Exhibit 10.20  
 Confidential Materials omitted and filed separately with the  
Securities and Exchange Commission. Double asterisks denote omissions.  
 MANUFACTURING AND SUPPLY AGREEMENT  
 THIS MANUFACTURING AND SUPPLY AGREEMENT (“Agreement”), is effective on January 10th 2017 (the “Effective Date”), by and between KALA PHARMACEUTICALS, INC., a Delaware corporation with a principal place of business at 000 Xxxxxx Xx., #000, Xxxxxxx, Xxxxxxxxxxxxx 00000, XXX (“Kala”) and CHEMO IBERICA SA, a Spanish company with a principal place of business at Gran Xxx Xxxxxx XXX, 00, Xxxxxx 0, 00000, Xxxxxxxxx (Xxxxx) (“Supplier”).  
 WHEREAS, Kala is engaged in the research and development, manufacture, distribution and marketing of certain pharmaceutical products;  
 WHEREAS, Supplier is engaged in the manufacture, sale, and distribution of certain pharmaceutical products;  
 WHEREAS, Kala desires that Supplier manufacture and supply the Product (defined below) to Kala; and  
 WHEREAS, Kala and Supplier desire to enter into this Agreement governing the supply of the Product upon the terms and conditions contained herein,  
 NOW THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:  
 1. DEFINITIONS  
 1.1 “Certificate of Analysis” (abbreviated “COA”) shall mean a document prepared by Supplier containing at a minimum the product name, Lot number, manufactured date, release date, retest date, test specifications, and test results for each Lot of Product supplied to Kala. COA must indicate the appropriate storage procedures. COA must also indicate that product was manufactured, packaged and tested according to cGMP requirements. Each COA shall be signature approved by Supplier’s Quality Assurance department.  
 1.2 “Current Good Manufacturing Practices” (abbreviated “GMPs” or “cGMPs”) shall mean the standards established by the United States Food and Drug Administration (the “FDA”) for current Good Manufacturing Practices, as specified in FDA 21 C.F.R. §211 Current Good Manufacturing Practice for Finished Pharmaceuticals (or its successor provisions) and FDA 21 C.F.R. §820 Quality Systems Regulations (or its successor provisions); the standards established in the European Council Directive 2004/27/EC of 31 March 2004 concerning medicinal products for human use, as amended (or its successor provisions); and other sections so designated by the title “Good Manufacturing Practices”; and further specified in the International Committee on Harmonization (1CH) Q7 guideline “Good Manufacturing Practices for Active Pharmaceutical Ingredients” (or its successor provisions); and further specified in the International Pharmaceutical Excipients Council (IPEC) and the Pharmaceutical Quality Group  
   
 (PQG) for current Good Manufacturing Practices for Pharmaceutical Excipients, as specified in the 2006 Guide (or their successor provisions).  
 1.3 “DMF” shall mean a Drug Master File as recognized by the FDA (or any other applicable Ministry of Health).  
 1.4 “Facilities” shall mean the facilities of the Manufacturer located at Xxx Xxxxx 00, 00000 Xxxxxxx (XX), Xxxxx.  
 1.5 “Lead Time” shall mean the time period that begins on the day Supplier receives a Purchase Order for Product from Kala and ends on the day Supplier is required to dispatch the Product to Kala or a third party designated by Kala.  
 1.6 “Batch” or “Lot” shall mean a defined quantity of product processed in one process or series of processes so that it could be expected to be homogeneous.  
 1.7 “Manufacturer” shall mean Industrial Chimica S.r.l., with industrial facilities at Xxx Xxxxx 00, 00000 Xxxxxxx (XX), Xxxxx.  
 1.8 “Ministry of Health” shall mean any governmental health department or regulatory agency outside of the United States that has jurisdiction over the Product, its manufacture, supply, sale and/or use.  
 1.9 “NDA” shall mean a new drug application.  
 1.10 “Product” shall mean the product(s) to be manufactured and supplied by Supplier to Kala under Purchase Order(s) issued under this Agreement and as more specifically detailed in Exhibit A attached hereto.  
 1.11 “Purchase Order” shall mean a purchase order issued by Kala to Supplier for the purchase of Product under this Agreement.  
 1.12 “Regulatory Filings” shall mean the DMF or NDA and its foreign equivalents to be filed with the FDA and its foreign equivalents.  
 1.13 “Span of Control” shall mean all operational activities that are necessary to occur at Supplier and component suppliers, if any, that are related to the procurement and manufacture of the Product.  
 1.14 “Specifications” shall mean the Product specifications attached hereto as Exhibit B. The Specifications shall also include all test protocols, packaging and labeling specifications, bills of material and other documentation, including COAs, synthetic routes, specifications for key starting materials and key intermediates, specifications for solvents and reagents, test methods, packaging specifications, storage conditions, and stability required to describe, control, and assure the quality of the manufacture of the Product as described in the applicable DMF.  
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 2. TERM AND TERMINATION  
 2.1 Term. This Agreement shall commence on the Effective Date and shall be valid for a period of seven (7) years (the “Initial Term”). Thereafter, this Agreement will automatically review for additional two (2) year periods (each a “Renewal Term”) unless a party provides written notice of its election not to renew this Agreement at least one (1) year prior to the expiration of the applicable Initial Term of Renewal Term. The Initial Term and each Renewal Term are referred to collectively as the “Term”.  
 2.2 Termination.  
 (a) Either party may terminate this Agreement by [\*\*] days prior written notice: (i) if the other party is in breach of this Agreement and fails to cure such breach within [\*\*] days following its receipt of written notice of such breach; (ii) if the other party shall formally declare bankruptcy, insolvency, reorganization, liquidation, or receivership; (iii) if the other party shall have instigated against it bankruptcy, insolvency, reorganization, liquidation, or receivership proceedings, and shall fail to remove itself from such proceedings within ninety (90) days from the date of institution of such proceedings; or (iv) if the Force Majeure situation, mentioned at Section 11.4 below, continues for more than six (6) months such that it is impossible for the impacted party to perform its obligations hereunder.  
 (b) In the event this Agreement is terminated by Supplier under Section 2.2(a), Kala shall pay Supplier for all work performed pursuant to any unfinished Purchase Order(s) prior to such termination.  
 (c) In the event this Agreement is terminated for any reason, Supplier shall promptly cease performing any work not necessary for the orderly close out of the affected Purchase Order(s) or for the fulfillment of regulatory requirements.  
 (d) Within [\*\*] working days following the termination of this Agreement, Supplier shall deliver to Kala all data and materials provided by Kala to Supplier for the manufacturing and supply activities under the impacted Purchase Order(s).  
 (e) Termination of this Agreement, for any reason, shall not release either party from liability which at said time has already incurred, nor affect in any way the survival of any rights, duties or obligations of either party which are expressly stated elsewhere in this Agreement to survive termination. Nothing in the immediately preceding sentence shall affect or be construed or operate as a waiver of the right of the party aggrieved by any breach of this Agreement to be compensated for any injury or damage resulting therefrom which is incurred before or after such termination. Without limiting the generality of the foregoing, the parties agree that Sections 2.2 and 3.2 and Articles 1, 6, 7, 8, 9, 10 and 11 shall survive termination of this Agreement for any reason.  
 (f) Termination of this Agreement, for whatever reason, shall not affect the obligation of any party to make any payments for which that party may be liable prior to such termination.  
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 3. MANUFACTURE AND SUPPLY OF PRODUCT  
 3.1 Performance Standards. Supplier shall ensure that Manufacturer manufactures the Product in accordance with the Specifications and this Agreement, and shall comply with all applicable cGMPs and all other applicable Federal, state, local laws, standards, requirements, and regulations (and their applicable foreign counterparts) in connection with the manufacture, testing, packaging, labeling, shipping, handling, distribution and dispensing of the Product.  
 3.2 Supplier Representations. Supplier makes the following representations to Kala:  
 (a) Supplier is duly organized, validly existing and in good standing under the laws of Spain. Supplier has all requisite power and authority to own, operate and lease its properties and to carry on its business as now conducted. Supplier has full corporate power and authority to execute, deliver and perform this Agreement; all corporate actions of Supplier necessary for such execution, delivery and performance have been duly taken; and this Agreement is a valid and binding obligation of Supplier.  
 (b) Supplier warrants that the Manufacturer shall perform all manufacturing, storage, handling, and testing of the Product(s) at the Facilities. Supplier warrants that the Facilities are in good standing with FDA and/or any other required government agency (including Ministry of Health), are fully compliant with cGMPs and that all employees working on the Product whose responsibilities involve work which must be performed under cGMP standards have been properly trained and tested in the requirements of those standards. Supplier additionally warrants that the Facilities hold all necessary licenses and permits required by applicable laws, rules, and regulations for the manufacture and testing of the Product and that all such licenses and permits are in full force and effect. Supplier is not aware of the existence of any outstanding violations of any such licenses or permits and warrants that no proceeding is pending or, to the knowledge of Supplier, threatened, seeking the revocation or limitation of any such licenses or permits.  
 (c) Supplier represents and warrants that the Manufacturer is part of the same company group of Supplier. Supplier shall ensure that Manufacturer is, and remains, fully compliant with the terms and conditions of this Agreement. Any breach by Manufacturer of this Agreement shall be deemed to be a breach by Supplier. Supplier shall fully indemnify, defend, and hold Kala harmless from and against the acts and/or omissions of Manufacturer.  
 3.3 Suppliers. Supplier assumes the responsibility for interacting with all chemical, component and packaging suppliers as required to deliver the Product in accordance with the terms of the applicable Purchase Order, including the Specifications, and this Agreement  
 3.4 Supply Chain Security. Supplier shall have in place a comprehensive and effective security program related to the security of the Product and the shipping containers used for transporting the Product. Supplier shall ensure that all Product is stored, handled and tested only at the Facilities and that physical security for the Product is maintained at all times at the Facilities until such time that the Product is transferred to an authorized freight handler. Supplier shall take all necessary steps to prevent unauthorized tampering with the Product and associated shipping containers.  
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 3.5 Compliance with Anti-Bribery Laws. In carrying out its responsibilities under this Agreement, Supplier shall comply with all applicable anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, (collectively hereinafter the (“FCPA”) and anti-bribery laws in the countries where Supplier has its principal place of business and where it conducts activities under this Agreement.  
 (a) Supplier warrants and represents to Kala that, in carrying out its responsibilities under this Agreement, neither Supplier nor any of its officers, directors, employees or other representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof, or to any political party or official thereof or to any candidate for political office corruptly for the purpose of: (i) influencing any act or decision of that person in his official capacity, including a decision to fail to perform his/her official functions with such governmental agency or instrumentality or such public international organization or such political party; (ii) inducing such person to use his/her influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof; or (iii) securing any improper advantage.  
 (b) If Supplier fails to inform Kala of any material event affecting its ability to comply with the FCPA or other applicable anti-bribery laws, or breaches any of the covenants set forth in clause (a) above: Kala, at its sole discretion, shall have the right to terminate this Agreement without obligations or any penalty to Supplier.  
 (c) At the request of Kala from time to time during the term of this Agreement, Supplier shall provide written certification indicating its understanding and acceptance of its obligations to comply with anti-bribery laws, including the FCPA. Additionally, Supplier will use reasonable efforts to comply with requests for information from Kala, including answering questionnaires and narrowly tailored audit inquiries, to enable Kala to ensure compliance with applicable anti-bribery laws, including the FCPA.  
 4. PRICING AND PAYMENT  
 4.1 Product Prices. Pricing for the Product ordered per the terms of this Agreement is set forth in Exhibit A attached hereto. The Parties agree to renegotiate in good faith the pricing of the Product in case that Supplier can demonstrate that there is a substantial shortage of supply of starting raw materials that results in an increase in the price of the starting raw materials of more than [\*\*]% in a single year, provided that any agreed upon increase in price for the Product shall continue only so long as the increase in the price of the starting raw materials continues. Supplier shall provide to Kala written documentation of the change in Supplier’s costs for such raw material justifying such price change. At Kala’s request from time to time, Supplier agrees to negotiate with Kala in good faith to ensure that pricing for the Product does not materially exceed more than [\*\*]% pricing for the Product offered by similar supplier on substantially similar terms (“Price Commitment”).  
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 4.2 Payment Terms. Unless otherwise agreed to by Kala in writing. Supplier shall invoice Kala for Product ordered at the time of shipment and Kala shall pay each undisputed invoice within [\*\*] days from the invoice date. Each invoice shall set forth, in U.S. Dollars, the applicable price for the shipment properly determined in accordance with the provisions of this Agreement. If Kala disputes any portion of an invoice received from Supplier, then Kala shall so notify Supplier in writing of the disputed amounts and shall pay the undisputed amounts as set forth in the preceding sentence, and the parties shall use good faith efforts to reconcile the disputed amounts as soon as practicable. Invoices should be sent to the address as specified in writing by Kala in the applicable Purchase Order. Kala’s failure to pay any undisputed amount invoiced in accordance with this Section 4.2 shall constitute a breach of this Agreement and, consequently, shall give rise to a right to terminate this Agreement pursuant to Section 2.2(a)(i) (following notice and an opportunity for Kala to cure).  
 5. FORECASTS, PURCHASE ORDERS AND DELIVERY  
 5.1 Forecasts. Kala shall provide Supplier, at least [\*\*] days prior to July 1, 2017, and each calendar quarter thereafter, a [\*\*] non-binding rolling forecast of the estimated quantities of Product believed to be required hereunder by Kala for the approaching [\*\*]. Subject to Supplier’s compliance with the terms of this Agreement, including, without limitation, the supply of conforming Product and ability to meet supply obligations, Kala agrees to purchase from the Supplier at least seventy-five percent (75%) of its annual requirements of the Product mentioned in its forecasts (“Purchase Requirement”), provided however that the Purchase Requirement is conditioned on Supplier’s continued compliance with Agreement, including the Minimum Supply Commitment and the Price Commitment. Kala may modify its forecasts from time to time by providing written notice to Supplier, provided, however, that Kala may not, without Supplier’s prior written consent, modify any portion of a forecast relating to a period that is less than ninety (90) days from the date that such change is to be made. Supplier shall ensure that it is able to supply Kala with quantities of Product that are consistent with Kala’s forecasts and Supplier will use its best efforts to supply Kala with any additional quantities of Product which are set forth in a Purchase Order (“Minimum Supply Commitment”).  
 5.2 Purchase Orders. All Product ordered by Kala shall be in the form of a firm written Purchase Order. The Lead Time for the Product shall not exceed [\*\*] days, unless a different Lead Time is set forth in Exhibit A. Each Purchase Order shall contain at a minimum, the following information: description of the Product and quantity ordered, price, delivery terms, delivery date, and Purchase Order number for billing purposes. Each Purchase Order issued pursuant to this Agreement shall be binding, except that delivery dates may be moved ahead or back by mutual written agreement of Supplier and Kala. To the extent there are any conflicts between the terms of any Purchase Order and the terms of this Agreement, the terms of this Agreement shall prevail and control.  
 5.3 Delivery. Unless expressly provided otherwise in the applicable Purchase Order, shipping terms for the Product shall be by air and CIP to a port of entry into the US to be designated by Kala in each Purchase Order (Incoterms 2010). It is understood between the parties that Supplier will fulfill its delivery obligation with the delivery of the Product to the carrier, with Supplier having contracted for and paid the cost of carriage and insurance necessary to bring the Products to the applicable port of entry into the US. Satellite samples at quantities to  
 6  
  
 be outlined in each Purchase Order will accompany the Product, which will be packaged and shipped per the Specifications or, if applicable, the packaging and shipping conditions described in Supplier’s DMF. Kala will be responsible for the cost of the satellite samples. In the event that any delivery of the Product is anticipated to be late, Supplier will promptly notify Kala of the circumstances for the delay. Supplier will make a reasonable effort to minimize the delay.  
 6. WARRANTIES  
 6.1 Product Warranty. Supplier warrants that all Product supplied under this Agreement shall, when it leaves Supplier’s possession and control, conform with the Specifications and with applicable laws and regulations according with this Agreement, and shall be of good and merchantable quality, free from defects in materials and workmanship, and fit for its intended purpose. Supplier further warrants that the Product shall be manufactured in accordance with applicable cGMPs and with applicable laws and regulations according with this Agreement. This warranty shall be a continuing guarantee and shall be binding upon any Product shipped or delivered by Supplier to Kala. This warranty shall not apply to any nonconformity in the Product arising from a modification to the Product following delivery, inclusion of the Product in a manufacturing process following delivery, or arising from other misuse or neglect following delivery.  
 6.2 Acceptance, Rejection, and Claims. Kala may inspect any or all shipments of Product for proper labeling, packaging and count within [\*\*] days following receipt of each shipment of Product, as per the agreed Incoterms, by Kala or Kala’s designee (“Date of Receipt”). If the Product is held by governmental authorities the Date of Receipt will be the date on which the Products are released by governmental authorities and available to be received by Kala or Kala’s designee; however, any such inspection shall not relieve Supplier of any obligations or warranties under this Agreement. Kala shall visually inspect, or require that its designee visually inspect each shipment of Product for damage at the port of entry and shall note any observed damage on the shipments xxxx of lading. Upon Kala’s, or Kala’s designees, receipt of the Products at the port of entry, risk of loss with respect to such Products shall transfer to Kala. Kala has the right to reject, via written notification to Supplier within this [\*\*] days period, any or all of a shipment of Product that fails to satisfy any warranty in this Agreement. If, within [\*\*] days following the Date of Receipt there is no notice of non-acceptance, the Product shall be deemed as accepted. Kala shall have no payment obligation with respect to any Product reject in accordance with this Section 6.2. Within a period of [\*\*] days following the Date of Receipt, Kala or Kala’s designee shall inspect the Product so as to determine the existence of any damage, shortage, adulteration or failure to meet the specifications set forth on DMF, COA, or this Agreement (collectively, ‘‘Damage”). If the parties disagree as to the existence of Damage, they will then appoint a mutually accepted independent laboratory whose decision shall be binding upon both parties and the costs associated with such steps shall be borne by the party against which the laboratory’ decided. If the Product delivered does not comply with the requirements according to the decision of such independent laboratory, Kala shall have the right to demand from Supplier a free-of-charge replacement of Product to be delivered as soon as reasonably practicable. Supplier shall likewise reimburse Kala for its reasonable handling costs incurred in connection with the replacement.  
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 6.3 Spoilage Due to Change or Obsolescence. Kala shall not be liable to Supplier for any printed packaging components, work in progress or finished Product which is damaged, destroyed or which become obsolete or otherwise spoiled and cannot be sold or distributed due to the acts or omissions of Supplier.  
 6.4 Third Party Claims. Supplier declares that, to the best of its knowledge the Product does not infringe or interfere with any patents, copyrights, trademarks, or other intellectual property rights of any third party. Notwithstanding the preceding, it shall be Kala’s obligation to determine if the Product or its use to manufacture the pharmaceutical finished dosage forms infringes intellectual property rights of third parties in the United States of America. Supplier declares that the processes and methods utilized by Supplier and/or Manufacturer in the manufacturing of the Product will not interfere with, or infringe upon the intellectual property rights of any third party in the manufacturing country.  
 7. REGULATORY AND QUALITY  
 7.1 Compliance. Supplier agrees that its work under this Agreement will be conducted in compliance with all applicable laws, rules and regulations applicable to a party’s performance hereunder and with the standard of care customary in the industry. Supplier agrees that all Product shipments to Kala shall be in accordance with Kala’s instructions and all applicable laws and regulations governing the shipment, labeling, and packaging of the Product applicable to a party’s performance hereunder.  
 7.2 Product Complaints/Reports. Except as otherwise noted below, in the event that Supplier receives any complaint, claim or adverse reaction report regarding any Product or regarding any regulatory non-compliance of Product, Supplier shall within [\*\*] business days in case of critical issues and within [\*\*] days in case of non-critical issues, provide Kala with all information contained in such complaint, report, or notice and such additional information regarding the Product as may be reasonably requested. If any complaint related to the Product contains a defect that could or did cause death or serious bodily injury. Supplier shall immediately provide Kala with a complete description of all relevant details known to Supplier concerning any such incident, including but not limited to, a description of any defect and such other information that may be necessary to report the incident to the FDA or any other Ministry of Health.  
 7.3 Recalls. Kala shall have the right to reasonably declare any recall of, or field corrective action to, any Product supplied to Kala under this Agreement. Supplier agrees to cooperate with Kala in connection with any such recall, and shall indemnify Kala for all expenses arising from any such recall to the extent the recall is attributable to a breach of any of Supplier’s warranties under this Agreement or is otherwise attributable to a defect in the Product, including without limitation, Supplier’s manufacturing, packaging and/or labeling processes.  
 7.4 Government Inquiries. Without limiting the generality of Section 7.2, Supplier shall use its best efforts to:  
 8  
 (a) Respond fully and accurately to all inquiries directed to it by the FDA or any government agency (including Ministry of Health) with respect to the manufacture, testing, and use of the Product.  
 (b) Assist Kala in responding to inquiries directed to Kala by the FDA or any government agency (including Ministry of Health) with respect to the manufacture, testing, and use of the Product.  
 (c) Promptly inform Kala of the existence and substance of any inquiry, investigation or inspection initiated by the FDA or any government agency (including Ministry of Health), department or body relating to the Product or its manufacture. The existence of any such inquiry, investigation or inspection shall not constitute a breach of this Agreement or excuse any performance due under this Agreement. Supplier shall promptly provide Kala with copies of any and all inspection reports, letters, documents or similar instruments submitted or received from the FDA or other government agency (including Ministry of Health) related to the Product or its manufacture, testing or use.  
 7.5 Inspection of Manufacturing Facilities.  
 (a) Supplier shall permit Kala and its agents, during business hours and upon an agreed notice to Supplier, to inspect the Facilities where the Product is manufactured, handled, stored or tested, as well as all processes relating to the manufacture, handling, storage, or testing of the Product, as well as all manufacturing, handling, storage, and test records regarding the Product. When required by applicable law, regulatory agency, or when deemed an emergency, Kala and its agents shall be permitted such access shall be granted within [\*\*] business days of request.  
 (b) Supplier shall extend the same inspection privileges set forth above to agents of the FDA or any other Ministry of Health, as required.  
 (c) Supplier warrants and agrees that it will correct, at its own expense and within a reasonable amount of time from the date of notification, all accepted deficiencies and/or non-conformances found during a Kala, FDA, or Ministry of Health audit; and that it will correct or issue an approved plan, including timetable, to correct all deficiencies and/or non-conformances within no more than [\*\*] days following such notification. The lack of acceptance of the deficiencies and/or non-conformances found during a Kala, FDA, or Ministry of Health audit will be fully justified by Supplier.  
 7.6 Regulatory Filings. Supplier shall be responsible for filing and maintaining all Regulatory Filings related to the Product. Such responsibility for Supplier shall include the associated cost of maintaining its Regulatory Filings.  
 7.7 DMF. Supplier shall provide Kala the appropriate documentation allowing Kala to reference Supplier’s DMF in its regulatory filings. Supplier shall also provide Kala and/or the applicable regulatory authority with the appropriate technical documentation for those regulatory filings where a reference to Supplier’s DMF is not sufficient or allowed; provided, however, if Supplier is not permitted to share such information with Kala directly, the information provided to Kala may be redacted. Upon request Supplier shall provide Kala yearly confirmation that it  
 9  
  
 has filed with the FDA the required annual progress report to Supplier’s DMF for the year then ended. Supplier shall provide Kala with written notification of an anticipated amendment to the DMF and any equivalent regulatory filing required by any other Ministry of Health authority as soon as practical with sufficient advance notice, if possible, in order to allow Kala to make necessary changes to its own regulatory filings. The Parties agree to work together in good faith regarding any DMF or similar Filing for other countries. Where applicable, Supplier will provide Kala with a reference letter to Supplier’s Certificate of Suitability for the Product. Kala, on a yearly basis, will inform Supplier on the registration status of the Product up to its approval.  
 7.8 Quality Control Testing. Supplier and/or Manufacturer shall perform quality control testing in accordance with the Specifications and Supplier’s DMF for release of each Lot of Product to Kala. Quality control testing shall include all testing associated with the production of the Product, including, but not limited to, incoming component and raw material testing, in process testing, and final release testing. Supplier shall provide all such testing data to Kala in the form of a COA. Each COA shall be in accordance with the format approved by Kala, as exemplified in Exhibit C, certifying that the Product has met all Specifications. Supplier shall notify Kala in writing of any third party or contract laboratory used for the testing of the Product. In the event that Kala requires Supplier to perform any additional testing, such testing shall be performed at Kala’s cost and expense.  
 7.9 Specifications and Change Control.  
 (a) Changes to the Specifications will be managed according to the classification reported in the Guidance for Industry “Changes to an Approved NDA or ANDA” — current version — paragraph VIII. For major proposed changes, Kala will assure an evaluation of the proposed changes within [\*\*] days following its receipt of notice of the proposed changes. All the actions will be agreed between the parties. For moderate and minor changes, Supplier will commit to promptly share all the relevant information to Kala.  
 (b) For all changes other than changes in Specifications, the Supplier notice will include enough information for the assessment of the change by Kala, considering that there will be details under the DMF Close Part that will not be revealed. Kala will not reject the changes without a sound justification and agrees to provide a written response with its evaluation of the change within [\*\*] days after receiving the proposal. The response should state the classification of the change according the applicable guidelines (e.g. AR/CBE/CBE30/PAS in US or the Variation Type in EU) as interpreted by Kala with the estimated timing and quantities to make it effective. If Supplier does not receive a response from Kala about the change communication within [\*\*] days, it will be understood that Kala accepts product involved in the change.  
 (c) In the event of a change to the Specifications, the Supplier shall provide reasonable prior notice of such change and: (i) for a reasonable period of time (but not less than [\*\*] days) following Kala’s response, or [\*\*] days following the expiration of such [\*\*] day period if no response was provided, Kala shall be entitled to place purchase orders under the unchanged Specifications in the quantities determined by Kala, and (ii) Kala shall be entitled to terminate this Agreement upon written notice to Supplier.  
 10  
  
 (d) Supplier will not deliver product involved in any significant change in the manufacturing process without previously informing Kala.  
 (e) Kala commits to keep Supplier updated within [\*\*] days after filing of the corresponding NDA/ANDA/Supplement in US or the equivalent Marketing Authorization Application or Variation in EU, or the equivalent in other Regulatory Markets/Territories, so that Supplier is aware of the regulatory situation of the final product on the Market.  
 7.10 Technical Assistance. Supplier shall provide Kala with certain technical support regarding the Product as reasonably requested by Kala, including, but not limited to, analytical test methods, method development, physical and chemical properties, and use of the Product.  
 7.11 Quality Agreement. Supplier and Kala shall execute a written Quality Agreement between the parties (the “Quality Agreement”). Upon execution, the Quality Agreement shall be automatically incorporated herein. The Quality Agreement may be updated from time to time upon the mutual written agreement of the parties. To the extent that any terms of the Quality Agreement relating to quality matters are inconsistent with the terms set forth in this Agreement, the terms of the Quality Agreement shall prevail. To the extent that any other terms of the Quality Agreement are inconsistent with the terms set forth in this Agreement, the terms of this Agreement shall prevail.  
 8. INDEMNIFICATION, LIMITATION OF LIABILITY AND INSURANCE  
 8.1 Indemnification by Kala. Kala agrees to indemnify, defend and hold harmless Supplier, its officers, agents, and employees from any and all liability, loss (including reasonable attorneys’ fees) or damage they may suffer as the result of claims, demands, costs or judgments by third parties (each, a “Claim”) against them arising out of the negligence, recklessness or willful misconduct on the part of Kala, its officers, agents, employees, contractors or consultants in connection with this Agreement.  
 8.2 Indemnification by Supplier. Supplier agrees to indemnify, defend and hold harmless Kala, its officers, agents, and employees from any and all liability, loss (including reasonable attorneys’ fees), or damage they may suffer as the result of Claims by third parties against them arising out of (a) the negligence, recklessness or willful misconduct on the part of Supplier, its officers, agents, employees, contractors or consultants in connection with this Agreement or (b) a breach of any applicable Federal, state or local law or of this Agreement by Supplier, its officers, agents, employees, contractors or consultants.  
 8.3 General Conditions of indemnification. If a party (the “Indemnified Party”) seeks indemnification under this Article, the other party’s (the “Indemnifying Party”) obligations are conditioned upon the Indemnified Party: (a) providing written notice to the Indemnifying Party of any Claim within [\*\*] days after the Indemnified Party has knowledge of such Claim (except that failure to timely provide such notice will relieve the Indemnifying Party of its obligations only to the extent the Indemnifying Party is materially prejudiced as a direct result of such delay); (b) giving the Indemnifying Party sole control over the defense thereof and any related settlement negotiations; and (c) cooperating and, at the Indemnifying Party’s request and expense, assisting in such defense. Notwithstanding the foregoing, the Indemnified Party  
 11  
  
 may participate at its own expense in the defense and any settlement discussions, and will have the right to approve any settlement agreement that involves an admission of fault by the Indemnified Party or imposes non- monetary obligations on the Indemnified Party; provided, however, that such approval will not be unreasonably withheld.  
 8.4 Limitation of Liability. TO THE EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR EXEMPLARY, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, ARISING FROM OR RELATING TO THE AGREEMENT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED, HOWEVER, THAT THIS LIMITATION SHALL NOT APPLY TO EACH PARTY’S: (a) VIOLATIONS OF ARTICLE 9; (b) INDEMNITY OBLIGATIONS; OR (c) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.  
 8.5 Insurance. Supplier and Manufacturer, at their sole cost and expense, will maintain appropriate insurance including, but not limited to Commercial General Liability Insurance with Broad Form Contractual Liability; premises, operations coverage including products and completed operations and Personal Injury/Property Damage Coverage, in line with the commitments arising from the Agreement; provided that in no case shall such limits be less than the following;  
 (a) Bodily injury by Accident: $[\*\*](US) each  
 (b) Commercial General Liability:  
 Each Occurrence: $[\*\*](US)  
 General Aggregate: $[\*\*](US)  
 (c) Product Completed Operations Aggregate: $[\*\*](US)  
 (d) Personal Injury: $[\*\*](US)  
 (e) Commercial Umbrella Liability:  
 Occurrence Limit: $[\*\*](US)  
 Aggregate Limit (where applicable); $[\*\*](US)  
 Policy to be in excess of the Commercial General Liability.  
 Supplier shall ensure that such insurance coverages will remain in place for a period of at least [\*\*] years following the termination of this Agreement for any reason. A Certificate of Insurance will be delivered to Kala upon request.  
 12  
  
 9. CONFIDENTIALITY  
 9.1 Information Defined. “Information’’ means any information, whether or not designated as confidential, disclosed to one party (“Recipient”) by the other party (“Discloser”), either directly or indirectly in writing, orally, electronically or by delivery of tangible objects, including, but not limited to confidential or proprietary information, including without limitation, (a) concepts, ideas, inventions, models, diagrams, designs, data, documents, research, studies, analyses, forecasts, processes, procedures, systems, technology, intellectual property, trade secrets, business plans or opportunities, business strategies, marketing plans or opportunities, marketing strategies, product development plans or opportunities, future projects or products, projects or products under consideration, and information relating to finances, costs, prices, suppliers, vendors, customers and employees, and (b) any information that contains, reflects, or is based upon, in whole or in part, any Information furnished to Recipient by Discloser, including without limitation any notes, analyses, compilations, studies, interpretations, memoranda or other documents or tangible objects. Information may also include information previously disclosed to Discloser by third parties.  
 9.2 Nondisclosure and Confidentiality Obligations. Recipient agrees that it will and will cause its directors, officers, employees, agents and advisors to: (a) hold Discloser’s Information in strict confidence using the same standard of care as it uses to protect its own confidential information of a similar nature, but in no event less than reasonable care; (b) not disclose the Information of Discloser to any third party without Discloser’s prior written consent, except as expressly permitted under this Agreement; and (c) limit access to Discloser’s Information to those of its employees or agents having a need to know for purposes of performance hereunder who are bound by confidentiality obligations at least as restrictive as those set forth herein. Notwithstanding the foregoing, Recipient may make disclosures as required or requested by a court of law or any governmental entity or agency, provided that Recipient provides Discloser with reasonable prior notice to enable Discloser to seek confidential treatment of such information through a protective order or otherwise.  
 9.3 Use of Information. Recipient agrees that it will not use Information other than as necessary for performing its obligations under this Agreement. Information disclosed by Discloser under this Agreement shall, in all respects, remain the sole property of Discloser and nothing contained herein shall be construed as granting or conferring to Recipient any license, interest, ownership rights or intellectual property rights in such Information.  
 9.4 Exclusions. The restrictions on the use and disclosure of Information shall not apply to any of Discloser’s Information (or portion thereof) which (a) is or becomes publicly known through no act or omission of Recipient; (b) is lawfully received from a third party without restriction on disclosure; (c) is already known by Recipient at the time it is disclosed by Discloser, as shown by Recipient’s written records; or (d) is independently developed by Recipient without reference to or reliance upon Discloser’s Information, as shown by Recipient’s written records.  
 9.5 Nondisclosure and Confidentiality Period. Recipient’s confidentiality obligations as set forth above shall survive the termination or expiration of this Agreement and shall continue until the applicable Information of Discloser falls within an exception set forth in Section 9.4.  
 13  
  
 9.6 Injunctive Relief. Recipient acknowledges that a breach or threatened breach of this Section 9 would cause irreparable harm to Discloser, the extent of which would be difficult to ascertain. Accordingly, Recipient agrees that, in addition to any other remedies to which Discloser may be legally entitled, Discloser shall have the right to immediate injunctive or other equitable relief in the event of a breach or threatened breach of this Article 9 by Recipient or any of its representatives.  
 9.7 Export Controls. Supplier shall not: (a) utilize any of such Information or materials for any purpose whatsoever, except as specifically authorized in this Agreement; (b) export, transfer, divert or disclose any of such Information or materials; or (c) use, or make any of such Information available for use, directly or indirectly, in the design, development, production, stockpiling or use of any chemical or biological weapons.  
 10. PUBLICITY  
 In addition to the other confidentiality obligations under this Agreement, neither Party shall make any announcement, take or release any photographs (except for its internal operation purposes for performance under this Agreement) or release any information concerning this Agreement or any part thereof or with respect to its business relationship with the other Party, to any member of the public, press, business entity or any official body except as required by applicable law, rule, injunction or administrative order, unless prior written consent is obtained from the other Party. If one of the Party determines it is obligated by law or a governmental authority to make any such announcement or release, such a Party shall promptly notify the other Party and cooperate with such other Party to ensure that suitable confidentiality obligations are afforded such information.  
 11. GENERAL PROVISIONS  
 11.1 Governing Law. This Agreement shall be governed, construed, and enforced by the laws of the State of New York, without regard to conflicts of law principles. The parties, if the disputes arising in connection with this Agreement cannot be settled in an amicable manner within [\*\*] days from the notice of the dispute, irrevocably submit and consent to jurisdiction in the State of New York, venue in New York County, New York and waive any right they may have to seek any change of jurisdiction or venue.  
 11.2 Assignment; Subcontracting. Without the prior written consent of the other party, neither party shall assign any of its rights, interests or obligations hereunder (including by operation of law, merger, consolidation, sale of all or substantially all of its assets, or a change of control). Any assignment in violation of the preceding sentence shall be void and no assignment shall relieve a party of any of its obligations under this Agreement. Notwithstanding the foregoing, Kala may assign this Agreement to an affiliate or a successor in the event of a merger or acquisition of all or substantially all of its assets relating to this Agreement. Supplier will not subcontract or otherwise delegate any of its obligations under this Agreement without Kala’s express prior written consent, which shall not be unreasonably withheld. Provided that Kala grants such consent, Supplier shall enter into a binding written agreement with such subcontractor that protects Kala’s rights and interests to at least the same degree as this  
 14  
  
 Agreement. Supplier will be responsible for the direction and coordination of the services of each approved subcontractor. Kala will have no obligation or liability to any subcontractor.  
 11.3 Notices. Any notice required hereunder shall be in writing and deemed effectively given: (a) upon personal delivery to the party to be notified; (b) on the date such notice is received from any reputable courier service that provides tracking and written verification of delivery; or (c) on the date on which such notice is delivered by email, with confirmation that such email has been received and read.  
 If to Supplier:  
[\*\*]  
Area Sales Manager  
CHEMO  
000 Xxxx Xxxxxx, Xxxxx 000  
Xxxxxxx Xxxx, XX 00000  
Telephone: 000-000-0000 Ext  
[\*\*]  
Email:  
[\*\*]  
 If to Kala:  
[\*\*]  
Director of Chemistry and  
Preformulation  
Kala Pharmaceuticals, Inc.  
000 Xxxxxx Xxxxxx #000  
Xxxxxxx, XX 00000  
Telephone: [\*\*]  
Email:  
[\*\*]  
 With a Copy To:  
Legal  
Kala Pharmaceuticals, Inc.  
000 Xxxxxx Xxxxxx #000  
Xxxxxxx, XX 00000  
 11.4 Force Majeure. Neither party shall be liable for any breach of this Agreement or for any delay or failure of performance resulting from any cause beyond such party’s reasonable control, including the weather, civil disturbances, acts of civil or military authorities or acts of God. The party claiming relief under this Section shall promptly notify the other party in writing, but in no event later than ten (10) calendar days following the occurrence, should any such cause arise and shall promptly take steps to remedy any delay or failure in performance upon removal of the circumstances causing such delay or failure. If an event of force majeure occurs, the party injured by the other’s inability to perform may elect one of the following remedies: (a) to terminate this agreement in whole or in part; or (b) to suspend the Agreement, in whole or part, for the duration of the force majeure circumstances. The party experiencing the force majeure circumstances shall cooperate with and assist the injured party in all reasonable ways to minimize the impact of force majeure on the injured party, which may include locating and arranging substitute services if necessary.  
 11.5 Severability. If any provision of this Agreement is held by an arbitrator or court of competent jurisdiction to be void or unenforceable, such provision will be deemed modified and will be interpreted to accomplish the objectives of such provision to the greatest extent possible under applicable law and the remaining provisions of this Agreement will continue in full force and effect.  
 11.6 Waiver. Any waiver or failure to enforce any provision of this Agreement by either party on one or more occasion shall not be deemed a waiver of any other provision or of such provision on any other occasion.  
 11.7 Construction. The headings used for the sections of this Agreement are for information purposes and convenience only and in no way define, limit, construe or describe the  
 15  
  
 scope or extent of the sections. The word “including” or any variation thereof means “including, without limitation” and will not be construed to limit any general statement that such word or variation thereof follows. The language used in this Agreement will be deemed to be the language chosen by the parties to express the parties collective mutual intent, and no rule of strict construction will be applied against any party.  
 11.8 Entire Agreement. This Agreement, together with any Purchase Order and the schedules and exhibits, attached hereto, each of which is incorporated herein, collectively constitutes the entire agreement between the parties and supersedes any prior or contemporaneous understandings, agreements or representations by or among the parties, written or oral, that may have related in any way to the subject matter of this Agreement. Any alterations or amendments to this Agreement (including any handwritten changes) will be null and void except by an instrument in writing, signed by authorized representatives of both parties.  
 11.9 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. Signatures to this Agreement transmitted by email, portable document format (.pdf) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as the physical delivery of the paper document bearing the original signatures.  
 11.10 Further Assurances. Each party shall execute and deliver to the other party such instruments and other documents, and shall take such other actions, as such other party may reasonably request at any time for the purpose of carrying out or evidencing any of the transactions contemplated hereby.  
 11.11 Remedies. Except as expressly set forth herein, the exercise of any remedies hereunder shall be cumulative and in addition to, and not in limitation of, any other remedies available to such party at law or in equity.  
 11.12 Export Control. Supplier shall comply with the applicable export control laws and regulations as per this Agreement.  
 11.13 Relationship Between the Parties. In fulfilling its obligations pursuant to this Agreement, each party shall be acting as an independent contractor. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party.  
 11.14 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.  
 [SIGNATURES ON FOLLOWING PAGE]  
 16  
 IN WITNESS WHEREOF, the parties hereto have executed this Manufacturing and Supply Agreement as of the Effective Date.  
 KALA PHARMACEUTICALS, INC.  
CHEMO IBERICA SA  
 By:  
/s/ Xxxxxxx XxXxxxxxx  
 By:  
/s/ Xxxx Xxxxxxx xx Xxxxxxxxxx  
 Name:  
Xxxxxxx XxXxxxxxx  
 Name:  
Xxxx Xxxxxxx xx Xxxxxxxxxx  
 Title:  
President and Chief Business Officer  
 Title:  
Legal Director  
 AND  
AND  
 By:  
/s/ Xxxx Xxxxxxx  
 By:  
/s/ Xxxxxx Xxxxxx Xxxxx  
 Name:  
Xxxx Xxxxxxx  
 By:  
Xxxxxx Xxxxxx Xxxxx  
 Title:  
VP Finance and Corp Controller  
 Title:  
General Counsel  
 17  
  
 EXHIBIT A  
 PRODUCT, PRICE, AND ANTICIPATED FORECAST  
 Product:  
Loteprednol Etabonate, micronized  
 Price:  
USD [\*\*] per kilogram  
 18  
  
 EXHIBIT B  
 PRODUCT SPECIFICATIONS  
 LOTEPREDNOL ETABONATE MATERIAL SPECIFICATIONS  
Attribute & Test Method  
 Acceptance Criteria  
 Description  
 [\*\*]  
Identity  
 [\*\*]  
Loss on Drying  
 [\*\*]  
Sulphated Ash  
 [\*\*]  
Heavy Metals  
 [\*\*]  
Specific Rotation  
 [\*\*]  
Residual Solvents  
 [\*\*]  
 [\*\*]  
Related Compounds  
 [\*\*]  
 [\*\*]  
Assay  
 [\*\*]  
Particle Size  
 [\*\*]  
 [\*\*]  
Total Aerobic Microbial Count (TAMC)  
 [\*\*]  
Total Yeast and Mold Count (TYMC)  
 [\*\*]  
Escherichia coli  
 Absent (CFU/1g)  
Staphylococcus aureus  
 Absent (CFU/1g)  
Pseudomonas aeruginosa  
 Absent (CFU/1g)  
Salmonella  
 Absent (CFU/10g)  
Enterobacteria + gram (-)  
 Absent (CFU/1g)  
 19  
  
 EXHIBIT C  
 CERTIFICATE OF ANALYSIS (COA)  
 Product: Loteprednol Etabonate micronized  
Manufacture Date:   
 Manufactured and Released In:   
 Release Date:   
 Batch Number:   
Retest Date:   
 Material Specifications  
 Test  
 Specifications  
 Results  
 Description  
 [\*\*]  
 Identity  
 [\*\*]  
 Loss on Drying  
 [\*\*]  
 Sulphated Ash  
 [\*\*]  
 Heavy Metals  
 [\*\*]  
 Specific Rotation  
 [\*\*]  
 Residual Solvents  
 [\*\*]  
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 Material Specifications  
 Results  
 Related Compounds  
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 Assay  
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 Particle Size  
 Test  
 Specifications  
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 [\*\*]  
 Total Aerobic Microbial Count (TAMC)  
 [\*\*]  
 Total Yeast and Mold Count (TYMC)  
 [\*\*]  
 Escherichia Coli  
 Absent (CFU/1g)  
 Staphylococcus aureus  
 Absent (CFU/1g)  
 Pseudomonas aeruginosa  
 Absent (CFU/1g)  
 Salmonella  
 Absent (CFU/10g)  
 Enterobacteria + gram (-)  
 Absent (CFU/1g)  
 COA must indicate (i) the appropriate storage procedures and (ii) that product was manufactured, packaged and tested according to cGMP requirements.  
 21