EXHIBIT 10.1  
\*Certain portions of this exhibit have been omitted pursuant to a request for confidential  
treatment which has been filed separately with the SEC.  
MANUFACTURING AND SUPPLY AGREEMENT  
for  
N-ACETYLCYSTEINE  
CUMBERLAND PHARMACEUTICALS INC.  
and  
BIONICHE LIFE SCIENCES, INC.  
January 15, 2002  
 MANUFACTURING AND SUPPLY  
AGREEMENT FOR N-ACETYLCYSTEINE  
THIS AGREEMENT is made and entered into as of the 15th day of January, 2002.  
BY AND BETWEEN:  
CUMBERLAND PHARMACEUTICALS INC., a corporation organized and existing under the laws of Tennessee, United States, with its principal offices located at 000 Xxxxx Xxxxxx Xxxxx, Xxxxx 000, Xxxxxxxxx, Xxxxxxxxx, 00000 (hereinafter referred to as “CUMBERLAND”)  
AND:  
BIONICHE LIFE SCIENCES INC., a corporation organized and existing under the laws of Ontario, Canada, with its principal place of business located at 000 Xxxxxx Xxxxxx, Xxxx Xxxxxxxxxx, Xxxxxxx, Xxxxxx X0X 0X0 (hereinafter referred to as “BIONICHE”);  
WHEREAS, CUMBERLAND is the owner of certain intellectual property rights with respect to a Drug Product (as hereinafter defined);  
WHEREAS, BIONICHE has the expertise and the manufacturing facility suitable for the pharmaceutical preparation and production of the Drug Product;  
WHEREAS, CUMBERLAND wishes to have BIONICHE manufacture the Drug Product on an exclusive basis for sale in the Territory (as hereinafter defined) and BIONICHE wishes to supply the Drug Product on an exclusive basis to CUMBERLAND on and subject to the terms and conditions set out herein;  
NOW, THEREFORE, in consideration of the premises and the undertakings, terms, conditions and covenants set forth below, the parties hereto agree as follows:  
1. DEFINITIONS  
 1.1 AFFILIATE shall mean, with respect to any Person, any other Person that controls, is controlled by or is under common control with, such Person. A Person shall be regarded as in control of another Person if such Person owns, or directly or indirectly controls, more than fifty percent (50%) of the voting securities (or comparable equity interests) or other ownership interests of the other Person, or if such Person directly or indirectly possesses the power to direct or cause the direction of the management or policies of the other Person, whether through the ownership of voting securities, by contract or any other means whatsoever.  
 1.2 BUFFER SOLUTION shall mean the buffer solution used for the manufacture of the Drug Product.  
 1.3 BULK DRUG SUBSTANCE shall mean the active ingredients in the Drug Product.  
 1.4 cGMP or GMP shall have the meaning set forth in Schedule I.  
 1.5 CONFIDENTIAL INFORMATION shall have the meaning set forth in Article 9.  
 1.6 DEVELOPMENT shall mean all work necessary to develop a process to manufacture the Drug Product in full accord with cGMP and to supply the Drug Product conforming to the Specifications. Development activities shall include, but not be limited to, pilot batches, scale-up batches, validation of the manufacturing process, and successful completion of the Drug Product manufacture and delivery as defined in Schedule I attached hereto.  
 1.7 DRUG PRODUCT shall mean the N-Acetylcysteine pharmaceutical product developed by CUMBERLAND and marketed under the trade name ACETADOTE or any other trade name selected by CUMBERLAND.  
 1.8 EXCIPIENT shall mean any inert substance selected by CUMBERLAND and used to give the Drug Product proper consistency.  
 1.9 FACILITY shall mean the manufacturing facility and the real property underlying such manufacturing facility operated by Bioniche Teoranta, an Affiliate of BIONICHE, located at Inverin, Co. Galway, Republic of Ireland.  
 1.10 FDA shall mean the United States Food and Drug Administration (FDA) or any successor entity thereto.  
 1.11 IN-PROCESS SOLUTION shall mean all Buffer Solutions and Excipients needed to produce Drug Product in the finished dosage form set forth in Schedule I.  
 1.12 INVENTION shall have the meaning set forth in Paragraph 9.4.  
 1.13 LABELING shall mean all labels and other written, printed, or graphic matter upon: (i) the Drug Product or any container or wrapper utilized with the Drug Product and (ii) any written material accompanying the Drug Product, including without limitation, package inserts.  
 1.14 MANUAL shall mean the Manufacturing Project Manual attached as Schedule II to this Agreement and reviewed and accepted by CUMBERLAND and BIONICHE, the terms and provisions of which are incorporated by reference as though fully set forth herein.  
 1.15 MANUFACTURE shall mean the act of compounding, component preparations, filling, packaging, testing and any other pharmaceutical manufacturing procedures, or any part thereof, involved in manufacturing the Drug Product from the Bulk Drug Substance.  
 1.16 PERSON shall mean an individual, corporation, partnership, limited liability company, or any other form of entity not specifically listed herein.  
 1.17 SPECIFICATIONS shall mean those specifications set forth in Attachment I to the Manual.  
 1.18 TERRITORY shall have the meaning set forth in Schedule III.  
2. DEVELOPMENT AND MANUFACTURING  
 2.1 Initiation: Upon request by CUMBERLAND and subject to the provisions hereof, BIONICHE, directly or through an Affiliate thereof, shall Manufacture and package at the Facility all of CUMBERLAND’s requirements for Drug Product in the Territory in the batch size set forth in Schedule I in accordance with the terms hereof, including without limitation, Schedules I and II hereof, the Specifications, and all applicable laws and regulations. Prior to distributing and selling the Drug Product, CUMBERLAND shall prepare and file submissions to the FDA in order to obtain and maintain during the term hereof regulatory approval of the Drug Product, BIONICHE shall prepare and test the Drug Product in accordance with cGMP.  
 2.2 Documentation: BIONICHE shall provide CUMBERLAND with required supporting documentation for the manufacture of the Drug Product in a form suitable for CUMBERLAND’s submission to the FDA or applicable governmental authorities for any country into which the Drug Product will be distributed. BIONICHE shall provide draft Chemistry, Manufacturing, and Controls sections for CUMBERLAND’s FDA submissions,  
 2.3 Bulk Drug Substance Supply: BIONICHE shall be responsible for the supply of all Bulk Drug Substance in accordance with Schedules I and II hereto; provided that the supply of Bulk Drug Substance shall be exclusively from such suppliers and in such grades as have been approved in writing by CUMBERLAND as reflected on an approved list to be attached hereto as Schedule IV, and provided further that such suppliers and  
 grades may not be changed without CUMBERLAND’s prior written consent, which consent shall not be unreasonably withheld or delayed. BIONICHE shall maintain, at its expense, secure storage areas for the Bulk Drug Substance at the Facility.  
 2.4 Supply of Components: BIONICHE shall be responsible for the supply of all Buffer Solution, Excipients, and all other components of the finished Drug Product in accordance with Schedules I and II hereto; provided that the supply of these components shall be exclusively from such suppliers and in such grades as have been approved in writing by CUMBERLAND as reflected on an approved list to be attached hereto as Schedule IV, and provided further that such suppliers and grades may not be changed without CUMBERLAND’s prior written consent which consent shall not be unreasonably withheld or delayed. BIONICHE shall maintain, at its expense, secure storage areas for the Buffer Solution, Excipients, and all other components at the Facility.  
 2.5 Delivery Terms: All deliveries of Drug Product under this Agreement shall be made by BIONICHE to CUMBERLAND in the manner set forth in Schedule I. CUMBERLAND shall, within twenty (20) working days after its receipt of any shipment, notify BIONICHE in writing, of any claim relating to a Drug Product not conforming to GMP or to the Specifications, and, failing such notification, notwithstanding Paragraph 5.1 of this Agreement, CUMBERLAND shall be deemed to have accepted the Drug Product. If BIONICHE disputes CUMBERLAND’s claim that the Drug Product is non-conforming, then such dispute shall be resolved by an independent testing organization of recognized repute within the pharmaceutical industry mutually agreed upon by BIONICHE and CUMBERLAND, the appointment of which shall not be unreasonably withheld or delayed by either party. In such event, CUMBERLAND shall ship the testing organization representative samples of the Drug Product from the disputed production lot, and the fees and costs of such testing organization and related shipping and supply costs shall be borne by the party whose position is not sustained by the testing organization. Should CUMBERLAND’s claim of non-conformity be sustained by the testing organization, BIONICHE shall, at CUMBERLAND’S sole option, (a) credit towards future orders, or (b) refund within thirty (30) days thereof; the payment for such non-conforming goods, plus the cost to CUMBERLAND of Manufacturing and shipping the related Bulk Drug Substance and components.  
 2.6 Forecasts: In order to permit BIONICHE to regularly supply CUMBERLAND with Drug Product hereunder, at least [\*\*\*] prior to its first requested delivery date, CUMBERLAND shall provide BIONICHE a non-binding twelve (12) month rolling forecast (the “Forecast”) of CUMBERLAND’s estimated requirements of Drug Product, itemized for use as commercial product or Regulatory Samples (as defined below), for the term of this Agreement. The Forecast shall be reviewed and updated by CUMBERLAND on a monthly basis, with copies delivered to BIONICHE. BIONICHE shall have an opportunity to confirm its ability to deliver the quantities set out in the Forecast and each update thereto, or to request amendments thereto to ensure its ability to supply. Once accepted by BIONICHE, the first three (3) months of each Forecast shall constitue a firm order for Drug Product. Each such Forecast shall reflect a good faith attempt by CUMBERLAND to estimate quantity requirements of Drug Product, based on anticipated demand therefore.  
 2.7 Periodic Orders: A purchase order (the “Purchase Order”) shall be provided by CUMBERLAND to BIONICHE with respect to Drug Product to be supplied at least [\*\*\*] prior to the scheduled delivery date of such Drug Product. Such Purchase Order shall specify the quantities ordered by CUMBERLAND for delivery by BIONICHE hereunder and the requested delivery date therefore, and, once delivered to BIONICHE, and shall be firm and binding on the parties (the “Delivery Date”). Each such Purchase Order shall become firm and binding on the parties and, except as specifically provided for herein, may not be increased or decreased by more than [\*\*\*] from the quantities shown in the Forecast accepted by BIONICHE pursuant to Section 2.6 without the prior written approval of the parties. If CUMBERLAND requires quantities of Drug Product exceeding those mentioned in the Forecast, as updated, BIONICHE shall deliver the amount indicated in the Forecast on the scheduled Delivery Date and shall use reasonable efforts to supply the additional amount exceeding such Forecast on the scheduled Delivery Date, but shall have no liability for failure to deliver the additional amount. Each Purchase Order shall constitute a separate agreement to purchase Drug Product but where in conflict with the terms and conditions of this Agreement, this Agreement, and not the standard terms and conditions set forth in the purchase orders, shall govern the Manufacturing, purchase and sale of the Drug  
 Product under this Agreement. Any Purchase Order for Drug Product shall be placed in the minimum amounts listed below or in integral multiples thereof.  
For the 10mL form of Drug Product [\*\*\*]  
For the 30mL form of Drug Product [\*\*\*]  
 2.8 Failure to Supply: Subject to the provisions of Article 7, BIONICHE shall supply all of the Drug Product ordered by CUMBERLAND within [\*\*\*] of receipt of a written order from CUMBERLAND. If BIONICHE is unable to meet its supply obligations with respect to any Purchase Order, CUMBERLAND shall be free to procure from third parties part or all of the quantities of the Drug Product covered by the relevant Purchase Order. In the event that BIONICHE is unable to supply the Drug Product to CUMBERLAND for any reason other than for Force Majeure or failure of CUMBERLAND to fulfill its obligations hereunder, BIONICHE will reimburse CUMBERLAND for any increase in the price of obtaining the Drug Product from an alternate supplier; provided that such replacement Drug Product was purchased on reasonable commercial terms, and provided further that such failure to supply was in respect of Drug Product that was the subject of a Purchase Order provided by CUMBERLAND and accepted by BIONICHE under Paragraph 2.7. Should BIONICHE reimburse CUMBERLAND as set out in this paragraph, BIONICHE shall have no further liability to CUMBERLAND for said failure to supply.  
 2.9 Payment for the Drug Product: At the time of each shipment, BIONICHE shall invoice CUMBERLAND for BIONICHE’s manufacturing services at the prices set forth in Schedule I. Payment shall be made in Canadian dollars within [\*\*\*] of each such shipment of conforming Product in accordance with the terms hereof.  
2.10 Price Variations:  
 (a) Prices are as set on Schedule I for the term hereof unless changed pursuant to Paragraph 2.10(b).  
 (b) Subject to Subparagraph 2.10(c), prices are subject to annual adjustment beginning two (2) years after the date hereof. Price increases or decreases will be commensurate with documented Manufacturing cost increases or decreases since the date that the then-current prices became effective. For purposes hereof, “Manufacturing cost” shall mean, with respect to the Drug Product, BIONICHE’s actual and documented cost of raw materials, direct labor, Manufacturing, packaging, and overhead amounts directly applicable to such Manufacturing costs (including appropriately amortized capital equipment costs and excluding non-manufacturing overhead and allocations and excluding costs representing Manufacturing changes for which CUMBERLAND does not provide prior written consent pursuant to Article 8), calculated in accordance with generally accepted accounting principles consistently applied (the allocation of overhead to be consistent with BIONICHE’s allocation of overhead as of the date of this Agreement). CUMBERLAND reserves the right to audit the records of BIONICHE in order to determine that such increases and/or decreases are appropriate. Any increase in price shall not exceed the twelve (12) month percent increase in the Producer Price Index as published by the U.S. government and shall be further subject to a maximum increase of five percent (5%) per year over the life of the Agreement.  
 (c) Notwithstanding any of the contrary herein contained, should CUMBERLAND: (i) request a change in Specifications, or (ii) unreasonably withhold the consent requested under Paragraphs 2.3 or 2.4, which request or refusal results in an increase in Manufacturing Costs, BIONICHE shall be entitled to pass on such costs to CUMBERLAND immediately in the form of a Drug Product price increase.  
3. TERM AND TERMINATION  
 3.1 Term: This Agreement shall commence on the date first above written and will continue until the fifth anniversary of the date on which the FDA grants approval to market and sell the Drug Product, unless sooner terminated pursuant to Paragraphs 3.2 or 3.3 hereof. Subject to Paragraphs 3.2 and 3.3, the Agreement shall be automatically renewed for successive three-year terms unless either party notifies the other party in writing at least twelve (12) months in advance of the expiration of the then current term that the party is terminating the Agreement.  
 3.2 Termination: This Agreement may be terminated at any time upon the occurrence of any of the following events:  
 (a) Default: Thirty (30) days following written notice, by either party to the other party, in the event that the other party breaches any provision of this Agreement, and such party fails to remedy the breach prior to the expiration of the thirty (30) day period; provided that, in the case of nonpayment of sums due hereunder, the remedy period shall be decreased to ten (10) days.  
 (b) Insolvency: Written notice by either party to the other upon insolvency or bankruptcy of the other party, and the failure of any such insolvency or bankruptcy to be dismissed within sixty (60) days.  
 (c) Force majeure: If, as a result of causes described in Paragraph 7.1, either party is unable to fully perform its obligations hereunder for a period of one hundred fifty (150) consecutive days, the other party shall have the right to terminate this Agreement upon at least thirty (30) days prior written notice; provided that if the required performance is met during that thirty-day period, this Agreement shall continue in full force and effect as if the notice had not been given.  
 (d) Costs: Immediately upon written notice by BIONICHE to CUMBERLAND if the Manufacturing cost per unit of Drug Product calculated in the manner set forth in Paragraph 2.10(a) hereof exceeds the purchase price per unit of Drug Product set forth in Schedule I, as adjusted pursuant to Paragraphs 2.10(b) and/or (c) hereof.  
 (e) No FDA Approval: Immediately upon written notice by BIONICHE to CUMBERLAND if the FDA does not grant CUMBERLAND approval to market and sell the Drug Product on or before the second anniversary of the date of this Agreement.  
 (f) By mutual agreement of the parties hereto.  
 Except as otherwise specifically set forth in this Paragraph 3.2, termination, expiration, cancellation or abandonment of this Agreement, through any means and for any reason, shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any of the provisions of this Agreement. Without limiting the generality of the foregoing, termination, expiration, cancellation, or abandonment of this Agreement shall not relieve CUMBERLAND of its obligation to pay the royalty provided for under Schedule I for Drug Product manufactured by BIONICHE hereunder.  
 3.3 Minimum Quantities Purchased: If the parties fail to agree on minimum purchase quantities as provided under Paragraph 5.7, or if following such agreement, CUMBERLAND should fail to meet the agreed upon minimum purchase requirements, BIONICHE shall have the right (but not the obligation) to terminate this Agreement in its entirety or with respect to any one or more format of the Drug Product upon ninety (90) days notice; provided, however, that CUMBERLAND shall have the right (but not the obligation) within such ninety (90) day period to pay BIONICHE any short-fall and avoid such termination. Such shortfall shall be calculated by subtracting the purchase price of the amount of each format of Drug Product actually ordered from the amount calculated by multiplying the minimum quantity of such format under Schedule V by the purchase price thereof. It is understood and agreed between the parties that BIONICHE shall not be required to supply Drug Product for such payment. Should BIONICHE exercise its right to terminate under this Paragraph 3.3, CUMBERLAND shall have no liability to BIONICHE for failing to purchase any minimum quantity of Drug Product hereunder.  
 3.4 Impact of Termination on Outstanding Purchase Orders: Upon termination of the Agreement for any reason whatsoever (except for termination by either party pursuant to Paragraphs 3.2(a), (b), or (c), or upon expiration of this Agreement), BIONICHE will, at CUMBERLAND’s written request delivered after termination, continue to supply Drug Product to CUMBERLAND in satisfaction of Purchase Orders already submitted to BIONICHE, subject to the same terms and conditions as applied during the term of the Agreement, for a period of sixty (60) days from the date of termination or expiration.  
 3.5 Survival: Paragraphs 2.5, 2.8, 3.2, 3.3, and 3.5 and Articles 5, 6, 9, and 10 shall survive the termination or cancellation of the Agreement for any reason.  
 4. CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE  
 4.1 Certificates of Analysis: BIONICHE shall perform, or cause to be performed, certain tests requested by CUMBERLAND in writing and as indicated in the Specifications on each batch of the Drug Product manufactured pursuant to this Agreement before delivery to CUMBERLAND. A certificate of analysis for each batch delivered shall be delivered with each batch and shall set forth the items tested, specifications, and test results. BIONICHE shall also indicate on the certificate of analysis that all batch production and control records have been reviewed and approved by the appropriate quality control unit. Subject to Xxxxxxxxx 0.0, XXXXXXXXXX shall test, or cause to be tested, prior to final release, each batch of the Drug Product as meeting the Specifications. As required by the FDA (see Paragraph 5.2 below), CUMBERLAND shall assume full responsibility for final release of each lot of the Drug Product.  
 4.2 Manufacturing Compliance: BIONICHE shall advise CUMBERLAND immediately if an authorized agent of any regulatory body visits the Facility and makes an inquiry regarding BIONICHE’s method of manufacture of the Drug Product for CUMBERLAND. Upon receipt of any Form 483 Notice of Inspectional Observations issued by the FDA or notice of deficit from any other regulatory inspection after a visit to the Facility, BIONICHE shall immediately send CUMBERLAND a copy thereof; provided that it may redact any language that is subject to a written confidentiality agreement between BIONICHE and a third party.  
 4.3 Regulatory Agency Requirements: BIONICHE shall prepare and test the Drug Product in conformity with GMP. Subject to the allocation of responsibility for regulatory compliance as set forth in Paragraph 5.2, each party shall consult with the other party hereto before implementing additional regulatory agency requirements concerning the control of Drug Product components, manufacture of the Drug Product, or storage and handling of the Drug Product. The full text of regulatory agency requests or comments will be provided by the party receiving such requests or comments to the other party hereto. The parties will mutually agree on how to respond to such requests and comments and on the allocation of the costs thereof; provided that BIONICHE shall be entitled to reimbursement from CUMBERLAND for any out-of-pocket expenses or extraordinary costs previously approved in writing by CUMBERLAND and required in connection with implementing such regulatory requirements other than the ordinary costs of compliance with GMP.  
 4.4 Regulatory Documents: Each party will advise the other party hereto of its intention to change any Drug Product regulatory documents prior to submission of the document to any regulatory body. If the change affects the rights and obligations of a party hereto under this Agreement, such party may seek to review or alter any part of the document at any time within ten (10) business days after receipt of notification thereof; provided that if no alterations are submitted to the other party within such ten-day period, each party will be deemed to have consented to the documents, as amended.  
5. REPRESENTATIONS AND WARRANTIES  
 5.1 Conformity with Specifications: BIONICHE represents and warrants that, at the time of Manufacture, the Drug Product is prepared and tested in accordance with cGMP and meets the Specifications. In the event that any production lot of a Drug Product is not Manufactured in accordance with the Specifications or other requirements hereunder, BIONICHE shall, at CUMBERLAND’s request, perform new Manufacturing as necessary to fulfill any then outstanding purchase order of CUMBERLAND. BIONICHE shall be fully responsible for the costs of any Bulk Drug Substance or components required for such new Manufacturing. Because BIONICHE has no control of the conditions under which the Drug Product is used, the diagnosis of the patient before or after treatment with the Drug Product, the method of use or administration of the Drug Product, and handling of the Drug Product after delivery to CUMBERLAND, BIONICHE does not warrant either a good effect, or against an ill effect, following the use of the Drug Product. The foregoing warranty is exclusive and in lieu of all other warranties either written, oral, or implied. No representative of BIONICHE may change any of the foregoing warranties and CUMBERLAND accepts the Drug Product subject to all terms hereof.  
 EXCEPT AS SPECIFICALLY PROVIDED FOR IN THIS ARTICLE 5 AND PARAGRAPH 11.4, BIOMCHE MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED (i) OF COMMERCIAL UTILITY; (ii) OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; OR (iii) THAT THE USE OF THE DRUG PRODUCTS BY CUMBERLAND OR ANY THIRD PARTY WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK OR OTHER PROPRIETARY OR PROPERTY  
 RIGHTS OF OTHERS. EXCEPT AS PROVIDED FOR HEREIN, BIONICHE WILL NOT BE LIABLE TO CUMBERLAND, CUMBERLAND’S SUCCESSORS OR ASSIGNS OR ANY THIRD PARTY WITH RESPECT TO ANY CLAIM ARISING FROM CUMBERLAND’S OR ANY THIRD PARTY’S USE OF THE DRUG PRODUCTS.  
 CUMBERLAND ACCEPTS ALL RISK AND RESPONSIBILITY FOR DETERMINING THE MANNER IN WHICH CUMBERLAND WILL USE THE DRUG PRODUCTS, AND BIONICHE MAKES NO REPRESENTATIONS OR WARRANTIES CONCERNING, AND ASSUMES NO RESPONSIBILITY FOR, THE PERFORMANCE OF ANY OTHER PRODUCT(S) INTO WHICH THE DRUG PRODUCTS MAY BE INCORPORATED.  
 5.2 Compliance: CUMBERLAND represents and warrants that CUMBERLAND assumes responsibility for coordinating all contact with the FDA and other regulatory bodies, pertaining specifically to the Drug Product. During the term of this Agreement, BIONICHE authorizes CUMBERLAND’s representatives to inspect the methods used in and facilities used for manufacturing, processing, packaging, and handling of the Drug Product; provided that each such inspection shall be at CUMBERLAND’S own cost, on reasonable prior notice, and subject to the prior execution of reasonable confidentiality agreement by each inspector who is not an employee of CUMBERLAND but has been selected by CUMBERLAND to represent it; and provided further that CUMBERLAND shall have no such obligation under this Agreement. Except as otherwise required by applicable regulations, CUMBERLAND’s inspections shall be conducted during normal business hours; provided that CUMBERLAND may inspect such facilities immediately after any regulatory inspection thereof.  
 5.3 Debarring: BIONICHE represents and warrants that it has not been debarred in the United States within the meaning of 21 U.S.C. § 335a(a) and 335a(b), nor will it use, knowingly after due inquiry, in any capacity the services of any person debarred pursuant to subsections 3.06(a) or 3.06(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 335(a) and (b).  
 5.4 FDA Submission: BIONICHE represents and warrants that it has submitted to the FDA information about the Facility and the operating procedures, and personnel at such site in the form required by the FDA. BIONICHE shall keep and maintain the equipment necessary for the Manufacture of any Drug Product in a manufacture-ready state and in good repair. During the term hereof and until the fifth anniversary of termination or expiration, BIONICHE shall maintain written documentation of all use, repair, service, and maintenance of such equipment and shall provide CUMBERLAND copies of such documentation; provided that in the event that a Person acquires substantially all of the assets and business of BIONICHE, BIONICHE may send all such documentation to CUMBERLAND promptly after such acquisition.  
 5.5 Reimbursement: BIONICHE shall not incur any costs for which it intends to seek reimbursement from CUMBERLAND unless BIONICHE has the prior written consent of CUMBERLAND. CUMBERLAND shall reimburse BIONICHE at a rate equal to one hundred fifty percent (150%) of all such costs actually incurred and documented and directly related to the production of materials or data for submissions to the FDA (“Pre-Approval Costs”) hereunder, provided that reimbursement of such Pre-Approval Costs shall be paid by means of twelve (12) equal installments thereof to be made on the first day of each of the twelve (12) months following the date on which the FDA issues final approval to CUMBERLAND to market and sell the Drug Product commercially in the United States (the “Approval Date”); and provided further that if the Approval Date has not occurred on or before one year from the date of signing of the Agreement then CUMBERLAND shall immediately reimburse BIONICHE at a rate equal to one hundred percent (100%) of all Pre-Approval Costs incurred prior to such date in complete satisfaction of its obligations to reimburse such Pre-Approval Costs.  
 5.6 Exclusivity:  
 (a) Neither BIONICHE nor any Affiliate thereof will sell, give away, or deliver to any other person, firm, or corporation any form of the Drug Product in the Territory for indications currently approved as of the date of signing this Agreement (“currently-approved indications”), while this Agreement is effective and for two years after the termination of this Agreement; provided that such restrictions shall not apply in the event of termination by BIONICHE pursuant to Subparagraphs 3.2 (a), (b), (e), or Paragraph 3.3 and shall not apply to the sale by BIONICHE of a product that contains the same active ingredients as the Drug Product for use as a chemoprotectant (“Excluded Products”) or Other Products, as defined below, subject to the rights set out in Subparagraph 5.6 (d).  
 (b) If, during the term hereof, BIONICHE wishes to market or distribute Excluded Products in the Territory in association with any third Person, BIONICHE shall give CUMBERLAND written notice thereof, and CUMBERLAND shall have thirty (30) days to notify BIONICHE of its interest in entering into an arrangement with BIONICHE, on terms to be negotiated by the parties in good faith during the period of one hundred twenty (120) days immediately following the receipt by CUMBERLAND of such notice (the “Option Period”). If the parties negotiate in good faith but do not conclude an agreement within the Option Period, BIONICHE agrees not to enter into an agreement covering the Excluded Products in the Territory with any third Person on terms that are more favorable than the terms previously offered to CUMBERLAND without first offering to enter into an agreement with CUMBERLAND, to be negotiated during an additional thirty day period, such offer to be made on terms no less favorable than the terms being offered to the third Person. If CUMBERLAND does not enter into negotiations with BIONICHE within thirty (30) days following receipt of such notice, then BIONICHE shall be free to negotiate with third Persons with no further obligation to CUMBERLAND.  
 (c) Notwithstanding the provisions of Subparagraph 5.6 (b) above, BIONICHE shall have no obligation to make any offer to CUMBERLAND with respect to any development, marketing or sale of Excluded Products in the Territory if it chooses to so develop, market or sell directly, rather than in association with any third Person.  
 (d) With respect to any product that contains the same active ingredient as the Drug Product for indications other than Excluded Products that BIONICHE may seek to develop (“Other Products”), BIONICHE shall provide notice to CUMBERLAND as set out in Subparagraph 5.6 (b) above, and the same procedures shall apply. Likewise, with respect to any indications other than currently-approved indications for the Drug Product that CUMBERLAND seeks to develop, CUMBERLAND shall provide notice to BIONICHE regarding the possibility of supply of said Drug Product to CUMBERLAND and the procedures described in Subparagraph 5.6 (b) above shall apply.  
 (e) If CUMBERLAND does not acquire rights to Excluded Products or to Other Products as described in Subparagraphs 5.6 (c) and (d) above, and CUMBERLAND establishes, through the dispute resolution process set forth in Paragraph 11.7, that sales by BIONICHE of said products have detrimentally impacted sales of the Drug Product then BIONICHE shall pay CUMBERLAND an amount equal to the lost profits so established by CUMBERLAND. CUMBERLAND shall bear the burden of establishing lost sales.  
 (f) Except in the event that BIONICHE fails to supply all Drug Product ordered within ninety (90) days of receipt of a Purchase Order in accordance with Paragraph 2.7, or in the event of Force Majeure, CUMBERLAND will order its entire requirement of the Drug Product for the Territory from BIONICHE, If CUMBERLAND notifies BIONICHE that it intends. to distribute the Drug Product in countries other than the United States and its territories, then the parties shall negotiate in good faith, for a period not to exceed one hundred twenty (120) days after CUMBERLAND provides such notice, to amend this agreement to expand the Territory hereunder; provided that if the parties fail to agree upon the terms of supply for an expanded Territory within such 120-day period, CUMBERLAND shall have no obligation to purchase requirements of Drug Products for such other countries from BIONICHE, but its obligations hereunder with respect to the United States and its territories shall remain in full force and effect.  
 (g) In the event of breach of this Paragraph 5.6, the parties shall have the right, in addition to other rights hereunder, to seek injunctive relief, notwithstanding any other provision of this Agreement.  
 5.7 Minimum Purchase Quantities: CUMBERLAND shall have no minimum purchase requirements for the first year following FDA approval of the Drug Product. The parties shall, no later than three (3) months before the end of the first year following FDA approval, negotiate in good faith to set on the minimum quantities applicable to the second to fifth years of commercial sale, which shall be incorporated into Schedule V and shall form part of this Agreement. The parties shall negotiate in good faith to set additional minimum purchase requirements for any extension of the Term of this Agreement under Paragraph 3.1. CUMBERLAND shall use its best efforts to achieve the minimum purchase requirements set forth in Schedule V of this Agreement for each format of Drug Product being sold in the Territory by CUMBERLAND. In the event CUMBERLAND is required to procure Drug Product from other sources in accordance with Paragraph 2.7, the minimum annual purchase obligation set out in Schedule V shall be decreased by the quantity BIONICHE failed to deliver hereunder.  
 6. DRUG PRODUCT RECALLS  
 6.1 Drug Product Recalls: In the event: (a) any government authority issues a request, directive or order that the Drug Product be recalled, or (b) a court of competent jurisdiction orders such a recall, (c) CUMBERLAND determines that the Drug Product should be recalled, or (d) BIONICHE recommends to CUMBERLAND that a recall be initiated, the parties shall take all appropriate corrective actions; provided that a recall pursuant to Subparagraph 6.1 (c) shall be without prejudice to the parties’ rights under Paragraph 2.5. In the event that BIONICHE recommends a recall of Drug Product by CUMBERLAND, such recommendation must take the form of a notice as per Paragraph 11.1, and CUMBERLAND shall respond promptly indicating to BIONICHE whether the Drug Product will be recalled. In no event, however, shall BIONICHE have responsibility for regulatory compliance in connection with any recall, except to the extent and under the circumstances set forth in the Manual or any other written agreement between the parties hereto or as required by law. All costs and expenses incurred in connection with such recall shall be the responsibility of CUMBERLAND unless caused by the negligence of BIONICHE.  
7. FORCE MAJEURE; FAILURE TO SUPPLY  
 7.1 Force Majeure Events: Failure of either party to perform under this Agreement (except the obligation to make payments) shall not subject such party to any liability to the other if such failure is caused by acts such as, but not limited to, acts of God, fire, explosion, flood, war, riot, sabotage, embargo, or by any cause beyond the reasonable control of the parties, provided that written notice of such event is promptly given to the other party.  
8. MANUFACTURING CHANGES  
 BIONICHE may implement commercially reasonable changes in the equipment used for Manufacturing of the Drug Product in the Facility, or the Manufacturing methods, labeling, or packaging of the Drug Product only as expressly provided in the Specifications unless BIONICHE has the prior written consent of CUMBERLAND, which consent shall not be unreasonably withheld or delayed.  
9. CONFIDENTIALITY  
 9.1 Confidential Information: “Confidential Information” means collectively Confidential Information of CUMBERLAND (as defined herein) and Confidential Information of BIONICHE (as defined herein).  
 9.2 Confidential Information of CUMBERLAND: Except as expressly set forth herein, “Confidential Information of CUMBERLAND” means all information obtained or developed by BIONICHE which relates to CUMBERLAND’s business or the Drug Product, regardless of the form in which such information is transmitted. The following shall not be considered Confidential Information of CUMBERLAND for purposes hereof:  
 (a) Information that is already in the possession of BIONICHE at the time it is received from CUMBERLAND or developed by BIONICHE on CUMBERLAND’s behalf, if BIONICHE notifies CUMBERLAND of its belief that the information is excepted under the terms of this subsection;  
 (b) Information received by BIONICHE from a person which has the right to disclose the same, when BIONICHE notifies CUMBERLAND of its belief that the information is excepted under the terms of this subsection;  
 (c) Information that is or becomes published, or is or becomes otherwise publicly available without the fault of BIONICHE;  
 (d) An Invention as defined in Paragraph 9.4; or  
 (e) Confidential Information of BIONICHE.  
 In the event of a dispute regarding the applicability of the above exceptions to the definition of Confidential Information of CUMBERLAND, BIONICHE shall have the burden of producing clear and convincing proof that the information should be excepted from the definition of Confidential Information of CUMBERLAND. BIONICHE shall not use or permit the use of the Confidential Information of CUMBERLAND other than for the limited purposes expressly permitted by or consistent with this Agreement. Recipients of Confidential Information of CUMBERLAND shall be granted access thereto strictly on a “need-to-know” basis. BIONICHE shall take all reasonable steps to ensure that recipients comply with the terms of this Agreement, including all restrictions on use, disclosure and dissemination of Confidential Information of CUMBERLAND. BIONICHE shall notify CUMBERLAND immediately upon becoming aware of any breach hereof and shall take all reasonable steps to prevent any further disclosure or unauthorized use.  
 Upon termination or expiration of this Agreement, BIONICHE shall deliver to CUMBERLAND all Confidential Information of CUMBERLAND, all copies thereof, and all documents or data storage media containing such Confidential Information of CUMBERLAND, except that one copy of such information may be retained by BIONICHE as required by regulation or law for future reference. The Confidential Information of CUMBERLAND shall remain confidential and not be disclosed by BIONICHE for a period of ten (10) years following the date of expiration or termination of this Agreement except as expressly set forth herein or in any other written agreement between the parties.  
 9.3 Confidential Information of BIONICHE: Except as expressly set forth herein, “Confidential Information of BIONICHE” means all information obtained or developed by CUMBERLAND which relates to the manufacture, sale, and distribution of pharmaceutical products by BIONICHE, regardless of the form in which such information is transmitted. The following shall not be considered Confidential Information of BIONICHE for purposes hereof:  
 (a) Information that is already in the possession of CUMBERLAND at the time it is received from BIONICHE or developed by CUMBERLAND on BIONICHE’s behalf, if CUMBERLAND notifies BIONICHE of its belief that the information is excepted under the terms of this subsection;  
 (b) Information received by CUMBERLAND from a person which has the right to disclose the same, when CUMBERLAND notifies BIONICHE of its belief that the information is excepted under the terms of this subsection;  
 (c) Information that is or becomes published, or is or becomes otherwise publicly available without the fault of CUMBERLAND; or  
 (d) Confidential Information of CUMBERLAND.  
 In the event of a dispute regarding the applicability of the above exceptions to the definition of Confidential Information of BIONICHE, CUMBERLAND shall have the burden of producing clear and convincing proof that the information should be excepted from the definition of Confidential Information of BIONICHE. CUMBERLAND shall not use or permit the use of the Confidential Information of BIONICHE other than for the limited purposes expressly permitted by or consistent with this Agreement. Recipients of Confidential Information of BIONICHE shall be granted access thereto strictly on a “need-to-know” basis. CUMBERLAND shall take all reasonable steps to ensure that recipients comply with the terms of this Agreement, including all restrictions on use, disclosure and dissemination of Confidential Information of BIONICHE. CUMBERLAND shall notify BIONICHE immediately upon becoming aware of any breach hereof and shall take all reasonable steps to prevent any further disclosure or unauthorized use.  
 Upon termination or expiration of this Agreement, CUMBERLAND shall deliver to BIONICHE all Confidential Information of BIONICHE, all copies thereof, and all documents or data storage media containing such Confidential Information of BIONICHE, except that one copy of such information may be retained by CUMBERLAND as required by regulation or law for future reference. The Confidential Information of BIONICHE shall remain confidential and not be disclosed by CUMBERLAND for a period of ten (10) years following the date of expiration or termination of this Agreement except as expressly set forth herein or in any other written agreement between the parties.  
 9.4 Invention: As between the parties, CUMBERLAND owns all intellectual property rights in any improvement to the Drug Product and, subject to Paragraph 5.6, any existing or further developments or modifications of the Drug Product in the Territory (“Invention”). Subject to Article 10, BIONICHE shall, at CUMBERLAND’s request and expense, take such actions and execute such documents as necessary or desirable, in CUMBERLAND’s sole judgment, to create, maintain, enforce or defend CUMBERLAND’s rights in any such Invention.  
 9.5 Press Release; Other Disclosure: Except pursuant to a press release subject to the prior written approval of both parties hereto, the parties agree that the contents of this Agreement shall not be disclosed to any third party except (i) the controlling companies of the parties, (ii) the companies controlled by the parties, (iii) individuals and entities providing paid services to either of the parties who are bound by confidentiality obligations, and (iv) governmental regulatory agencies, including, but not limited to, environmental protection authorities, without prior written consent of the other party.  
 9.6 Production of Records: BIONICHE shall prepare, maintain, and submit all documents or reports required under applicable laws and regulations or as reasonably requested by CUMBERLAND concerning the Manufacture of the Drug Products, including without limitation, batch production records for each Drug Product. Notwithstanding the restrictions set forth in this Agreement, BIONICHE shall retain production records for batches of Drug Product for a period of at least one year after the respective expiration date for each batch. These records will be stored by appropriate means, including without limitation, optical disk or microfilm in a secure manner in compliance with current GMP with duplicate copies submitted to CUMBERLAND promptly after the creation thereof and shall be made available on request of the FDA or any other authorized regulatory body.  
10. INDEMNIFICATION  
 10.1 Indemnification by CUMBERLAND: Subject to Xxxxxxxxx 0.0, XXXXXXXXXX shall indemnify and hold BIONICHE (and any Affiliate and their officers, directors, shareholders, agents, and the employees and insurers of any of them and/or their successors and assigns thereto), free and harmless from any and all claims, demands, liability, actions or causes of actions, and any and all expenses associated therewith (including, without limiting the generality of the foregoing, defense costs and reasonable attorney’s fees), arising out of or in connection with, as a result of, or otherwise related to any third party claims arising from: (i) any negligence or recklessness of CUMBERLAND, its agents, or employees; (ii) the promotion, distribution, use, misuse or sale or effects of the Drug Product except to the extent any alleged Drug Product defects were caused by BIONICHE; (iii) CUMBERLAND’s non-compliance with any applicable FDA or other applicable regulations; or, (iv) any failure of CUMBERLAND to perform, in whole or in part, any of its obligations hereunder in each case, unless caused by the acts or omissions of BIONICHE. Beginning prior to delivery of the first order of Drug Products pursuant to this Agreement and continuing until the third anniversary of termination of this Agreement, CUMBERLAND shall maintain products liability insurance with limits of liability of not less than Five Million U.S. Dollars ($5,000,000) and shall name BIONICHE as additional insured under said policy.  
 10.2 Indemnification by BIONICHE: Subject to Paragraph 5.1, BIONICHE will indemnify and hold CUMBERLAND (and any Affiliate and their officers, directors, shareholders, agents, and the employees and issuers of any of them and/or their successors and assigns thereto), free and harmless from any and all claims, demands, liability, actions or causes of action, and any and all expenses associated therewith (including, without limiting the generality of the foregoing, defense costs and reasonable attorney’s fees), arising out of or in connection with, as a result of, or otherwise related to any third party claims arising from: (i) any negligence or recklessness of BIONICHE, its agents or employees; (ii) personal injury (including death) or property damage arising out of or in connection with BIONICHE’s manufacture or handling of the Drug Product otherwise than in accordance with the Specifications and CUMBERLAND’S written directions; (iii) BIONICHE’s non-compliance with any applicable FDA or other applicable regulations; or (iv) any failure of BIONICHE to perform any of its obligations hereunder, in each case, unless caused by the acts or omissions of CUMBERLAND. Beginning prior to delivery of the first order for Drug Product pursuant to this Agreement and continuing until the third anniversary of termination of this Agreement, BIONICHE shall maintain products liability insurance with limits of liability of not less than U.S. $5,000,000 and shall name CUMBERLAND as additional insured under said policy.  
 10.3 Conditions of Indemnification: If either party seeks indemnification from the other under Paragraphs 10.1 or 10.2, it shall promptly give written notice to the other party of any such claim or suit threatened, made or filed against it, which forms the basis for such claim of indemnification and shall cooperate fully with the other party in the defense of all such claims or suits. No settlement or compromise shall be binding on a party hereto without its prior written consent.  
 10.4 Limitation: Except as expressly set forth herein, neither party will be liable to the other for any claim for loss of profits, for loss or interruption of business or for indirect, special or consequential damages of any kind under this Agreement.  
11. GENERAL PROVISIONS  
 11.1 Notices: Any notice permitted or required by this Agreement may be sent by facsimile with the original document being sent by certified (or registered) mail, return receipt requested, or overnight delivery and shall be effective when received (or refused) via facsimile or mail or overnight if faxed and sent and addressed as follows (or to such other facsimile number or address as may be designated by a party in writing):  
 If to CUMBERLAND: CUMBERLAND PHARMACEUTICALS INC.  
 000 Xxxxx Xxxxxx Xxxxx, Xxxxx 000  
 Xxxxxxxxx, Xxxxxxxxx 00000  
 Attn: Chief Executive Officer  
 Telephone: 615-255-0068  
 Facsimile: 000-000-0000  
 If to BIONICHE: BIONICHE LIFE SCIENCES, INC.  
 000 Xxxxxx Xxxxxx Xxxx,  
 Xxxxxxxxxx, Xxxxxxx, Xxxxxx X0X 0X0  
 Attn: Chief Executive Officer  
 Telephone: 000-000-0000  
 Facsimile: 000-000-0000  
 With a copy to: BIONICHE PHARMA (CANADA) LIMITED  
 000 Xxxxxx Xxxxxx, Xxxxx 000  
 Xxxxxx, Xxxxxxx, Xxxxxx X0X 0X0  
 Attn: President  
 Telephone: 000-000-0000  
 Facsimile: 000-000-0000  
 And to: BIONICHE LIFE SCIENCES, INC.  
 Attn: Vice President, Corporate Counsel  
 Telephone: 000-000-0000  
 Facsimile: 000-000-0000  
 11.2 Master Agreement; Amendment: This Agreement is being entered into pursuant to the Strategic Alliance Agreement dated January 15, 2002, between CUMBERLAND and BIONICHE (the “Master Agreement”), and this Agreement (including any and all exhibits hereto, whether entered into now or hereafter) constitutes an Addendum (as defined in the Master Agreement). In the event of any conflict or inconsistency between the terms of this Agreement and the Master Agreement, the terms of this Agreement shall govern. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by both parties hereto. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.  
 Without limiting the generality of the foregoing, no provisions of any CUMBERLAND purchase order that are inconsistent with the terms of this Agreement shall apply.  
 11.3 Waiver: None of the provisions of the Agreement shall be considered waived by any party hereto unless such waiver is agreed to, in writing, by both parties. The failure of a party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any rights of any party hereto.  
 11.4 Obligations to Third Parties: Each party warrants and represents that this Agreement is not inconsistent with any contractual obligations, expressed or implied, undertaken with any third party.  
 11.5 Assignment: This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the parties and may not be assigned, transferred, or subcontracted by either party without the prior written consent of’ the other, which consent will not be unreasonably withheld or delayed, except that no consent shall be required in the case of a transfer to an Affiliate of a party hereto or transaction involving the merger, consolidation or sale of substantially all of’ the assets of the party seeking such assignment or transfer and such transaction relates to the business covered by this Agreement and the resulting entity assumes all the obligations of the assigning party under this Agreement.  
 11.6 Independent Contractor: BIONICHE shall act as an independent contractor for CUMBERLAND in providing the services required hereunder and shall not be considered an agent of or joint venturer with CUMBERLAND. Unless otherwise provided herein to the contrary, BIONICHE shall furnish all expertise, labor, supervision, machining and equipment necessary for performance hereunder and shall obtain and maintain all building and other permits and licenses required by public authorities.  
 11.7 Governing Law and Dispute Resolution: This Agreement is subject to and shall be governed by the laws of the State of New York. Any dispute, controversy, or claim arising out of or relating to this Agreement, any purchase orders between the parties hereto, or the breach, termination, or invalidity thereof shall be settled under the Rules of the American Arbitration Association by one or more arbitrators appointed in accordance with said Rules. The place of arbitration shall be within the State of New York. The parties agree that the award of the arbitrator(s) shall be the sole and exclusive remedy between them regarding any claims, counterclaims, issues or accountings presented or pled to the arbitrator(s); that it shall be made and shall promptly be payable in U.S. dollars free of any tax, deduction, or offset; that any costs and attorney fees incurred by the prevailing party as determined by the arbitrator(s) incident to the arbitration, shall be included as part of the arbitration award; and that any costs. fees, or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the party resisting such enforcement. The award shall include interest from the date of any damages incurred for breach or other violation of the Agreement, and from the date of the award until paid in full, at a rate to be fixed by the arbitrator(s), but in no event less than the prime interest rate for Bank of America in Nashville, Tennessee, U.S.A.  
 11.8 Severability: In the event that any term or provision of this Agreement shall violate any applicable statute, ordinance, or rule of law in any jurisdiction in which it is used, or otherwise be unenforceable, such provision shall be ineffective to the extent of such violation without invalidating any other provision hereof.  
 11.9 Headings, Interpretation: The headings used in this Agreement are for convenience only and are not part of this Agreement.  
 11.10 Conflict: In the event of conflict between the terms and provisions of this Agreement and the terms and provisions of the Manual, the terms of this Agreement shall control.  
 11.11 Limitation: The parties hereto acknowledge and agree that the International Sale of Goods Act and the United Nations Convention on Contracts for the International Sale of Goods have no application to this Agreement.  
 IN WITNESS WHEREOF, the parties hereto have each caused this Agreement to be executed by their duly authorized representatives effective as of the date first above written.  
 CUMBERLAND PHARMACEUTICALS INC. BIONICHE LIFE SCIENCES, INC.   
 /s/  
 X. X. Xxxxxx /s/ Xxxxxx Xxxxxxx   
 Authorized Signature Authorized Signature   
 X.X. Xxxxxx Xxxxxx Xxxxxxx   
Chief Executive Officer Vice President, Business Development   
 SCHEDULE I  
Shipping and Storage  
 1. Finished Drug Product shall be stored by BIONICHE after completion, at 20 degrees C to 25 degrees C.  
 2. Drug product will be delivered by BIONICHE to CUMBERLAND by air on the basis of FCA (ex works) ex works BIONICHE’s plant in Galway, Ireland with the carrier to be selected by CUMBERLAND.  
 3. The terms “FCA” (“ex works”) and “DDP” and the Parties’ respective obligations shall be determined in accordance with the INCOTERMS adopted by the International Chamber of Commerce, effective July 1, 1990, unless otherwise specifically provided in this Agreement.  
 4. Additional details regarding packaging shall be incorporated herein upon adoption thereof by written agreement of BIONICHE and CUMBERLAND.  
Pricing —  
The prices to be paid by CUMBERLAND to BIONICHE for the Drug Products arc as follows:  
N-acetylcysteine 30 mL Canadian [\*\*\*]  
N-acetylcysteine 10 mL Canadian [\*\*\*]  
Canadian currency conversions will be based upon the then current exchange rate listed in the Wall Street Journal.  
The minimum size of any order of the Drug Product shall be one production lot of [\*\*\*] for the 30 mL Drug Product and [\*\*\*] for the 10 mL Drug Product.  
In addition, CUMBERLAND shall pay to BIONICHE a royalty equal to [\*\*\*] percent ([\*\*\*]%) of Net Sales (as defined herein) during each calendar year; provided that CUMBERLAND shall pay BIONICHE such royalty within [\*\*\*] days after the last day of the applicable calendar year, For purposes hereof, “Net Sales” shall mean the aggregate amount billed for sales of the Drug Product by CUMBERLAND, less returns, hospital buying group chargebacks, hospital buying group/group purchasing organization administration fees, managed care organization rebates, sales/purchasing discounts, federally mandated discounts and rebates, and state medical assistance program rebates and discounts, and determined on an accrual basis by CUMBERLAND.  
Within sixty (60) days following the close of each calendar quarter following the first sale of a Drug Product, CUMBERLAND shall furnish to BIONICHE a written report for the calendar quarter showing the Net Sales for each format of the Drug Product during such calendar quarter and the corresponding amount payable to BIONICHE under this Agreement for such calendar quarter. Simultaneously with the submission of the written report, CUMBERLAND shall pay to BIONICHE a sum equal to the aggregate royalty due for such calendar quarter calculated in accordance with this Agreement.  
Payments to be made by CUMBERLAND to BIONICHE under this Agreement shall be made by cheque made to the order of BIONICHE or by bank wire transfer in immediately available funds to such bank account designated in writing by BIONICHE from time to time.  
For a period of at least five (5) years after the end of each calendar quarter following the first sale of each Drug Product, CUMBERLAND shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. Upon the written request of BIONICHE and not more than once in each calendar year and only with reasonable prior notice to CUMBERLAND, CUMBERLAND shall permit an independent certified public accounting firm of nationally recognized standing selected by BIONICHE and reasonably acceptable to CUMBERLAND to have access during normal business hours to such of the records of CUMBERLAND as may be reasonably necessary to verify the accuracy of the Royalty reports hereunder for any calendar year ending not more than twenty-four (24) months prior to the date of such request.  
If such accounting firm concludes in its review that additional royalties were owed during such period, CUMBERLAND shall pay the additional amounts within forty-five (45) days of the date BIONICHE delivers to CUMBERLAND such accounting firm’s written report so concluding. The fees charged by such accounting firm shall be paid by BIONICHE, except CUMBERLAND shall pay such fees in the event that the additional amounts owed by CUMBERLAND vary from amounts paid with respect to the calendar year in question by five percent (5%) or greater.  
 SCHEDULE II  
Technical Agreement  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
TECHNICAL AGREEMENT  
This Agreement is entered into on this 5th day of April, 2005, by and between Cumberland Pharmaceuticals Inc., a company organized and existing under the laws of the United States, with offices located at 0000 Xxxx Xxx Xxxxxx, Xxxxx 000 Xxxxxxxxx, Xxxxxxxxx 00000 XXX. (“Cumberland”) and Bioniche Teoranta, a company organized and existing under the laws of the Republic of Ireland, having a principal place of business, Inverin, Co. Galway, Republic of Ireland. (“Bioniche”).  
Whereas, Cumberland requested Bioniche to manufacture and supply the Products (as defined in section 1.1 hereof); and  
Whereas the parties to this Agreement wish to establish in greater detail, the responsibilities of Cumberland as the Contractor, and Bioniche as Suppliers, for the manufacture of the Products; and  
Whereas, a detailed listing of responsibilities of the Contractor and Suppliers, is attached as Exhibit I;  
Now therefore, in consideration of the mutual covenants and promises contained herein, the parties agree as follows:  
I. Purpose.  
This Technical Agreement is intended to serve as the Manufacturing Project Manual to be attached as Schedule II to the Manufacturing and Supply Agreement, dated January 15, 2002, between Cumberland and Bioniche Life Sciences, Inc. (the “Manufacturing Agreement”), and is not intended to supersede any of the parties’ rights and obligations set forth therein. Only in the event that this Technical Agreement expressly amends and restates specified subsections of the Manufacturing Agreement shall this Technical Agreement serve as an amendment of the parties rights and obligations set forth in the Manufacturing Agreement. Except as specifically amended hereby, the Manufacturing Agreement shall remain in full force and effect, and any conflicting provision hereof shall be null and void. The parties have entered into this Agreement to clearly define the responsibilities of each party and to ensure that the Products are manufactured, packaged, released, stored and shipped in accordance with current European and US GMP’s or other relevant equivalent cGMP’s, agreed by Bioniche and Cumberland.  
1.1 Product  
 Bioniche will supply Cumberland with Products, as follows:  
 1.1.1   
Acetadote® — Acetylcysteine Injection  
 200mg/mL Bioniche Code Number : 0164AI01  
1  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
All references to Bioniche or Cumberland shall include Affiliates of these companies. “Affiliate” shall be defined as any entity (i) at least fifty percent (50%) of whose outstanding securities or assets are owned or controlled, directly or indirectly, by said party, or (ii) which owns or controls directly or indirectly fifty percent (50%) of the outstanding securities or assets of said party, or (iii) is owned or controlled directly or indirectly, to the extent of fifty percent (50%) or more of the outstanding securities or assets by any of the entities described in (i) and (ii) above. The term “Manufacture” as used in this Agreement shall be understood to include the specification and the purchase of all necessary components of the Product, the manufacturing process, quality control and assurance. The term “Packaging” as used in this Agreement shall be understood to include the specification and purchase of all necessary components of the Product, the packaging and the final quality control and assurance.  
II. General Quality Issues  
2.1 Good Manufacturing Practices  
Bioniche represents that it shall observe and adhere to the requirements of the current EU Guide to Good Manufacturing Practice for Medicinal Products for Human Use, including supplementary recommendations issued by the Commission of the European Communities (cGMPs) and current US cGMPs. All terms defined in the cGMPs shall have the same meaning when used in this document. Bioniche represents and warrants that all processes and equipment used in the manufacture of the Product shall have been validated or are in the process of being validated in accordance with the cGMPs and current US cGMPs. The reference to other regulatory requirements will be agreed between the two parties.  
2.2 Qualified Persons  
The Qualified Person (“QP”), as defined in EU Directive 75/319/EEC, for Bioniche is named in Exhibit II, and sample of the signature is affixed.  
2.3 Supplier Quality Monitoring and Assessments  
It is the responsibility of Bioniche to perform quality monitoring and assessment on suppliers of all materials, involved in the manufacturing of the Product, in accordance with written quality monitoring protocols.  
2.4 Traceability  
It is the responsibility of Bioniche to properly track each batch number of the Product, for traceability, so as to be able to provide a full manufacturing history. Bioniche shall keep manufacturing records, analytical records and reference samples for each batch of Product. Copies of records and reference samples shall be made available to Cumberland promptly upon request. Reference samples shall be kept for a period of one (1) year after the expiration date for the batch. Manufacturing and quality control records shall be kept for a minimum period of six (6) years from the date of manufacture or a minimum of one (1) year after the expiration date, whichever is longer.  
2  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
2.5 Stability Studies  
Bioniche has the responsibility for the performance of 36-month stability studies on the Products in accordance with Bioniche stability SOP ST.001 Stability data are to be reported to Cumberland on request but Cumberland will be alerted concerning any out-of-specification results within 48 hours.  
III. Specifications.  
Attached hereto is a complete set of every Specification related to Products, which are referenced in 1.1. Bioniche shall prepare the Master Manufacturing Formula and the Manufacturing and Packaging Batch Instructions for the Product. The Batch Instruction will be approved by Bioniche. Copies of completed Batch Instructions will be provided to Cumberland following the completion of manufacture if requested.  
IV. Manufacture, Controls, Release and Shipment  
4.1 Purchases and Management of Materials.  
It is the responsibility of Bioniche to source the Active Pharmaceutical Ingredients (APIs), from Bioniche’s designated approved suppliers, for the manufacture of the Products. Bioniche shall supply excipients and materials required for the manufacture of the Product, and/or ancillary operating materials used in the manufacture. Bioniche is responsible for all quality control testing and release of materials used in the manufacturing of the Product  
4.2 Product Testing & Release  
Bioniche shall test or cause to be tested by an approved, qualified entity each lot of the Product pursuant to the Specifications before release to Cumberland. Each test shall set forth the items tested, the specific release Specifications and test results in a certificate of analysis for each lot delivered and be certified by Bioniche’s QP and sent separately to Cumberland. Cumberland shall be entitled to rely on the certificate of analysis and is not required to perform any further testing,  
4.3 Non Conforming Activities  
During the course of manufacture:  
4.3.1 All deviations and events not affecting the agreed Technical Specifications will be documented by Bioniche. These documents will be retained as part of the batch record. Bioniche shall inform Cumberland of all deviations prior to release of the batch.  
3  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
4.4 Manufacturing Batch Records  
4.4.1 Bioniche shall also provide as part of the Batch Certificate of Analysis, a manufacturing compliance statement with each lot delivered to Cumberland. This certificate will certify that the lot of Product was manufactured in accordance with the Specifications and applicable cGMP laws or regulations.  
4.4.2 The manufacturing lot records shall contain, at a minimum, the following information:  
 • The name and dosage form of the medicinal product.  
 • The batch number or test number of the API and all other raw materials (excluding water).  
 • The date of manufacture and the Product’s batch number.  
 • Details of the amounts of Product manufactured during each operation and the quantity of the Product in the various stages.  
 • Both the expected and actual results of the in-process controls. If expected results are expressed in a quantified manner, actual results shall also be quantified.  
 • Confirmation that the critical steps of the operations proceeded in accordance with the Manufacturing Instructions by the signature of the persons in charge of the various stages.  
 • Special observations made during manufacturing.  
 • Certification that the process operating lines have been cleared, at the beginning of the batch processing.  
 • A list of deviations and their resolution.  
4.4.3 Labeling of the product for Clinical Trials will be the responsibility of Cumberland.  
4.5 Shipment  
Bioniche shall ship the Product in accordance with instructions agreed to by the parties. Bioniche shall only place one lot number on any single pallet. Shipment of Product batches under quarantine shall be made only when specifically authorized in writing by Cumberland, and will be according to the Bioniche procedure.  
V. Changes in Site, Quality Standards, Formula and Manufacturing Procedures  
5.1 Changes Control  
Bioniche shall inform Cumberland of any proposed intent to change the site of manufacture, the specifications, labeling, the procedures for the manufacturing processes or record keeping of Product.  
4  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
VI. Quality Audit  
During normal working hours and upon reasonable notice, Cumberland shall be entitled to inspect such areas of Bioniche’s plant where the Product is manufactured or otherwise stored or handled. Such inspections will include, but not be limited to:  
A review of Production facilities and utilities  
The taking of physical inventory samples  
Reviewing of Quality and Documentation Control systems  
Reviewing batch records  
A written report of observation shall be issued by Cumberland quality auditors, including a listing of significant items, which must be corrected prior to the supply of further Product to Cumberland.  
VII. Product Complaints/Recall  
Bioniche and Cumberland shall each notify the other of any claims related to damage, defective or nonconforming Product. Bioniche shall supply Cumberland with all relevant information for the investigation of complaints related to the Product.  
Cumberland shall be responsible for the collection of adverse events reported on the Finished Product. It shall be Cumberland’s responsibility to notify Bioniche of such reports, if such reports relate to Bioniche’s manufacture of the Product, and to keep the appropriate records and to promptly report such adverse reports to the appropriate regulatory authorities. In the event any adverse events are reported to Bioniche, Bioniche shall notify Cumberland in writing within 3 business days.  
VIII. Regulatory Communications  
8.1 Maintenance of Licenses  
Cumberland is the current Authorization Holder (NDA) for the Finished Product to be manufactured under this Technical Agreement and shall be responsible for the maintenance and renewal of said Marketing Authorizations.  
Bioniche shall be responsible for the maintenance and renewal of its manufacturing license.  
8.2 Notifications  
Cumberland and Bioniche shall promptly inform each other of any material communications to or from governmental authorities or agencies relating to the Product, including but not limited to providing each other promptly with copies of any written communications, and “reports of visits by a governmental authority or agency to any areas within the facilities where the Product is manufactured that could impact upon the continued supply of Product. The parties shall consult with each other regarding any issues raised in such communications and shall attempt in good faith to agree upon any action to be taken or response to be made in connection with such communications.  
5  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
IX. Effective Date and Term, Interpretation  
This Technical Agreement shall become effective on the date first written above and shall remain in force until the termination of the Agreement between the parties for the supply of Products.  
X. Modifications  
Any modifications or amendments to this Agreement must be in writing and signed by both parties to be effective.  
In Witness Whereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers, effective as of the first day above written.  
 Bioniche Teoranta  
 By: /s/ Xxxxxx Xxxx   
 Date: 5th April 0000   
 Xxxxxx Xxxx XXx(Xxxx) M.RS.C. M.I.Q.A  
Director Of Quality and Qualified Person  
  
  
Cumberland Pharmaceuticals Inc.  
 By: /s/ Xxx Xxxxxx   
 Date: 26 April 2005   
 Xxx Xxxxxx  
Vice President Operations   
 6  
 Technical Agreement Rev 1 5th April 2005  
Bioniche/Cumberland  
Exhibit I  
DETAILED RESPONSIBILITES  
X = Responsible  
A = Approval/Authority  
 BIONICHE CUMBERLAND  
 1  
 SPECIFICATIONS/DOCUMENTATION   
 1.1  
 Specification of Active Bulk Ingredient X A  
 1.2  
 Master Manufacturing Formula X A  
 1.3  
 Product Lot Identification System X   
 1.4  
 Specification of Inactive Ingredients X A  
 1.5  
 Test Method for ID of Active Bulk X   
 1.6  
 Test Method for Inactive Ingredients X   
 1.7  
 Test Method for Release of Product X   
 1.8  
 Local Manufacturing and Packaging Instructions X   
 1.9  
 Specification for In-Process Control X   
1.10  
 Change Control for Active Ingredient X A  
1.11  
 Change Control for Manufacturing Formulas X A  
1.12  
 Change Control for Inactive ingredients X A  
1.13  
 Bulk product package specification, box & labels X   
1.14  
 Finished Artwork A X  
1.15  
 Change Control for Artwork/Finishing Materials X A  
 2  
 PRODUCTION   
 2.1  
 Procurement of Bulk Active ingredient X   
 2.2  
 Purchase Inactive Substances X   
 2.3  
 Store Active/Inactive Substances X   
 2.4  
 Sample/Test/Acceptance of Active & Inactive Substances X   
 2.5  
 Test Method Transfer N/A   
 2.6  
 On-Going Stability Testing of Product X   
 2.7  
 Retention of Certificate of Analysis for Active Substance X   
 2.8  
 Validation of Manufacturing Processes X   
 2.9  
 Bills of Material for Manufacturing Process X   
2.10  
 In Process Control Instructions and Testing X   
2.11  
 Batch Record Reconciliation X   
2.12  
 Batch Record Retention X   
2.13  
 Retention of Samples of Active Ingredient X   
2.14  
 Retention of Samples of other Materials (Except water) X   
2.15  
 Retention of Samples of Product X   
2.16  
 Maintenance of Pharmaceutical Manufacturing Licenses X   
2.17  
 Disposal of Waste X   
7  
 Technical Agreement Rev 1 5th April2005  
Bioniche/Cumberland  
 BIONICHE CUMBERLAND  
3.0  
 TESTING & RELEASE OF FINISHED PRODUCT   
3.1  
 Analysis of Product X   
3.2  
 Certificate of Analysis for the Product X   
3.3  
 Internal QP certification of the Product as per approved production and control documents X   
3.4  
 Final QP Release of the product to Cumberland X   
3.5  
 Complaint   
 - Collection and Logging X X  
 - Investigation and Report Issue X   
 - Follow Up Corrective Action X   
 - Response to Customer X  
3.6  
 Product Recall   
 - Decision to Initiate Recall X X  
 - Approval of Notification Wording X X  
 - Management of Recall X X  
 - Reconciliation of Returned Product X X  
3.7  
 Liaison with Regulatory Authorities for Approval, Maintenance and Updating Marketing Authorisations/Product Authorisations (NDA) X  
 3.8  
 Final Release to Market X  
8  
 Technical Agreement Rev 1 5th April 2005 Bioniche/Cumberland  
Exhibit II  
Qualified Person  
(14th January 2004)  
Qualified Persons of Bioniche Teoranta  
 Xx. X. Xxxx   
 Signature : /s/ Xxxxxx Xxxx   
 9  
 SCHEDULE III  
Territory  
The United States of America and all its possessions and territories  
 SCHEDULE IV  
Approved Suppliers  
[\*\*\*]  
 Schedule V  
Minimum Purchase Quantities  
[Intentionally omitted. Exhibit 10.3 to Form S-1 filed on May 1, 2007 (File No. 333-142535) incorporated by reference herein.]