Exhibit 10.3  
MANUFACTURING AGREEMENT  
 THIS MANUFACTURING AGREEMENT (the “Agreement”), effective as of the 1st day of January, 2006, (the “Effective Date”), is by and between ALCON PHARMACEUTICALS LTD., a Swiss corporation with its principal offices at Xxxxx 00, X.X. Xxx 00, 0000 Xxxxxxxxx, Xxxxxxxxxxx (hereinafter referred to as “ALCON”) and LIFECORE BIOMEDICAL, INC., a Minnesota corporation with its principal offices at 0000 Xxxxx Xxxx., Xxxxxx, XX 00000 (hereinafter referred to as “SELLER”).  
WITNESSETH:  
 WHEREAS, ALCON is desirous of entering into a contract supply arrangement with SELLER with respect to Sodium Hyaluronate as specifically described in the Product Specifications referenced in Article 1.02 (the “Product”), which Product shall be used by ALCON to manufacture ALCON’s finished VISCOAT® ophthalmic viscoelastic solution (the “Alcon Finished Product”), and SELLER is willing to enter into such an arrangement with ALCON, all on the terms and conditions set forth herein.  
 NOW, THEREFORE, in consideration of the mutual covenants, promises, and agreements herein contained, it is mutually agreed as follows:  
ARTICLE I  
MANUFACTURING AND SALE  
 1.01 During the term of this Agreement, SELLER agrees that it shall manufacture for and sell to ALCON (or its Affiliate) on a non-exclusive basis, and ALCON agrees that it (or its Affiliate) shall, on a non-exclusive basis, purchase and accept from SELLER the Product as set forth in the terms of this Agreement. “Affiliate” means any legal entity that directly or indirectly owns, is owned by, or is under common control with the party specified.  
 1.02 SELLER agrees that it shall manufacture the Product and perform all of its obligations hereunder in accordance with (a) the written specification for the Alcon Product numbers BE.Q02.7SPSHCC.S0032A and BE.Q02.7SPSHCC.S0032B, as amended or supplemented from time to time (the “Product Specifications”) and quality control testing procedures corresponding to SELLER’S product numbers 10025 and 80349, (b) Standard Purchase Description number BE.Q02.7SPDCC.S0042A for the Product (“SPD”), as amended or supplemented from time to time, (c) the current good manufacturing practices applicable to the manufacturing of the Product as defined by Good Manufacturing Practices and Quality System Regulations as promulgated under the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq, as amended (the “FFDCA”), at 21 CFR Part 820 and European Directive 93/42/EEC of 14 June 1993, the Medical Device Directive (including Annex 1 thereof), and applicable national implementing laws, regulations and guidelines, and including ISO 13485 standard, ISO 14971, EN 46001, EN 46002 and EN 724 standards, (d) the procedures, terms and conditions set forth in Exhibit “A” hereto, and (e) all other applicable laws, rules and regulations (the foregoing clauses (a) through (e) collectively, the “Product Standards”). The parties acknowledge that the Product Specifications and the SPD referenced above are the versions in  
 effect on the Effective Date; however, the parties agree that the Product Specifications and the SPD may be updated from time to time with the written agreement of the parties as a separate change control process. In that event, the referenced Product Specifications and SPD will automatically be superceded and replaced by the new Product Specifications and SPD.  
 1.03 Except as otherwise expressly set forth herein, all raw materials and packaging components necessary to manufacture the Product will be supplied by SELLER.  
 1.04 From time to xxxx XXXXXX may recommend to ALCON changes in the design, processes or procedures relative to the manufacturing, packaging and/or labeling of the Product. In the event any of said recommendations are adopted by ALCON pursuant to Exhibit “A” attached hereto, they shall be deemed to amend the Product Specifications. For the avoidance of doubt, SELLER may not change the design, processes or procedures relative to the manufacture of the Product, including the materials or components thereof, in any respect without the prior written consent of ALCON as set forth in the preceding sentence. ALCON shall assess any requested changes based on the potential risk and will not unreasonably withhold or delay consent.  
 1.05 SELLER shall conduct all manufacturing of the Product at its facility located at Chaska, Minnesota, or such other facility as the parties may agree. SELLER shall supply all equipment or machinery used by SELLER in the production, packaging, labeling, holding or quality control testing of the Product, unless specified otherwise herein, and shall maintain its facilities, including such equipment, in a state of repair and operating efficiency consistent with the requirements of the Product Standards. SELLER shall obtain and maintain during the term hereof all government and regulatory authority licenses, permits, registrations, and approvals required in order to manufacture the Product pursuant to the terms hereof, including, without limitation, to the extent applicable, registration as a device establishment and submission to the FDA of a device list pursuant to 21 CFR 807.20, and compliance with the Medical Device Directive (including Annex 1 thereof).  
ARTICLE II  
FORECASTS, ORDERS AND DELIVERY  
 2.01 During the term of this Agreement, SELLER agrees that it will sell to ALCON and ALCON agrees that it will purchase from SELLER, such requirements of the Product that ALCON orders pursuant to the terms of this Agreement.  
 2.02 ALCON shall furnish SELLER with a written updated six (6) month rolling forecast of the quantities of the Product that ALCON intends to order from SELLER during the next following six (6) months. It is understood and agreed that any forecasts issued to SELLER by ALCON pursuant to the terms hereof, shall not be binding nor constitute a firm order of the Products. The ordering of Products shall be by means of individual purchase orders and change orders thereto (hereinafter referred to collectively as “Purchase Order(s)”), issued from time to time by ALCON’s procurement personnel and ALCON’s subcontractors who are authorized herein to do so. ALCON’s sole liability to SELLER shall be limited to actual quantities ordered against individual Purchase Orders. In the event that the terms of any Purchase Order are not consistent with those of this Agreement, then the terms of this Agreement will prevail.  
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 2.03 If ALCON requests changes to any Purchase Order after receipt thereof by SELLER, SELLER shall be obligated to comply with all changes to Purchase Orders that increase or decrease by twenty percent (20%) or less the aggregate quantity of Product ordered by ALCON for the relevant period. SELLER shall exercise its best efforts to comply with all other changes to Purchase Orders that ALCON may request.  
 2.04 In the event SELLER discovers that there is a likelihood that it will fail to deliver a shipment of Product on the date set forth in a Purchase Order, SELLER shall notify ALCON within five (5) business days of the discovery of such failure. Furthermore, in the event that because of SELLER’s failure to timely deliver a shipment of Product as set forth herein, ALCON is forced to purchase a Product equivalent from a third party, ALCON shall have the right to terminate all or a portion of the Purchase Order related to the Product delivery in question.  
 2.05 SELLER shall deliver the quantities of each Product set forth in each Purchase Order on the delivery date specified therein. All shipments shall be F.C.A. (INCOTERMS 2000) SELLER’S facilities, at which point all title to, and risk of loss of, the Products shall pass to ALCON (or its Affiliate issuing the purchase order). SELLER shall not be liable for any delay in shipment of the Product that is beyond the reasonable control of SELLER.  
 2.06 ALCON shall purchase a minimum of \*\* of Product during each 12-month period of this Agreement (Minimum Volume). If ALCON fails to purchase the Minimum Volume, ALCON shall pay to SELLER, pursuant to the terms of Paragraph 3.02, the difference between the Minimum Volume and the volumes actually purchased by ALCON as of the end of each such 12 month period.  
ARTICLE III  
PRICE AND TERMS OF PAYMENT  
 3.01 ALCON shall pay SELLER for the Product in accordance with the following price schedule:  
 Year Price-USD   
 2006  
 USD \*\*   
2007  
 USD \*\*   
2008  
 USD \*\*   
 \*\* The appearance of a double asterisk denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.  
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 3.02 ALCON will pay for the Product within thirty (30) days of the date of SELLER’s invoice.  
 3.03 If the Product Specifications are changed in accordance with the terms hereof and said change affects SELLER’s costs to manufacture the Product, a revised price for the Product shall be determined by mutual agreement of the parties, provided that SELLER shall not withhold its agreement to any revised price proposed by ALCON if such revised price includes reimbursement of SELLER’s reasonably documented increased costs to manufacture the Product as a result of such changes.  
 3.04 ALCON agrees that any sales taxes, gross receipts or similar taxes that are assessed as a result of this Agreement (except taxes on SELLER’s net income), including, without limitation, Value Added Tax, are the responsibility and liability of ALCON, and will not be transferred to, or paid by, SELLER, in any form.  
ARTICLE IV  
RECORDS  
 4.01 SELLER agrees to maintain accurate records of Product production, shipment, and such other records as are required by the Product Standards, including any requirements applicable to electronic records and signatures (21 CFR Part 11), or otherwise mutually agreed upon by the parties for such period as may be required by applicable laws (and in any case for a minimum of six years), and shall provide to ALCON, upon ALCON’s request, copies of all such records. The obligations of SELLER under this Paragraph 4.01 shall survive the expiration or termination for whatever reason of this Agreement for a period of six years.  
ARTICLE V  
WARRANTIES INDEMNITIES, AND INSURANCE  
 5.01 SELLER warrants that Product delivered to ALCON under this Agreement (a) shall have been manufactured, packaged, labeled, held and shipped in accordance with the written Product Specifications and quality control testing procedures for the Product; and (b) shall conform to the current good manufacturing practices applicable to the manufacturing of the Product as defined in Article 1.02; (c) shall conform to the procedures, terms and conditions set forth in Exhibit A; and (d) shall conform to the Product Standards as defined in Article 1.02; and (e) will be free from defects in material and workmanship for a period of twelve (12) months from delivery to ALCON. SELLER also warrants to ALCON that SELLER has not been debarred and is not subject to debarment and will not use in any capacity, in connection with the services to be performed under this Agreement, any person who has been debarred pursuant to section 306 of the FFDCA, 21 U.S.C. § 335a, or who is the subject of a conviction described in such section (or undergoes any analogous proceedings under foreign law). SELLER shall not be obligated under the foregoing warranty if any nonconformance in the Product results from ALCON’s mishandling, misuse or improper storage of the Product.  
 5.02 ALCON shall have a period of ninety (90) days from date of receipt to inspect and reject, by written notice to SELLER, any Product shipment on the grounds that it does not comply with the warranty set forth in Paragraph 5.01. In the event ALCON rejects any Product  
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 as a result of such non-compliance, ALCON shall return such rejected Product (or a sample thereof) to SELLER for further testing. If SELLER confirms that such returned Product fails to comply with the warranty set forth in Paragraph 5.01, SELLER shall, promptly replace such Product with substitute Product that complies with the warranty set forth in Paragraph 5.01 at SELLER’s own cost and expense. Such replacement of the Product by SELLER shall be ALCON’s sole and exclusive remedy, and SELLER’s sole and exclusive liability, with the exception of any indemnification obligations pursuant to Article 5.04, for any breach of the warranty set forth in Paragraph 5.01. If there is any dispute between the parties concerning whether any Product complies with the warranty set forth in Paragraph 5.01 at the time of delivery to ALCON, such dispute shall be referred for decision to an independent expert to be appointed by agreement between SELLER and ALCON. The costs of such independent expert shall be borne by SELLER if the testing confirms the non-conformity and otherwise by ALCON. The decision of such independent expert shall be in writing and, save for manifest error, shall be binding on both SELLER and ALCON. Acceptance by ALCON of any Product pursuant to this Article V shall not in any way affect ALCON’s rights under the warranty provisions of this Agreement.  
 5.03 ALCON will indemnify and hold SELLER harmless from and against any and all liability, damage, loss, cost or expense resulting from any third party claim(s) made or suits brought against SELLER to the extent arising out of (a) any sale or other distribution of the ALCON Finished Product except to the extent that the claim arises out of SELLER’s breach, negligent act or omission, or willful act or omission as described in Article 5.04; or (b) any negligent or willful act or omission of ALCON in relation to the promotion, distribution, sale or use of the Product which SELLER manufactured hereunder and which complies with the warranty set forth in Paragraph 5.01 hereof. Upon the filing of any such claim or suit, SELLER shall immediately notify ALCON thereof and shall permit ALCON, at its cost, to handle and control such claim or suit; provided, however, that SELLER may, at its own expense, retain such additional attorneys as it may deem necessary. SELLER’s attorneys will be permitted by ALCON and their attorneys to reasonably observe and/or participate in all aspects of the defense of such claims or suits. ALCON shall not settle or consent to an entry of judgment in any such claims or suits without the prior written consent of SELLER, which shall not be unreasonably withheld.  
 5.04 SELLER will indemnify and hold ALCON harmless from and against any and all liability, damage, loss, cost, or expense resulting from any third party claims made or suits brought against ALCON to the extent arising out of (a) SELLER’s breach of any representation or warranty set forth in Article 5.01; or (b) any negligent or willful act or omission of SELLER in relation to the manufacture or delivery of the Product hereunder. Upon the filing of any such claim or suit, ALCON shall immediately notify SELLER thereof and shall permit SELLER, at its cost, to handle and control such claim or suit; provided, however, that ALCON may, at its own expense, retain such additional attorneys as it may deem necessary. ALCON’s attorneys will be permitted by SELLER and their attorneys to reasonably observe and/or participate in all aspects of the defense of such claims or suits. SELLER shall not settle or consent to an entry of judgment in any such claims or suits without the prior written consent of ALCON, which shall not be unreasonably withheld.  
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 5.05 SELLER, at the time of signing, shall furnish ALCON with a Certificate of Insurance (provided by an insurance carrier(s) reasonably acceptable to ALCON) evidencing that SELLER has in effect and shall throughout the term of this Agreement maintain comprehensive General Liability insurance coverage including Products Liability and Blanket Contractual, affording a limit of IUD 5,000,000 Bodily Injury/Property Damage Liability per occurrence and in the aggregate. SELLER’s insurance policies shall name ALCON as an additional insured party and shall be endorsed to provide that ALCON shall be notified at least sixty (60) days in advance of any material change or cancellation of insurance.  
 5.06 Except as specifically set forth in this agreement, SELLER makes no warranties with respect to the Product, express or implied, including without limitation, any warranty of merchantability, fitness for a particular purpose or non-infringement.  
 5.07 The provisions of this Article V shall survive the expiration or termination for whatever reason of this Agreement.  
ARTICLE VI  
CONFIDENTIALITY  
 6.01 All information, including, without limitation, know-how, furnished by or on behalf of one party hereto (the “Disclosing Party”) to the other party hereto (the “Receiving Party”) either in connection with the discussions and negotiations pertaining to, or in the course of performing, this Agreement (the “Confidential Information”) shall he kept confidential by the Receiving Party and the Receiving Party shall not make use of said Confidential Information, except for purposes authorized by this Agreement, nor disclose the same to any person or firm unless previously authorized in writing by the Disclosing Party to do so; provided, however, that the Receiving Party may disclose such Confidential Information to its responsible officers and employees who require said information for the purposes contemplated by this Agreement, provided that said officers and employees shall be subject to like obligations of confidentiality.  
 6.02 Any other provision hereof to the contrary notwithstanding, it is expressly understood and agreed by the parties hereto that the obligations of confidence and non-use set forth in Paragraph 6.01 shall not apply to any information which:  
 (a) is lawfully, at the time of disclosure or thereafter so becomes, a part of the public domain;  
 (b) is independently discovered or developed by, or otherwise in the lawful possession of, the Receiving Party without the use of Confidential Information belonging to the Disclosing Party, as shown by its written records;  
 (c) is lawfully disclosed to the Receiving Party by a third party who is not in violation of an obligation of confidentiality to the Disclosing Party relative to said information; or  
 (d) is, by mutual agreement of the parties hereto, released from a confidential status; or  
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 (e) the Receiving Party must disclose pursuant to applicable laws, regulations or court order, provided that the Receiving Party gives the Disclosing Party reasonable notice of its intent to disclose such information.  
 6.03 Neither party shall use the name of the other party in any discussions with third parties, advertising, press release, sales literature, or fund-raising efforts without the prior written consent of the other party.  
 6.04 The provisions of this Article VI shall survive the expiration or termination for whatever reason of this Agreement  
ARTICLE VII  
TERM AND TERMINATION  
 7.01 Unless terminated in accordance with the provisions of Paragraph 7.02 below, the term of this Agreement shall be for a period of thirty-six (36) months starting from the Effective Date and shall cover all Purchase Orders issued during such term.  
 7.02 This Agreement may be terminated as follows:  
 (a) By either party, immediately upon written notice to the other, if the other party becomes insolvent or seeks protection under any bankruptcy, receivership, trust deed, creditors arrangement, composition or comparable proceeding, or if any such proceeding is instituted against the other party which proceeding remains undismissed for a period of thirty (30) days; or  
 (b) By either party, in the event that the other party fails to perform or otherwise breaches any of its material obligations hereunder (except to the extent permitted by Paragraph 8.01 due to a Force Majeure Event), by giving notice of its intent to terminate and stating the grounds therefor. The party receiving such notice shall have sixty (60) days from the receipt thereof to cure the failure or breach, after which sixty (60)-day period this Agreement shall terminate if said failure or breach has not been cured. In no event, however, shall such notice of intention to terminate be deemed to waive any rights to damages or any other remedy which the party giving notice of breach may have as a consequence of such failure or breach.  
 7.03 The termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a party, and shall not relieve either party from any obligation or liability arising, prior to such termination or expiration and all provisions which are expressed to survive this Agreement, including this Paragraph 7.03, shall remain in full force and effect after any termination or expiration.  
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 ARTICLE VIII  
GENERAL PROVISIONS  
 8.01 Force Majeure. The provisions of this Agreement are binding upon the parties hereto except where prevented, delayed or interfered with by causes beyond the reasonable control of the non-performing party, including, without limitation, riot, terrorism, war or hostilities between nations, governmental action (other than action taken in response to violation or failure to act of a party or any of its Affiliates with respect to any law or governmental regulation, in which case the party at fault shall not be permitted to claim the benefit of this Paragraph 8.01), acts of God (including, for example, floods, windstorms, earthquakes and other natural disasters), fire, accidents, and strikes and other labor disputes (a “Force Majeure Event”). The party affected by a Force Majeure Event shall give notice to the other party of such Force Majeure Event promptly after the occurrence thereof, stating therein the nature of the suspension of performance and reasons therefor. Such party shall use its best efforts to resume performance as soon as reasonably possible. Upon restoration of the affected party’s ability to perform its obligations hereunder, the affected party shall give immediate notice to the other party. Under no circumstances shall a Force Majeure Event relieve either party of any obligation hereunder for a period of more than ninety (90) days.  
 8.02 Assignment: Successors In Interest. Neither party shall be entitled to sell, assign, transfer, or otherwise dispose of this Agreement or any of its rights or duties hereunder without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed provided, however, that without such consent either party may assign this Agreement, in whole or in part, to an Affiliate of such party. Any purported assignment or transfer in violation of this Paragraph shall be void ab initio and of no force or effect. This Agreement shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of ALCON and SELLER, as the case may be.  
 8.03 Entire Understanding. This Agreement shall constitute the entire agreement between parties hereto and shall supersede any other agreements, whether oral or written, expressed or implied, as they pertain to the subject matter hereof (including but not limited to the Hyaluronate Purchase Agreement dated March 28, 1990, as amended, between Lifecore Biomedical, Inc. and Alcon Pharmaceuticals Ltd., including the renewal of the Hyaluronate Purchase Agreement and terms sheet dated December 22, 2004), and shall supersede any conflicting preprinted portions of SELLER’s quotation and acknowledgment forms. This Agreement may not be changed or modified except as specifically and mutually agreed upon in writing.  
 8.04 Relationship.  
 (a) The relationship created by this Agreement shall be strictly that of independent contractors and shall not constitute a partnership, joint venture or agency. Neither party is hereby constituted an agent nor legal representative of the other party for any purpose whatsoever and is granted no right or authority hereunder to assume or create an obligation, expressed or implied, or to make any representation, warranties or guarantees, except as are expressly granted or made in this Agreement.  
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 All persons employed by a party shall be employees of such party and not of the other party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such party.  
 (b) Neither SELLER nor ALCON has relied in any way upon the other, directly or indirectly, or any legal, financial or similar professional advice relating to its execution of this Agreement, and each has sought such advice on its own behalf from professionals of its choice.  
 8.05 Litigation. In the event that the Parties hereto become involved in litigation with one another with reference to all or any part of the subject matter of this Agreement, or with reference to any issue connected with or related thereto, the unsuccessful party in such litigation shall pay the legal fees, costs and expenses, including, without limitation, all reasonable and verifiable attorneys’ fees, of the successful party. This Paragraph shall survive the expiration or termination for whatever reason of this Agreement.  
 8.06 Notice. Any notice required hereunder may be served by either party on the other by sending same, by first class or certified mail to the address first set forth above or such other address as either party may subsequently designate to the other in writing as the address for mailing notice(s) under this Agreement. This Paragraph shall survive the expiration or termination for whatever reason of this Agreement.  
 8.07 Waiver. The parties hereto mutually agree that a waiver by either party of any right hereunder or the failure to perform or breach of any of the terms of this Agreement by the other party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other party.  
 8.08 Governing Law. This Agreement is to be performed in accordance with the laws of Delaware, USA and shall be construed and enforced in accordance with the laws of Delaware, USA excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The parties further agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods. This Paragraph shall survive the expiration or termination for whatever reason of this Agreement.  
 8.09 Severability. The illegality, invalidity or unenforceability of any provision (or any part thereof) of this Agreement shall not affect or limit the legality, validity or enforceability of any other provision or the other parts of such provision as the case may be, provided the rights or obligations of either party under this Agreement will not be materially and adversely affected thereby. In lieu of any such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties.  
 8.10 Subcontracting. SELLER shall be responsible for identifying and qualifying all sub-contractors of materials, testing and services necessary to manufacture the Product. Unless  
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 the parties agree otherwise, SELLER shall remain solely liable for the performance of any of SELLER’s obligations by its approved subcontractor.  
 8.11 Further Assurance. Each party shall execute such other instruments, give such further assurance and perform such acts which are or may become necessary or appropriate to effectuate and carry out the provisions of this Agreement.  
 8.12 Remedies Cumulative. Except as provided herein, each and every right granted hereunder and the remedies provided for under this Agreement are cumulative and are not exclusive of any remedies or rights that may be available to any party at law, in equity, or otherwise.  
 8.13 No Benefit to Others. Except as provided in Paragraphs 5.03 and 5.04, the provisions set forth in this Agreement are for the sole benefit of the parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other persons or entities.  
 8.14 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile signatures and such signatures shall be deemed to bind each party hereto as if they were original signatures.  
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 IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed by their duly authorized representative.  
 ALCON PHARMACEUTICALS LTD.   
 By:  
 /s/ XXXXXX XXXX  
 Name: Xxxxxx Xxxx  
Its: General Manager By: /s/ XXXXXX XXXXXX  
 Name: Xxxxxx Xxxxxx  
Its: Finance Manager   
 LIFECORE BIOMEDICAL, INC.   
 By  
 /s/ XXXXX XXXXXXX  
 Name: Xxxxx Xxxxxxx  
Its: Vice President of Operations   
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 EXHIBIT “A”  
1. Ownership and Maintenance of Regulatory Approvals: ALCON shall own and maintain all regulatory applications, notifications, and dossiers with respect to the ALCON Finished Product (or any other ALCON product that results from use of the Product), including, without limitation, PMAs, 510(k)s, Technical Files and other marketing authorizations. SELLER shall provide ALCON with all data and information necessary or reasonably useful to maintain such regulatory approvals, including, without limitation, chemistry, manufacturing and control data.  
 2. Device Master Record and Device History Record: To the extent applicable, ALCON shall maintain an accurate Device Master Record for the ALCON Finished Product in accordance with 21 CFR 820.181 and grant to SELLER a right of access to the Device Master Record as reasonably necessary to manufacture the Product. SELLER shall maintain a Device History Record (DHR) in accordance with 21 CFR 820.184 and shall provide ALCON with a right to audit and obtain copies of the DHR as may be necessary or reasonably useful to comply with requirements of the FDA or other governmental or regulatory authorities.  
 3. Quality System Requirements: SELLER shall have in place and maintain for the duration of the contract, a Quality System that is in compliance with ISO 13485, and EN 724 standards and, where applicable, that has been inspected and determined to be satisfactory by a European Union Notified Body in accordance with the Medical Device Directive 93/42/EEC. SELLER shall make available to ALCON all relevant documentation, reports, decisions, registrations and Surveillance Audit Reports, upon request.  
 4. Changes to the Technical File: Changes in specifications, manufacturing or packaging agreed to by ALCON and SELLER may result in amendments to the Technical File. As necessary, the amendments will be submitted to the affected Notified Body within the requested time frame.  
 5. It is understood that ALCON’s Notified Body is not obligated to accept any non-EU Notified Body registrations or certifications and may elect to perform inspections or audits of SELLER.  
 6. Labeling: SELLER shall be responsible for labeling the Product in accordance with applicable Good Manufacturing Practices Regulations or other applicable standards.  
 To the extent applicable, SELLER shall be responsible for placing labeling on the Product in accordance with artwork and drawings provided by ALCON.  
 7. Product or Manufacturing Chances Informed Prior to Implementation:  
 (a) SELLER shall be responsible for manufacturing, packaging and labeling the Product in accordance with the Product Specifications. SELLER agrees to promptly incorporate all changes to the Product Specifications implemented  
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 pursuant to this Section, consistent with appropriate manufacturing procedures and regulatory requirements.  
 (b) ALCON from time to time may amend or supplement the Product Specifications, in its sole discretion, for the purpose of complying with applicable laws, rules and regulations. In addition, ALCON may amend or supplement the Product Specifications for any other reason, with the prior written approval of SELLER, which consent shall not be unreasonably delayed or withheld. ALCON shall notify SELLER in writing of any such amendment or proposed amendment, as the case may be. In the event that SELLER shall fail to notify ALCON in writing of its approval or disapproval thereof within ten (10) days after receipt thereof, then SELLER shall be deemed to have given its prior written approval thereof.  
 (c) In the event that ALCON shall amend the Product Specifications, ALCON shall, if required, (i) amend the PMA, Technical File or other registration relevant to the intended use of the Product, (ii) obtain any required approval of such amendment, or (iii) file a 510(k) notification or any other required regulatory submission, and (iv) reimburse SELLER for reasonable costs actually incurred by SELLER in connection with such change, including, without limitation, reasonable costs of obsolescence of raw materials, goods-in-process, packaging materials and finished goods not suitable.  
8. Customer Complaint Handling/Post Marketing Vigilance: ALCON will handle, process and respond to all customer complaints related to the Alcon Finished Product, including complaints related to the Product included therein, for all markets. ALCON and SELLER shall maintain complaint files regarding the Product, including, without limitation, any Product quality complaints for such period as may be required by applicable law. All complaints received by SELLER relating to a Product provided to ALCON will be promptly forwarded, in no event later than ten (10) days after receipt thereof, to ALCON for appropriate and timely reporting and response in accordance with applicable law, including, without limitation, medical device adverse event reporting pursuant to 21 CFR Part 803 or near incident or incident reporting pursuant to European Community Medical Devices Vigilance System requirements; provided, however, SELLER shall notify ALCON of any serious adverse event, as defined in FDA or other applicable regulations, pertaining to the Product, within twenty-four (24) hours after receipt thereof. SELLER agrees to cooperate with ALCON to investigate and resolve all complaints and to take remedial action to avoid similar complaints in the future. This Section shall survive the expiration or termination for whatever reason of this Agreement.  
 9. Product Validation: It is understood and agreed by the parties hereto that all processes affecting the purported identity, strength, or quality of the Product being manufactured, assembled and/or packaged shall be qualified and maintained in a validated state. ALCON shall be notified in advance of such validations and the protocols describing these validations shall be reviewed by ALCON’s Quality Assurance Department prior to the commencement of any validation and in accordance with Article I, Section 1.04. ALCON shall assess any intended product validation protocols based on the potential risk and will not unreasonably withhold or delay consent. Copies of validation reports and  
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 data will be made available to ALCON by the SELLER in the event such documentation is needed to support Product applications or dossiers.  
 10. Recall: At any time, should information come into the possession of SELLER which would indicate the need or the necessity for a review for a possible recall of the Product. SELLER will notify ALCON immediately and will assist ALCON as required in the course of any recall. In the event ALCON shall be required or shall voluntarily decide to recall any Alcon Finished Product which incorporates any Product manufactured by SELLER pursuant to this Agreement, then SELLER shall cooperate with ALCON in implementing such recall. ALCON shall bear the cost and expense of any such recall, provided, however, if such recall is initiated because of the failure of the Product to conform to the warranty set forth in Paragraph 5.01, SELLER shall promptly reimburse ALCON for all direct costs and expenses associated with such recall. The obligations of SELLER under this Section shall survive the expiration or termination for whatever reason of this Agreement. Any reimbursement obligation of SELLER hereunder shall not include lost profits, lost revenues or internal costs of ALCON resulting from any recall.  
 11. Inspections/Audits by ALCON: SELLER agrees that ALCON may send representatives to SELLER’s manufacturing facility to observe, audit and inspect the production facilities for the Product, and SELLER will allow ALCON’s representatives reasonable access to all manufacturing records for the Product so as to ensure that SELLER is in compliance with the Product Standards, provided that ALCON shall give SELLER at least five (5) business days in advance of any such audit the names of the representatives and the visit agenda. Any observation, audit, or inspection of SELLER by ALCON shall be during normal working hours, of reasonable duration, at the sole expense of ALCON and shall be subject to the obligations of confidentiality set forth in Article VI of this Agreement. For the avoidance of doubt, the right to inspect granted to ALCON shall not be deemed as granting to ALCON access to any trade secrets owned by SELLER. SELLER shall use reasonable commercial efforts to correct any material non-compliance with the Product Standards or other applicable laws, standards, rules, regulations or requirements that are discovered and brought to its attention as a result of such visits.  
 12. Inspections/Audits by Regulatory Organizations: SELLER shall notify ALCON in writing, within three (3) business days after receipt of notice thereof, of any proposed or unannounced visit or inspection of SELLER’s facility or the manufacturing process for the Product by any government or regulatory agency, including, without limitation the FDA or a Notified Body. SELLER shall provide to ALCON a copy of any report and other written communications received from such government or regulatory agency in connection with such visit or inspection and any written correspondence received from any governmental agency relating to the Product, or SELLER’s facility including support systems or manufacturing processes impacting the Product, within five (5) business days after receipt thereof, and shall provide to ALCON SELLER’s response to each such communication.  
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