

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **June 4, 2018**

**SONOMA PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-33216**  
(Commission  
File Number)

**68-0423298**  
(IRS Employer  
Identification No.)

**1129 N. McDowell Blvd.**  
**Petaluma, CA 94954**  
(Address of principal executive offices)  
(Zip Code)

**(707) 283-0550**  
(Registrant's telephone number, including area code)

**Not applicable.**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 1.01 Entry into a Material Definitive Agreement.**

On June 4, 2018, we entered into a 5-year exclusive license and distribution agreement with EMS S.A., headquartered in Sao Paulo, Brazil. Pursuant to the license and distribution agreement with EMS, we granted EMS the exclusive right to purchase, import, distribute, sell and promote certain of our dermatology products within Brazil for a period of five years, with the possibility of renewal. We also agreed to assign our trademarks filed or registered in Brazil to EMS on a royalty-free basis for the purpose of marketing, distributing, and selling our products in Brazil. EMS agreed to minimum annual purchase amounts of \$100,000 in year one; \$250,000 in year two; \$500,000 in year three; \$750,000 in year four; and \$1,000,000 in year five, respectively.

This report does not constitute an offer to sell or the solicitation of an offer to buy, and these securities cannot be sold in any state or jurisdiction in which this offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any state or jurisdiction. Any offer will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement.

This report contains forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements related to our future activities, our planned spin-off, or future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performances and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors, including those risks discussed in our Annual Report on Form 10-K and in other documents that we file from time to time with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of this report, except as required by law.

The foregoing description of the exclusive license and distribution agreement is qualified in its entirety by reference to the full text of the exclusive license and distribution agreement, which is attached to this Current Report on Form 8-K as Exhibit 10.1, with confidential information redacted, and incorporated herein by reference in its entirety.

**Item 9.01 Financial Statements and Exhibits.**

10.1† [Exclusive License and Distribution Agreement entered into by and between Sonoma Pharmaceuticals, Inc. and EMS S.A. dated June 4, 2018.](#)

† Confidential treatment is being sought for portions of this agreement.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Sonoma Pharmaceuticals, Inc.**  
(Registrant)

Date: June 5, 2018

By: /s/ Robert Miller  
Name: Robert Miller  
Title: Chief Financial Officer

**EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT**

**This Agreement is made and entered into as of June 4, 2018 (hereinafter the “Effective date”) by and between:**

**Sonoma Pharmaceuticals, Inc.**, a company incorporated and existing under the laws of the State of Delaware, USA, having its registered offices at 1129 North McDowell Boulevard, Petaluma, California, 94954, United States of America, hereby represented by its legal representatives

hereinafter referred to as «SONOMA», on the one hand

and

**EMS S.A.**, a private corporation duly incorporated and existing under the laws of the Federative Republic of Brazil, with head office located at Rodovia Jornalista Francisco Aguirre Proença, KM 08, Bairro Chácara Assay, CEP 13186-901 Hortolândia, São Paulo – Brazil, enrolled with CNPJ/MF under number 57.507.378/0003-65, hereby represented by its legal representatives

hereinafter referred to as «EMS», on the other hand.

SONOMA and EMS are herein individually referred to as a “Party” and collectively referred to as “Parties”.

**WHEREAS:**

- A. SONOMA manufactures, through its wholly-owned subsidiary, Oculus Technologies of Mexico, S.A. de C.V. the product described in Schedule 4 hereto (hereinafter referred to as the “Product”) and currently holds all rights to the Product, including in particular in the country listed in Schedule 2 hereto (hereinafter referred to as the “Territory”).
- B. SONOMA currently markets the Product internationally, but outside of Brazil, and has obtained marketing authorizations for the Product in various countries.
- C. EMS wishes that SONOMA grant to EMS the exclusive right to purchase, import, distribute, sell and promote the Products in the Territory under its own Trademark (as defined in Article 1.1(xiv) of the Agreement).
- D. In order to enable EMS to Market and Distribute the Product in the Territory, SONOMA has obtained from the competent Governmental Authorities in the Territory all Regulatory Approvals which are required under local Laws to Market and Distribute the Product.
- E. The Parties may discuss the possibility that EMS comes to register the Product by itself and obtain the Regulatory Approvals in its own name to Market and Distribute the Product in the Territory under certain circumstances described in this Agreement.
- F. EMS has all suitable resources and shall hold all necessary administrative permits to register, import, handle, store, sell, distribute and promote the Product in the Territory.
- G. On December 19, 2017, EMS S/A and SONOMA entered into a non-binding Term Sheet (the “Term Sheet”) for the negotiation of EMS S/A as SONOMA’s exclusive licensee and distributor of the Product in the Territory, pursuant to this Agreement, when signed;

- H. EMS wishes to appoint its Affiliate Luxbiotech Farmacêutica Ltda. to Market and Distribute the Product under such Affiliate's trade name Underskin or USK and SONOMA agrees with such appointment.

Now, therefore, in consideration of the above and the mutual promises set forth below, SONOMA and EMS agree as follows:

## 1. INTERPRETATION AND DEFINITIONS

1.1 For the purposes of this Agreement or any notice, consent, authorization, direction or other communication required or permitted to be given hereunder, the singular shall include the plural and vice versa and the following expressions shall have the following meanings, respectively, unless the context otherwise requires:

- (i) "Affiliate" means a company that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the company specified. For the purposes of this definition, control will mean the direct or indirect ownership of (a) in the case of corporate entities, securities authorized to cast more than fifty percent (50%) of the votes in any election of directors, (b) in the case of non-corporate entities, more than fifty percent (50%) ownership interest with the power to direct the management and policies of such non-corporate entity.
- (ii) "ANVISA" means the Brazilian Health Surveillance Agency, a Brazilian Governmental Authority, or any successor agency thereof.
- (iii) "Approved Dossier" means the Brazilian Dossier in its final form and content as approved by ANVISA, based on which the Marketing Authorization for the Product in the Territory is granted. During the life cycle of the Product, "Approved Dossier" could also mean the dossier as amended from time to time in accordance with the applicable Laws in the Territory and approved by ANVISA.
- (iv) "Approved Facility" means the Oculus Technologies of Mexico S.A. de C.V. facility in Industria Vidriera 81, Fraccionamiento Industrial Zapopan Norte, Zapopan, Jalisco, Mexico, duly approved by the competent Governmental Authority in the Territory for manufacturing the Product for import into, and Marketing and Distribution in, the Territory.
- (v) "Artwork" means any and all features, logos, trade names, descriptive information and copy pertaining to the Product on either the Primary Packaging or the Secondary Packaging for Finished Product.
- (vi) "Brazilian Dossier" means the CTD Dossier transformed, translated and compiled by EMS according to Brazilian requirements to be filed with ANVISA.
- (vii) "Business Day" means any day except Saturday, Sunday and statutory holidays, on which commercial banking institutions in Petaluma/CA, USA and Hortolandia/SP, Brazil are open for business. Any reference in this Agreement to "day" whether or not capitalized will refer to a calendar day, not a Business Day.
- (viii) "Change" means any change which may have impact on the Product's Regulatory Approval in the Territory, according to local Laws, e.g. a change related to (i) the site of manufacture/packaging of the drug substance or Product, (ii) ingredient or Product including but not limited to the releasing specification; (iii) the manufacturing and/or Packaging process of the drug substance or Product; (iv) the analytical methodology used in the Product or the Packaging Material; (v), any new indication or use of the Product; (vi) the Approved Facility; or (vii) any other aspect of the ingredient or Product which may have an impact on Regulatory Approvals in the Territory.

- (ix) “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party in the performance of such Party’s obligations hereunder, the reasonable, diligent efforts to accomplish such objective as a similarly situated party in the pharmaceutical industry would normally use to accomplish a similar objective under similar license grants and circumstances.
- (x) “Confidential Information” means all secret, confidential or proprietary information or data, whether provided in written, oral, graphic, video, digital or other form, provided by one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”) pursuant to this Agreement or generated pursuant to this Agreement, including but not limited to, information relating to the Disclosing Party’s existing or proposed research, development efforts, patent applications, promotional materials, ideas, strategies, clinical trials, quotations, development lists, formulae, manufacture processes, concepts, businesses plans, marketing data, scientific data, prototypes, samples, scientific and technical information, projects, processes, procedures, know-how, products, the terms of this Agreement and any other materials that have not been made available by the Disclosing Party to the general public, including all information disclosed during the negotiations preceding this Agreement. Notwithstanding the foregoing, Confidential Information will not include any information or materials that:
- (a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party to the extent such Receiving Party has documentary evidence to that effect;
  - (b) were generally available to the public at the time of its disclosure to the Receiving Party;
  - (c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of the confidentiality obligations under this Agreement;
  - (d) were subsequently lawfully disclosed to the Receiving Party by a Third Party who had no obligation not to disclose such information to others;
  - (e) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party and the Receiving Party has documentary evidence to that effect; or
  - (f) is approved for disclosure by the Disclosing Party in writing.

Information included in the Confidential Information shall not be deemed to be in the public domain or in the possession of either Party merely because the information is embraced by partial or generalized disclosures in the public domain, nor will a combination of information be deemed to fall within any of the exceptions set forth above simply because each of the elements is itself included within an exception if the significance of the combination does not fall within any of the exceptions;

- (xi) “Contract Year” means each consecutive 12 (twelve) months period during the term of this Agreement commencing from the Launch Date.
- (xii) “Distribute”, “Distributed” or “Distribution” means the import, storage, handling, transportation, sale, and offer for sale of Product.
- (xiii) “CTD Dossier” means SONOMA’s CTDs (Modules 2-3) of the Products updated as agreed during the due diligence, the Brazilian specific documents as identified during the due diligence, the GMP (Good Manufacturing Practices) documents as identified during the due diligence and all administrative documents (e.g. certificates, authorizations, approvals) required for Regulatory Approvals in the Territory.

- (xiv) “EMS Trademarks” means any Trademark owned by EMS that the Parties agree may be used by EMS or its Affiliates in the Marketing and sale as the brand name for the Finished Product, and includes, without limitation, Gramacyn® and Celacyn®.
- (xv) “Field” means human dermatology field for use or intended use as approved by ANVISA in the Marketing Authorization in issuing the CE-mark for each Product.
- (xvi) “Finished Product” means Product ready to use, with final consumer Packaging Materials conforming to Finished Product Release Specifications.
- (xvii) “Finished Product Release Specifications” means the specifications for Finished Product defined by SONOMA and in accordance with the Approved Dossier, which may be amended from time-to-time during the Term and according to local laws and regulations.
- (xviii) “Force Majeure Event” means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by the Party of any of its obligations hereunder (other than payment obligations), if such occurs by reason of any act of God, flood, fire, explosion, earthquake, strikes, out of the reasonable control of the affected Party, casualty or accident; or war, revolution, civil commotion, acts of public enemies, terrorist attack, blockage or embargo; or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government (to the extent such government has ruling authority over such Party) or of any subdivision, authority or representative of any such government; or other similar event, beyond the reasonable control of such Party.
- (xix) “Governmental Authority” means any court, tribunal, arbitrator, agency, legislative body, commission, department, bureau, official or other entity of (a) any government of any country, (b) a federal, state, province, region, local, county, city or other political subdivision thereof, (c) any governmental or regulatory authority responsible for the grant of Regulatory Approval including, without limitation, ANVISA, or (d) any supranational body, in each case exercising governmental powers and having jurisdiction in connection with this Agreement and action to be taken hereunder.
- (xx) “Intellectual Property” shall mean any and all licenses, Know-How, rights to inventions (whether or not reduced to writing), patents (including patents of addition, substitutions, reissues, extensions, reexaminations, renewals, supplemental patent certificates, confirmation patents and registration patents), patent applications (including any provisionals, divisionals, continuations, continuations-in-part and substitutions thereof), designs, design applications and design registrations, trademarks, trademark applications, trademark registrations, trade names, trade dress, service marks, logos (whether registered or unregistered), copyrights, copyright applications, copyright registrations, and other intellectual property rights now or hereafter recognized anywhere in the world now or hereafter owned, held, prepared for or used by any of the Parties or any of its Affiliates.
- (xxi) “Know-How” shall mean any data, results, technology, business information and other information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, research, preclinical and clinical test data (including original patient report forms, investigator reports, clinical protocols, statistical analyses, expert opinions and reports)), manufacturing data (including, analytical and quality control data, stability data, other study data and procedures and other chemistry, manufacturing and control (CMC) data), safety or other adverse reaction files and complaint files, presentations and papers from academic meetings or market research, in each case, together with all supporting data and raw source data therefor, whether or not reduced to writing, now or hereafter owned by, in the possession of, known to or controlled by any the Parties or its Affiliates.

- (xxii) "Launch Date" shall mean the first actual sale of the Product made by EMS, its Affiliate, or subdistributor in the Territory.
- (xxiii) "Law" or "Laws" means the laws, statutes, rules, codes, regulations, orders, judgments and/or ordinances of a Governmental Authority, including, without limitation, ANVISA, and any implementing legislation or other applicable laws promulgated by a Governmental Authority in the Territory, as any of the same may be amended from time-to-time, and directives, regulations, promulgations, guidance and guidelines promulgated thereunder having jurisdiction over or related to the development, registration, approval, manufacture, Marketing, Distribution and use of a Product in the Territory, as may be in effect from time-to-time.
- (xxiv) "Market" or "Marketing" means activities directed to the marketing or promotion of Finished Product, including appropriate mailings, attendance and participation at industry meetings and congresses, general sales-force promotion, telesales, pre-marketing, advertising, educating and planning activities related to Finished Product. Marketing will not include any activities related to research, manufacture or development of a Product.
- (xxv) "Marketing Authorization" shall mean the approval by the competent Governmental Authority to Market the Product in the Territory.
- (xxvi) "Packaging Material Specifications" means the technical specifications for the Packaging Materials, including the layout of the Artwork as determined by EMS (as per cutlines provided by SONOMA) and communicated to SONOMA from time-to-time, or other packaging materials specifications as may be approved by ANVISA.
- (xxvii) "Packaging Materials" means the Primary Packaging, label, package insert and carton for the outer packs and all other packaging materials necessary for packaging Finished Product as described on Schedule 1.
- (xxviii) "Product" or "Products" means, collectively or individually as the context requires, those SONOMA products specified in Schedule 4 of this Agreement.
- (xxix) "Primary Packaging" means the materials that come in direct contact with the Product and have been proven to maintain the integrity of the Product through the stated expiration date of the Product.
- (xxx) "Purchase Order" means each purchase order submitted by EMS to SONOMA pursuant to Section 5.1(f) pursuant to which EMS orders Product from SONOMA. The first Purchase Order submitted by EMS hereunder shall be called the "Initial Purchase Order".
- (xxxi) "Regulatory Approval" or "Regulatory Approvals" means at the Effective Date, all approvals (including, without limitation, where applicable, pricing approval), company and product registrations and renewals, authorizations, permits, licenses, filings, and certifications of any Governmental Authority required to be held by a Party for the use, Marketing and Distributing of a Product in the Territory, including without limitation, the Marketing Authorization. For the avoidance of doubt, "Regulatory Approval" does not include any trademark registration with the Brazilian National Institute of Intellectual Property (INPI) relating to the EMS Trademarks, and any business permits that are generally required to be maintained by a distributor of CE-mark products in the same class and industry as of the Products and are not specific to EMS's Marketing and Distribution of the Product.

- (xxxii) “Secondary Packaging” means the outer Packaging Material such as cartons and labels (in the form Marketed) which contains the Primary Packaging.
- (xxxiii) “Sonoma Trademark” means a Trademark owned by SONOMA and used or required to be on the Packaging Materials and Marketing purposes for the Finished Products pursuant to this Agreement, applicable Laws, or the Approved Dossier in order to specify the technology owned by SONOMA and used in the Finished Product or SONOMA itself, and shall include, without limitation, Microcyn, Sonoma and Oculus, as further described under Schedule 3.
- (xxxiv) “Territory” means the Federative Republic of Brazil.
- (xxxv) “Third Party” means any person or company other than SONOMA, EMS or their respective Affiliates.
- (xxxv) “Trademark” means a trademark owned by a Party and any related word, name, symbol, color, shape or designation or any combination thereof as well as any other word, name, symbol, color, shape or designation used in the performance by a Party of its obligations hereunder or in the operation of its business, including any service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.2 The following are the Schedules annexed to and incorporated in this Agreement by reference and deemed to be a part hereof:

Schedule “1” Packaging

Schedule “2” Territory

Schedule “3” Microcyn Technology description

Schedule “4” Minimum Annual Purchase Amount and Pricing

Schedule “5” Customs Letter

## 2. GRANT of RIGHTS

2.1 Under the terms and conditions hereinafter set out, SONOMA hereby grants to EMS and its Affiliates the exclusive right during the term of this Agreement:

- a) to purchase the Product from SONOMA for import into the Territory.
- b) to use SONOMA’s Trademarks filed or registered in the Territory on a royalty-free basis, on the Finished Product Packaging Materials and the promotional material produced by EMS and solely to Market, Distribute and sell the Finished Product in the Territory for use in the Field.
- c) to register and obtain the Marketing Authorization in its own name (if and when agreed between the Parties in an amendment to this Agreement signed by the Parties), store, Market and sell Finished Product in the Territory using its own Trademark, which shall be the exclusive property of EMS at all times, in relation thereto.



2.2 EMS may utilize its Affiliates and Third Party sub-distributors, provided that EMS remains liable for all the work, acts and omissions of its Affiliates and sub-distributors, including compliance with the terms of this Agreement. No use of Affiliates or subcontractors will release EMS from its responsibilities and liabilities under this Agreement including, but not limited to, its indemnification obligations.

2.3 EMS hereby grants to SONOMA the use of EMS' Trademarks on a royalty-free basis, solely for use on the Product Packaging Materials to be supplied to EMS.

### **3. EXCLUSIVITY**

3.1 SONOMA hereby appoints EMS, and EMS hereby accepts appointment, as SONOMA's exclusive and sole importer, handler, storer, seller, distributor and promoter of the Product solely for the purpose of Marketing, Distributing and Selling the Product in the Territory for use in the Field as provided in this Agreement and shall grant to EMS an exclusive license to use SONOMA's Intellectual Property and Know How related to the Product solely to the extent required for EMS to Market the Product in the Territory for use in the Field. EMS acknowledges and agrees that this Section does not grant to EMS any license or rights, whether express or implied, to any trade secret owned by SONOMA. In addition, for the purposes of Marketing as provided in this Section, EMS shall only be entitled to use the Intellectual Properties and Know How disclosed by SONOMA for this purpose.

3.2 EMS shall not have any right to and shall not import, export, Market, Distribute, obtain Regulatory Approval or use any Product outside of the Territory or for any use outside the Field, or solicit any Third Party to maintain offices, storage depots, etc. outside the Territory with the intention to Market, Distribute, import, export, sell or obtain Regulatory Approval for a hypochlorous-based product; or (ii) to duplicate, reverse engineer, modify or adapt (A) Product, or (B) any documentation provided by SONOMA, without SONOMA's prior written consent.

3.3 EMS warrants that: (i) it has and will maintain an adequate organization for the fulfilment of its obligations under this Agreement; and (ii) it is an independent Party assuming the risks of its own activity and nothing contained herein will be construed to create an agency, partnership, employment or joint venture relationship between SONOMA and EMS.

### **4. GENERAL OBLIGATIONS of the PARTIES**

#### **4.1 REGISTRATION and APPLICATION of the PRODUCT**

##### **Registration**

4.1.1 The Parties acknowledge that, prior hereto, SONOMA has caused the Products to be registered with the competent Governmental Authority in the Territory in SONOMA's name by its authorized representative, "Mandala" and shall cause Mandala to perform a new Marketing Authorization application for the Product, if any, in order to attend the terms of this Agreement. As such, SONOMA warrants and represents that Mandala (or any successor or licensee of Mandala other than EMS, in the manner and as permitted in this Agreement) is and shall remain in compliance with all applicable Laws as well as with the terms of this Agreement during the period under which Mandala holds the Products' Marketing Authorization, and that SONOMA shall bear any claims, costs, damages and liabilities related to any violation of Mandala's regulatory obligations or compliance with the applicable Laws or any obligations required to be performed by Mandala in accordance with the terms of this Agreement.

- 4.1.2 As long as the Mandala remains responsible for procuring the Marketing Authorization for the Products, subject to the provisions of “Section 4.1.3”, SONOMA will bear all costs related to the filing for Regulatory Approvals, including, but not limited to translation costs, filing and approval fees. If at any time EMS and SONOMA enter into an amendment allowing EMS to assume responsibilities for obtaining and maintaining the Marketing Authorizations, for the Products, EMS will bear all costs related to the Marketing Authorization.
- 4.1.3 SONOMA will keep EMS informed in writing of all communications with the competent Governmental Authorities and will send one copy of the Product Marketing Authorizations to EMS within 15 (fifteen) Business Days after they have been granted by the competent Governmental Authorities and published at the Brazilian Official Gazette (Diário Oficial da União – D.O.U.). SONOMA shall be liable for compliance with this provision during the term of this Agreement, unless otherwise provided in an amendment to this Agreement signed by the Parties.
- 4.1.4 Retention of Samples. At no additional costs to SONOMA, EMS agrees to store and retain, from the Finished Products purchased from SONOMA, an appropriate number of samples (identified by batch number) of Finished Product it distributes within the Territory to permit required internal and regulatory checks and references.
- 4.1.5 Costs. SONOMA will be responsible for all costs associated with the maintenance and procurement of the Marketing Authorization in connection with the Marketing and Distribution of the Product in the Territory. However, if any tests or studies are required to be performed for the procurement or maintenance of the Marketing Authorization EMS agrees to discuss about perform such tests or studies, subject to the provisions set forth under Section 4.18, and the samples required for the performance of such tests or studies shall be supplied by SONOMA to EMS, free of charge, and in the amount sufficient to comply with registration purposes and the costs will be beared by SONOMA.

#### **Renewal**

- 4.1.6 SONOMA shall handle, or cause to be handled, at its own cost and discretion all formalities and actions which shall be necessary to maintain or renew the effectiveness of the Regulatory Approvals of the Product in the Territory. The Parties will cooperate with each other to provide all reasonable assistance and take all actions reasonably requested by SONOMA that are necessary to comply with the renewal process.

#### **Change Management**

- 4.1.7 During the course of this Agreement, if either SONOMA or EMS wish to or is required to make a Change, the Parties agree that:
- a) If either Party is requested to implement a Change by the other Party as result of a demand made by a Governmental Authority, the other Party shall use its best efforts to fulfil Governmental Authority requirements. The Party requested to implement a Change under this Section “4.1.7” shall, as soon as practicable, provide the other Party requesting the implementation of a Change with relevant data and information necessary to inform and obtain approval of the Change before the Governmental Authority.

- b) Should SONOMA or EMS need to implement a Change as a sole consequence of a request of a Governmental Authority of the Territory prior to ANVISA granting Marketing Authorization, SONOMA shall bear the costs arising out of such Change (including a Change related to GMP), and the Parties will use commercially reasonable efforts to accommodate such Change, in accordance with Section “4.1.7.a” above. In the event that the requested Change is related to Approved Facility, SONOMA shall use commercially reasonable efforts to implement the requested Change to the extent permitted by applicable local Laws of the country of where the Approved Facility is located.
  - c) Should SONOMA be required to implement a Change (other than as provided in Section 4.1.7.d.) as a sole consequence of a demand from a Governmental Authority other than from the Territory, SONOMA shall bear the costs arising out of such Change, in accordance with the Section 4.1.9.
  - d) If EMS requests a Change that is not required by any Governmental Authority, SONOMA shall as soon as practicable review such proposed Change and may provide EMS with its likely effect on SONOMA’s production systems together with the investment and/or cost necessary to implement such Change. If EMS wishes to proceed, and SONOMA approves (which approval shall not be unreasonably withheld), SONOMA shall use commercially reasonable efforts to implement such Change within a reasonable time. Notwithstanding the immediately preceding sentence, SONOMA may, at its sole discretion, reject any Change proposed by EMS except for Changes mandated by Governmental Authority in the Territory and to the extent permitted by applicable local Laws of the site of SONOMA’s Approved Facility. The cost arising out of such Change shall be borne by EMS. If any such Change increases SONOMA’s Cost of Goods, the Parties shall negotiate in good faith on a new purchase price.
- 4.1.8 If modifications, additions or Changes to the Dossiers become necessary for the granting of EMS Marketing Authorization by the Governmental Authority of the Territory or for its maintenance during the Term of this Agreement, EMS undertakes to bear all related costs up to a budget of USD 20.000,00 (Twenty thousand US Dollars). If the necessary investments exceeds the USD 20.000,00 (Twenty thousand US Dollars) budget, the Parties will discuss in good faith if the remaining difference could be procured. If the Parties do not come to an agreement regarding the remaining difference and its procurement either Party may terminate the Agreement.
- 4.1.9 If modifications, additions or Changes to the Dossiers become necessary for the granting or maintenance of the Marketing Authorization due to a requirement of a Governemental Authority other than from the Territory, SONOMA undertakes to bear all related costs up to a budget of USD 20.000,00 (Twenty thousand US Dollars). If the necessary investments exceeds the USD 20.000,00 (Twenty thousand US Dollars) budget, the Parties will discuss in good faith if the remaining difference could be procured. If the Parties do not come to an agreement regarding the remaining difference and its procurement either Party may terminate the Agreement.
- 4.1.10 SONOMA shall not and shall cause Mandala (or any other contracted third party or licensee) not to make any Change in the Brazilian Dossiers or in the Approved Dossiers nor to make any modifications in the Product without prior written consent of EMS. In case of changes due to Governmental Authorities’ request, EMS will not unreasonably withhold its consent to such modification or variation. SONOMA shall be liable for compliance with this provision during the term of this Agreement, unless otherwise provided in an amendment to this Agreement signed by the Parties. Mandatory Changes required by the Governmental Authorities in the Territory do not require the consent of EMS, but any such Change shall be duly notified in advance to EMS.

## Product Change Management

- 4.1.11 During the Term of this Agreement, if the manufacturer of the Product (approved in the Marketing Authorization) wishes or is required by a Governmental Authority to make a Change, the Parties agree that SONOMA shall, as soon as practicable, inform EMS of such Change promptly. SONOMA shall provide the appropriate Regulatory Authority and EMS with relevant data and information necessary to inform and obtain approval of the Change before the Governmental Authority in the Territory. No change shall be implemented without the prior approval of the appropriate Governmental Authority in the Territory.

## Communication with Regulatory Authorities and Others

- 4.1.12 SONOMA agrees to meet all standards and take all actions required by Law in order to obtain and maintain, at its sole cost and expense, any and all Regulatory Approvals required by a Governmental Authority in relation to the Product in the Territory:
- i. Filing of documents. SONOMA will be responsible for the validation of the pertinent documents to be submitted to Governmental Authorities and the filing of all submissions relating to the Regulatory Approvals of the Product in the Territory and the Parties agree to comply with reasonable timelines established and periodically reviewed by the Parties for such submissions and according to applicable local Laws in force in the Territory.
  - ii. Governmental Authority Communications. SONOMA will be responsible for interfacing, corresponding and meeting with all Governmental Authorities in the Territory with respect to the Product during the period under which the Products are registered under its own name through Mandala.
  - iii. Information. Upon the reasonable request of SONOMA, EMS will provide to EMS within the period instructed by Governmental Authority such information in its possession relating to the Product as may be required for the foregoing regulatory activities and also provide reasonable assistance to SONOMA in complying with all regulatory obligations and Laws in the Territory.
  - iv. Cooperation. The Parties will cooperate with each other to provide all reasonable assistance and take all actions reasonably requested by either Party that are necessary to comply with any applicable laws.
  - v. Medical Inquiries for the Product. EMS will be responsible for handling all medical questions or inquiries for the Product in the Territory and shall consider all input from SONOMA in connection therewith. SONOMA will immediately forward any and all medical questions or inquiries which it receives in relation to the Product in the Territory to EMS in accordance with all applicable Laws.

## 4.2 Recall

- 4.2.1 Records. During the Term of this Agreement and for a period of three (3) years after the end of the Term, EMS shall keep and maintain records of all sales and other distributions of Products made by EMS or its Affiliates or sub distributors sufficient to effectively, efficiently and economically implement any recall or investigation of any Product, but at a minimum the Term, EMS shall keep and maintain records of all sales and other distribution of Products containing information about:
- i. Supplier Product description;
  - ii. Supplier Product lot number;
  - iii. Customer identification (name and location);
  - iv. Product Manufacturing date;
  - v. Shelf-life of the Product; and
  - vi. Shipping date.

- 4.2.1.2 Upon SONOMAS's request, EMS shall make such records available to SONOMA
- 4.2.2 Complaints. All complaints received by EMS shall be communicated to Mandala and SONOMA.. All traceability information accompanied by such complaint shall be made available to SONOMA. The Parties will endeavor to sign the Quality Agreement within a reasonable period of time but not later than eight (8) months from the first Marketing of the Product. Until the Quality Agreement is duly executed between the Parties, the Parties shall perform its activities under this Agreement in accordance with good industry standards and local practice for cosmetics products, and shall attend all Applicable Law and Governmental Authorities requirements for quality control, quality assurance activities.
- 4.2.3 Recall. The Parties shall cooperate fully with one another in any of the following events involving a recall of Product resulting in a market withdrawal covered by this Agreement, including any correction, post-sale warning or mailing of information (each, a "Recall"):
- i. A Recall is requested or ordered by a Governmental Authority due to the Products not meeting the labelling or manufacturing related issues or requests a Recall for Product quality or manufacturing related issues;
  - ii. A Recall is requested or ordered by a Government Authority issued due to off-label promotion, illegal marketing or misrepresentation of Product quality or attributes; and
  - iii. Any Recall other than those specified in (i) and (ii) above.
- 4.2.3.1 Each Party shall inform the other Party in writing on a reasonable timely basis in light of the events concerning any Product related issues that have the potential to result in a Recall in the Territory or elsewhere if impacting this Agreement. SONOMA and EMS and its Affiliates and Sub Distributors shall further cooperate with one another using reasonable efforts and acting in good faith in conducting a Recall. The Parties will provide reasonable assistance to each other to investigate the root cause(s) related to a Recall subject to this Agreement.
- 4.2.3.2 The Parties will endeavor to sign the Quality Agreement within a reasonable period of time but not later than eight (8) months from the first Marketing of the Product. Until the Quality Agreement is duly executed between the Parties, the Parties shall perform its activities under this Agreement in accordance with good industry standards and local practice for cosmetics products, and shall attend all Applicable Law and Governmental Authorities requirements for quality control, quality assurance activities.
- 4.2.3.3 The out-of-pocket costs and expenses incurred in connection with a Recall under subsection (i) shall be borne by SONOMA; the out-of-pocket costs and expenses incurred in connection with a Recall under subsection (ii) shall be borne by EMS; the out-of-pocket costs and expenses incurred in connection with a Recall under subsection (iii) shall be borne by SONOMA and EMS on a 50%-50% basis.

## **5. TERMS OF IMPORTATION, PURCHASE AND SUPPLY**

- 5.1 During the term of this Agreement, EMS shall:
- a) Purchase its requirements of the Product from SONOMA at the price set out in Schedule 1 hereto. Except if otherwise provided in this Agreement, or agreed to by the Parties in writing, the Product prices set forth in Schedule 4 are fixed during the Term;

- b) at all times have suitable resources and shall hold all administrative permits to register, import, handle, store, Market and Distribute the Product in the Territory. Costs for licenses and permits necessary to import, Market, Distribute the Product as well as taxes, duties, levies and other charges in the Territory shall be borne by EMS. Any customs, fees, fines or penalties applied to EMS by the Governmental Authority due to misinformation, errors, gross negligence or willful misconduct of SONOMA shall be borne exclusively by SONOMA;
- c) make all payments through wire transfer within seventy-five (75) days after receipt of the respective Invoice;
- d) provide SONOMA on a monthly basis on or before the 10<sup>th</sup> Business of each month, a non-binding rolling 12 (twelve) month's forecast, broken down by month, of its estimated requirements of Product for the next 12 (twelve) months (the "Forecast");
- e) purchase a quantity of Products in each Contract Year equivalent to the amounts in USD stated in Schedule 4 of this Agreement. Such amounts comprehend the entire portfolio of Products and do not refer to any specific Product. As such, the Parties agree that EMS is not obligated to purchase any minimum amount of any individual Product. In the event that EMS fails to make purchases of Products at least equal to the Minimum Annual Purchase Amount set forth in Schedule 4, EMS shall have up to six months to make Product purchases equal to the difference between the Minimum Annual Purchase Amount for the applicable Contract Year and the amount actually received by SONOMA in such Contract Year (the "Deficit Amount"), in which case the Deficit Amount shall be counted for the preceding Contract Year, and shall not be counted for the then current Contract Year in which it is paid. If EMS cannot achieve the current Minimum Purchase Amount in the following Contract Year with the addition of the Deficit Amount of the preceding Contract Year, SONOMA shall be entitled to cancel EMS' exclusivity for the Products in the Territory or to terminate the Agreement pursuant to Section 9.4.a. Under no circumstances shall EMS be liable to pay any amounts or to purchase any quantities of Products in the event that, despite good faith efforts, EMS fails to achieve the Minimum Annual Purchase Amount or the Deficit Amount. Revocation of exclusivity or termination, in whole (if the noncompliance is in regard to all Products under this Agreement) or in part (if the noncompliance is in regard to one or more Products, but not to all Products at such given moment, under this Agreement) of this Agreement shall be SONOMA exclusive remedy under this Agreement.
- f) provide SONOMA a Purchase Order for the Product specifying the quantity of Products and desired delivery date, which shall not be less than 60 (sixty) days prior to the desired delivery date. Each Purchase Order shall specify such date and the quantities of the Product ordered. The Parties can agree a shorter delivery date for any single Purchase Order only if SONOMA accepts such Purchase Order in writing, and, if so accepted by SONOMA, such delivery time will supersede the sixty (60) day delivery time for such Purchase Order);
- g) handle and store all Products in good condition and in compliance with the applicable Laws, regulations and specific handling and storage instructions provided by SONOMA or contained in the Approved Dossier until their resale to customers;

- h) Market and Distribute the Product bearing the appropriate EMS Trademarks and SONOMA Trademarks that are required to be set forth on the Packaging Materials in compliance with applicable Law and the Approved Dossier and as provided herein, and showing all printed information required and in accordance with the Approved Dossier, applicable Laws in force in the Territory, including the wording Microcyn Technology as described on Schedule 3 of this Agreement;
- i) refrain, without SONOMA's prior written consent, from (i) any modification to the delivered Product or (ii) using or disposing of the Product for any purpose other than the purpose permitted hereunder or by applicable Law;
- j) monitor and control the stocks of the Product and comply with all applicable Laws as well as any specific instructions for the Product as set forth in the Approved Dossier. EMS will bear the risk for expired Product delivered in accordance with the agreed shelf-life, as per Section 5.2.c;
- k) This Agreement is entered into by EMS considering the reference currency exchange rate from Brazilian Reais (BRL) to United States Dollars (USD) as published by the Brazilian Central Bank on the day of the execution of this Agreement. During the term of this Agreement, at the time of the first purchase order placement and then on an annual basis (counted from such first purchase order) if the exchange rate fluctuates more than 20% (twenty) compared to the reference rate, and such a fluctuation is in place for a continuous period of more than three (3) months the Parties agree to renegotiate in good faith the Product supply prices set forth herein. In case the Parties do not reach an agreement, this Agreement may be terminated by either Party upon 6 (six) months prior written notice without penalties or damages of any kind, be it direct, punitive, exemplary, special, indirect, incidental or consequential, including, without limitation, loss of profits, loss of business or loss of goodwill.

5.2 During the term of this Agreement, SONOMA shall:

- a) within 10 (ten) business days from the receipt of each Purchase Order, accept in writing to EMS the respective Purchase Order as long as the amount ordered is no more than the amount forecasted in the Forecast for the relevant month specified in Section 5.1(d). If a Purchase Order exceeds the amount forecasted for the relevant month in the Forecast, SONOMA may accept all or part of the amount ordered exceeds the Forecast amount. SONOMA shall not be entitled to reject any Purchase Order, as long as the Purchase Order is consistent with the agreed Forecast and complies with Section 5.1.f above. If SONOMA does not expressly accept or reject the Purchase Order within the aforementioned period, the Purchase Order shall be deemed accepted as to the amount that is consistent with the Forecast, and the delivery date shall be sixty (60) days from the date of receipt of such Order. Any variation to this commitment will be managed by exception and agreed, in good faith, between the Parties. The quantities to be delivered by SONOMA shall not vary more than 10% (ten percent) from the quantities ordered or EMS shall be entitled to reject delivery, and all costs and expenses, including taxes, duties and levies, for the return of the rejected quantities shall be borne by SONOMA;
- b) tender the ordered Product to the forwarding agent appointed by EMS on the confirmed date of delivery pursuant to paragraph (a) above. All shipment of Product shall be Ex-works, at the Approved Facility located at Industria Vidriera 81, Fraccionamiento Industrial Zapopan Norte, Zapopan, Jalisco, Mexico (INCOTERMS 2010).
- c) warrant to EMS that all quantities of the Product delivered shall (i) be in strict conformity with the Approved Dossier; (ii) have a remaining shelf-life of at least 90% (ninety per cent) of the shelf-life approved in the Marketing Authorization at the date of delivery to EMS; and (iii) be tested in accordance with the analytical methodologies related to Quality Control (QC) for batch release implemented by SONOMA and the release will be done by EMS as per Approved Dossier.

- d) replace at its own cost and as soon as possible after receipt of a written claim from EMS:
  - i. subject to such claim being made within not more than 30 (thirty) days after delivery by SONOMA of the Product in question as provided in Section 5.2(b) all quantities of the Product which are in shortage and/or present any visible defect that are not in conformity with SONOMA's warranty in Section 5.2(c).
  - ii. all quantities of the Product with defects that are not in conformity with SONOMA's warranty in Section 5.2(c) that are not readily discoverable within 30 (thirty) days (the "Latent Defects"). EMS shall promptly notify SONOMA of any Latent Defects, but not later than 10 (ten) days after the date of discovery.
  - iii. should any dispute arise between the Parties in relation to the conformity of any batch of the Product delivered to EMS, either Party shall be entitled to refer such batch to an independent expert who shall be appointed by mutual consent of both Parties and whose decision, which shall be made within fifteen (15) days from the appointment, shall be binding and enforceable upon both Parties, and the costs and fees of such expert and the transportation costs of the Product shall be borne by the Party whose views shall not be upheld by the expert's decision.
- e) warrant to EMS that the Product does not infringe any third party rights whether it be by importing, storing, selling, marketing or promoting the Product in the Territory.
- f) warrant and represent to EMS that Mandala shall cooperate fully with EMS in order to enable EMS to perform all obligations and to exercise any rights provided in this Agreement, including (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to enable EMS or EMS' Affiliates to import, transport, Market, sell and distribute the Products in the Territory, including the template letter attached hereto as Schedule 5, whenever required, , and (b) promptly informing EMS of any matters coming to Mandala's attention that may affect the performance of its obligations or the exercise of its rights provided under this Agreement.

5.3 The Parties shall negotiate in good faith further details, duties and obligations in a Quality Agreement and in a Safety Data Exchange Agreement ("SDEA") consistent with good industry standards and local practice for cosmetics products, and both agreements, when agreed to and signed by the Parties, shall be an integral part of this Agreement. The Parties will endeavor to sign the Quality Agreement and the SDEA within a reasonable period of time but not later than eight (8) months from the first Marketing of the Product. Until the Quality Agreement and the SDEA is duly executed between the Parties, the Parties shall perform its activities under this Agreement in accordance with good industry standards and local practice for cosmetics products, and shall attend all Applicable Law and Governmental Authorities requirements for quality control, quality assurance and pharmacovigilance activities.

## **6. TERMS OF DISTRIBUTION of the PRODUCT**

6.1 EMS shall Market, distribute and sell the Product to customers for use in the Field in the Territory on its own account.



6.2 During the term of this Agreement, EMS agrees that it shall:

- a) make Commercially Reasonable Efforts to promote and continue promoting the Finished Product in the Territory, using techniques and methods admissible and customary for the Marketing of health products in the Territory;
- b) sell and deliver the Finished Product to local customers in the Territory for use in the Field in the Packaging Materials and labeling as specified in Schedule 1 and in the Approved Dossier. EMS shall not modify, alter or add to, or authorize any Affiliate or sub-distributor or other Third Party to modify, alter or add to, any labelling of any Product without the prior written consent of SONOMA. EMS shall only sell the Product unexpired and in good condition;
- c) (i) use Commercially Reasonable Efforts to monitor and inform SONOMA as soon as it becomes aware of any change in the Laws and regulations applicable to the Marketing or Distribution of the Product as well as to the Regulatory Approvals in the Territory, and (ii) promptly notify SONOMA of any decision from the competent Governmental Authorities to suspend or discontinue the sale of the Product in the Territory and/or to recall the Product from the market in the Territory;
- d) forthwith notify SONOMA of any infringement, misuse, misappropriation, act of tort, unfair competition, passing off or violation relating to any Intellectual Property right of SONOMA that comes to EMS' attention. In the event of any above-mentioned infringement, misuse, misappropriation, act of tort, unfair competition, passing off or violation relating to the activities of EMS, any Affiliate, any sub distributor, or any Third Party acquiring any Product directly or indirectly from EMS, any Affiliate, any Sub distributor, or any Third Party, EMS shall cooperate with SONOMA to protect SONOMA's Intellectual Property rights;
- e) refrain from, and cause its Affiliates and Sub Distributors to refrain from, Marketing and Distributing any hypochlorous-based product in the Field, regardless of strength or form.
- f) promptly inform SONOMA of any adverse event to the Product occurring in the Territory of which EMS is notified or becomes aware as agreed in the SDEA.

6.3 During the term of this Agreement, SONOMA agrees that it shall:

- a) be responsible for all packaging and labelling of Product purchased by EMS under this Agreement.
- b) provide EMS, free of any payment, with such data already in SONOMA's possession relating to the Product as shall be reasonable for Marketing the Product in the Territory;
- b) inform EMS of adverse reaction to the Product occurring outside the Territory and known to SONOMA and as agreed in the SDEA;
- c) maintain, during the Term of this Agreement all applicable licenses, permits, authorizations and GMP certificates necessary to manufacture and sell the Products as provided herein;
- d) SONOMA shall have control over the commencement, prosecution and settlement of any legal proceeding with respect to any infringement, misuse, misappropriation, act of tort, unfair competition, passing off or violation relating to any Intellectual Property rights of SONOMA. In connection with any such legal proceeding, EMS shall provide such assistance related to such proceeding as SONOMA may reasonably request; provided that SONOMA shall reimburse the expenses reasonably incurred by EMS to provide such assistance in accordance with SONOMA's request for the same. EMS shall not have any right to commence, prosecute or settle any legal proceeding with respect to any infringement, misuse, misappropriation, act of tort, unfair competition, passing off or violation relating to any Intellectual Property right of SONOMA.

- e) Any agreement or pact related to the commencement, prosecution and settlement of any legal proceeding with respect to any infringement, misuse, misappropriation, act of tort, unfair competition, passing off or violation relating to any SONOMA Trademark used on the Packaging Materials for the Finished Product and which may have a material impact on the Marketing or Distribution of Finished Products in the Territory shall be approved by EMS.

## **7. PRODUCT LAUNCH**

- 7.1 EMS shall launch the Product within following the Effective Date. The first actual sale shall be communicated to SONOMA by EMS within 15 (fifteen) days.
- 7.2 Should the launch of a Product or Finished Product not be feasible for reasons beyond either Party's reasonable control (e.g. competent Governmental Authorities refuse to issue the Marketing Authorization) neither Party shall be entitled to claim any damages or compensation from the other Party as a result of the partial termination of this Agreement for such Product. The Agreement shall remain in full force and effect in relation to any other Product or Finished Product provided herein and to which this Agreement were not partially terminated.

## **8. ARTWORK AND LABEL TEXT**

- 8.1 SONOMA shall use reasonable efforts to develop the Artwork to be used in accordance with Brazilian Laws and Marketing Authorization. All branding, labelling and marketing materials shall include reference to Microcyn technology as provided on Schedule 3.
- 8.2 The Artwork shall be developed for the Secondary Packaging using the Packaging Material Specification as further described under the "Description of Packaging Material" on Schedule 1.

## **9. TERM AND TERMINATION**

- 9.1 This Agreement shall enter into force on the Effective Date hereof and shall continue, subject to the provisions of this Section 9, for a period of five (5) years from the Launch Date ("Initial Term"). The Initial Term may be extended through written amendments executed between the Parties. Neither Party shall be entitled to make any claim or present any legal challenge as a result of the expiration or non-renewal of this Agreement under the provisions of this Section 9.1.
- 9.2 Either Party shall be entitled to terminate this Agreement upon written notice to the other Party if the other Party is in material breach of any of its obligations hereunder for reasons other than Force Majeure and, if such breach is curable, fails to remedy such breach at the end of a period of 60 (sixty) days after receipt of formal notice of breach and demand to cure such breach.
- 9.3 Either Party shall be entitled to terminate this Agreement upon written notice to the other Party if (a) the other Party is placed in voluntary or compulsory liquidation or falls into bankruptcy or ceases its activities for any reason or (b) the other Party is prevented, in full or in material part, from performing any of its obligations hereunder for reasons of a Force Majeure Event for a period of 3 (three) consecutive months or more or (c) for reasons beyond either Party's reasonable control, the competent Governmental Authorities refuses to renew the Regulatory Approvals or revokes the Regulatory Approvals or any other license or permit necessary to import, Market or Distribute the Product in the Territory, or (d) if both parties fail to reach an agreement upon mutually acceptable revised prices for the Product pursuant to Section 5.1.k.
- 9.4 SONOMA may terminate this Agreement with immediate effect by providing written notice:
  - a) in the event that EMS fails to make purchases of Products at least equal to the Minimum Annual Purchase Amount in any Contract Year and to make Product purchases equal at least the Deficit Amount in the 6 month following the end of such Contract Year as provided in Section 5.1(f);

- b) if two (2) consecutive payments from EMS to SONOMA are delayed by more than 30 (thirty) days after the due date and such payments are not made within 30 (thirty) days of receipt of SONOMA's written notice to EMS in respect thereto;
- c) in the event that any Governmental Authorities takes any action or raises any objection, that prevents SONOMA from supplying and/or exporting the Product into the Territory. In this case, before termination, SONOMA and EMS shall use commercially diligent efforts to remove the objections and, if such efforts are unsuccessful, discuss in good faith an option to manufacture the Product at a Third Party premises selected by SONOMA, or at EMS' premises. If agreed, EMS and SONOMA shall use good faith efforts to negotiate a mutually agreeable amendment to this Agreement;
- d) in the event of any unauthorized use of SONOMA's technical information or Confidential Information, dossiers, registrations or registration documents.

9.5 EMS may terminate this Agreement with immediate effect by providing written notice:

- a) in the event two (2) Finished Product deliveries are delayed for more than 30 (thirty) days for reasons other than for Force Majeure Event and such delivery is not made within 30 (thirty) days of receipt of EMS' written notice to SONOMA in respect thereto;
- b) in the event any Governmental Authorities takes any action or raises any objection that prevents EMS from buying and/or importing the Product in the Territory for a period longer than 6 (six) months;
- c) in the event the Governmental Authorities require additional development for granting the Marketing Authorization which results in costs higher than the stated on Schedule 4 and if there is no common agreement on how to deal with the exceeding difference; or
- d) in the event SONOMA implements any Change without necessary Governmental Authorities approval.

## 10. CONSEQUENCES OF TERMINATION

10.1 Upon expiry as well as upon termination of this Agreement, EMS shall:

- a) within six (6) months from the termination or expiration of this Agreement, be entitled to sell all unexpired Products already delivered to EMS as provided in Section 5.2(b) subject to the terms of this Agreement, and cease using any SONOMA Trademarks immediately upon the earlier of the expiration of such period or the sale of all Product inventory; provided, however, that if SONOMA terminates this Agreement due to breach of EMS' obligations under Sections 3.1, 3.2 or 12 of this Agreement, EMS shall have no right to continue to sell the Product inventory or to use SONOMA's Trademarks.
- b) pay SONOMA all amounts related to Purchase Orders placed and not yet paid pursuant to Section 5.1(c); and
- c) return forthwith to SONOMA free of charge all documents or records, in whatever media, in EMS' possession or under its or any of its Affiliates or sub-distributors' control, except for digital backups automatically generated and stored at EMS' servers, containing SONOMA's Confidential Information, which shall continue to be subject to the confidentiality and non-use provisions of this Agreement;

- (d) refrain from using the EMS Trademarks in connection with any hypochlorous-based product in the Field, regardless of strength or form.

10.2 Upon expiry as well as upon termination of this Agreement, SONOMA shall:

- a) return forthwith free of charge to EMS, at EMS's request, all documents or records, in whatever media, in SONOMA's possession or under its or any of its Affiliates containing EMS's Confidential Information;
- b) have the right to repurchase from EMS any or all Products held by EMS in good condition at a price equal to the Product purchase price;
- c) cease using any EMS Trademark and the Marketing Authorization.

10.3 The provisions of Sections 1, 10, 11, 12, 13 and 14 shall survive for a period of 5 (five) years after the date of expiration or termination of this Agreement.

## **11. GOVERNING LAW AND SETTLEMENT OF DISPUTES**

11.1 This Agreement shall be governed by and interpreted in accordance with the laws of England.

11.2 Each Party shall use its best reasonable endeavours to settle amicably any dispute which may arise with the other Party in relation to the construction, performance or termination of this Agreement.

11.3 Any disputes, controversies, doubts or questions between the Parties whether relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or breach hereof (a "Dispute") which cannot be settled amicably shall be finally settled by arbitration by and according to the Rules of Arbitration of the London Court of International Arbitration (LCIA) by one (1) arbitrator chosen in common agreement between the Parties from the LCIA list of arbitrators. If the Parties does not reach an agreement within 30 (thirty) days from the notice of arbitration, the LCIA shall be entitled to appoint the arbitrator in accordance with its Rules. The arbitration proceedings shall be conducted in the English language and the venue of the arbitration shall be the city of London, England.

11.4 The Parties shall not disclose the arbitration procedure or its object, and shall maintain confidential all the information directly or indirectly related to the controversy submitted to arbitration.

11.5 The arbitral award shall be given in writing. It shall be binding upon the Parties and shall be enforceable in accordance with its terms and conditions. The arbitral award can be enforced in any court having jurisdiction on the Parties or on their assets.

## **12. CONFIDENTIALITY**

12.1 Receiving Party acknowledges that it received or that it shall receive Confidential Information during the Term of this Agreement, and that such Information shall be kept confidential by Receiving Party with the same degree of care given to its own Confidential Information. Receiving Party shall not make use of or disclose the Confidential Information to any third party, except for the purposes expressly authorized herein or with the express prior written authorization of the Disclosing Party involved. Confidential Information may be disclosed only to the officers, directors, consultants and employees of the Receiving Party on a need to know basis, provided that such personnel are advised and subject to obligations of confidentiality as strict as the ones established herein. Furthermore, Receiving Party is aware that it may be held liable for the acts and omissions of their officers, directors, consultants, employees or subcontractors.

- 12.2 Disclosures to Regulatory Authorities as required by Law or necessary to secure the registration, licensing and commercialization of the Products shall not be deemed as a breach of the confidentiality provisions established herein.
- 12.3 The obligations of confidentiality and non-use stated in this Section are independent of all other rights and obligations of the Parties under this Agreement and shall remain in effect beyond the termination, cancellation or expiration of this Agreement for any reason for the period provided in Section 10.3.
- 12.4 Receiving Party hereby acknowledges and agrees that any breach of or noncompliance with the confidentiality obligations stated herein may result in immediate and irreparable harm to Disclosing Party who shall be entitled to pursue any legal measures and remedies provided under the Law or in equity to prevent or cease the disclosure, as well as to repair any damages and losses.
- 12.5 Upon termination or expiration of this Agreement, or upon request of Disclosing Party, Receiving Party shall immediately return all Confidential Information received from Disclosing Party, including, but not limited to, Dossiers, registration documents, scientific information, publications or any other material deemed confidential, without making or retaining any copies.
- 12.6 If Receiving Party becomes aware or has knowledge of any unauthorized use or disclosure of Confidential Information, it shall promptly notify Disclosing Party of such unauthorized use or disclosure and, thereafter, shall take all reasonable steps to assist Disclosing Party in attempting to minimize any potential or actual damages or losses resulting from such unauthorized use or disclosure.
- 12.7 Receiving Party agrees that it shall not claim to have any rights, title or ownership over the Confidential Information, and that rights, title and ownership over the Confidential Information shall rest in Disclosing Party.

### **13. LIABILITY AND INDEMNIFICATION**

- 13.1 EMS shall indemnify, defend and hold harmless SONOMA for any loss, damage, liability, cost or expenses (including without limitation, any reasonable costs or legal fees thereby incurred by SONOMA) arising out of any demands, suits, or actions, to the extent arising or resulting from (i) death, bodily injury or damage to property caused by any fault or negligence by EMS's employees or agents in the importation, Marketing or distribution of the Product in the Territory, or (ii) any sale or Marketing not consistent with the relevant Regulatory Approval and label claims; provided that SONOMA shall (i) notify forthwith EMS of any such claim and (ii) not take any action or admit any liability or pay any amount to, or compromise with, any Third Party in respect of such claim, except with EMS's prior consent or in compliance with a court order. EMS liability is limited to the amount equal to the aggregate Minimum Annual Purchase Amount for the first five years set forth on Schedule 4.
- 13.2 EMS shall not be liable in contract, tort, negligence, breach of statutory duty or otherwise for any special, indirect, incidental or consequential damages or for any economic loss or loss of profits suffered by SONOMA, including any loss of prospective sales, investments made or expenses incurred in connection with this Agreement.
- 13.3 SONOMA shall indemnify, defend and hold harmless EMS for any loss, damage, liability, cost or expenses (including without limitation, any reasonable costs or legal fees thereby incurred by EMS) arising out of any demands, suits, or actions, to the extent arising or resulting from (i) the sale or import of Products without the necessary regulatory approval during the period SONOMA is responsible therefor, to the extent the lack of Regulatory Approval is due to SONOMA's gross negligence or willful misconduct, or (ii) manufacturing defects in the Products; provided that EMS shall (i) notify forthwith SONOMA of any such claim and (ii) not take any action or admit any liability or pay any amount to, or compromise with, any Third Party in respect of such claim, except with SONOMA's prior consent or in compliance with a court order. SONOMA liability is limited to the amount equal to the first five year forecast but it shall not exceed the amount comprised by SONOMA's liability insurance. During the Term of this Agreement SONOMA undertakes to maintain a liability insurance policy covering at least an amount equal to the aggregate Minimum Annual Purchase Amount for the first five years forecast set forth on Schedule 4.

- 13.4 SONOMA will not be liable in contract, tort, negligence, breach of statutory duty or otherwise for any special, indirect, incidental or consequential damages or for any economic loss or loss of profits suffered by EMS, including any loss of perspective sales, investments made or expenses incurred in connection with this Agreement.
- 13.5 Each of SONOMA and EMS shall maintain a liability insurance that covers Product liability for an amount up to \$5 million with a deductible of \$25,000 per claim and in the aggregate and shall name the other as an additional insured under such policy effective as of the Launch Date. Each Party shall provide the other Party evidence of this coverage upon written request.

**14. MISCELLANEOUS PROVISIONS**

- 14.1 This Agreement, its Schedules, and, when and if executed and attached hereto, the Quality Agreement and the SDEA, constitute the entire agreement between the Parties in relation to the registration, purchase, Marketing, distribution, and sale of the Product in the Territory and supersede all prior oral or written agreements between the Parties, including, without limitation, the Term Sheet, relating to the same subject matter, including without limitation each of the Parties' general conditions of sale or purchase. No change to this Agreement and/or its Schedules shall be binding upon the Parties unless it is made in a written document signed by authorized representatives of both Parties or of their legal successors. Unless otherwise expressly provided in SONOMA's order acceptance for a particular Purchase Order, as provided under Section XX of this Agreement, the terms of this Agreement shall apply to all purchases by EMS from SONOMA. Any terms or conditions proposed by EMS inconsistent with or in addition to the terms and conditions in this Agreement shall be void and of no effect unless and until specifically agreed to in a writing executed by an authorized representative of SONOMA.
- 14.2 After the Effective Date, each Party may use the other Party's name(s) and trademark(s) exclusively in order to issue a press release or public announcement of the Parties' relationship under this Agreement. EMS acknowledges that SONOMA may make a public announcement and such filings that are required under state and federal securities laws applicable to SONOMA. SONOMA shall provide the press release to EMS for approval, prior to public release and filing. Except for the foregoing, no public announcement or press release shall be made without both Parties' prior written consent as to the content of such announcement or press release.
- 14.3 Any notice required to be given by either Party to the other under this Agreement shall be validly given through overnight carrier, considered delivered after three days from posting, or through electronic mail with receipt confirmation, sent to the address of the Parties as set out hereafter or to any new address notified to the other Party:

- i. If to SONOMA to the attention of:

*Bruce Thornton, Executive Vice President; Address: 1129 North McDowell Blvd., Petaluma, CA 94954, USA*

ii. If to EMS to the attention of:

*Peter Maurice Lay, Business Development Director; Address: Rodovia Jornalista Francisco Aguirre Proença - SP 101, KM 08, Parque Odimar, Hortolândia/SP - Brazil*

- 14.4 Should any provision of this Agreement become invalid or unenforceable under applicable Laws, this shall not invalidate or render any other provision invalid or unenforceable. The invalidated or unenforceable provision shall be deleted and replaced, by mutual consent of both Parties, by a valid or enforceable provision having the same effect as, or an effect as close as possible to the effect of the original provision. If such effect is deemed illegal, such clauses shall be eliminated automatically from this Agreement, without affecting the validity of the Agreement.
- 14.5 The headings in this Agreement are for information only and will not be considered in the interpretation of this Agreement.
- 14.6 This Agreement is made in English and the English text shall prevail over its translation into any other language.
- 14.7 Neither this Agreement nor any of the rights or obligations of the Parties may be assigned or sublicensed without the prior written consent of the other Party; provided, however, that EMS may assign it to one Affiliate of EMS and that either Party may, without the consent of the other Party, assign this Agreement or any of its rights or obligations hereunder in connection with the sale of substantially all its assets; and provided, further, that any transfer or transfers of shares of either Party, or the merger of a Party with a Third Party, shall not constitute an assignment of this Agreement.
- 14.8 Any waiver of the terms and conditions hereof must be explicitly in writing and executed by a duly authorized officer of the Party waiving compliance. The waiver by either of the Parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same.
- 14.9 The relationship between the Parties is that of independent contractors and each Party agrees to conduct its affairs accordingly. Neither Party shall, by reason of this Agreement, be deemed to be a member of a partnership or joint venture with the other Party.
- 14.10 This Agreement shall be binding upon and inure solely to the benefit of SONOMA and EMS, and their respective successors and permitted assigns, and nothing in this Agreement, express or implied, is intended to or shall confer upon any Third Party any right, benefits or remedies of any nature whatsoever under or by reason of this Agreement.
- 14.11 This Agreement may be executed in three (3) or more counterparts, each of which is to be considered an original and taken together as one and the same document.

Made on the date hereof in two original copies, including one for each Party.

**Sonoma Pharmaceuticals, Inc.**

**EMS S.A.**

/s/ Jim Schutz

Name: Jim Schutz

Position: CEO

/s/ Dr. Roberto Amazonas

Name: Dr. Roberto Amazonas

Position: CEO

\_\_\_\_\_  
Name:

Position:

SCHEDULE 1

Packaging

<p>Primary and Secondary Packaging</p> <p><b>Gramaderm/Gramacyn Combo-Pack (120 g Hydrogel &amp; 120 ml Solution)</b></p>	<ul style="list-style-type: none"><li>[ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>o [ ]†</li><li>o [ ]†</li><li>o [ ]†</li><li>o [ ]†</li><li>o [ ]†</li></ul>
<p>Primary and Secondary Packaging</p> <p><b>Gramacyn (9 g Hydrogel &amp; 9 ml Solution):</b></p>	<ul style="list-style-type: none"><li>[ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>· [ ]†</li><li>o [ ]†</li><li>o [ ]†</li><li>o [ ]†</li><li>o [ ]†</li><li>o [ ]†</li></ul>

† Confidential material redacted and separately filed with the Commission.





Leaflet (PIL) <b>Gramacyn (9 g Hydrogel &amp; 9 ml Solution ):</b>	· [ ]† · [ ]† · [ ]† · [ ]†
Leaflet (PIL) <b>Epicyn/Celacyn (45 g Tube)</b>	· [ ]† · [ ]† · [ ]† · [ ]†
Leaflet (PIL) <b>Epicyn/Celacyn (9 g Tube)</b>	· [ ]† · [ ]† · [ ]† · [ ]†

† Confidential material redacted and separately filed with the Commission.

**SCHEDULE 2**

**Territory**

Federative Republic of Brazil.

## SCHEDULE 3

### Trademarks

#### Sonoma's Trademarks

Microcyn Technology



Oculus

Sonoma

#### EMS' Trademarks

Celacyn

Gramacyn

Underskin

EMS



Luxbiotech Farmaceutica Ltda

**SCHEDULE 4**

**Minimum Annual Purchase Amount and Pricing**

**Product to be supplied as Finished Products**

Sonoma Product	Supply Price
<b>Gramaderm/Gramacyn (120 g Hydrogel or 120 ml Solution)</b>	[ ]†USD
<b>Gramaderm/Gramacyn Combo-Pack (120 g Hydrogel &amp; 120 ml Solution)</b>	[ ]†USD
<b>Epicyn/Celacyn (45 g Tube)</b>	[ ]†USD
<b>Pediacycyn (45 g Tube)</b>	<b>To be defined</b>
<b>Lasercyn (Hydrogel or Spray)</b>	<b>To be defined</b>

Samples in smaller sizes to be provided at [ ]†USD / unit as per described below:

- (i) **Gramaderm/Gramacyn (9 g Hydrogel & 9 ml Solution)** : [ ]†USD (US Dollars);
- (ii) **Epicyn/Celacyn (9g Tube)**: [ ]†USD (US Dollars).

All samples shall be labeled “Not for Sale” or similar.

<b>Product description</b>	Minimum Annual Purchase Amount (US DOLLARS)				
	<b>Y1</b>	<b>Y2</b>	<b>Y3</b>	<b>Y4</b>	<b>Y5</b>
Gramaderm (US)/ Gramacyn (Brazil) (120g Hydrogel or 120ml Solution)					
Gramaderm (US)/ Gramacyn (Brazil) Combo-Pack (120g Hydrogel & 120ml Solution)	\$100,000	\$250,000	\$500,000	\$750,000	\$1,000,000
Epicyn (US) /Celacyn (Brazil) (45g Tube)					

The Term “Year” (Y) means the Contract Year. All prices agreed herein are in US Dollars (USD).

Products can be added and/or cancelled from this Schedule 4 according to mutual written agreement. SONOMA shall have the right to remove any Product that is subject to Recall.

† Confidential material redacted and separately filed with the Commission.

**SCHEDULE 5**

**Customs letter to be filled and signed for each importation**

**DECLARAÇÃO DO DETENTOR DA REGULARIZAÇÃO DO PRODUTO AUTORIZANDO  
A IMPORTAÇÃO POR TERCEIRO**

A empresa ....., CNPJ nº ....., devidamente autorizada pela ANVISA – AFE nº ....., detentora da regularização do(s) produto(s) abaixo relacionados, representada por seu responsável legal e seu responsável técnico, em concordância com o estabelecido na RDC 81, de 05 de novembro de 2008, autorizam a empresa ..... CNPJ nº ..... a realizar a atividade exclusiva de importação terceirizada.

<b>Nome comercial do produto</b>	<b>Apresentação Comercial do produto</b>	<b>Número da regularização na ANVISA</b>

Declaramos que após a importação os produtos serão expostos ao comércio ou ao consumo sob nossa responsabilidade, de forma exclusiva e intransferível, garantindo-se assim, a rastreabilidade desses produtos desde sua importação até o seu consumidor final, conforme estabelecem os incisos X do artigo 3º da Lei nº 6360, de 23 de setembro de 1976 e parágrafo 1º do artigo 15 do Decreto 8.077, de 14 de agosto de 2013.

Assume, também, o compromisso de observar rigorosamente as normas e procedimentos estabelecidos pela legislação sanitária, e está ciente das penalidades que ficará sujeita nos termos da Lei 6.437, de 20 de agosto de 1977, sempre que ficar comprovado o descumprimento dessas normas.

Esta declaração tem validade de 90 dias a contar da data de sua assinatura.

Município (UF),..... de ..... de 20 \_\_\_\_

\_\_\_\_\_  
Assinatura do Responsável Legal ou Representante Legal da  
empresa detentora da regularização do produto

\_\_\_\_\_  
Assinatura do Responsável Técnico da empresa detentora da  
regularização do produto