

SUPPLY AGREEMENT
FERRER INTERNACIONAL, S.A.
AND
CUTANEA LIFE SCIENCES, INC.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED
BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

SUPPLY AGREEMENT

This Supply Agreement (the “Agreement”) is made as of this ____ day of March, 2018 (the “Effective Date”), by and between Cutanea Life Sciences, Inc., a corporation duly organized and existing under the laws of the State of Delaware with its principal place of business at 1500 Liberty Ridge Drive, Suite 3000, Wayne, PA 19087 hereinafter referred to as “CUTANEA”), and Ferrer Internacional, S.A., a Spanish corporation with its principal place of business at Av. Diagonal, 549, 5th floor, 08029 Barcelona (Spain) (hereinafter indistinctly referred to as “Ferrer” and/or “Supplier”). CUTANEA and Ferrer taken together hereinafter are referred to as “PARTIES”.

WITNESSETH:

WHEREAS, CUTANEA is engaged in the distribution, promotion and sale of certain pharmaceutical, OTC and medical device products and in particular desires that Ferrer manufacture (directly and/or through a third party) and supply CUTANEA with the “Products” (as defined below); and

WHEREAS, Ferrer and Medimetriks Pharmaceuticals, Inc. (hereinafter “Medimetriks”) entered into a License and Supply Agreement dated March 10, 2014, as amended, (hereinafter referred as “LSA”) pursuant to which among other things, Ferrer granted Medimetriks exclusive commercialization and distribution rights to the Product (as defined in the LSA) throughout the Territory (as defined in the LSA); and

WHEREAS, with Ferrer’s consent, CUTANEA has acquired and assumed the rights, duties and obligations of Medimetriks under the LSA; and

WHEREAS, Ferrer desires to manufacture (directly and/or through a third party) and supply CUTANEA with such Products;

NOW, THEREFORE, in consideration of the mutual covenants hereinafter expressed, the Parties, intending to be legally bound hereby, agree as follows:

1. DEFINITIONS

1.1 Act

“Act” means the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated hereunder.

1.2 Business Day

“Business Day” means any day other than a Saturday, Sunday or other day on which banks in Philadelphia, Pennsylvania and/ or Barcelona, Spain are permitted or required to close by any applicable law.

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1.3 Confidential Information

“Confidential Information” means, other than information described in Section 9.1.2, all business and technical information, including third party information, in whatever form or manner presented, which is: (a) disclosed by or on behalf of a party (the “Disclosing Party”) to the other party (the “Receiving Party”) or learned or observed by the Receiving Party before or during the term of this Agreement; and (b) disclosed during any discussions and proceedings relating to any of the foregoing information, whether disclosed in oral, electronic, visual, written or any other form. “Confidential Information” shall include all information of the Disclosing Party that the Disclosing Party would consider confidential or proprietary under the circumstances. The fact that the Disclosing Party may have marked or identified as confidential or proprietary any specific information shall be indicative that such Disclosing Party believes such information to be confidential or proprietary, but the failure to so mark information shall not determine that such information is or is not considered confidential information by such Disclosing Party.

1.4 FDA

“FDA” means the United States Food and Drug Administration, or any successor entity thereto.

1.5 Forecasted Needs

“Forecasted Needs” means CUTANEA’s estimate of Products (including in trade/sample form) to be ordered from Supplier for the upcoming rolling [***] period.

1.6 Governmental or Regulatory Authority

“Governmental or Regulatory Authority” means governments, regulatory authorities, governmental departments, agencies, agents, commissions, bureaus, officials, courts, bodies, boards, tribunals or dispute settlement panels or other law, rule or regulation-making organizations or entities (a) having or purporting to have jurisdiction on behalf of any nation, territory or state or any other geographic or political subdivision of any of them, or (b) exercising, or entitled or purporting to exercise any administrative, executive, judicial, legislative, policy, regulatory or taxing authority or power.

1.7 Manufacture

“Manufacture” means all the activities relating to production of the Products including packaging and shipment preparation, quality control and release of Products. All the references contained in this Agreement regarding manufacturing activities shall be deemed rendered by Supplier, even if performed by its designee (whether in the form of a subcontractor, agent or otherwise). In consequence, all Manufacturing activities with respect to the Products to be Manufactured hereunder by Supplier shall be carried out by Supplier (or its designee) at the notified facility and utilizing equipment in the manner set forth in the Specifications, except to the extent that Supplier receives CUTANEA’s advance written permission to alter the location or specified usage of the equipment that may be required under the Specifications or the NDA, as applicable.

1.8 Product(s)

“Product(s)” means product(s) as listed from time to time in Schedule A Manufactured by the Supplier (directly or through a third person) to meet the Specifications (as hereinafter defined); except as otherwise set forth on Schedule A, the Product will be ready for re-sale by CUTANEA to its customers in finished, final packaged form bearing CUTANEA’s labels, it being understood that, after generic competition of the Product enters the market in the United States of America including Puerto Rico and the U.S. Virgin Islands, CUTANEA will be permitted to place orders for Product under a generic label. The term “Generic” shall be interpreted as defined under Section 1.17 of the LSA.

1.9 Specifications

“Specifications” means, with respect to the Products, the critical quality standards that include test attributes, analytical procedures, and appropriate acceptance criteria and Manufacturing procedures for which such Product should conform to be considered acceptable for its intended use and conform to quality standards approved by Governmental and Regulatory Authorities and as provided in the NDA for the Products, and required for the Manufacture and supply of such Product(s).

1.10 Supply Price

“Supply Price” means the price to be charged to CUTANEA from time to time by Supplier for Products Manufactured and supplied hereunder, as set forth in Schedule A.

2. PRODUCT MANUFACTURE AND SUPPLY

2.1 Manufacture and Purchase.

Subject to the terms and conditions of this Agreement, Supplier agrees that it will, on a non-exclusive basis (but exclusive for supply of the Product in the United States of America including Puerto Rico and the U.S. Virgin Islands), Manufacture (directly or through a designee) for and provide and supply to CUTANEA, and CUTANEA agrees that it will purchase exclusively from Supplier, all of its requirements of the Products as follows:

Supplier shall supply Products in accordance with the Specifications and in sufficient quantity to meet CUTANEA’s Forecasted Needs for the length of this Agreement. All deviations from the Specifications must be approved by CUTANEA, in writing, prior to Supplier Manufacturing the Product.

2.2 Raw Materials and Components.

As between Supplier and CUTANEA, Supplier shall be responsible for the supply of all raw materials and components necessary for the Manufacture of Products at no additional cost to CUTANEA. Supplier (or its designee) shall order the initial components for each Product as soon as CUTANEA provides Supplier (or its designee) with the relevant artwork for the Product.

2.3 Quality Tests and Checks.

In order to assure the conformity of the Products to the Specifications, the Supplier shall deliver or cause to be delivered to CUTANEA, at the time of shipment, a certificate of analysis and compliance or other batch documentation upon reasonable request (such as, deviations, investigations, batch records) with respect to each batch of Product supplied hereunder in the form required by the Quality Agreement.

2.4 Forecasting and Other Obligations.

2.4.1 As soon as practicable following execution of this Agreement, but in any event within ten (10) Business Days, CUTANEA agrees to provide Supplier with a best estimate, non-binding (except for the first six months) forecast of its Forecasted Needs for Products (including in trade/sample form) for the upcoming rolling 18-month period (the "Forecast"). Thereafter, CUTANEA will update this rolling [***] Forecast quarterly.

2.4.2 With regards to the FDA Fees, CUTANEA shall maintain the NDA for the Products and pay, from time to time, all required FDA filing and related Product fees.

2.4.3 CUTANEA shall notify Supplier within one Business Day, after it receives any materially adverse contact or communication from any Governmental or Regulatory Authority that relates to any Product. Supplier shall notify CUTANEA as soon as reasonably possible after it receives any materially adverse contact or communication from any Governmental or Regulatory Authority that relates to any Product and may reasonably be expected to affect patient safety. For matters that would not reasonably be expected to affect patient safety, Supplier shall notify CUTANEA of such communications in its discretion.

2.4.4 CUTANEA shall provide Supplier with copies of all communications received from or sent to any Governmental or Regulatory Authority with respect to any Product within three business days after receipt or sending of the communication, as the case may be (subject to confidentiality and privilege restrictions, if any). CUTANEA shall consult with Supplier regarding the response to any inquiry or observation from a Governmental or Regulatory Authority relating to a Product. CUTANEA shall consider all reasonable requests and comments by Supplier with respect to all contacts and communications with a Governmental or Regulatory Authority.

2.5 Purchase Orders.

2.5.1 CUTANEA agrees to purchase from Supplier all Products Manufactured for CUTANEA in accordance with valid CUTANEA Purchase Orders pursuant to the terms of this Agreement and provided that such Products meet the Specifications approved by CUTANEA.

2.5.2 During the term of this Agreement, CUTANEA will order Product(s) by issuing firm Purchase Orders not less than [***] business days before the requested delivery date(s) of such Product(s), and Supplier shall provide approval of the Purchase Order by the Supplier within five (5) business days following the Purchase Order reception, such approval signifying Supplier's commitment to deliver such Product(s) on the requested deliver date(s), it being understood that Supplier must accept a Purchase Order for delivery of Product not less than [***] business days before the requested delivery date when included in the first [***] of the Forecasted Needs. Each purchase order shall set forth the Product for which the purchase order is being issued, the quantity being ordered (in trade/sample form), the Supply Price for the Product(s) being ordered and the requested delivery date for the Product being ordered, and the locations to which such quantities shall be delivered.

2.5.3 Within ten (10) Business Days following this Agreement becoming effective and thereafter on or before the last day of each calendar quarter, CUTANEA shall provide Supplier with specific data as to its Forecasted Needs for such Product (including in trade/sample form) for the following rolling [***]. Supplier will use commercially reasonable efforts to deliver Product to CUTANEA with minimum expiry dating remaining of [***]% of the approved shelf-life.

2.5.4 CUTANEA's purchase orders shall designate the desired quantities of Products, delivery dates and destinations. Supplier shall fill and ship all orders of Products in accordance with CUTANEA's reasonable written instructions. CUTANEA'S purchase order may specify up to three (3) shipping destinations per batch of Product but will be in full pallet quantities. Additional destinations can be accommodated only upon CUTANEA payment of a shipping preparation fee to be negotiated by Supplier and CUTANEA.

2.6 Acceptance / Rejection of Products.

2.6.1 All Products shall be submitted to inspection and evaluation by or on behalf of CUTANEA to determine whether or not said Products meet the Specifications. CUTANEA will provide in good faith written acceptance of a batch of Product or written notification of any deficiencies within two (2) Business Days after receipt of the Certificate of Analysis for the Product batch. Written acceptance of a batch of the applicable Product is required as a condition to the delivery of Product to Cutanea's designated shipping agent in accordance with Section 3. If for any reason Supplier does not receive any such notification within such two (2) Business Day period, Supplier will promptly notify CUTANEA of such fact and CUTANEA will as soon as practicable and, in any event within another two (2) Business Days thereafter provide such written notice to Supplier and be responsible for any storage or similar charges that Supplier may incur for not delivering such Product. The lack of reception of such written acceptance within the second two (2) Business Day period shall be deemed as the batch is accepted. If, once the Product is delivered, CUTANEA determines that there is any deficiency with respect to any Product, CUTANEA will notify Ferrer of such claim within fifteen (15) Business Days of delivery of the Products. Each such notice of rejection to Supplier shall specify in reasonable detail the ways in which the Product batch failed to meet Specifications. CUTANEA shall grant to Supplier (or its designee) the right to inspect or test said Product batch and dispute CUTANEA rejection according to the provisions provided in this Section 2.6. In the event that Supplier disagrees with CUTANEA's defective Product claim, the issue shall be submitted to a mutually agreed upon independent third party laboratory, whose decision shall be final and binding upon the Parties. The costs arising from the laboratory's intervention and the costs of the replaced Products (including return and destruction costs of the defective Products) shall be borne by the Party whose results were mistaken. As to any such Product batch which is determined to fail the Specifications ("Rejected Product"), CUTANEA shall have no obligation to pay for such Rejected Product and Supplier shall replace such Rejected Product as soon as possible and no later than ninety (90) days thereafter.

2.6.2 In the event of a conflict between the test results of Supplier and the test results of CUTANEA with respect to any shipment of Product batch, within thirty (30) days following receipt by Supplier of CUTANEA's notice of rejection, sample of such Product batch shall be submitted by Supplier (and/or its nominee) to an independent laboratory designated by Supplier (and/or its nominee) and reasonably acceptable to CUTANEA, which shall perform an assessment and whose findings shall be conclusive. The cost of the assessment shall be borne by (i) CUTANEA if the findings indicate the Product met all Specifications or (ii) Supplier (or its nominee) if the findings indicate the Product failed to meet any Specifications.

2.7 Supply Price.

The initial Supply Price for each Product (commercial trade and sample units) to be paid by CUTANEA to Supplier are listed in Schedule A. These Supply Prices are for finished forms of the Products [***] (except as otherwise set forth herein).

2.8 Quality Agreement.

The Parties shall enter into a Quality Agreement for the Products. If there is any conflict between this Agreement and the Quality Agreement solely with respect to quality assurance matters, the Quality Agreement will prevail, and with respect to all other matters, this Agreement will prevail.

2.9 Pharmacovigilance Agreement.

The Parties shall enter into a pharmacovigilance agreement with respect to the Products (the "Pharmacovigilance Agreement"). If there is any conflict between this Agreement and the Pharmacovigilance Agreement solely with respect to adverse events and patient safety, the Pharmacovigilance Agreement will prevail, and with respect to all other matters, this Agreement will prevail.

2.10 Failure to Supply.

2.10.1 Supplier will promptly notify CUTANEA in writing in the event that Supplier is unable or anticipates that it will be unable to supply compliant Products in accordance with the requirements of this Agreement (each a “Failure to Supply”). Supplier undertakes to implement appropriate methods to ensure consistency of supply of the Product for the Territory throughout the Term of the Agreement, including but not limited to using its commercially reasonable efforts to qualify an alternative site owned or operated by Supplier or its Affiliates to Manufacture the Product and obtain approval thereof from the FDA and, if necessary the possible qualification of alternate sources of supply by Supplier. CUTANEA shall be entitled to propose to Supplier such alternate sources of supply if Supplier has not taken any steps to qualify such alternate supplier before the Failure to Supply, and Supplier shall evaluate in good faith the proposal from CUTANEA. Should the Parties agree to such qualification as a remedy to a Failure to Supply, then Supplier will grant any necessary licenses and conducting technology transfer as reasonably necessary to enable such alternate supplier to Manufacture the Product during Supplier’s Failure to Supply.

2.10.2 If Supplier fails to supply all or part of any shipment of Products ordered by CUTANEA on the delivery date specified on the applicable purchase order for such shipment, in addition to any other remedies the CUTANEA may have, CUTANEA at its sole discretion, may require Supplier to supply the undelivered Products at a future date agreed upon by CUTANEA and Supplier, but nonetheless such Products shall count toward any binding purchase obligation of CUTANEA, whether as part of the Forecast or otherwise.

3. SHIPMENT AND RISK OF LOSS

Supplier shall ship the Products ordered by CUTANEA hereunder [***]. Title to, and risk of loss for, Product, shall transfer from Supplier to CUTANEA upon [***]. [***].

4. TERM AND TERMINATION

4.1 Term.

This Agreement comes into force as of the Effective Date and shall remain valid during the term of the LSA. In consequence, if the LSA to be signed by the Parties is terminated for any reason whatsoever, the present Agreement will automatically terminate and be extinguished.

4.2 Termination.

This Agreement may be terminated at any time upon the occurrence of any of the following events:

4.2.1 The failure of either party to comply with its obligations herein, which failure is not remedied within forty-five (45) calendar days after receipt by the breaching party of written notice of such default.

4.2.2 Either party may terminate this Agreement immediately by giving the other party written notice thereof in the event such other party in the event of (a) a voluntary assignment by the other party for the benefit of creditors; (b) the institution of voluntary proceedings by the other party in bankruptcy, insolvency, moratorium or for a receivership, or for a winding-up or for the dissolution of the other party; or (c) the taking of any action by the other party under any statutory act for relief from creditors, to the extent permitted by applicable Law.

4.2.3 The LSA is terminated or expires for any reason.

4.3 Additional Rights and Remedies.

Termination under this Section 4 shall be in addition to the other rights and remedies of the terminating party as specified herein.

4.4 Return of Materials.

Upon the expiration or termination of this Agreement for any reason whatsoever, Confidential Information of either party delivered to the other pursuant to this Agreement, including all formulae for the Products, shall promptly be collected and returned in whatever form it may exist.

Upon the effective date of expiration or termination of this Agreement for any reason whatsoever, Supplier shall deliver to CUTANEA all Products Manufactured hereunder under valid Purchase Orders and shall invoice CUTANEA for such Products. Subsequent to the expiration or termination of this Agreement, the Parties shall continue to be responsible for rejected Products in accordance with the terms of this Agreement.

4.5 Survival.

Termination or expiration of this Agreement shall not relieve either party of obligations or liability for breaches of this Agreement incurred prior to or in connection with termination or expiration. Sections 4.3, 4.4, 5, 6, 8.4, 9, 10, and 12 hereof and this Section 4.5 shall survive the termination or cancellation of this Agreement for any reason along with Section 1 and any other section of this Agreement to the extent necessary to interpret the other surviving sections of this Agreement.

5. WARRANTIES

5.1 Conformity with Specifications.

Supplier warrants that all Products sold pursuant to this Agreement will have been Manufactured in accordance with the Specifications for the release of the Product.

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5.2 Compliance with the Act.

Supplier shall bear sole responsibility for the validity of all test methods and appropriateness of all Specifications. In addition, Supplier shall bear sole responsibility for all regulatory approvals, filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies including responsibility for adequacy of all validation, stability, and preservative effectiveness studies performed by Supplier on behalf of CUTANEA. Supplier warrants that it has obtained and shall maintain any and all necessary approvals, licenses and permits necessary to perform its obligations under this Agreement. CUTANEA warrants that it has obtained any and all necessary approvals from all applicable Governmental or Regulatory Authorities necessary to distribute all Products under this Agreement.

5.3 Conformity with FDA Regulations and cGMPs.

Subject to CUTANEA's compliance with the provisions set forth in Section 5.2 and Section 5.4 hereof, Supplier warrants that all Products Manufactured, held for sale, sold and shipped pursuant to this Agreement shall have been Manufactured and shipped by Supplier in compliance with applicable FDA regulations and current Good Manufacturing Practices as that term is defined under the Act.

5.4 Compliance of Packaging and Labeling with Laws and Regulations.

CUTANEA warrants that all labeling copy and other material developed or produced by CUTANEA for use in connection with the Products and artwork approved, designated or supplied by CUTANEA shall be in compliance with all applicable laws and governmental regulations. Compliance with all federal, state, and local laws and regulations concerning Specifications for packaging and labeling provided by CUTANEA shall be the sole responsibility of CUTANEA. Supplier warrants that all packaging and labeling services performed hereunder will be in accordance with CUTANEA's Specifications. CUTANEA hereby warrants to Supplier that, to CUTANEA's knowledge, all CUTANEA labeling and artwork related to the Product do not violate or infringe any patent, copyright or trademark laws, and agrees to indemnify Supplier, its employees, officers, directors and representatives for any claim, loss or damage including reasonable attorney's fees paid or incurred by any of them in connection therewith.

5.5 Access to Supplier's Facilities.

5.5.1 Access. Supplier shall use its commercially reasonable efforts to permit CUTANEA to have access to Supplier's (and its agents' and subcontractors') facilities upon reasonable notice, during normal business hours for any reasonable purpose, including compliance with current Good Manufacturing Practices and the Act. Such access shall in no way give CUTANEA the right to any of Supplier's confidential or proprietary information not related to this Agreement or used in the Manufacture of any Product.

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5.5.2 Audit. Without limiting the generality of the foregoing, but subject to the Quality Agreement, Supplier shall use its commercially reasonable efforts to permit CUTANEA to conduct, once annually during the Term, one quality assurance and Manufacturing costs audit for any reasonable purpose, including access to those portions of Supplier's (and its agent's and subcontractor's) facilities where services are conducted under this Agreement, upon reasonable advance notice and at reasonable times during regular business hours (an "Annual Audit"). Supplier shall not charge CUTANEA for time and expenses incurred by Supplier (or its agents and subcontractors) in connection with an Annual Audit. For purposes of this subsection, CUTANEA shall ensure that its duly authorized agents and representatives involved in the audit have signed or are otherwise bound to maintain the confidentiality of Confidential Information learned as a result of the audit in accordance with Section 9 and CUTANEA shall be liable for any breach of such obligation by such agents or representatives.

5.6 Patent and Other Intellectual Property Rights.

Supplier represents and warrants to CUTANEA that, as of the Effective Date, to the best of Supplier's knowledge, information and belief, Supplier is not infringing (and does not guarantee that under its knowledge is infringing) upon any Third Party patent or the intellectual property rights of any Third Party relating to the Products. In addition, Ferrer can make no representations or warranties regarding any possible future infringement of Supplier Patent by a Third Party nor guarantee that the Products do not infringe future patents and/or any intellectual property right of a Third Party.

5.7 Disclaimer.

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, SUPPLIER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, INCLUDING LOST PROFITS, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THIS AGREEMENT. THIS LIMITATION OF LIABILITY WILL APPLY EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.

5.8 Debarment.

5.8.1 Each of the parties, to the best of its knowledge, hereby represents, warrants, certifies and covenants that it is not debarred under Section 306 of the Act or similar local law. In the event that a party becomes debarred, the debarred party agrees to notify the other party immediately if the same affects Supplier's ability to lawfully supply the Products or CUTANEA's ability to lawfully purchase the Products.

5.8.2 Each of the parties represents, warrants, certifies and covenants that to the best of its knowledge it has not and will not use in any capacity the services of any individual, corporation, partnership, or association which has been convicted or debarred under Section 306 of the Act or similar local law. In the event that a party becomes aware of or receives notice of the conviction or debarment of any individual, corporation, partnership, or association providing services to such party, which relates to the execution or performance of this Agreement, Supplier agrees to notify CUTANEA immediately.

6. PRODUCT RECALLS

6.1 Initiating and Effecting Recall.

Supplier, as the NDA holder for the Product, shall make all decisions with respect to any complaint or “adverse drug experience”, or any recall, market withdrawal or any other corrective action related to any Product. Supplier shall be responsible for processing and submitting to the applicable authorities or agencies all reports of adverse drug experiences and Product complaints in accordance with applicable Acts. Supplier shall investigate all complaints associated with the Manufacture, safety or efficacy of the Product. CUTANEA shall notify Supplier in accordance with the terms of the Quality Agreement and the Pharmacovigilance Agreement of any complaints received by CUTANEA concerning any Products.

6.2 Implementation of Recall.

Supplier shall implement recalls of Products from the market or other corrective actions related to the Product. CUTANEA shall assist Supplier, to the extent necessary or relevant, in implementing withdrawals or recalls of Products from the market or other corrective actions related to Products. Upon the receipt by either party of any direction to withdraw or recall any Product from the market from any Governmental or Regulatory Authority having jurisdiction, the receiving party shall notify the other party as soon as practicable in accordance with the terms of this Agreement and the Quality Agreement. With respect to notice to CUTANEA, it should be sent to [].com or via phone at []. To the extent any seizure, withdrawal, recall (whether voluntary or involuntary), or corrective action with respect to any Product (collectively, “Product Action”) results from the adulteration or contamination (other than any naturally occurring contamination that can be traced back to the Manufacturing process) of Product while in the care and custody of CUTANEA, CUTANEA shall be responsible for the costs of the Product Action. Otherwise, Supplier shall be responsible for all of the costs of the Product Action.

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7. FORCE MAJEURE

The occurrence of an event which materially interferes with the ability of a party to perform its obligations or duties hereunder which is not within the reasonable control of the party affected (or in the case of Supplier, any current manufacturer of the Product) not due to the affected party's malfeasance, and which could not with the exercise of reasonable due diligence have been avoided ("Force Majeure"), including, but not limited to, fire, accident, labor difficulty, strike, riot, terrorism, civil commotion, act of God, delay or errors by shipping companies or change in Law, Governmental or Regulatory Authority action or inaction, shall not excuse such party from the performance of its obligations or duties under this Agreement, but shall merely suspend such performance during the continuation of Force Majeure. The party prevented from performing its obligations or duties because of Force Majeure shall promptly notify the other party hereto (the "Other Party") of the occurrence and particulars of such Force Majeure and shall provide the Other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof. The party so affected shall use its commercially reasonable efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the performance of any suspended obligation or duty shall promptly recommence. Neither party shall be liable to the other party for any direct, indirect, consequential, incidental, special, punitive or exemplary damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of Force Majeure.

8. CHANGES

8.1 Changes by CUTANEA.

Any changes to the Specifications requested by CUTANEA must be approved by Supplier (or its designee) in its reasonable discretion and shall be incorporated and all costs and expenses associated with such changes shall be borne by CUTANEA.

8.2 Changes by Supplier.

Any changes to the Specifications requested by Supplier must be notified to CUTANEA in advance to its implementation, and shall be incorporated only after approval of Governmental or Regulatory Authorities. All costs and expenses associated with such changes shall be borne by Supplier.

8.3 Changes by Governmental or Regulatory Authorities.

The costs and expenses of any changes to the Specifications requested by any Governmental or Regulatory Authority shall be borne by Supplier unless the change, in the opinion of the JSC (as that term is defined in the LSA), entails a benefit to CUTANEA, in which case the costs arising from the changes and its implementation shall be borne by CUTANEA.

8.4 Obsolete Inventory.

Any CUTANEA-specific inventory including, but not limited to, raw materials, work-in-process, packaging and finished goods rendered obsolete as a result of Supplier's supplier minimum order quantities that exceed the binding quantities of Product of Forecasted Needs, formula, artwork or packaging changes not requested by CUTANEA or by changes required by any Governmental or Regulatory Authority shall be destroyed in accordance with all applicable laws and regulations and Supplier shall indemnify CUTANEA for any liability, costs or expenses, including attorney's fees and court costs, relating to Supplier's failure to dispose of such inventory in accordance with such laws and regulations. Supplier shall also provide CUTANEA with all manifests and other applicable evidence of proper destruction as may be requested by CUTANEA or required by applicable laws and regulations. Any other materials rendered obsolete that are not result of Supplier's supplier minimum order quantities that exceed the binding quantities of Product of Forecasted Needs, formula, artwork or packaging changes requested by CUTANEA shall be reimbursed to Supplier by CUTANEA.

9. CONFIDENTIAL INFORMATION: INTELLECTUAL PROPERTY RIGHTS

9.1 Confidential Information.

9.1.1 All Confidential Information furnished by the Disclosing Party during the term of this Agreement shall be kept confidential and not used by the Receiving Party, except for purposes authorized by this Agreement, and shall not be disclosed to any person or firm, unless previously authorized in writing to do so, during the term of this Agreement and for an indefinite period thereafter. The Receiving Party may, however, disclose the same to its responsible officers and employees who require said information in order to perform such party's obligations under this Agreement, provided that said officers and employees shall have assumed like obligations of confidentiality.

9.1.2 Any other provisions hereof to the contrary notwithstanding, it is expressly understood and agreed by the Parties hereto that the obligations of confidence and nonuse herein assumed shall not apply to any information which may be demonstrated by documented means of sufficient evidence that:

- (1) is at the time of disclosure or thereafter becomes a part of the public domain through no fault, omission or other act of the Receiving Party or any individual or entity receiving such information, directly or indirectly, from the Receiving Party; or
- (2) was otherwise in the Receiving Party's lawful possession with no obligation or duty to maintain the confidentiality thereof prior to disclosure as shown by its written record; or
- (3) is hereafter disclosed to the Receiving Party by a third party lawfully entitled to possession of such Confidential Information and under no obligation or duty of confidentiality; or
- (4) is released from a confidential status by Disclosing Party as evidence by an instrument or agreement duly executed by Disclosing Party; or
- (5) is required to be disclosed pursuant to regulatory or legal requirements, provided that the Receiving Party provides reasonable advance notice to the Disclosing Party and the Receiving Party reasonably cooperates with the Disclosing Party to obtain confidentiality protection of such information.

9.1.3 The Receiving Party agrees that money damages would not be a sufficient remedy for any breach of the confidentiality obligations hereunder and that, in addition to all other remedies, the Disclosing Party will be entitled to seek injunctive or other equitable relief as a remedy for any such breach by the Receiving Party without having to post a bond. The Receiving Party will notify the Disclosing Party in writing immediately upon the occurrence of any unauthorized release of Confidential Information or other breach of the confidentiality obligations hereunder of which it is or becomes aware.

9.2 Intellectual Property.

Except as the Parties may otherwise expressly agree in writing, each party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property ("Intellectual Property"), without conferring any interests therein on the other party. Neither party shall acquire any right, title or interest in the other's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

9.3 Publicity and SEC Filings.

The Parties agree that, unless mutually agreed by the Parties in writing otherwise, no public announcement or press release regarding the execution of this Agreement shall be made. Notwithstanding anything to the contrary contained herein, each party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures required to be made to the SEC or any other Governmental or Regulatory Authority, including providing written notice to the other party and sufficient time to review and request confidential treatment of Confidential Information of either party included in any such disclosure.

10. INDEMNIFICATION

10.1 Indemnification by Supplier.

Supplier shall indemnify, defend and hold CUTANEA harmless from any and all losses, damages, liabilities, costs, charges, expenses, including, without limitation, court fees and reasonable lawyers' fees and other legal expenses (collectively, "Losses") to which CUTANEA may become subject as a result of any claim, complaint, suit, demand, action or other proceeding by any Third Party (collectively "Claims"), to the extent such Losses arise out of or in connection with: (i) the development, use, Manufacturing, storage, handling or distribution of the Products by Supplier or any of its Affiliates or contract suppliers of Products; (ii) the negligence or willful misconduct of Supplier or any of its Affiliates or contract suppliers of Products; or (iii) a breach or non-fulfilment by Supplier of its obligations according to this Agreement and/or any law in force; or (iv) a breach by Supplier of any warranty, representation, covenant or agreement made by it in this Agreement; except, in each case, to the extent such Losses result from (a) the negligence or willful misconduct of CUTANEA or (b) the breach by CUTANEA of any warranty, representation, covenant or agreement made by it in this Agreement and to the extent that such negligence, willful misconduct or breach it is stated by a final court decision. Notwithstanding the foregoing, Supplier shall have no obligation to indemnify CUTANEA for reasonable lawyers' fees and other legal expenses incurred by CUTANEA after Supplier has taken over the defense of such claim, "Action or Proceeding" in accordance with Section 10.3 unless and then only to the extent otherwise agreed to in advance in writing by Supplier.

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10.2 Indemnification by CUTANEA.

CUTANEA shall indemnify, defend and hold Supplier harmless from any and all Losses, to which Supplier may become subject as a result of any Claim to the extent such Losses arise out of or in connection with: (i) the development, use, storage, handling, distribution, marketing or selling of the Products by CUTANEA and its Affiliates; (ii) the negligence or willful misconduct of CUTANEA and its Affiliates; (iii) the breach or non-fulfilment by CUTANEA of its obligations according to this Agreement and/or any law in force; or (iv) a breach by CUTANEA of any warranty, representation, covenant or agreement made by it in this Agreement; except, in each case, to the extent such Losses result from: (a) the negligence or willful misconduct of Supplier (b) the breach by Supplier of any warranty, representation, covenant or agreement made by it in this Agreement and to the extent that such negligence, willful misconduct or breach it is stated by a final court decision. Notwithstanding the foregoing, CUTANEA shall have no obligation to indemnify Supplier for reasonable lawyers' fees and other legal expenses incurred by Supplier after CUTANEA has taken over the defense of such claim, "Action or Proceeding" in accordance with Section 10.3 unless and then only to the extent otherwise agreed to in advance in writing by CUTANEA.

10.3 Assertion of Claim.

In the event that any claim is asserted against any party hereto, or any party hereto is made a party defendant in any action or proceeding, and such claim, action or proceeding (which shall mean any action, claim, suit, proceeding, arbitration or Governmental or Regulatory Authority action, notification, investigation or audit, hereinafter referred to as an "Action or Proceeding") involves a matter which is subject to a claim for indemnification under this Section, then such party (an "Indemnified Party") shall promptly give written notice to the other party or parties (the "Indemnifying Party") of such claim, Action or Proceeding. If the Indemnifying Party agrees in writing to be bound by and to promptly pay the full amount of any final judgment from which no further appeal may be taken (or otherwise confirms its indemnification obligation responsibility to the satisfaction of the Indemnified Party) and if the Indemnified Party is reasonably assured of the Indemnifying Party's ability to satisfy such agreement, then such Indemnifying Party shall take over the defense of such claim, Action or Proceeding, except that, in such case, the Indemnified Party shall have the right to approve any attorney or counsel selected by the Indemnifying Party (which approval shall not be unreasonably delayed or withheld) and to join in the defense of said claim, Action or Proceeding at its own cost and expense. In no event shall the Indemnifying Party settle any such claim or potential claim, Action or Proceeding without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld.

10.4 Insurance.

10.4.1 Each of Supplier and CUTANEA shall maintain and keep in force at its sole cost and expense throughout the Term of this Agreement and for three years following the effective date of expiration or termination hereof (if such policies are on a claims made basis), Commercial General Liability Insurance from carriers having an A. M. Best rating of A, including Product Recall, Bodily Injury and Property Damage Insurance, with a combined single limit of not less than \$[***] per occurrence and \$[***] in the aggregate annually (this limit can be secured via a combination of primary and excess/umbrella policies). In addition, each of the Parties shall maintain and keep in force at its sole cost and expense throughout the Term of this Agreement and for three years following the effective date of expiration or termination hereof (if such policies are on a claims made basis), Product Liability Insurance from carriers having an A.M. Best rating of A with a combined single limit of not less than \$[***] per occurrence and in the aggregate annually.

10.4.2 Each party agrees to provide the other party with a Certificate of Insurance evidencing such coverage, naming the other party as an additional insured. Each party agrees to give the other party written notice, promptly, of any material change in or cancellation of coverages or limits. In addition, if and for so long as Supplier utilizes any subcontractor(s) or agents to provide services hereunder, Supplier will use its commercially reasonable efforts to cause each such subcontractor to hold, at least, the minimum insurance coverages listed above.

11. REPRESENTATIONS AND WARRANTIES 11.1 REPRESENTATIONS BY SUPPLIER.

Supplier makes the following representations and warranties and agrees to notify CUTANEA immediately upon any future breach of these representations and warranties:

11.1.1 Organization of Supplier. Supplier is a Spanish corporation, duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

11.1.2 Enforceability of this Agreement. The execution and delivery of this Agreement has been authorized by all requisite corporate action on the part of Supplier. This Agreement is and will remain a valid and binding obligation of Supplier, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

11.1.3 Absence of Other Contractual Restrictions. Supplier is under no contractual or other obligation or restriction that is inconsistent with Supplier's execution or performance of this Agreement. Supplier will not enter into any agreement, either written or oral, that would conflict with Supplier's responsibilities under this Agreement.

11.1.4 Qualifications of Supplier Personnel. Supplier has, and will engage, employees, subcontractors and/or consultants (“Supplier Personnel”) with the proper skill, training and experience to provide the services under this Agreement. Supplier will be solely responsible for paying Supplier Personnel and providing any employee or other benefits that they are owed.

11.1.5 Legal Compliance. Supplier will comply, in all material respects, with all laws, regulations and orders applicable to its operations. Supplier has and at all times during the term of this Agreement shall maintain all permits, licenses and similar authorizations required for it to perform its obligations under this Agreement.

11.2 Representations by CUTANEA.

CUTANEA makes the following representations and warranties and agrees to notify Supplier immediately upon any future breach of these representations and warranties:

11.2.1 Organization of CUTANEA. CUTANEA is a Delaware corporation, duly organized, validly existing and in good standing under the laws of Delaware.

11.2.2 Enforceability of this Agreement. The execution and delivery of this Agreement has been authorized by all requisite corporate action on the part of CUTANEA. This Agreement is and will remain a valid and binding obligation of CUTANEA, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

11.2.3 Absence of Other Contractual Restrictions. CUTANEA is under no contractual or other obligation or restriction that is inconsistent with CUTANEA’s execution or performance of this Agreement. CUTANEA will not enter into any agreement, either written or oral, that would conflict with CUTANEA’s responsibilities under this Agreement.

11.2.4 Legal Compliance. CUTANEA will comply, in all material respects, with all laws, regulations and orders applicable to its operations. CUTANEA has and at all times during the term of this Agreement shall maintain all permits, licenses and similar authorizations required for it to perform its obligations under this Agreement.

11.3 Anti-Corruption Undertaking

Both parties shall comply with, and will not cause any party and its Affiliates, associates, directors, officers, shareholders, employees, representatives, sublicensees or agents worldwide to be in violation with any applicable anti-corruption laws, rules and regulations including but not limited to the United States Foreign Corrupt Practices Act (the “FCPA”) or U.K. Bribery Act 2010. Without limiting the foregoing, neither party will, directly or indirectly, pay any money to, or offer or give anything of value to, any Government Official, in order to obtain or retain business or to secure any commercial or financial advantage for the other party or for itself or any of their respective Affiliates. Each of the parties undertakes not to bribe Government Officials or any private companies or individuals, “bribes” having the following definition: Offering, promising, or giving a financial or other advantage to another person where it is intended to bring about the improper performance of a relevant function or activity, or to reward such improper performance; acceptance of the advantage offered, promised or given in itself constitutes improper performance of a relevant function or activity. “Improper Performance” means a breach of expectations that a person will act in good faith, impartially, or in accordance with a position of trust. Both parties must also (1) make and keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the company, (2) devise and maintain a system of internal accounting controls, and (3) at any time a party so requests in writing, but no more than once a year, grant to the other party commercially reasonable access to said books, records, systems and accounts to verify compliance. Such inspection shall be undertaken by an independent public accountant or accounting firm appointed by the requesting party and about whom the other party does not express a legitimate concern. For the avoidance of doubt, this restricted annual audit shall not apply to for-cause audits, which may be conducted at any time.

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12. GENERAL PROVISIONS

12.1 Notices.

Except for invoices, which shall be sent in accordance with Schedule A, all notices required or permitted under this Agreement must be written and sent to the address or facsimile number identified in this Agreement or a subsequent notice. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile followed by hard copy delivered by the methods under (c) or (d), (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at such later time as stated in the notice. Notices shall be sent:

If to Supplier:

Ferrer Internacional, S.A.
Attention: Legal Department
Av. Diagonal, 549, 5th Floor
08029 Barcelona, Spain

If to CUTANEA:

Cutanea Life Sciences, Inc.
Attention: President and CEO
1500 Liberty Ridge Drive
Suite 3000
Wayne, PA 19087

With a copy (which shall constitute notice) to:

Cutanea Life Sciences, Inc.
Attention: General Counsel
1500 Liberty Ridge Drive
Suite 3000
Wayne, PA 19087
Fax: +1 484.652.0223

12.2 Entire Agreement; Amendment.

The Parties hereto acknowledge that this Agreement, including the Quality Agreement and the Pharmacovigilance Agreement and any exhibits, schedules or other attachments hereto sets forth the entire agreement and understanding of the Parties and supersede all prior written or oral agreements or understandings with respect to the subject matter hereof. In the event of any conflict between this Agreement and the LSA, this Agreement will control with respect to issues of quality assurance, patient safety, Supply Unit Price and changes to it, and other terms and conditions customarily associated with supply agreements for commercial pharmaceutical products. Notwithstanding the precedent, in the event of any conflict between Quality Agreement and/or Pharmacovigilance Agreement and this Agreement, Quality Agreement or Pharmacovigilance Agreement shall prevail with respect to terms and conditions customarily associated with Quality or Pharmacovigilance as respectively applicable. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by the party against whom enforcement is sought. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.

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12.3 Waiver.

No waiver by either party of any default shall be effective unless in writing, nor shall any such waiver operate as a waiver of any other default or of the same default on a future occasion.

12.4 Assignment.

This Agreement shall be assignable or transferable by either party hereto only with the consent in writing of the other party, such consent not to be unreasonably withheld. However, Supplier shall be free to assign this Agreement along with the LSA in favor of any third party, provided that the succeeding entity assumes all of the obligations under this Agreement and the LSA, and further provided that Supplier provides CUTANEA with prior written notice of such assignment. Any assignments, including but not limited to, sale, transfer, or license of brand or Products, shall not release the original party hereto from their duties and obligations under this Agreement. For the purposes of this Agreement, the terms “subsidiaries” and “affiliates” shall mean any entity controlling, controlled by, or under common control with, either of the Parties hereto.

12.5 Governing Law.

This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, without reference to any principles of conflicts of law thereof. Any suit or proceeding arising in respect of this Agreement will be tried exclusively in the United States District Court of the Southern District of the State of New York or, if that court declines to accept or does not have jurisdiction over a particular matter, any other State Court in the State of New York or Federal court of the United States of America located in the State of New York, and both parties irrevocably and unconditionally agree to submit to the exclusive jurisdiction of, and to venue in, such courts (and agree not to commence any action, suit, or proceeding relating thereto except in such courts). Both parties hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit, or proceeding arising out of this Agreement in such court, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum. Both parties further agree that service of any process, summons, notice or document by U.S. registered mail to the respective addresses set forth below shall be effective service of process for any action, suit or proceeding brought against the parties in any such court. BOTH PARTIES HEREBY IRREVOCABLY WAIVE THE RIGHT TO A TRIAL BY JURY IN ANY ACTION, SUIT OR PROCEEDING REGARDING THE SUBJECT MATTER OF THIS AGREEMENT.

12.6 Severability.

In the event that any term or provision of this Agreement shall violate any applicable statute, ordinance, or rule of law in any jurisdiction in which it is used, or otherwise be unenforceable, such provision shall be ineffective to the extent of such violation without invalidating any other provision hereof.

12.7 Headings, Interpretation.

The headings used in this Agreement are for convenience only and are not a part of this Agreement.

12.8 Counterparts.

This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same original.

12.9 Independent Contractor.

In performing its services hereunder, Supplier shall act as an independent contractor.

[Signature page follows.]

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IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their duly authorized officers as of the date first above written.

CUTANEA LIFE SCIENCES, INC.

By: /s/ [***]
Its: [***]
Date:

FERRER INTERNACIONAL, S.A.

By: /s/ [***]
Its: [***]
Date:

FERRER INTERNACIONAL, S.A.

By: /s/ [***]
Its: [***]
Date:

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Schedule A

Capitalized terms in this Exhibit A are defined in LSA.

The initial purchase price for trade units of the Products shall be set at \$[***] per [***] sample tube of the Product, \$[***] per [***] trade unit of the Product, \$[***] per [***] trade unit of the Product, and \$[***] per [***] trade unit of the Product, FCA manufacturing site (the "Supply Unit Price"). Notwithstanding the foregoing, after December 31, 2018 and during the term of this Agreement, Ferrer may change its Supply Unit Price on any or all the Products from time to time, but no more than once annually, based on documented actual increases to Ferrer's direct manufacturing and labor (but specifically excluding overhead) costs (or those charged by its nominee), provided that Ferrer furnishes the Company with at least thirty (30) days prior written notice of any such change. The increase shall apply to any order received by Ferrer after the communication date of the increase. In the event that the new Supply Unit Price for the Products may make the business not feasible, the Parties, in good faith and through the Joint Steering Committee, agree to meet and negotiate in good faith an alternative solution.

The purchase price for the Products shall be paid in US Dollars by the Company and such payment terms shall be [***] following the date that the Products are received and accepted (as per Article 4.4 of the LSA) by the Company, by wire transfer into an account designated by Ferrer. Invoices shall be generated upon shipment of Product from Supplier. Invoices should be sent by email to the following address: invoice@cutanea.com. Failure to send invoices to the email address provided herein may cause a delay in approval and payment. In the event that the Company does not fulfill such terms, Parties agree to discuss in good faith alternative payment conditions. In case there is not an agreement between the Parties after 30 days, Ferrer will accept an irrevocable and guaranteed letter of credit payable as term of payment.

Additionally, Parties agree to share exchange EUR/ USD rate fluctuations covering the payment of royalties. More concretely, within the first 30 days after every calendar year, Ferrer will calculate the average annual EUR/USD rate based on the EUR/USD rates published in the Financial Times the last business day of every month. Such EUR/USD average rate will be compared with the rate applied in every invoice during the year. If, as a result of this reconciliation, there arises a difference above or under [***]%, Parties agree to share the resulting amount on an equitable basis (50%). Ferrer will report the reconciliation to the Company for its acceptance and, after 15 business days, issue an invoice which will be debited/credited in the next 30 days by wire transfer into the accounts designated by the Parties.

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