Exhibit 10.58  
 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 ADDENDUM NO. 1 to  
AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT  
 THIS ADDENDUM NO. 1 (this “Addendum”) is dated as of , 2010 and is between ANIP ACQUISITION COMPANY, d/b/a ANI PHARMACEUTICALS, INC., a Delaware corporation (“ANI”) and ALAVEN PHARMACEUTICALS, LLC, a Delaware limited liability company, (“ALAVEN”).  
 The parties wish to set forth additional terms and conditions under which ANI will purchase and store, on behalf of ALAVEN, the active pharmaceutical ingredient [\*\*\*].  
 TERMS AND CONDITIONS FOR [\*\*\*] PURCHASE AND STORAGE  
 I. ANI will place purchase orders, as requested by ALAVEN, for [\*\*\*] from ALAVEN’S designated [\*\*\*] Supplier;  
II. Immediately upon receipt of invoice from Supplier, ANI will forward such invoice to ALAVEN for reimbursement to ANI;  
III. ALAVEN will reimburse ANI upon receipt of Supplier’s invoice, whereupon ANI will immediately pay Supplier’s invoice;  
IV. Upon receipt of the [\*\*\*], ANI will store the material under cGMP conditions. Risk of damage or loss of the material shall remain with ALAVEN, unless ANI was negligent in the storage or handling of the [\*\*\*];  
V. ALAVEN will pay ANI $500 per month for up to two pallets of [\*\*\*], payable quarterly in advance.  
 IN WITNESS WHEREOF, the parties have caused this Addendum to be duly executed on the date first written above.  
 ANI PHARMACEUTICALS, INC.  
 ALAVEN PHARMACEUTICALS. INC.  
 By:  
/s/ Xxxxx X. Xxxxxx  
 By:  
/s/ Xxxxxxxx Xxxxx  
Name:  
Xxxxx X. Xxxxxx  
 Name:  
Xxxxxxxx Xxxxx  
Title:  
VP Operations  
 Title:  
Director, Supply Chain  
Date:  
12/1/2010  
 Date:  
12/1/2010  
 MEDA PHARMACEUTICALS INC.  
 By:  
/s/ Xxxxxx Xxxx  
 Name:  
Xxxxxx Xxxx  
 Title:  
VP of Supply Chain  
 Date:  
12/1/2010  
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 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 AMENDED AND RESTATED  
MANUFACTURING AND SUPPLY AGREEMENT  
 THIS AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”) is dated as of June 10, 2008, and is between ANIP ACQUISITION COMPANY, d/b/a ANI PHARMACEUTICALS, INC., a Delaware corporation (“ANI”), and ALAVEN PHARMACEUTICAL, LLC, a Delaware limited liability company, (“ALAVEN”).  
 The parties wish to set forth the terms and conditions under which ANI will manufacture for and supply to ALAVEN 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 thereunder from time to time.  
 “Additional Purchase Price” shall have the meaning given to that term in Section 2.4(b) hereof.  
 “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.  
 “API” means, as applicable to specific Products, [\*\*\*].  
 “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 each period of three (3) successive calendar months during each Contract Year, ending on March 31, June 30, September 30, and December 31.  
 “Contract Year” shall mean the period from the Effective Date through and including the date each year that is the day before the anniversary of the Effective Date, unless terminated before such later date as provided herein.  
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 “Closing Date” shall mean the date ANI closes on the Asset Purchase Agreement with Solvay Pharmaceuticals, Inc. and thereby acquires the equipment and facilities necessary to fulfill its obligations to ALAVEN under this Agreement.  
 “Effective Date” shall mean the Closing Date.  
 “Equipment” shall mean the equipment used by ANI in the production of the Products which is to be sold to ALAVEN as provided in Section 4.4(b).  
 “FDA” shall mean the United States Food and Drug Administration and any successor agency.  
 “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.  
 “Generic Product” shall have the meaning given that term in the License Agreement.  
 “Indemnitee” shall have the meaning given to that term in Section 5.3 hereof.  
 “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 hereto 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.  
 “Law” means any applicable statute, law, ordinance, rule, regulation, order, judgment, ruling or decree enacted, adopted, issued or promulgated by any Regulatory Authority.  
 “License Agreement” shall mean the License Agreement dated as of the date of this Agreement by and between ANI and ALAVEN.  
 “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.  
 “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.  
 “Original Date” shall mean April 30, 2007, the date the original Manufacturing and Supply Agreement was signed.  
 “PPI” shall have the meaning given to that term in Section 2.4(b) hereof.  
 “Products” shall mean the pharmaceutical dosage form consisting of:  
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 [\*\*\*] as an active ingredient in the presentations [\*\*\*] and incorporated herein by reference, including, without limitation, [\*\*\*], whether to be ultimately sold by ALAVEN under the [\*\*\*] or in generic form.  
 [\*\*\*] in the presentations [\*\*\*] incorporated herein by reference, including, without limitation, [\*\*\*], whether to be ultimately sold by ALAVEN under the [\*\*\*] or in generic form.  
 [\*\*\*] as an active ingredient in the presentations [\*\*\*] incorporated herein by reference, including, without limitation, [\*\*\*], whether to be ultimately sold by ALAVEN under the [\*\*\*] or in generic form.  
 [\*\*\*] in the presentations [\*\*\*] and incorporated herein.  
 “Product Specifications” shall mean the specifications for the Products attached hereto as Exhibit C and 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.  
 “Reglan Products” shall mean the Products to be manufactured hereunder in which Metoclopramide is the active ingredient.  
 “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.  
 “ANI’s Shipping Point” shall mean ANI’s facility in Baudette, Minnesota,  
 “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.  
 “Tooling” means the tooling currently or hereafter owned by ALAVEN which ALAVEN will permit ANI to use during the Term of this Agreement for the sole purpose of facilitating the manufacture of the Products by ANI. ANI will not have, and no provisions of the Agreement will be deemed to give to ANI, any interest in the Tooling.  
 ARTICLE II  
SUPPLY  
 2.1 Generally. Subject to the terms and conditions of this Agreement, ANI shall supply to ALAVEN and ALAVEN shall purchase from ANI the Products in such quantities as ALAVEN may order hereunder from time to time for its worldwide requirements. ANI shall supply the Products in  
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 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 ALAVEN. 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. Notwithstanding any other provision of this Agreement, ANI agrees not to manufacture, package or sell to any other person or entity any enema product containing [\*\*\*], any perianal wash, cream or lotion product, or any product containing [\*\*\*] (i) during the Term (as hereinafter defined), or (ii) for a period of two (2) years following termination of this Agreement by ANT or termination by ALAVEN pursuant to Section 4.3.  
 2.2 Forecasts.  
 (a) Initial Forecast. Within fifteen (15) business days of the Original Date, ALAVEN submitted to ANI a written forecast of its requirements for the Products (other than the [\*\*\*]) for the first Contract Year, the first Contract Quarter of which shall constitute a firm commitment of ALAVEN.  
 (b) Subsequent Forecasts. ALAVEN 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 ALAVEN.  
 2.3 Purchase Orders. Within thirty (30) days of the Original Date of this Agreement, ALAVEN placed its initial purchase order for the first quarter which is the initial firm commitment period described in Section 2.2(a). ALAVEN shall place orders for Products only in whole number multiples of specified-size lots. ALAVEN 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 efforts to fill any orders for quantities in excess of such maximum amount. ANI shall acknowledge and accept each purchase order received from ALAVEN which complies with the forecast and order procedures set forth herein, within four (4) business days after receipt. All contrary, inconsistent or additional provisions, terms or conditions of any purchase order, sales or order acknowledgement, invoice or other standard business form (a “Form”) of either party shall be superseded by this Agreement and shall be disregarded and have no force or effect. If a Form purports to be conditioned in any manner on agreement to and/or acceptance of any provisions, terms or conditions other than those set forth herein, then such condition is hereby deemed waived.  
 2.4 Pricing and Payment.  
 (a) General Price. The purchase price of Products supplied to ALAVEN hereunder shall be as shown in Exhibit A plus any applicable sales or use taxes, duties and other similar taxes, unless ALAVEN provides ANI with a valid resale certificate or other proof of exemption; provided, however, that ALAVEN has received a credit of [\*\*\*] against the costs that it would otherwise be required to reimburse to ANI under Section 2.10 hereof, reflecting the difference between the price paid for the [\*\*\*] products ordered by ALAVEN prior to June 30, 2007, and the price that ALAVEN would have paid for the [\*\*\*] products based on the price in effect as of the day prior to the Effective Date; provided further, that notwithstanding the foregoing, Product orders which are in process by Solvay prior to the Effective Date shall be invoiced at the purchase price in effect when the purchase order was placed with Solvay.  
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 (b) Price Changes. For purposes hereof, “Standard Cost” with respect to the initial two Contract Years shall mean [\*\*\*]. The Standard Cost for each Product shall be adjusted, effective as of the annual date of each Contract Year, beginning with the third Contract Year during the Term hereof, to equal [\*\*\*]. No later than sixty (60) days prior to the annual date of the Contract Year in the Initial/ Renewal Term, beginning with the Third Contract Year, ANI shall notify ALAVEN in writing of the new Standard Costs for the next Contract Year identifying the basis for any increases with reasonable specificity. Any upward adjustment shall not exceed the change in the U.S. Pharmaceutical Producer Price Index (“PPI”) over the preceding 12-month period.  
 (c) Other Increases and/or Payments: ANI may charge to ALAVEN and ALAVEN shall promptly pay (i) subject to agreement with ALAVEN as contemplated hereby, specific capital purchases that are directly and uniquely required for the ongoing Production of Products and/or to maintain the manufacture of Products in cGMP compliance (title to any such items vesting in ALAVEN upon payment), (ii) any other extraordinary expenses which are beyond the control of ANI but which are directly and uniquely required to maintain Production and supply of Products (for example environmental or other regulatory requirements that may be adopted after the date of this Agreement). In addition, specific material price increases for the active pharmaceutical ingredient charged by unaffiliated third parties that directly affects the Products and that exceeds the annual PPI may be included in Standard Cost as incurred on a first-in, first-out basis (subject to notification by ANI to ALAVEN of any such increase identifying the amount thereof with reasonable specificity). ALAVEN reserves the right to require ANI to provide explanations and records of any such Products specific issues and their necessity. ANI will consult with ALAVEN for consensus and written agreement prior to initiating capital purchases specific for the Products. ALAVEN acknowledges that any refusal of consent to such capital purchases may detrimentally affect the ability of ANI to perform its obligations hereunder and any resulting failure to perform shall be deemed a consensual cessation of supply hereunder, pending agreement being reached on which party will purchase such items and the allocation of the cost between the parties. Except for the adjustments to Standard Cost expressly permitted by this subsection (c), costs paid by ALAVEN to ANI pursuant to this subsection shall not be included in Standard Cost.  
 (d) Invoicing and Payment. ANI shall invoice ALAVEN for each shipment of the Products simultaneously with ANI’s actual shipment of Products and delivery to ALAVEN of a certificate of analysis relating to such shipment. Payment shall be due within [\*\*\*] 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 ALAVEN 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 ALAVEN at least once per year solely for the purpose of verifying price increases pursuant to this Section 2.4 and other costs for which ALAVEN is responsible. ALAVEN shall be responsible for the costs of any such inspection and audit, provided that if it is determined that ALAVEN has paid costs which exceed the costs as to which ALAVEN 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 ALAVEN overpayment.  
 (f) FDA Establishment Fee. ALAVEN will be responsible for the entire FDA Establishment Fee, but only so long as ALAVEN is the sole NDA holder (without generic equivalent) for the Facility; it being acknowledged and agreed by ANI that if there are any other present or future NDA holders whose products do not have generic equivalents who are supplied from the Facility such NDA holders will share such costs on a pro rated basis.  
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 2.5 Delivery.  
 (a) Generally. All Products sold to ALAVEN hereunder shall be delivered to ALAVEN FOB ANI’s Shipping Point. All risk of loss shall pass to ALAVEN when ANI so delivers Products to a carrier for ALAVEN. ALAVEN shall designate a carrier and mode of shipment on each purchase order submitted to ANI; provided, however, that should ALAVEN fail to designate a carrier on its purchase order, ANI shall use the common carrier designated by ALAVEN as its default carrier, or if ALAVEN shall fail to designate a default carrier, ANI may select a common carrier for the account and risk of ALAVEN.  
 (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 ALAVEN’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 ALAVEN. Deviations of more than forty-five (45) days shall be deemed unreasonable, unless ALAVEN has on hand an inventory of Products sufficient to meet ALAVEN’s requirements (based on its forecasts delivered to ANI under Section 2.2) for 90 days, in which case deviations of more than 60 days will be deemed unreasonable.  
 (c) Delay in Delivery. ALAVEN recognizes the inherent difficulty in producing the Products and also recognizes that delays in shipment, while non-routine, may occur from time to time. ANI shall notify ALAVEN 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 therefore. ANI shall use commercially reasonable efforts to avoid or minimize the delay, including, when necessary or at ALAVEN’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 ALAVEN shall be borne solely by ALAVEN. 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 ALAVEN may have hereunder, ALAVEN shall have the right to cancel any order which is not made available for shipment FOB ANI’s Shipping Point for more than sixty (60) days 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 ALAVEN. 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 ALAVEN’s demand for Products and the demands of ANI’s other customers (including ANI and ANFs Affiliates), ANI shall give ALAVEN’s demand at least equal priority to those of ANFs other customers (including ANI and ANFs Affiliates).  
 2.6 Labeling and Packaging.  
 (a) Generally. ALAVEN 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 ALAVEN’s forecasts under Section 2.2 hereof constitute a firm commitment. Acquisition of  
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 additional inventory of Labeling components beyond the three (3) month commitment shall be made only with advance consultation of ALAVEN.  
 (b) Changes. Should ALAVEN desire or be required to change any component of Labeling or to introduce a new packaging component to which Labeling will be affixed, ALAVEN 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 ALAVEN printer’s proofs of all Labeling for ALAVEN’s review. Within fifteen (15) business days of its receipt of such proofs, ALAVEN shall either provide to ANI any necessary corrections thereto or notify ANI of its approval of such proofs. Upon ALAVEN’s acceptance thereof, ANI shall return all artwork provided by ALAVEN. ANI shall be entitled to directly charge ALAVEN, 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 ALAVEN’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 ALAVEN direct, out-of-pocket expenses in a one-time charge after completion of the Labeling transition.  
 2.7 Stability Testing; Inspection of Products.  
 (a) Stability Testing. ANI shall provide stability testing for Products manufactured hereunder, and shall provide all stability results to ALAVEN in a timely fashion. ANI and ALAVEN shall agree to a work outline to accomplish an acceptable stability program, including, but not limited to, the stability testing and release costs associated with the [\*\*\*] as set forth on Exhibit E hereto, which is incorporated herein. ANI shall retain a suitable quantity of retained samples until twelve (12) months after the stated expiration date for the tested Product. ANI shall promptly notify ALAVEN in advance 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, once approved by ALAVEN (with such approval not unreasonably withheld), shall be charged to and shall be the sole responsibility of ALAVEN (through an adjustment to the Standard Cost). ANI will notify ALAVEN of stability failures within 24 hours of ANFs becoming aware of any such failure.  
 (b) Certificate of Analysis. ANI will provide ALAVEN with a certificate of analysis for all batches of Products shipped to ALAVEN which shall include, without limitation, the expiry date. Such certificate of analysis shall be delivered to ALAVEN at the time of shipment of the Products. Delivery of any Products by ANI to ALAVEN 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. ALAVEN shall store all Products in conditions as specified in the Product Specifications. All Products delivered to ALAVEN 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 Products that has an initial labeled expiry period of 24 months, the Products delivered must have at least 21 months remaining expiry period upon receipt by ALAVEN.  
 (c) Nonconformance. Within thirty (30) days after its receipt of each shipment of Products at the destination specified in the shipping instructions, ALAVEN 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, ALAVEN discovers any Nonconformance, ALAVEN [\*\*\*] reject the nonconforming portion of such shipment by giving prompt written notice to ANI. Such notice shall include a copy of ALAVEN’s test  
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 results and specify the precise Nonconformance upon which such rejection is based. Absent such notification, ALAVEN 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 Nonconformance arising out of the shipment, storage, use or handling of the Products following its delivery FOB AM’s Shipping Point.  
 (d) Procedure. Upon notifying ANI of any Nonconformance, or upon notifying ANI of any Latent Defects, ALAVEN 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 ALAVEN with respect to such undelivered or nonconforming Products and reimburse ALAVEN for the costs of shipping such Products. ANI may, at its sole option, either direct ALAVEN to return nonconforming Products to ANI or have it destroyed by ALAVEN, 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 ALAVEN may have against ANI with respect to undelivered or nonconforming Products in that shipment, provided replacement Products is available to ALAVEN within thirty (30) days of the identified shortage.  
 2.8 Inspection of Facility. ALAVEN 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. ALAVEN 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), ALAVEN shall have the exclusive responsibility to appropriately manage such action; provided, however, that for the first seven (7) days following any such action, ALAVEN may delegate such responsibility to ANI and ANI agrees to discharge such responsibility with the same degree of care and diligence as ANI would with respect to its own products. If such corrective action or market action is 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 ALAVEN shall be responsible for such costs. ALAVEN shall also be exclusively responsible for handling all customer complaints, inquiries and the like, and ANI shall appropriately cooperate with ALAVEN,  
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 including the completion of an investigation and the preparation and submission of a complaint report to ALAVEN or its designees.  
 2.10 Process Improvements and Development Activities. All future development and/or process improvement activities will require the discussion, evaluation and approval of a joint team, comprised of named ad-hoc members as appropriate, based on functional roles, from both ALAVEN and ANI, prior to implementation. All costs of materials for these additional mutually agreed improvement and development activities will be the responsibility of ALAVEN. The costs of ANI’s personnel that execute the experiments, physical development activities and other related activities resulting from this team will be the responsibility of ALAVEN and will be invoiced at ANI’s usual and customary rates; provided, however, that the specific current development activities associated with any reformulation of the [\*\*\*] which are to be paid by ALAVEN under this Section 2.10, will be paid based on ANI’s cost, including laboratory and manufacturing personnel costs, materials and supplies. Issues that cannot be resolved through this joint team will be escalated to the CEO’s of both organizations for final resolution.  
 2.11 Transfer of [\*\*\*]. ANI agrees, [\*\*\*], to have the manufacture of the [\*\*\*] transferred to ANI in accordance with the transfer responsibilities set forth on Exhibit F hereto, as incorporated herein. ALAVEN agrees to complete the required regulatory filing for the transfer of the manufacture of the [\*\*\*] to ANI, it being agreed, however, that ANI will promptly provide ALAVEN with CMC and such information as shall be required for ALAVEN to complete the regulatory filing. Based upon the knowledge and experience of ANI and ALAVEN, the Parties anticipate that: (i) the transfer of the manufacture of the [\*\*\*] will be completed by December 31, 2008, and (ii) the regulatory filing associated with such transfer will be completed within thirty (30) days of the receipt of the final three (3) month stability report (or other documentation deemed essential by ALAVEN to the regulatory filing) for the registration batches.  
 2.12 On-going Stability. Cost associated with on-going stability presently being conducted by the current manufacturer of the Products will be paid by ALAVEN. In the event of ALAVEN product discontinuation, stability testing and associated cost will continue as ALAVEN’s responsibility through the conclusion of the required stability testing with respect to the Branded Product, unless a single stability test is being conducted for both the Branded Product and the Generic Product, in which case the costs will continue to be paid by ANIP as provided in Exhibit E.  
 ARTICLE III  
REPRESENTATIONS AND WARRANTIES  
 3.1 Representations and Warranties of ANI. ANI represents and warrants to ALAVEN as follows:  
 (a) Conformance of Products. Subject to ALAVEN’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.  
 (b) Adulteration: Misbranding. Subject to ALAVEN’s obligations with respect to supplies of the Labeling Specifications under Section 2.6 hereof, no Products supplied by ANI to ALAVEN under this Agreement shall, at the time of delivery to the carrier FOB ANI’s Shipping Point, be adulterated or misbranded within the meaning of the Act or be an article which may not be introduced into interstate commerce under the provisions of Section 505 of the Act.  
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 (c) 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.  
 (d) 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.  
 (e) No Conflict: Consents. The execution and delivery of this Agreement by ANI 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) no consents or agreements of any third party (including governmental bodies) is 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.  
 3.2 Representations and Warranties of ALAVEN. ALAVEN represents and warrants to ANI as follows:  
 (a) Organization: Standing. ALAVEN 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 ALAVEN of this Agreement, the performance by ALAVEN of its obligations hereunder and the consummation by ALAVEN of the transactions contemplated hereby have been duly authorized by all necessary action on the part of ALAVEN. This Agreement has been duly executed and delivered by a duly authorized officer of ALAVEN and constitutes the valid and legally binding obligation of ALAVEN enforceable against ALAVEN in accordance with its terms.  
 (c) No Conflict: Consents. The execution and delivery of this Agreement by ALAVEN 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 ALAVEN or any Affiliate is a party, or any Law to which ALAVEN or any Affiliate is subject and (b) no consents or agreements of any third party (including governmental bodies) is necessary for the performance by ALAVEN of its obligations under this Agreement.  
 3.3 Limitations.  
 (a) EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, THE 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 ALAVEN 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;  
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 (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 AND THE ASSET PURCHASE 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.  
 (b) THE MAXIMUM AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT SHALL NOT 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 IV; provided further that ALAVEN shall have the option, in its sole discretion, (a) to terminate this Agreement in the event the Closing Date has not occurred on or prior to June 30, 2007 and (b) 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 Termination By Mutual Agreement. The parties may terminate this Agreement any time by mutual written agreement.  
 4.3 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  
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 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.  
 4.4 Rights and Duties Upon Termination.  
 (a) Supply and Purchase of Products. Unless otherwise mutually agreed by the parties, ANI shall supply, and ALAVEN shall purchase in accordance with the provisions hereof, all quantities of Products ordered by ALAVEN 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, ALAVEN shall remain liable for and shall duly pay all costs incurred prior to the effective date of expiration or termination which are properly chargeable to ALAVEN pursuant to the terms of this Agreement. ALAVEN 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 and Equipment. Upon the expiration or termination of this Agreement, ALAVEN 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, ALAVEN 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 ALAVEN shall be limited solely to materials obtained, Products manufactured and non-cancelable commitments incurred by ANI for quantities of the Products as to which ALAVEN’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 ALAVEN become the property of ALAVEN and ANI will, at the request of ALAVEN, arrange to ship such materials to locations designated by ALAVEN. The cost of the freight shall be borne by ALAVEN. The foregoing purchase and payment obligations shall not apply in the event of a termination by ALAVEN based on a breach by ANI of its supply obligations. In addition, upon request from ALAVEN, which request shall [\*\*\*], ANI shall be obligated to promptly sell to ALAVEN such of the following equipment [\*\*\*]: (i) the machinery used by ANI to produce the [\*\*\*], at a price of not more than [\*\*\*]; (ii) the [\*\*\*] at a price of not more than [\*\*\*]; and (iii) the [\*\*\*] at a price of not more than [\*\*\*] at the time of sale to ALAVEN.  
 (c) Tooling: Upon any termination of this Agreement by either party for any reason, all Tooling shall be promptly returned to ALAVEN.  
 ARTICLE V  
INDEMNIFICATION  
 5.1 By ANI. Subject to the limitations described in Section 3.3, ANI shall defend, indemnify and hold harmless ALAVEN 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  
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 negligent storage or handling of the Products by ANI prior to delivery to ALAVEN 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 ALAVEN 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 ALAVEN. Subject to the limitations set forth in Section 3.3, ALAVEN 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 ALAVEN hereunder, (b) any negligent act or omission of ALAVEN or its employees, agents or other contractors with respect to the Products, (c) the failure of ALAVEN 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 ALAVEN, (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 ALAVEN FOB ANI’s Shipping Point. Notwithstanding the preceding sentence, ALAVEN shall not be required to indemnify ANI with respect to any Claim arising from ANI’s breach of its representations, warranties or covenants hereunder or under the Asset Purchase Agreement 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  
 Subject to the terms of the Asset Purchase Agreement, ALAVEN 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 Products, and for reporting all such matters to appropriate Regulatory Authorities in accordance with applicable law. ANI shall provide ALAVEN with any technical  
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 information relating to formulation, manufacture or stability of the Products necessary to enable ALAVEN to perform all such activities and to determine whether the adverse event, customer inquiry or complaint involves a Nonconformance, Latent Defect or necessitates a recall or other corrective or market action. Should ANI receive any notice or inquiry regarding adverse events, it shall transmit them to ALAVEN within 24 hours.  
 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 nor 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 or in the Asset Purchase Agreement or the Transition Services Agreement (as defined in the Asset Purchase Agreement).  
 7.3 Exceptions. Notwithstanding Section 7.1 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 reasonable 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 ALAVEN is required to submit. The costs and expenses of such cooperation, if applicable, shall be subject to the parties’ mutual agreement. ALAVEN shall be responsible for all regulatory reporting of Products. ANI shall assist ALAVEN by providing necessary support and information and shall prepare the annual cGMP Products reviews.  
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 ARTICLE IX  
FORCE MAJEURE  
 9.1 Effects of Force Maieure. 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.  
 9.4 Limitation. Notwithstanding anything to the contrary herein, in the event a Regulatory Change or Force Majeure Event continues for more than 90 days, ALAVEN shall have the right to terminate this Agreement upon notice and upon ALAVEN’s request, ANI shall cooperate to assist in the transfer of technology to a new manufacturer at no additional labor cost to ALAVEN. ALAVEN 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 ALAVEN 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 ALAVEN. 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.  
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 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 Chief Operating Officer of ANI, or such person’s designee of equivalent or superior position, and the Chief Operating Officer of ALAVEN, 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 ALAVEN, one (1) of whom is selected by ANI and one (1) of whom is selected by ANI and ALAVEN (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 the 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.  
 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 ALAVEN:  
 ALAVEN Pharmaceutical, LLC  
0000 Xxxxxxxxx Xxxxxxx, Xxxxx X  
Xxxxxxxx, XX 00000  
Attn: CEO  
 With a copy to:  
 Xxxxx, Xxxxxx, XxxXxx & Xxxxxxxxxx, P.C.  
000 X. Xxxxxx Xxxxxx, Xxxxx 0000  
 00  
  
 Xxxxxxx, XX 00000  
Attn: Xxxxxxxxxxx X. Xxxxxxx  
 If to ANI:  
 ANIP Acquisition Company  
d/b/a ANI Pharmaceuticals, Inc.  
0000 Xxxxxxxxxx Xxxx, Xxxxx 000  
Xxxxxxxx, XX 00000  
Attention: President & CEO  
 With a copy to:  
 Xxxxxxxxxxxx Xxxx & Xxxxxxxxx LLP  
1221 Avenue of the Xxxxxxxx  
00xx Xxxxx  
Xxx Xxxx, XX 00000  
Attn: Xx. Xxxx X. Xxxxx  
 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. ANI may assign this agreement with the consent of ALAVEN, which consent will not be unreasonably withheld. ALAVEN shall have the right to assign all of its right, title and interest hereunder to any third party. In the event that this Agreement is assigned by ALAVEN to a competitor of ANI, ANI shall have the right to increase the price charged for Products hereunder to include a conventional contract manufacturer’s profit. This Agreement shall be binding upon and inure to the benefit of the parties, their successors and permitted assigns.  
 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  
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 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.  
 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 VI (Adverse Event Reports), 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.  
 IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed on the date first written above.  
 ANI PHARMACEUTICALS, INC.  
 ALAVEN PHARMACEUTICAL, LLC  
 By:  
/s/ Xxxxxx X. Xxxxxxxx  
 By:  
/s/ Xxxxxxx Xxxxxxxx  
Name:  
Xxxxxx X. Xxxxxxxx  
 Name:  
Xxxxxxx Xxxxxxxx  
Title:  
President & CEO  
 Title:  
VP & CFO  
Date:  
June 10, 2008  
 Date:  
6/13/2008  
 18  
  
 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 EXHIBIT A  
 Amended and Restated  
 Initial Product Quantity and Purchase Price  
 Manufacture and Packaging  
 PRODUCT  
 SIZE  
 NDA#  
 BATCH  
QTY  
 PRICE/Unit  
 2007 Annual  
Units  
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 \* Price Based on [\*\*\*]  
 \*\* Price for [\*\*\*]  
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 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 EXHIBIT B  
 AMENDED AND RESTATED LABELING SPECIFICATIONS  
 [NOT ATTACHED TO EXECUTED AGREEMENT]  
 B-1  
  
 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 EXHIBIT C  
 AMENDED AND RESTATED PRODUCTS SPECIFICATIONS  
 [NOT ATTACHED TO EXECUTED AGREEMENT]  
 C-1  
  
 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 EXHIBIT D  
 QUALITY AGREEMENT  
 [NOT ATTACHED TO EXECUTED AGREEMENT]  
 D-1  
 Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]  
 EXHIBIT E  
 [\*\*\*](1)  
 TIME - 0  
 TIME - 1  
 TIME - 2  
 TIME - 3  
 TIME - 6  
 TIME - 9  
 TIME - 12  
 TIME - 18  
 TIME - 24  
 TOTAL  
INITIAL STABILITY PROGRAM  
 MFG. OF FIRST THREE PRODUCTS(2)  
 [\*\*\*]  
 [\*\*\*]  
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 · Costs Reflect Ongoing Manufacturing of [\*\*\*]  
· Lab test cost/hrs subject to annual review for hourly rate, materials and man hours  
· Rate is based upon estimated lab cost. Actual hours and out of pocket cost will be Invoiced  
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