate commerce under the provisions of Section 505 of the Act.  
Organization; Standing. ANI is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted.  
Authorization; Binding Effect. The execution and delivery by ANI of this Agreement, the performance by ANI of its obligations hereunder and the consummation by ANI of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of ANI This Agreement has been duly executed and delivered by a duly authorized officer of ANI and constitutes the valid and legally binding obligation of ANI enforceable against ANI in accordance with its terms.  
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 No Conflict; Consents. The execution and delivery of this Agreement by ANI (a) will not violate or result in the breach of, constitute a default under, or accelerate the performance required by, any term of any covenant, agreement or understanding to which ANI or any Affiliate is a party, or any Law to which ANI or any Affiliate is subject and (b) requires no consents or agreements of any third party (including governmental bodies) necessary for the performance by ANI of its obligations under this Agreement, and ANI has, and at all times will maintain, all necessary Manufacturing Authorizations.  
Representations and Warranties of JDS. JDS represents and warrants to ANI as follows:  
(a) Organization; Standing. JDS is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted.  
(b) Authorization; Binding Effect. The execution and delivery by JDS of this Agreement, the performance by JDS of its obligations hereunder and the consummation by JDS of the transactions contemplated hereby have been duly authorized by all necessary action on the part of JDS. This Agreement has been duly executed and delivered by a duly authorized officer of JDS and constitutes the valid and legally binding obligation of JDS enforceable against JDS in accordance with its terms.  
(c) NoConflict;Consents. The execution and delivery of this Agreement by JDS (a) will not violate or result in the breach of, constitute a default under, or accelerate the performance required by, any term of any covenant, agreement or understanding to which JDS or any Affiliate is a party, or any Law to which JDS or any Affiliate is subject and (b) requires no consents or agreements of any third party (including governmental bodies) necessary for the performance by JDS of its obligations under this Agreement.  
3.2 Limitations.  
 (a) EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, HE PARTIES AGREE THAT ANI MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS, IMPLIED OR OTHERWISE, AND SPECIFICALLY DISCLAIMS AND SHALL NOT BE LIABLE TO JDS OR OTHERS IN RESPECT OF:  
(i) ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCTS, WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES OR MATERIALS;  
(ii) ANY LIABILITY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (OTHER THAN TO THE EXTENT REASONABLY FORESEEABLE IN LIGHT OF THE OBJECTIVES OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT , BUT SUBJECT TO THE FURTHER LIMITATIONS IN SECTION 3.3(C) BELOW), WHETHER ARISING OUT OF A BREACH OF THE REPRESENTATIONS AND WARRANTIES CONTAINED HEREIN OR OTHERWISE AND WHETHER IN CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE; AND  
(iii) ANY LIABILITY TO THE EXTENT ARISING AS A RESULT OF PRODUCTS: (I) HAVING BEEN TAMPERED WITH OTHER THAN BY ANI OR ITS AGENTS, (II) HAVING BEEN SUBJECT TO MISUSE, NEGLIGENCE OR ACCIDENT OTHER THAN BY ANI OR ITS AGENTS, (III) HAVING BEEN STORED, HANDLED OR USED OTHER THAN BY ANI OR ITS AGENTS IN A MANNER CONTRARY TO REGULATORY STANDARDS OR THE INSTRUCTIONS CONTAINED ON LABELING, OR (IV) HAVING EXCEEDED ITS STATED EXPIRATION.  
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 (b) THE MAXIMUM AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT SHALL NOT IN ANY EVENT EXCEED \*\*\*.  
 (c) NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NONE OF THE LIMITATIONS ON LIABILITY SET FORTH IN THIS SECTION SHALL APPLY TO ACTS OR OMISSIONS OF ANI TAKEN OR OMITTED TO BE TAKEN WITH INTENT TO BREACH THE REPRESENTATIONS, WARRANTIES OR OBLIGATIONS OF ANI UNDER THIS AGREEMENT.  
ARTICLE IV  
TERM AND TERMINATION  
4.1 Term. This Agreement shall become effective as of the date hereof and shall continue until five (5) years following the Effective Date (the “Initial Term”), unless terminated earlier by mutual agreement of the parties or by one of the parties in accordance with this Article 4.1; provided further that JDS shall have the option, in its sole discretion, to extend the Initial Term of this Agreement for three (3) successive terms of one (1) year each (each a “Renewal Term” and collectively with the Initial Term, the “Term”) by providing ANI written notice of such election not less than six (6) months prior to the expiration of the Initial Term or then current Renewal Term.  
4.2 Term. The term of this agreement shall commence on the date hereof and shall continue for a period of five years, unless terminated earlier pursuant to Section 4.2 or Section 4.3 hereof. This Agreement may be renewed for such additional period and upon such other terms as the parties may mutually agree  
4.3 Termination by Mutual Agreement. The parties may terminate this Agreement any time by mutual written agreement  
4.4 Termination upon Material Breach. Subject to the last two sentences of this Section 4.3, either party may terminate this Agreement upon not less than sixty (60) days written notice thereof to the other party of the material breach by the other party of any of its representations, warranties, covenants or agreements contained in this Agreement (provided, however, that the breaching party may extend such notice period by up to thirty (30) additional days upon its written certification that (i) such breach is not reasonably capable of being cured within such 60-day period and (ii) it has commenced and is diligently pursuing efforts to cure such breach). Upon the expiration of such notice period, this Agreement shall terminate without the need for further action by either party; provided, however, that if the breach upon which such notice of termination is based shall have been fully cured to the reasonable satisfaction of the non-breaching party within such notice period, then such notice of termination shall be deemed rescinded, and this Agreement shall be deemed reinstated and in full force and effect. Such right of termination shall be in addition to such other rights and remedies as the terminating party may have under any Law. The time periods for termination stated above in this Section 4.3, shall be suspended during the period commencing upon a bona fide dispute arising between the parties as to whether a material breach has occurred and ending upon the date such dispute is finally determined. In the event such final determination provides for the payment of money and such amount is paid in full by the obligor within ten (10) days of such determination, no termination right shall arise hereunder with respect to the matter in question.  
4.5 Rights and Duties upon Termination.  
(a)Supply and Purchase of Products. Unless otherwise mutually agreed by the parties, ANI shall supply, and JDS shall purchase in accordance with the provisions hereof, all quantities of Products ordered by JDS hereunder prior to the date of expiration or termination; provided, however, that ANI shall not be required to supply volumes of Products which exceed the amounts for which ANI is responsible under the forecast and firm order procedures herein for the balance of the Calendar Quarter in which the termination occurs. In addition, JDS shall remain liable for and shall duly pay all costs incurred prior to the effective date of expiration or termination which are  
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 properly chargeable to JDS pursuant to the terms of this Agreement. JDS shall have the right to use and sell any such Products in the ordinary course including Products which may contain reference to ANI  
(b)Purchase of Additional Materials. Upon the expiration or termination of this Agreement, JDS shall, if so requested by ANI, purchase (i) all dedicated raw and packaging materials acquired by ANI hereunder to manufacture the Products, at ANI’s actual cost thereof, (ii) all work-in-progress of the Products at ANI’s actual cost thereof, and (iii) all inventory of finished Products then in ANI’s possession at the then-current purchase price hereunder. In addition, JDS shall pay ANI the actual out of pocket cost for any non-cancelable commitments made by ANI for materials hereunder. Notwithstanding anything to the contrary in the preceding two sentences, the foregoing purchase and payment obligations of JDS shall be limited solely to materials obtained, Products manufactured and non-cancelable commitments incurred by ANI for quantities of the Products as to which JDS’s forecasts under Section 2.2 hereof constitute a firm commitment or for which purchase orders have been received and which, in the case of Products, comply with the Product Specifications and all Manufacturing Standards. All materials purchased by JDS become the property of JDS and ANI will, at the request of JDS, arrange to ship such materials to locations designated by JDS. The cost of the freight shall be borne by JDS. The foregoing purchase and payment obligations shall not apply in the event of a termination by JDS based on a breach by ANI of its supply obligations.  
ARTICLE V  
INDEMNIFICATION  
5.1 By ANI. Subject to the limitations described in Section 3.3, ANI shall defend, indemnify and hold harmless JDS and its Affiliates, successors, permitted assigns and their respective officers, directors, managers, members, stockholders, partners and employees from and against any and all Claims arising out of (a) any breach of any representation, warranty or covenant of ANI hereunder, (b) any negligent storage or handling of the Products by ANI prior to delivery to JDS FOB ANI’s Shipping Point, (c) any negligent act or omission of ANI or its employees, agents or other contractors with respect to the Products, (d) the failure of ANI to comply with any applicable Regulatory Standards with respect to the manufacture or storage, or (e) all personal injury (including death) and/or property damage resulting from the manufacture, handling, or possession of the Products prior to ANI’s delivery of the Products to JDS FOB ANI’s Shipping Point. For purposes of this Agreement, “Claims” shall mean any and all liabilities and expenses whatsoever, including, without limitation, claims, adversary proceedings (whether before a court, Regulatory Authority or any other tribunal), damages (other than special, incidental, consequential or punitive damages except to the extent awarded to a third party), judgments, awards, penalties, settlements, investigations, costs, and attorneys’ fees and disbursements  
5.2 By JDS. Subject to the limitations set forth in Section 3.3., JDS shall defend, indemnify and hold harmless ANI and its Affiliates, successors, permitted assigns and their respective officers, directors, stockholders, partners and employees from and against any and all Claims arising out of (a) any breach of any representation, warranty or covenant of JDS hereunder, (b) any negligent act or omission of JDS or its employees, agents or other contractors with respect to the Products, (c) the failure of JDS to comply with any applicable Regulatory Standards with respect to the importation, marketing, distribution or sale of the Products, (d) any Labeling for the Products approved by JDS, (e) the infringement of any patent, trademark or other intellectual property rights by the sale or use of the Products, or (f) all personal injury (including death) and/or property damage resulting from the handling, possession, marketing, promotion or use of the Products following ANI’s delivery of the Products to JDS FOB ANI’sShipping Point. Notwithstanding the preceding sentence, JDS shall not be required to indemnify ANI with respect to any  
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 Claim arising from ANI’s breach of its representations, warranties or covenants hereunder or ANI’s willful misconduct with respect to the Products.  
5.3 Procedure. Any person or entity intending to claim indemnification hereunder (an “Indemnitee”) shall notify the party hereunder from whom indemnification is sought (the “Indemnitor”) in writing within a reasonable time of any third-party Claim for which indemnification is sought hereunder. The failure to give timely notice to the Indemnitor shall not release the Indemnitor from any liability to the Indemnitee to the extent the Indemnitor is not prejudiced thereby. The Indemnitor shall have the right, by notice to the Indemnitee within fifteen (15) business days after the Indemnitor’s receipt of notice thereof, to assume the defense of any such third-party Claim with counsel of the Indemnitor’s choice and at Indemnitor’s sole expense. If the Indemnitor so assumes such defense, the Indemnitee may participate therein through counsel of its choice, but at its sole expense. The party not assuming the defense of the third-party Claim shall render all reasonable assistance to the party assuming the defense, and all reasonable out-of-pocket costs of such assistance shall be for the account of the Indemnitor. No such third-party Claim shall be settled other than by the party defending it, and then only with the consent of the other party (which shall not be unreasonably withheld or delayed). The Indemnitee shall, however, have no obligation to consent to any settlement which imposes on the Indemnitee any liability or obligation which cannot be assumed and performed in full by the Indemnitor, and the Indemnitee shall have no right to withhold its consent to any settlement which involves only the payment of money by the Indemnitor or its insurer.  
ARTICLE VI  
ADVERSE EVENT REPORTS  
JDS shall be solely responsible for receiving, recording and responding to all customer inquiries and complaints and all reports of alleged adverse events relating to the Product, and for reporting all such matters to appropriate Regulatory Authorities in accordance with applicable law. ANI shall provide JDS with any technical information relating to formulation, manufacture or stability of the Product reasonably necessary to enable JDS to perform all such activities. Should ANI receive any notice or inquiry regarding adverse events, it shall immediately transmit them to JDS.  
ARTICLE VII  
CONFIDENTIALITY  
7.1 Generally. Each party shall hold all Confidential Information disclosed to it by the other in the strictest confidence and shall protect all such Confidential Information with the same degree of care that it exercises with respect to its own proprietary information. Without the prior written consent of the disclosing entity, the receiving party shall neither use, disclose, divulge or otherwise disseminate any Confidential Information to any person or entity outside of the party, except for the receiving party’s attorney and such other professionals as the receiving party may retain in order for it to enforce the provisions of this Agreement. For purposes of this Agreement, “Confidential Information” shall consist of any information, whether or not reduced to writing, which either party shall from time to time possess in relation to the development, formulation, manufacture, testing or packaging of the Products and which is not generally known to the public or within the pharmaceutical industry and which one party hereto discloses to the other party.  
7.2 Restriction. Neither party shall use the other’s name or disclose the existence or terms of this Agreement without the written permission of the other except for references in Products packaging or labeling required by law or otherwise contemplated herein.7.3 Exceptions. Notwithstanding Section 7.1  
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 hereof, neither party shall have any obligations with respect to any Confidential Information which (a) is or becomes within the public domain through no act of the receiving party in breach of this Agreement, (b) was lawfully in the possession of the receiving party without any restriction on use or disclosure prior to its disclosure hereunder, (c) is lawfully received from another source subsequent to the date of this Agreement without any restriction on use or disclosure, (d) is deemed in writing by the disclosing entity no longer to be Confidential Information, or (e) is required to be disclosed by order of any court of competent jurisdiction or other governmental authority (provided, however, in such latter case, that the receiving party shall timely inform the disclosing party of all such legal or governmental proceedings so that the disclosing party may attempt by appropriate legal means to limit such disclosure, and the receiving party shall further use its best efforts to limit the disclosure and maintain confidentiality to the maximum extent possible).  
ARTICLE VIII  
COOPERATION WITH GOVERNMENTAL REQUIREMENTS  
The parties shall cooperate with one another as may be reasonably necessary or appropriate to satisfy all governmental requirements and obtain all needed permits, approvals and licenses with respect to the manufacture, storage, packaging and sale of the Products. Such cooperation shall include, without limitation, communicating with Regulatory Authorities and making available as promptly as reasonably practicable all information, documents and other materials which result from the performance by ANI of its obligations hereunder which JDS is required to submit. The costs and expenses of such cooperation, if applicable, shall be subject to the parties’ mutual agreement. JDS shall be responsible for all regulatory reporting of Products. ANI shall assist JDS by providing necessary support and information and shall prepare the annual cGMP Products reviews.  
ARTICLE IX  
FORCE MAJEURE  
9.1 Effects of Force Majeure. Notwithstanding any other provision of this Agreement to the contrary, neither party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement to the extent that such failure or delay results from any cause beyond its reasonable control, including, without limitation, fire, flood, explosion, war, strike, labor unrest, riot, embargo, inability to obtain necessary raw materials or supplies, acts or omissions of carriers, or act of God (each, a “Force Majeure Event”). Subject to Section 9.4, such excuse shall continue as long as the Force Majeure Event continues, following which such party shall promptly resume performance hereunder.  
9.2 Effects of Regulatory Changes. Notwithstanding any other provision of this Agreement to the contrary, neither party shall be held responsible or liable for failure or delay in fulfilling or performing any of its obligations under this Agreement to the extent that such failure or delay results from good faith efforts to comply with the enactment or revision of any law, rule, regulation or regulatory advisory opinion or order applicable to the manufacturing, marketing, sale, reimbursement and/or pricing of the Products (a “Regulatory Change”). Such excuse shall continue as long as performance is prevented by the affected party’s good faith efforts to comply with such Regulatory Change, following which such party shall promptly resume performance hereunder.  
9.3 Notice. The party affected by a Force Majeure Event or a Regulatory Change shall notify the other party thereof as promptly as practicable after its occurrence. Such notice shall describe the nature of such Force Majeure Event or Regulatory Change and the extent and expected duration of the affected party’s inability fully to perform its obligations hereunder. The affected party shall use all reasonable efforts to minimize the effects of or end any such event so as to facilitate the resumption of full performance hereunder and shall notify the other party when it is again fully able to perform such obligations.  
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 9.4 Limitation. Notwithstanding anything to the contrary herein, in the event a Regulatory Change or Force Majeure Event continues for more than 180 days, JDS shall have the right to terminate this Agreement upon notice and upon JDS’s request, ANI shall cooperate to assist in the transfer of technology to a new manufacturer at no additional labor cost to JDS. JDS shall bear the cost and expense of the foregoing technology transfer in the case of a Regulatory Change, and the parties shall bear the cost and expense of a technology transfer in such proportion as is just and equitable in the case of a Force Majeure Event.  
ARTICLE X  
INDEPENDENT CONTRACTORS  
The relationship between ANI and JDS is that of independent contractors, and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between ANI and JDS. Neither party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other party or to bind the other party to any contract, agreement or undertaking with any third party  
ARTICLE XI  
FURTHER ACTIONS  
The parties shall execute such additional documents and perform all such other and further acts as may be necessary to carry out the purposes and intents of this Agreement.  
ARTICLE XII  
DISPUTE RESOLUTION  
12.1 Negotiation. Any dispute, controversy or claim arising out of or relating to this Agreement or the breach, termination, or invalidity hereof shall be submitted for negotiation and settlement in the first instance to the Senior Vice President of Sales & Marketing of ANI, or such person’s designee of equivalent or superior position, and the Senior Vice President Strategic Alliances, or such person’s designee of equivalent or superior position.  
12.2 Arbitration. If the parties are unable to settle a dispute, controversy or claim hereunder pursuant to Section 12.1, the matter shall be finally resolved by arbitration in accordance with the rules of American Arbitration Association, except as modified by this Section 12.2. The number of arbitrators shall be three (3), one (1) of whom is selected by JDS, one (1) of whom is selected by ANI and one (1) of whom is selected by ANI and JDS (or by the other two (2) arbitrators if the parties cannot agree). The arbitration proceeding shall be conducted in the English language. The arbitration proceeding shall be brought in State of Delaware, unless the parties agree in writing to conduct the arbitration in another location. The arbitration decision shall be binding and not be appealable to any court in any jurisdiction. The prevailing party may enter such decision in any court having competent jurisdiction. Each party shall pay its own expenses of arbitration and the expenses of the arbitrators shall be equally shared except that if, in the opinion of the arbitrators, any claim by a party hereto or any defense or objection thereto by the other party was unreasonable, the arbitrators may in their discretion assess as part of the award any part of the arbitration expenses of the other party (including reasonable attorneys’ fees) and expenses of the arbitrators against the party raising such unreasonable claim, defense or objection.  
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 12.3 Interim Relief. Any party may, without inconsistency with this Agreement, apply to any court having jurisdiction hereof and seek injunctive relief so as to maintain the status quo until such time as the arbitration award is rendered or the controversy is otherwise resolved.  
ARTICLE XIII  
MISCELLANEOUS  
13.1 Notices. All notices, requests, instructions, consents and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed received (a) on the same day if delivered in person, by same-day courier or by telegraph, telex, facsimile, electronic mail or other electronic transmission, (b) on the next day if delivered by overnight mail or courier, or (c) on the date indicated on the return receipt, or if there is no such receipt, on the third calendar day (excluding Sundays) if delivered by certified or registered mail, postage prepaid, to the party for whom intended to the following addresses:  
 If to JDS:  
 JDS Pharmaceutical, LLC  
Xxxxx X. Xxxxxxxx  
Vice President Technical Operations  
000 Xxxxxxxxx Xxx  
Xxx Xxxx, XX 00000  
 With a copy to:  
 Noven Pharmaceuticals, Inc.  
Xx. Xxxx Xxxx  
Vice President and General  
00000 XX 000xx Xxxxxx  
Xxxxx,XX 00000  
 If to ANI:  
 ANIP Acquisition Company  
d/b/a ANI Pharmaceuticals, Inc.  
Xx. Xxxxxx X. Xxxxxxxx  
CEO  
0000 Xxxxxxxxxx Xxxx; Xxxxx 000  
Xxxxxxxx, Xxxxxxxx 00000  
 With a copy to:  
 Xxxxxxxxxxxx Xxxx & Xxxxxxxxx LLP  
1221 Avenue of the Xxxxxxxx  
00xx Xxxxx  
Xxx Xxxx, XX 00000  
Attn: Xx. Xxxx X. Xxxxx  
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 Each party may by written notice given to the other in accordance with this Agreement change the address to which notices to such party are to be delivered.  
13.2 Entire Agreement. This Agreement and the agreements being executed contemporaneously herewith contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, whether written or oral, between them with respect to the subject matter hereof and thereof. Each party has executed this Agreement without reliance upon any promise, representation or warranty other than those expressly set forth herein and in such other agreements.  
13.3 Amendment. No amendment of this Agreement shall be effective unless embodied in a written instrument executed by both of the parties.  
13.4 Waiver of Breach. The failure of either party at any time to enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any provisions hereof or the right of any party hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the party against whom or which enforcement of such waiver is sought; and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.  
13.5 Assignability. This Agreement may not be assigned by either party to any third party without the prior written consent of the other party: except that (i) either party may assign this Agreement, without the prior written consent of the other party, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation with or into such corporation and (ii) ANI may assign this Agreement, without the prior written consent of JDS, to any purchaser of the Facility. In the event of any such assignment, the assignee shall expressly assume in writing the performance of all the terms and conditions of this Agreement and all of the obligations to be performed by the assignor. Any assignment not in accordance with this Agreement shall be void.  
13.6 Governing Law; Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of Delaware without regard to its conflicts of laws principles. The parties consent to the personal jurisdiction and venue of the United States Federal Courts and further consent that any process, notice of motion or other application to either such court or a judge thereof may be served by registered or certified mail or by personal service, provided that a reasonable time for appearance is allowed.  
13.7 Severability. All of the provisions of this Agreement are intended to be distinct and severable. If any provision of this Agreement is or is declared to be invalid or unenforceable in any jurisdiction, it shall be ineffective in such jurisdiction only to the extent of such invalidity or unenforceability. Such invalidity or unenforceability shall not affect either the balance of such provision, to the extent it is not invalid or unenforceable, or the remaining provisions hereof, nor render invalid or unenforceable such provision in any other jurisdiction.  
13.8 Publicity. Neither party shall issue any press release or make any similar public announcement concerning the transactions contemplated in this Agreement, except as may be required by law (including federal securities law) or judicial order, without the prior written consent of the other party. Neither party shall issue any press release or make any similar announcement which includes the name of the other party or its affiliates or otherwise uses the name of the other party in any public statement or publicly released document except as required by law (including federal securities law) or with the prior written consent of the other party.  
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 13.9 Survival. The provisions of Section 2.5 (Delivery), Section 2.7 (Inspection of Products), Section 2.9 (Recalls), Section 3 (Representation and Warranties), Section 4.4 (Rights and Duties Upon Termination), Article V (Indemnification), Article VII (Confidentiality), Section 13.6 (Governing Law; Jurisdiction), Section 13.8 (Publicity) and this Section 13.9 (Survival) shall survive the termination or expiration of this Agreement for any reason.  
13.10 Headings. The headings of sections and subsections have been included for convenience only and shall not be considered in interpreting this Agreement.  
13.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. This Agreement may be executed and delivered via electronic facsimile transmission with the same force and effect as if it were executed and delivered by the parties simultaneously in the presence of one another.  
13.12 Execution. At the time of execution of this Agreement, the parties shall cause their authorized officers to execute two original copies of this Agreement, one copy of which shall be maintained by each party at that party’s offices. Each party represents that the person who executes this Agreement is authorized and empowered to obligate and bind his party under this Agreement.  
13.13 Facsimile Signatures. Any counterpart of this Agreement may be signed and transmitted by facsimile with the same force and effect as if such counterpart was an ink-signed original.  
[SIGNATURE PAGE FOLLOWS]  
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 IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed on the date first written above.  
 ANIP ACQUISITION COMPANY  
ANI PHARMACEUTICALS, INC.  
 By: /s/ Xxxx Xxxxxxxx   
 Name: Xxxx Xxxxxxxx   
 Title: Sr. Vice President, Sales and Marketing   
 Date: December 6, 2007   
 JDS PHARMACEUTICALS, LLC  
  
 By: /s/ Xxxxxxx X. Xxxxxxx   
 Name: Xxxxxxx X. Xxxxxxx   
 Title: Vice President, Operations   
 Date: January 2, 2008   
   
  
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