18-03277-E

March 14 2018

US Securities & Exchange Commission Office of FOIA and Privacy Act Operations 100 F Street, NE Mail Stop 5100 Washington, DC 20549-5100



Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following:

A copy of: Exhibit 10.6 to the form 10-Q filed by NOVEN PHARMACEUTICALS INC on November 9, 2007

In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to \$61.00 in processing fees. Thank You,

Paul D'Souza Editor - Deals

Clarivate Analytics Friars House, 160 Blackfriars Road London, UK SE1 8EZ

Phone: +44-2074334789 paul.dsouza@clarivate.com



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

April 9, 2018

Mr. Paul D'Souza Clarivate Analytics 160 Blackfriars Road London, UK SE18EZ

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552

Request No. 18-03277-E

Dear Mr. D'Souza:

This letter is in response to your request, dated March 14, 2018 and received in this office on March 14, 2018, for Exhibit 10.6 to the Form 10-Q filed by Noven Pharmaceuticals, Inc. on November 9, 2007.

The search for responsive records has resulted in the retrieval of 19 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed for the process of this request. If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Clarissa Anderson FOIA Research Specialist

larissa Anderson

Enclosure



MANUFACTURING AND SUPPLY AGREEMENT

THIS MANUFACTURING AND SUPPLY AGREEMENT (this "Agreement") is dated as of August 25, 2004 and is between SOLVAY PHARMACEUTICALS, INC., a Georgia corporation ("SOLVAY"), and JDS PHARMACEUTICALS, LLC, a New York limited liability company, ("JDS").

The parties wish to set forth the terms and conditions under which SOLVAY will manufacture for and supply to JDS the Product 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% of more of such voting power of a party hereto.

"Agreement" shall have the meaning given to that term in the introductory paragraph hereof.

"Asset Purchase Agreement" shall mean the Asset Purchase Agreement dated August ___, 2004, between JDS and SOLVAY providing for the sale and purchase of the Purchased Assets (as defined therein) by SOLVAY to JDS.

"cGMP" means the current Good Manufacturing Practice regulations applicable to the manufacture of the Product hereunder.

"Claims" shall have the meaning given to that term in <u>Section 5.1</u> 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, 2004 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, 2004 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.

"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.

"Indemnitor" shall have the meaning given to that term in Section 5.3 hereof.

"Labeling" shall mean all unit Product labels, package inserts, carton imprints, tablet debossing and/or imprinting and all other markings on packaging for, or other similar materials related to, the Product that are defined as labels or labeling under any applicable law or regulation.

"Labeling Specifications" shall mean the labeling and packaging specifications for the Product 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.

"Manufacturing Standards" shall mean all U.S. Laws applicable to the manufacture of the Product.

"Net Sales" shall have the meaning given to that term in Section 2.4(b)(iii) hereof.

"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(c) hereof.

"Product" 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 Product attached hereto as Exhibit C, incorporated by reference herein, the Product 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 Product (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 Product 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 Product.

"Sales Year" shall have the meaning given to that term in Section 2.4(b) hereof.

"SOLVAY's Shipping Point" shall mean either SOLVAY's facility in Marietta, Georgia or Baudette, Minnesota, as SOLVAY may designate.

"Specifications" shall mean the Product Specifications and the Labeling Specifications.

"Standard Cost" shall have the meaning given to that term in Section 2.4(c) hereof.

ARTICLE II SUPPLY

2.1 Generally. Subject to the terms and conditions of this Agreement, SOLVAY shall supply to JDS and JDS shall purchase from SOLVAY the Product 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, SOLVAY shall supply the Product in finished, packaged form and tested in accordance with the Specifications and Manufacturing Standards. SOLVAY will not implement any change in materials, components, processes or test methods without consulting with and receiving the prior written approval of JDS. SOLVAY 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) <u>Initial Forecast</u>. Within fifteen (15) business days of the signing of this Agreement, JDS shall submit to SOLVAY a written forecast of its requirements for the Product for the first Contract Year, the first Contract Quarter of which shall constitute a firm commitment of JDS.
- (b) <u>Subsequent Forecasts</u>. JDS shall submit to SOLVAY by the first day of each successive Contract Quarter a 12-month rolling forecast, by Contract Quarter, of its requirements for the Product, the first quarter of which shall constitute a firm commitment of JDS.
- 2.3 <u>Purchase Orders</u>. 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 Product only in whole number multiples of specified-size lots. JDS shall place each subsequent order for Product by delivering to SOLVAY 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 SOLVAY 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 SOLVAY hereunder; <u>provided</u>, <u>however</u>, that SOLVAY will use commercially reasonable efforts to fill any orders for quantities in excess of such maximum amount.

SOLVAY 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. All contrary, inconsistent or additional provisions, terms and conditions of any purchase order, sales or order acknowledgment, 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) <u>General Price</u>. The purchase price of Product supplied to JDS hereunder shall be equal to (i) <u>SOLVAY's Standard Cost of the Product supplied as shown in <u>Exhibit A</u> plus (ii) any applicable sales or use taxes, duties and other similar taxes, unless JDS provides SOLVAY with a valid resale certificate or other proof of exemption.</u>
- (b) Additional Purchase Price. During any period that SOLVAY continues to supply JDS's requirements of Product from a SOLVAY facility pursuant to the terms hereof, JDS agrees to pay SOLVAY, as additional purchase price (the "Additional Purchase Price"), an amount equal to 10% of the amount, if any, by which JDS's Net Sales (as defined below) of Product for any consecutive 12 month period-beginning with the Closing (each such consecutive 12 month period, a "Sales Year") exceeds \$12,000,000 (representing the approximate annualized net sales of Product based upon SOLVAY'S net sales for the quarter ended June 30, 2004), payable in accordance with, and subject to the following terms and conditions:
- (i) Additional Purchase Price shall only be payable in respect of a Sales Year if, during such Sales Year, (A) SOLVAY has delivered at least 90% of the quantities of Product ordered by JDS, which orders comply with the forecast and firm order procedures set forth-herein, within 60 days of the delivery dates specified in the JDS purchase orders and (B) there has been a period of at least 150 consecutive days during such Sales Year during which no generic equivalent to the Product manufactured by a third party has been sold on a commercial basis to retailers in the Territory.
- (ii) Additional Purchase Price due shall be payable within 60 days of the end of the Sales Year to which such payment relates. Each payment of Additional Purchase Price will be accompanied by a statement which sets forth the calculation of Additional Purchase Price with reasonable specificity. JDS shall maintain accurate books and records reflecting Net Sales, which books and records shall be available for inspection and audit by SOLVAY no more than once per Sales Year solely to the extent necessary, and for purposes of, verifying the amount of Additional Purchase Price payable hereunder. The cost of any such inspection and audit shall be for the account of SOLVAY; provided that if any such audit reveals an underpayment of Additional Purchase Price for any Sales Year of 5% of more, JDS shall be responsible for the reasonable costs of such audit together with correcting the payment shortfall.
- (iii) For purposes of this Section, "Net Sales" shall mean the amount invoiced by JDS, its Affiliates or licensees for Product in the Territory to third parties, less deductions for returns (including withdrawals and recalls), allowance for doubtful accounts, rebates (price reductions, including Medicaid and similar types of discounts or rebates, e.g., chargebacks and administrative fees charged by third parties directly related to Product sales), volume and cash discounts earned, and sales, use, excise and other taxes incurred directly in connection with the sales of Product. Sales and deductions from sales shall be recognized and accrued in accordance with generally accepted

accounting principles. Net Sales shall be determined on the basis of the Product alone and shall not reflect discounts or price concessions attributable to the purchase of any other JDS product.

- (c) Price Changes. For purposes hereof, "Standard Cost" with respect to the initial Contract Year and each Product shall mean SOLVAY's cost for manufacturing such Product as set forth on Exhibit A attached hereto and incorporated by reference herein. The Standard Cost for each Product shall be adjusted, effective as of January 1 of each Contract Year during the term hereof, to equal SOLVAY's costs for manufacturing such Product for such year, determined by SOLVAY in accordance with its usual and customary accounting procedures. No later than November 1 of each Contract Year, SOLVAY shall notify JDS in writing of the new Standard Costs for the next Contract Year identifying the bases 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.
- Other Increases and/or Payments: SOLVAY may charge to JDS and JDS shall promptly pay (i) subject to agreement with JDS as contemplated hereby, specific capital purchases that are directly and uniquely required for the ongoing production of Product and/or to maintain the manufacture of Product in cGMP compliance (title to any such items vesting in JDS upon payment), (ii) the costs of rejected material for the Product at the granulation and/or compression stages of processing, to be billed at SOLVAY's material and labor costs only, subject to an annual maximum of \$50,000, and (iii) any other extraordinary expenses directly and uniquely required to maintain production and supply of Product (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 Product 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 SOLVAY to JDS of any such increase identifying the amount thereof with reasonable specificity). JDS reserves the right to require SOLVAY to provide explanations and records of any such Product specific issues and their necessity. SOLVAY will-consult with JDS for consensus and written agreement prior to initiating capital purchases specific for the Product. JDS acknowledges that any refusal of consent to such capital purchases may detrimentally affect the ability of SOLVAY 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 (d), costs paid by JDS to SOLVAY pursuant to this subsection shall not be included in Standard-Cost.
- (e) <u>Invoicing and Payment</u>. SOLVAY shall invoice JDS for each shipment of the Product simultaneously with SOLVAY's actual shipment of Product 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.
- (f) <u>Books and Records</u>. SOLVAY shall maintain accurate books and records of Standard Cost and other costs for which JDS is responsible pursuant to <u>Section 2.4</u> which shall 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 <u>Section 2.4</u> 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 <u>Section 2.4</u> by more than 5%, SOLVAY 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) <u>Generally</u>. All Product sold to JDS hereunder shall be delivered to JDS FOB SOLVAY's Shipping Point. All risk of loss shall pass to JDS when SOLVAY so delivers Product to carrier for JDS. JDS shall designate a carrier and mode of shipment on each purchase order submitted to SOLVAY; <u>provided</u>, <u>however</u>, that should JDS fail to designate a carrier on its purchase order, SOLVAY may select a common carrier for the account and risk of JDS.
- (b) <u>Deviation from Agreed Delivery Time</u>. SOLVAY 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 ninety (90) days shall be deemed unreasonable, unless JDS has on hand an inventory of Product sufficient to meet JDS's requirements (based on its forecasts delivered to SOLVAY under Section 2.2) for 150 days, in which case deviations of more than 150 days will be deemed unreasonable.
- Delay in Delivery. JDS recognizes the inherent difficulty in producing the (c) Product and also recognizes that delays in shipment, while non-routine, may occur from time to time. SOLVAY shall notify JDS promptly of any circumstance that may cause a delay in making Product available for shipment FOB SOLVAY's Shipping Point, stating the estimated period of delay and the reasons therefore. SOLVAY 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 SOLVAY'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 JDS. Notwithstanding the foregoing, SOLVAY 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 hereunder or under Article IX hereof.
- (d) <u>Priority of Supply</u>. If for any reason (including without limitation, a back order situation, a Force Majeure Event or a Regulatory Change) SOLVAY is unable to supply JDS's demand for Product and the demands of SOLVAY's other customers (including SOLVAY's affiliates), SOLVAY shall give JDS's demand at least equal priority to those of SOLVAY's other customers.

2.6 <u>Labeling and Packaging</u>.

- (a) Generally. JDS shall provide to SOLVAY 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. SOLVAY shall be responsible for procuring all Labeling, which shall be created in accordance with the Labeling Specifications. With respect to all Product to be supplied in finished, packaged form, SOLVAY shall procure sufficient Labeling to cover quantities of the Product 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.
- Changes. Should JDS desire or be required to change any component of Labeling (b) or to introduce a new packaging component to which Labeling will be affixed, JDS shall so inform SOLVAY and shall be responsible for updating the artwork or text, as applicable, and providing it to SOLVAY in camera-ready or electronic form and in compliance with the Labeling Specifications. SOLVAY 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 SOLVAY any necessary corrections thereto or notify SOLVAY of its approval of such proofs. Upon JDS's acceptance thereof, SOLVAY shall return all artwork provided by JDS. SOLVAY 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. SOLVAY will charge JDS direct, out-of-pocket expenses in a one-time charge after completion of the Labeling transition.

2.7 Stability Testing; Inspection of Product.

- (a) <u>Stability Testing</u>. SOLVAY shall provide stability testing for Product manufactured hereunder, and shall provide all stability results to JDS in a timely fashion. SOLVAY and JDS shall agree to a work outline to accomplish an acceptable stability program. SOLVAY shall retain a suitable quantity of retained samples. Any costs associated with the agreed upon stability testing program for the Product beyond those which SOLVAY customarily and routinely incurs in connection with stability testing shall be charged to and shall be the sole responsibility of JDS (through an adjustment to the Standard Cost). SOLVAY will notify JDS of stability failures within 48 hours of SOLVAY's becoming aware of any such failure.
- (b) <u>Certificate of Analysis</u>. SOLVAY will provide JDS with a certificate of analysis for all batches of Product 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 Product. Delivery of any Product by SOLVAY to JDS shall constitute a certification by SOLVAY that at the time of delivery the Product conforms to the certificate of analysis provided therewith and the Product Specifications and was manufactured in accordance the Manufacturing Standards. JDS shall store all Product in conditions as specified in the Product Specifications. All Product delivered to JDS shall have a remaining expiry period of no more than four 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 18 months, the Product delivered must have at least 14 months remaining expiry period upon receipt by JDS.

- (c) <u>Nonconformance</u>. Within thirty (30) days after its receipt of each shipment of Product 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 SOLVAY 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 SOLVAY. 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. In no event shall SOLVAY be liable for any Nonconformance arising out of the shipment, storage, use or handling of the Product following its delivery FOB SOLVAY's Shipping Point.
- Procedure. Upon notifying SOLVAY of any Nonconformance, JDS shall afford (d) SOLVAY 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 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, then SOLVAY shall use commercially reasonable efforts to make up the shortage or replace any nonconforming Product, as the case may be, with such new Product to be shipped at SOLVAY's expense to the same destination as the original shipment. If SOLVAY is unable to make up the shortage or replace any nonconforming Product, it shall promptly refund any money paid by JDS with respect to such undelivered or nonconforming Product and reimburse JDS for the costs of shipping such Product. SOLVAY may, at its sole option, either direct JDS to return nonconforming Product to SOLVAY, have it destroyed by JDS, or destroy them (and certify such destruction to SOLVAY), all at SOLVAY's expense. SOLVAY's supply of substitute Product 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 SOLVAY with respect to undelivered or nonconforming Product in that shipment, provided replacement Product is available to JDS within thirty (30) days of the identified shortage.
- 2.8 <u>Inspection of Facility.</u> JDS or its designees may, at its sole expense, inspect the facilities being used by SOLVAY to manufacture, package, store or ship the Product 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 SOLVAY'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 Product (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 necessitated by the breach by one of the parties of any of its warranties, representations, obligations, covenants or agreements contained herein, 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 SOLVAY 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. JDS recognizes that SOLVAY has been conducting activities to support process changes and improvements in the manufacturing and analysis of the Product. SOLVAY commits to continuing the activities listed in Exhibit E, Part 1, with the intent of filing these changes with the FDA, followed by subsequent implementation. SOLVAY also has other improvement activities underway (listed in Exhibit E, Part 2) and commits to continuing these to a reasonable point of cessation. 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 JDS and SOLVAY, prior to implementation. All costs of materials for these additional mutually agreed improvement and development activities will be the responsibility of JDS. The costs of SOLVAY's personnel that execute the experiments, physical development activities and other related activities resulting from this team will be the responsibility of JDS and will be invoiced at SOLVAY's usual and customary rates. Issues that cannot be resolved through this joint team will be escalated to the CEO's of both organizations for final resolution.

ARTICLE III REPRESENTATIONS AND WARRANTIES

- 3.1 <u>Representations and Warranties of SOLVAY</u>. SOLVAY represents and warrants to JDS as follows:
- (a) <u>Conformance of Product</u>. Subject to JDS's obligations with respect to supplies of the Labeling Specifications under <u>Section 2.6</u> hereof, each certification by SOLVAY pursuant to <u>Section 2.7(b)</u> shall be deemed a representation and warranty hereunder, any breach of which representation and warranty being subject to the provisions of <u>Section 5.1</u>, <u>Section 2.7(c)</u> and <u>Section 2.7(d)</u> and the limitations contained in <u>Section 3.3</u>.
- (b) Adulteration; Misbranding. Subject to JDS's obligations with respect to supplies of the Labeling Specifications under Section 2.6 hereof, no Product supplied by SOLVAY to JDS under this Agreement shall, at the time of delivery to the carrier FOB SOLVAY'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.
- (c) <u>Organization; Standing</u>. SOLVAY is a corporation duly organized, validly existing and in good standing under the laws of the State of Georgia 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) <u>Authorization; Binding Effect</u>. The execution and delivery by SOLVAY of this Agreement, the performance by SOLVAY of its obligations hereunder and the consummation by SOLVAY of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of SOLVAY. This Agreement has been duly executed and delivered by a duly authorized officer of SOLVAY and constitutes the valid and legally binding obligation of SOLVAY enforceable against SOLVAY in accordance with its terms.

- (e) No Conflict: Consents. The execution and delivery of this Agreement by SOLVAY 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 SOLVAY or any Affiliate is a party, or any Law to which SOLVAY or any Affiliate is subject and (b) no consents or agreements of any third party (including governmental bodies) is necessary for the performance by SOLVAY of its obligations under this Agreement.
- 3.2 <u>Representations and Warranties of JDS</u>. JDS represents and warrants to SOLVAY 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 New York 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) <u>Authorization</u>; <u>Binding Effect</u>. 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) <u>No Conflict; Consents</u>. The execution and delivery of this Agreement by JDS 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) no consents or agreements of any third party (including governmental bodies) is necessary for the performance by JDS of its obligations under this Agreement.
- 3.3 <u>Limitations</u>. (a) EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, THE PARTIES AGREE THAT SOLVAY 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 PRODUCT, 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 FORESEABLE 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 PRODUCT: (I) HAVING BEEN TAMPERED WITH OTHER THAN BY SOLVAY OR ITS AGENTS, (II) HAVING BEEN SUBJECT TO MISUSE, NEGLIGENCE OR ACCIDENT

OTHER THAN BY SOLVAY OR ITS AGENTS, (III) HAVING BEEN STORED, HANDLED OR USED OTHER THAN BY SOLVAY OR ITS AGENTS IN A MANNER CONTRARY TO REGULATORY STANDARDS OR THE INSTRUCTIONS CONTAINED ON LABELING, OR (IV) HAVING EXCEEDED ITS STATED EXPIRATION.

- (b) IN NO EVENT SHALL SOLVAY'S LIABLITY FOR REASONABLY FORSEEABLE CONSEQUENTIAL DAMAGES EXCEED THE ORIGINAL PRINCIPAL AMOUNT OF THE NOTE AND ANY SUCH LIABILITY SHALL BE SATISFIED SOLELY BY OFFSET AGAINST THE PAYMENTS OF INTEREST AND PRINCIPAL UNDER THE NOTE (UNLESS THE NOTE HAS BEEN PREPAID BY JDS, IN WHICH CASE SOLVAY'S LIABLITY FOR REASONABLY FORSEEABLE CONSEQUENTIAL DAMAGES SHALL NOT EXCEED AN AMOUNT EQUAL TO THE PRINCIPAL AND INTEREST THAT WOULD HAVE BEEN OUTSTANDING (ASSUMING TIMELY AMORTIZATION OF THE NOTE) AT THE TIME OF THE RELEVANT CLAIM HAD THE NOTE NOT BEEN PREPAID).
- (c) THE MAXIMUM AGGREGATE LIABILITY OF SOLVAY UNDER THIS AGREEMENT, WHEN AGGREGATED WITH ANY LIABILITY UNDER THE ASSET PURCHASE AGREEMENT, SHALL NOT IN ANY EVENT EXCEED \$7,500,000 (BUT THIS LIMITATION SHALL NOT AFFECT JDS'S RIGHT TO BRING ANY CLAIM UNDER THE ASSET PURCHASE AGREEMENT WHICH IS NOT SUBJECT TO A MAXIMUM THEREUNDER).
- (d) NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NONE OF THE LIMITATIONS ON LIABILITY SET FORTH IN THIS SECTION SHALL APPLY TO ACTS OR OMISSIONS OF SOLVAY TAKEN OR OMITTED TO BE TAKEN WITH INTENT TO BREACH THE REPRESENTATIONS, WARRANTIES OR OBLIGATIONS OF SOLVAY UNDER THIS AGREEMENT.

ARTICLE IV TERM AND TERMINATION

4.1 <u>Term.</u> 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 <u>Section 4.2</u> or <u>Section 4.3</u> hereof. This Agreement may be renewed for such additional period and upon such other terms as the parties may mutually agree.

4.2 Termination Without Cause; SOLVAY Reserved Right.

- (a) By Mutual Agreement. The parties may terminate this Agreement any time by mutual written agreement.
- (b) <u>By SOLVAY</u>. SOLVAY may terminate this Agreement at any time upon not less than eighteen (18) months notice to JDS; <u>provided</u>, <u>however</u>, that no such notice may be furnished prior to the second anniversary of the date hereof and further provided that no such termination shall be effective prior to July 1, 2009, unless JDS has secured or caused an alternative manufacturer to secure all regulatory approvals necessary to manufacture the Product at an alternative manufacturing site and shall have had a reasonable period to assure a smooth transition of supply arrangements.
- (c) <u>By JDS</u>. JDS may terminate this Agreement at any time upon not less than twelve (12) months notice to SOLVAY.

- (d) Alternative Facility. Within fifteen (15) months of the date of this Agreement, JDS shall commence and thereafter diligently pursue with commercially reasonable efforts all activities necessary to secure an alternative manufacturer for the Product and shall keep SOLVAY advised of its progress. Toward this end, SOLVAY agrees to provide reasonable assistance and/or consultation to JDS to support its development and qualification activities. These services will be defined by written agreement prior to the initiation of any activities. JDS agrees to reimburse SOLVAY for all pertinent time, materials, reasonable travel and related expenses associated with this assistance and/or consultation.
- (e) <u>SOLVAY Reserved Right</u>. SOLVAY reserves the right, at its discretion and at its sole cost and expense but in consultation with JDS, to commence and diligently pursue all activities necessary to secure an alternative manufacturer for the Product, prior to the termination period in <u>Section 4.2(b)</u>, should SOLVAY (i) elect to cease manufacturing operations in its Baudette, Minnesota Main Street facility, (ii) have business requirements that necessitate the cessation of the manufacture of Product, or (iii) if JDS has not been diligent in the pursuit of an alternative facility as required in <u>Section 4.2(d)</u>. If an alternative manufacturer identified by SOLVAY under this <u>Section 4.2(e)</u> charges more for the Product than SOLVAY would have charged under the terms of this Agreement, then SOLVAY shall, during the minimum period of time it would have been obligated to supply Product hereunder, bear the cost of such excess, except in the case of <u>Section 4.2(e)(iii)</u>, in which case JDS shall bear any such excess. To be utilized as a source of supply hereunder, any such alternative manufacturer shall be duly qualified under all applicable Manufacturing Standards and Regulatory Standards. Subject to JDS's obligations pursuant to <u>Section 4.2(d)</u>, the use of an alternate supplier by SOLVAY pursuant to this Section shall not limit, modify or amend the obligations, representations or warranties of the parties hereto.
- 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 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) <u>Supply and Purchase of Product</u>. Unless otherwise mutually agreed by the parties, SOLVAY shall supply, and JDS shall purchase in accordance with the provisions hereof, all quantities of Product ordered by JDS hereunder prior to the date of expiration or termination; <u>provided</u>, <u>however</u>, that SOLVAY shall not be required to supply volumes of Product which exceed the amounts for

which SOLVAY 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 properly chargeable to JDS pursuant to the terms of this Agreement. JDS shall have the right to use and sell any such Product in the ordinary course including Product which may contain reference to SOLVAY.

(b) Purchase of Additional Materials. Upon the expiration or termination of this Agreement, JDS shall, if so requested by SOLVAY, purchase (i) all materials acquired by SOLVAY hereunder to manufacture the Product, at SOLVAY's actual cost thereof, (ii) all work-in-progress of the Product at SOLVAY's actual cost thereof, and (iii) all inventory of finished Product then in SOLVAY's possession at the then-current purchase price hereunder. In addition, in such case JDS shall pay SOLVAY the actual out of pocket cost for any non-cancelable commitments made by SOLVAY 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, Product manufactured and non-cancelable commitments incurred by SOLVAY for quantities of the Product 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 Product, comply with the Product Specifications and all Manufacturing Standards. All materials purchased by JDS become the property of JDS and SOLVAY 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 SOLVAY of its supply obligations.

ARTICLE V INDEMNIFICATION

- 5.1 By SOLVAY. Subject to the limitations described in Section 3.3, SOLVAY shall defend, indemnify and hold harmless JDS 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 SOLVAY hereunder, (b) any negligent storage or handling of the Product by SOLVAY prior to delivery to JDS FOB SOLVAY's Shipping Point, or (c) any negligent act or omission of SOLVAY or its employees, agents or other contractors with respect to the Product. 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. JDS shall defend, indemnify and hold harmless SOLVAY 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 Product, (c) the failure of JDS to comply with any applicable Regulatory Standards with respect to the importation, marketing, distribution or sale of the Product, (d) any Labeling for the Product approved by JDS, (e) the infringement of any patent, trademark or other intellectual property rights by the manufacture, sale or use of the Product, or (f) all personal injury (including death) and/or property damage resulting from the manufacture handling, possession, marketing, promotion or use of the Product following SOLVAY's delivery of the Product to JDS FOB SOLVAY's Shipping Point. Notwithstanding the preceding sentence, JDS shall not be required to indemnify SOLVAY with respect to any Claim arising from SOLVAY's breach of its representations,

warranties or covenants hereunder or under the Asset Purchase Agreement or SOLVAY's willful misconduct with respect to the Product.

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) 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. SOLVAY 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 SOLVAY 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, 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 nonpublic, proprietary materials disclosed by a party in writing and marked "confidential."
- 7.2 <u>Restriction</u>. 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 Product 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).

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, however, 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 Product. 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 SOLVAY 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 Product. SOLVAY shall assist JDS by providing necessary support and information and shall prepare the annual cGMP Product reviews.

ARTICLE IX FORCE MAJEURE

- 9.1 <u>Effects of Force Majeure</u>. 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 <u>Section 9.4</u>, such excuse shall continue as long as the Force Majeure Event continues, following which such party shall promptly resume performance hereunder.
- 9.2 <u>Effects of Regulatory Changes</u>. 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 Product (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.

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- 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 due diligence, where practicable, 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 <u>Limitation</u>. Notwithstanding anything to the contrary herein, in the event a Regulatory Change or Force Majeure Event continues for more than 18 months, JDS shall have the right to terminate this Agreement upon notice and upon JDS's request, SOLVAY shall cooperate to assist in the transfer of technology to a new manufacturer. 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 SOLVAY 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 SOLVAY 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 MISCELLANEOUS

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 Pharmaceuticals, LLC 158 Mercer Street New York, NY 10012 Attn: Chairman

With a copy to:

Dornbush Schaeffer Strongin & Weinstein, LLP 747 Third Avenue

New York, NY 10017

Attn: Herschel S. Weinstein, Esq.

Fax: (212) 753-7673

If to SOLVAY:

Solvay Pharmaceuticals, Inc. 901 Sawyer Road
Marietta, GA 30062
Attention: President & CEO

With a copy to:

Solvay Pharmaceuticals, Inc. 901 Sawyer Road Marietta, GA 30062 Attention: Law Department

Fax: (770) 578-5749

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.

- 12.2 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.
- 12.3 <u>Amendment</u>. No amendment of this Agreement shall be effective unless embodied in a written instrument executed by both of the parties.
- 12.4 <u>Waiver of Breach</u>. 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.
- 12.5 <u>Assignability</u>. Either party may assign this agreement upon notice to the other party. In the event that this Agreement is assigned by JDS to a competitor of SOLVAY, SOLVAY shall have the right to increase the price charged for Product 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.

- 12.6 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.
- 12.7 <u>Severability</u>. 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.
- 12.8 <u>Publicity</u>. 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.
- 12.9 <u>Survival</u>. The provisions of <u>Section 2.5</u> (Delivery), <u>Section 2.7</u> (Inspection of Product), <u>Section 2.9</u> (Recalls), <u>Section 3</u> (Representation and Warranties), <u>Section 4.4</u> (Rights and Duties Upon Termination), <u>Article V</u> (Indemnification), <u>Article VI</u> (Adverse Event Reports), <u>Article VII</u> (Confidentiality), <u>Section 12.6</u> (Governing Law; Jurisdiction), <u>Section 12.8</u> (Publicity) and this <u>Section 12.9</u> (Survival) shall survive the termination or expiration of this Agreement for any reason.
- 12.10 <u>Headings</u>. The headings of sections and subsections have been included for convenience only and shall not be considered in interpreting this Agreement.
- 12.11 <u>Counterparts</u>. 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.
- 12.12 <u>Execution</u>. 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.
- 12.13 <u>Facsimile Signatures</u>. 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]

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed on the date first written above.

SOLVAY PHARMACEUTICALS, INC.

JDS PHARMACEUTICALS, LLC

By:

SATOW ASSOCIATES, LLC

as its sole member

By: /s/ W. A. Linscott

Name: W. A. Linscott

Title: V.P. Law, Gov't + Public Affairs

By: /s/ Phillip M. Satow

Name: Phillip M. Satow

Title: Manager

By: /s/ Harold H. Shlevin

Name: Harold H. Shlevin

Title: President & CEO