

# SOMAXON PHARMACEUTICALS, INC.

## FORM 8-K/A (Amended Current report filing)

Filed 05/17/12 for the Period Ending 04/26/12

Address	10935 VISTA SORRENTO PARKWAY SUITE 250 SAN DIEGO, CA 92130
Telephone	(858) 876-6500
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Industry	Biotechnology & Drugs
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K/A**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): April 26, 2012**

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**SOMAXON PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

**000-51665**  
(Commission  
File Number)

**20-0161599**  
(IRS Employer  
Identification No.)

**10935 Vista Sorrento Parkway, Suite 250,  
San Diego, CA**

(Address of Principal Executive Offices)

**92130**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 876-6500**

(Former name or former address, if changed since last report.)

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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))
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## EXPLANATORY NOTE

On May 2, 2012, Somaxon Pharmaceuticals, Inc. (“Somaxon”) filed a Current Report on Form 8-K (the “Prior 8-K”) to report that it had entered into a License Agreement (the “License Agreement”) and a Supply Agreement (the “Supply Agreement”), each dated as of April 26, 2012 with CJ CheilJedang Corporation. This amendment to the Prior 8-K is being filed solely to include a reference to the incorporation by reference of the Amended and Restated License Agreement between Somaxon and ProCom One, Inc. included as Schedule 1.57 to the License Agreement.

### Item 1.01 Material Contracts

The description of the License Agreement appearing in the Prior 8-K is qualified in its entirety by reference to the License Agreement which is being filed with this Current Report on Form 8-K/A as Exhibit 10.1 is incorporated herein by reference.

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
10.01†	License Agreement between Somaxon Pharmaceuticals, Inc. and CJ CheilJedang Corporation dated April 26, 2012.

† Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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**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.

Date: May 17, 2012

**SOMAXON PHARMACEUTICALS, INC.**

By: /s/ Matthew W. Onaitis

Name: Matthew W. Onaitis

Title: Senior Vice President and General Counsel

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.01†	License Agreement between Somaxon Pharmaceuticals, Inc. and CJ CheilJedang Corporation dated April 26, 2012.
†	Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT (INDICATED BY ASTERISKS) HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT.

**LICENSE AGREEMENT**  
**DATED AS OF APRIL 26, 2012**  
**BY AND BETWEEN**  
**S OMAXON P HARMACEUTICALS , I NC .**  
**AND**  
**CJ C HEIL J EDANG C ORPORATION**

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## LICENSE AGREEMENT

**T HIS L ICENSE A GREEMENT** (this **“Agreement”**) is made as of April 26, 2012 (the **“Effective Date”**), by and between Somaxon Pharmaceuticals, Inc., a Delaware corporation, having a place of business at 10935 Vista Sorrento Parkway, Suite 250, San Diego, California 92130, USA (**“Somaxon”**), and CJ CheilJedang Corporation, a corporation duly incorporated under the laws of the Republic of Korea with its registered address at CJ Cheiljedang Center, 330, Dongho-ro, Jung-gu, Seoul, 100-400, Korea (**“Licensee”**). Somaxon and Licensee may hereinafter be referred to individually as a **“Party”** or collectively as the **“Parties.”**

**WHEREAS**, Licensee desires to license from Somaxon and Somaxon desires to license to Licensee, on an exclusive basis, certain intellectual property rights with respect to the Licensed Product in the Territory (as hereinafter defined), subject to and in accordance with the terms and conditions of this Agreement; and

**WHEREAS**, the Parties will enter into a Supply Agreement (the **“Supply Agreement”**) concurrently with the execution of this Agreement which will set forth the terms and conditions under which Somaxon (or its Third Party manufacturers) will manufacture and supply to Licensee, and Licensee will purchase from Somaxon (or its Affiliates), all of Licensee’s, its Affiliates’, licensees’ and distributors’ requirements for bulk Licensed Product.

**NOW, THEREFORE**, in consideration of the foregoing premises and the representations, warranties, covenants and agreements herein contained, the Parties hereto, intending to be legally bound, agree as follows:

### **ARTICLE 1 DEFINITIONS**

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

- 1.1** “ **Acts** ” means the Pharmaceutical Affairs Act and the National Health Insurance Act, as either may be amended from time to time, and any and all decrees, rules, regulations, requirements, provisions, codes, and codices of the Korea Food & Drug Administration (**“KFDA”**), the Ministry of Health & Welfare (**“MHW”**), and the Health Insurance Review & Assessment Service (**“HIRA”**), in each case as delegated under the Acts as may be in effect from time to time in the Territory.
- 1.2** “ **Adverse Drug Reaction** ” means a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function.
- 1.3** “ **Adverse Event** ” means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

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- 1.4** “ **Affiliate** ” means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with, such first Person. For the purposes of this definition, “control” (including with correlative meanings, the terms “controlling,” “controlled by” and “under common control with”), as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of that Person, whether through the ownership of voting securities, by contract or otherwise.
- 1.5** “ **Agreement** ” has the meaning set forth in the Preamble of this Agreement.
- 1.6** “ **Bulk Product** ” means Licensed Product, released as a finished good, unlabeled and packaged as specified in the Supply Agreement.
- 1.7** “ **Business Day** ” means a day other than a Saturday, Sunday, or bank or other public holiday in California, USA or Seoul, Korea.
- 1.8** “ **Calendar Half-Year** ” means each six (6) month period beginning on the 1st of January or the 1st of July (including any partial calendar half-year during the Term).
- 1.9** “ **Calendar Quarter** ” means each three (3) month period beginning on the 1st of January, the 1st of April, the 1st of July or the 1st of October (including any partial calendar quarter in the case of the first or last calendar quarter during the Term).
- 1.10** “ **Calendar Year** ” means each twelve (12) month period beginning on the 1st of January and ending on the 31<sup>st</sup> of December of the same year (including any partial calendar year in the case of the first or last calendar year of the Term).
- 1.11** “ **cGCP** ” means the rules concerning current good clinical practices specified by the EU/PIC guidelines (and the corresponding national laws and regulations), the US Food and Drug Administration (or any successor entity thereto) (“ **FDA** ”) regulations codified in the U.S. Code of Federal Regulations, or any other comparable regulatory criteria or guidelines as applicable, all as amended from time to time.
- 1.12** “ **cGLP** ” means the rules concerning current good laboratory practices specified by the EU/PIC guidelines (and the corresponding national laws and regulations), the FDA regulations codified in the U.S. Code of Federal Regulations, or any other comparable regulatory criteria or guidelines as applicable, all as amended from time to time.
- 1.13** “ **cGMP** ” means the rules concerning current good manufacturing practices requirements specified by the EU/PIC guidelines (and the corresponding national laws and regulations), FDA regulations, including those set forth in 21 C.F.R. Parts 210, 211 and 606, and all similar regulatory requirements of foreign Governmental Bodies applicable to the Manufacture of the Licensed Product for Commercialization.

**1.14** “ **Change of Control** ” means:

- (a) the acquisition by any person or group of beneficial ownership of any capital stock of a Party or any direct or indirect parent of a Party, if after such acquisition, such person or group would be the beneficial owner, directly or indirectly, of securities of a Party or any direct or indirect parent of a Party representing more than fifty percent (50%) of the combined voting power of a Party’s or such direct or indirect parent’s then outstanding securities entitled to vote generally in the election of directors;
- (b) the consummation by a Party or any direct or indirect parent of a Party of a consolidation, amalgamation, merger, reorganization or arrangement with any Person or group, if the Persons who were not shareholders of such Party or such direct or indirect parent of such Party immediately prior to such consolidation, amalgamation, merger, reorganization or arrangement own immediately after such consolidation, amalgamation, merger, reorganization or arrangement more than fifty percent (50%) of (i) the continuing or surviving entity or (ii) any direct or indirect parent of such continuing or surviving entity; or
- (c) the sale, assignment, spin-off, divestiture or other transfer by a Party to any Person other than to an Affiliate in a single or series of related transactions of all or substantially all of the assets or business of a Party involved in performing all or substantially all of the obligations of such Party under this Agreement.

**1.15** “ **Commercialization** ” or “**Commercialize**” means any and all activities directed to the commercial exploitation of the Licensed Product in the Territory in the Field in accordance with applicable Laws before and after Marketing Approval has been obtained, including advertising, marketing, promoting, consumer and physician education, market and consumer research, customer services, detailing, distributing, labeling, offering to sell and selling the Licensed Product in the Territory, final packaging for commercial use and importing the Licensed Product for sale in the Territory, but specifically excluding Manufacturing. When used as a verb, “to Commercialize” and “Commercializing” means to engage in Commercialization and “Commercialized” has a corresponding meaning.

**1.16** “ **Commercialization Plan** ” has the meaning set forth in Section 4.2.3.

**1.17** “ **Commercially Reasonable Efforts** ” means (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent and good faith efforts and resources, consistent with applicable Laws, as such Party would normally use to accomplish a similar objective under similar circumstances, and (b) with respect to any objective relating to Regulatory Approval or Commercialization by a Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts such Party would normally devote to its own branded product in that particular country and at a similar stage in its product life as the Licensed Product taking into account, without limitation, scientific, development, technical, commercial and regulatory factors, target product profiles, product labelling, past performance, present and future market potential, present and future regulatory environment and competitive market conditions in the therapeutic area, the safety and efficacy of the Licensed Product and the strength of its proprietary position.

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- 1.18** “ **Commercial Sale** ” means any sale or other transfer of the Licensed Product by Licensee to a Third Party.
- 1.19** “ **Competing Product** ” means (other than the Licensed Product) any prescription oral dosage product or drug treatment for use in the treatment of insomnia in the Territory.
- 1.20** “ **Confidential Information** ” means any and all information, technical and nontechnical, written and oral, regardless of media or format, which is not published or otherwise in the public domain, relating to a Party’s business, operations, assets and products (including the Licensed Product) and information of Third Parties that a Party is obligated to keep confidential.
- 1.21** “ **Controlled** ” means, with respect to Patent Rights or Know-How, that the Party or one of its Affiliates owns in whole or in part, or has a license or sublicense to such Patent Rights or Know-How, subject to any restrictions expressly set forth in those agreements set forth on Schedule 1.21 as of the Effective Date, and with respect to Patent Rights or Know-How that Somaxon or one of its Affiliates acquires or obtains from a Third Party at any time after the Effective Date, (i) to the extent that Somaxon or an Affiliate has the right to grant a license or sublicense to Licensee pursuant to Section 2.1 and (ii) subject to any restrictions to which Somaxon or its Affiliates is subject under any applicable agreement such as field of use restrictions.
- 1.22** “ **Cover** ”, “ **Covering** ” or “ **Covered** ” means, with respect to the Licensed Product, that the using, making, having made, selling, offering for sale or importing of such Licensed Product would, but for ownership of, or the rights and license granted under this Agreement to the relevant Patent Rights, infringe a Valid Claim of the relevant Patent Rights in the country in which the activity occurs.
- 1.23** “ **Effective Date** ” has the meaning set forth in the Preamble of this Agreement.

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- 1.24** “ **Exclusivity Period**” means that period beginning on the Effective Date and ending on earlier of the date (i) that is five (5) years from the Effective Date or (ii) of Marketing Approval of a Generic Competing Product in the Territory, to which neither Licensee nor any of its Affiliates hold any rights.
- 1.25** “ **Executive Officers** ” has the meaning set forth in Section 14.2.
- 1.26** “ **Field** ” means insomnia or such other indication(s) as provided in a Marketing Approval.
- 1.27** “ **First Commercial Sale** ” means, with respect to the Licensed Product in the Territory, the first commercial sale of the Licensed Product in the Territory, after Marketing Approval has been obtained in the Territory.
- 1.28** “ **FTE** ” means the equivalent of a full-time individual’s work, at one thousand eight hundred (1,800) hours per year for a twelve (12)-month period.
- 1.29** “ **Generic Competing Product** ” has the meaning set forth in Section 2.6.
- 1.30** “ **Governmental Body** ” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, provincial, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority.
- 1.31** “ **Improvements** ” means any modifications, advances or improvements to the Licensed Product that do not require the filing of an NDA or an sNDA with KFDA.
- 1.32** “ **Indemnitees** ” has the meaning set forth in Section 12.2.
- 1.33** “ **KGMP** ” shall mean Korean good manufacturing practices requirements specified by KFDA regulations applicable to the Manufacture of the Licensed Product for Commercialization.
- 1.34** “ **Know-How** ” means any scientific or technical knowledge, information and expertise to make or do something in any tangible or intangible form whatsoever including discoveries, inventions, trade secrets, databases, practices, protocols, Regulatory Filings, methods, processes, techniques, specifications, formulations, formulae, data and results (including pharmacological, biological, chemical, toxicological and clinical information, analytical, quality control, and stability data, studies and procedures), and manufacturing process and development information, whether or not patentable, all to the extent not Covered by a Patent Right.

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- 1.35 “ **Law** ” or “ **Laws** ” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any applicable Governmental Body, including without limitation, the Acts.
- 1.36 “ **Licensed Product** ” means Silenor <sup>®</sup> (doxepin), and all other formulations or dosage strengths of doxepin or other Improvements Controlled by Somaxon during the Term, but specifically excluding any doxepin isomers or metabolites or OTC Products, subject to Section 2.7 and 2.8.
- 1.37 “ **Licensed Technology** ” means Somaxon Patents, Somaxon Know-How and New Technology.
- 1.38 “ **Licensee** ” has the meaning set forth in the Preamble of this Agreement.
- 1.39 “ **Licensee Indemnitees** ” has the meaning set forth in Section 12.2.
- 1.40 “ **Licensee Trademarks** ” means any word, name, symbol, slogan, design or any combination thereof, owned, registered, or controlled by Licensee.
- 1.41 “ **Losses** ” has the meaning set forth in Section 12.1.
- 1.42 “ **Manufacture** ” or “ **Manufacturing** ” means any and all activities directed to the formulation, manufacture, fill/finish, testing or packaging of the Bulk Product for Commercialization in accordance with applicable Laws before and after Marketing Approval has been obtained but excluding, for greater certainty, final packaging.
- 1.43 “ **Manufacturing Know-How** ” means Know-How related to Manufacturing.
- 1.44 “ **Marketing Approval** ” means final approval of a new drug application, health registration, marketing authorization application, common technical document, regulatory submission, notice of compliance or equivalent application (excluding local and general business licenses and permits) necessary to Commercialize the Licensed Product in the Field in the Territory.
- 1.45 “ **Marks** ” means all trademarks, service marks, trade names, trade dress, logos, brand names and other indicia of origin, including all common law rights with respect thereto, and all applications for registration and registrations of any such marks and renewals for any of the foregoing, and all goodwill associated therewith.

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- 1.46** “ **Milestone** ” has the meaning set forth in Section 7.2.
- 1.47** “ **Milestone Payment** ” has the meaning set forth in Section 7.2.
- 1.48** “ **NDA** ” means a New Drug Application for the Licensed Product, as more fully defined in the Acts, as the same may be amended from time to time, together with all additions, deletions or supplements thereto.
- 1.49** “ **Net Sales** ” means with respect to each Unit sold in the Territory in an arm’s length sale by Licensee (and its Affiliates and permitted sublicensees) to a Third Party, an amount equal to “ProCom Net Sales”.
- 1.50** “ **New Technology** ” has the meaning set forth in Section 9.3.
- 1.51** “**OTC Product**” means a pharmaceutical product for insomnia containing doxepin as an active ingredient and for which a prescription from a physician or other professional is not required in order to dispense, purchase or use such product.
- 1.52** “ **Party** ” or “ **Parties** ” has the meaning set forth in the Preamble of this Agreement.
- 1.53** “ **Patent Rights** ” means any: (a) unexpired issued or granted patent or registration covering one or more inventions, including any correction, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension or renewal thereof; (b) pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction; and all inventions disclosed or claimed therein, and all associated rights granted therein or thereby.
- 1.54** “ **Person** ” means any natural person, corporation (including any non-profit corporation), general or limited partnership, limited liability company, firm, business, trust, joint venture, association, organization, or other business entity, or any Governmental Body.
- 1.55** “ **Pharmacovigilance Agreement** ” has the meaning set forth in Section 6.1.
- 1.56** “ **Phase IV Trial** ” means any research study or data collection effort for the Licensed Product in the Field in the Territory that is initiated after receipt of Marketing Approval to obtain additional information, including risks, benefits and optimal use.
- 1.57** “**ProCom Agreement**” means that certain Amended and Restated License Agreement dated September 15, 2010 by and between Somaxon and ProCom One, Inc., as the same may be further amended from time to time. The ProCom Agreement in its current form is attached hereto as Schedule 1.57.

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- 1.58** “**ProCom Net Sales**” means “Net Sales” as defined in the ProCom Agreement.
- 1.59** “**ProCom Term**” means “Term” as defined in the ProCom Agreement.
- 1.60** “**Product Labels and Inserts**” means (a) all labels and other written, printed or graphic matter affixed to any container, packaging or wrapper, or (b) package inserts, in each case to be utilized in connection with the Commercialization in the Field by Licensee.
- 1.61** “**Product Marks**” means the Marks under which the Licensed Product is Commercialized, as designated by the Parties pursuant to Section 2.4.1.
- 1.62** “**Promotional Materials**” means all written, printed, electronic and graphic materials (other than Product Labels and Inserts) provided by or on behalf of Licensee or its Affiliates in accordance with this Agreement for use by Sales Representatives in connection with the Commercialization in the Field.
- 1.63** “**Quality Agreement**” has the meaning set forth in Section 5.1.2.
- 1.64** “**Regulatory Activities**” means with respect to the Licensed Product in the Territory: (a) the preparation, review, filing and maintenance of any and all Regulatory Filings; (b) maintaining contact and communication with KFDA, MHW, HIRA and/or all other applicable Governmental Bodies; and (c) otherwise complying with all requirements of a holder of any Regulatory Approval and applicable Law.
- 1.65** “**Regulatory Approval**” means any and all approvals, authorizations, designations, licenses, or registrations, of KFDA, MHW, HIRA and/or all other applicable Governmental Bodies, necessary for the manufacture, Commercialization, use, handling, storage, import, or transport of the Licensed Product in the Field in the Territory, including Marketing Approval and any related pricing or reimbursement approvals.
- 1.66** “**Regulatory Filings**” means any applications, communications, data, documents, regardless of format or media, filed with or submitted to KFDA, MHW, HIRA and/or all other applicable Governmental Bodies for purposes of obtaining Marketing Approval or as a post-obtainment commitment or requirement relating to such Marketing Approval, including any NDA.
- 1.67** “**Sales Representative**” means a sales representative (a) employed by Licensee in the Territory, or (b) employed or contracted by a Third Party contracted by Licensee in the Territory. For the avoidance of doubt, “Sales Representative” shall not include any medical scientific personnel.
- 1.68** “**Sell-Off Period**” has the meaning set forth in Section 13.3.3(C).

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- 1.69** “ **Serious Adverse Event or Drug Reaction** ” means any untoward medical occurrence that at any dose results in death; is life threatening; requires inpatient hospitalization or prolongation or existing hospitalization; results in persistent or significant disability/incapacity; or is a congenital anomaly/birth defect.
- 1.70** “ **Somaxon** ” has the meaning set forth in the Preamble of this Agreement.
- 1.71** “ **Somaxon Indemnitees** ” has the meaning set forth in Section 12.1.
- 1.72** “ **Somaxon Know-How** ” means all Know-How Controlled by Somaxon as of the Effective Date and/or thereafter during the Term, in each case, necessary for seeking Regulatory Approval or Commercialization, and specifically including the Manufacturing Know-How.
- 1.73** “ **Somaxon Patents** ” means (a) the Patent Rights set forth on Schedule 1.73 hereto, and (b) all Patent Rights in the Territory Controlled by Somaxon following the Effective Date during the Term Covering the Licensed Product or Commercialization thereof.
- 1.74** “ **Supply Agreement** ” has the meaning set forth in the Preamble to this Agreement.
- 1.75** “ **Term** ” has the meaning set forth in Section 13.1.
- 1.76** “ **Termination Date** ” has the meaning set forth in Section 13.1.
- 1.77** “ **Territory** ” means the Republic of Korea.
- 1.78** “ **Third Party** ” means any Person other than Somaxon, Licensee or Affiliates of either of them.
- 1.79** “ **Third Party Action** ” has the meaning set forth in Section 9.7.
- 1.80** “ **Trademark** ” means each of the following Marks: (a) the Product Marks, and (b) the Somaxon name and logo designated by Somaxon pursuant to Section 2.4.1.
- 1.81** “ **Transfer Price** ” has the meaning assigned to such term in the Supply Agreement. The initial Transfer Price of the Licensed Product is set out in Schedule 1.81 attached hereto.
- 1.82** “ **Unexpected Adverse Drug Reaction** ” means an adverse reaction, the nature or severity of which is not consistent with the applicable product information.

**1.83** “ **Unit** ” means a single dose of Licensed Product.

**1.84** “ **Valid Claim** ” means a claim within the Somaxon Patents which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.

## **ARTICLE 2**

### **LICENSES AND TECHNOLOGY TRANSFER**

#### **2.1 License Grants.**

**2.1.1 Commercialization .** Subject to the terms and conditions of this Agreement, Somaxon hereby grants to Licensee an exclusive payment-bearing right and license, with the right to sublicense solely upon the prior written consent of Somaxon, not to be unreasonably withheld, delayed or conditioned, under the Licensed Technology (a) to Commercialize the Licensed Product in the Field in the Territory and (b) in order to obtain and maintain Regulatory Approvals or as otherwise approved by Somaxon in writing, to conduct Regulatory Activities in the Field. Notwithstanding the foregoing, Licensee shall be permitted to sublicense to its Affiliates upon notice to (but without requiring the consent of) Somaxon the rights granted to Licensee pursuant to this Section 2.1.1.

The foregoing license does not include the right to, and Licensee agrees that it shall not, (i) market, detail, promote, or advertise the Licensed Product for use outside the Field or (ii) commercialize in any manner the Licensed Product outside the Territory. For the avoidance of doubt, subject to the above referenced obligations of Licensee and its other obligations hereunder including its obligation to comply with all applicable Laws, the writing of a prescription in the Territory for the Licensed Product for an unapproved use shall not, in and of itself, constitute a breach of this Agreement.

**2.1.2 Manufacturing.** Subject to the terms and conditions of this Agreement, Somaxon hereby grants to Licensee a non-exclusive right and license, with the right to sublicense solely upon the prior written consent of Somaxon, not to be unreasonably withheld, delayed or conditioned, under the Licensed Technology and the Manufacturing Know-How to Manufacture Licensed Product solely for Commercialization; provided that so long as Licensee has the right to Manufacture or have Manufactured the Licensed Product, Licensee shall be permitted to sublicense to its Affiliates upon notice to (but without requiring the consent of) Somaxon the rights granted to Licensee pursuant to this Section 2.1.2. For further clarification, both Parties shall have a good faith discussion in order for Licensee to Manufacture or have Manufactured Licensed Product upon either Party’s written request. Any such grants to have Manufactured Licensed Product shall be subject to the prior written consent of Somaxon, notwithstanding the foregoing, which shall not be unreasonably withheld or delayed, or disadvantageous to Licensee relative to any other licensee of rights to doxepin. For greater certainty, Licensee shall be entitled to conduct any and all trials, studies and other requirements necessary for Manufacturing of Licensed Product, in the case of each such trial, study or requirement, with the prior written notice to Somaxon, provided, however, that in the event any such trial, study or other requirement is a clinical trial utilizing doxepin, Licensee shall procure the prior written consent of Somaxon prior to commencing such clinical trial, such consent not to be unreasonably withheld, delayed or conditioned. Licensee shall from time to time notify Somaxon of the progress of such Licensee activities after their commencement.

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- 2.1.3 Licensee Development.** Subject to the terms and conditions of this Agreement, Somaxon hereby grants to Licensee a non-exclusive right and license, with the right to sublicense solely upon the prior written consent of Somaxon, not to be unreasonably withheld, delayed or conditioned, under the Licensed Technology to conduct in the Territory any and all trials, studies and other requirements necessary for Regulatory Approval, in the case of each such trial, study or requirement, with the prior written consent of Somaxon, not to be unreasonably withheld, delayed or conditioned. Licensee shall from time to time notify Somaxon of the progress of such Licensee development activities after their commencement.
- 2.2.1 Subcontractors and Affiliates .** Either Party will be permitted to subcontract certain of its business functions or other obligations thereunder associated with the Commercialization and/or obtaining or maintaining Regulatory Approvals, such as utilizing a contract sales force, ad agency or contract safety service; provided however, that such Party will remain fully liable and responsible to the other for all actions and/or omissions of its subcontractors under this Agreement as though such actions and/or omissions of its subcontractors under this Agreement were made by such Party itself.
- 2.3 Technology Transfer ; Transfer of Somaxon Know-How.** Within a reasonable period of time after the Effective Date, Somaxon and Licensee will consult with each other in good faith to identify in writing those items of Somaxon Know-How that the Parties identify as necessary in connection with Licensee's exercise of its rights and performance of its obligations under this Agreement and to which Somaxon has access without undue effort. As promptly as reasonably practicable after the Effective Date and the identification in writing by Licensee of items from the list prepared by the Parties pursuant to the foregoing sentence (but in no event more than 30 days after such items are identified by Licensee to Somaxon in writing), Somaxon will provide to Licensee, at Somaxon's cost and expense, a copy of all such items of Somaxon Know-How identified by Licensee. The foregoing shall in no event require Somaxon to provide copies of laboratory notebooks or manufacturing run records required to be maintained by Somaxon under applicable Law. Licensee may review such notebooks or records in person upon the prior written consent of Somaxon. In addition, throughout the term of this Agreement, Somaxon shall provide to Licensee, at Somaxon's cost and expense, a copy of items of Somaxon Know-How reasonably necessary in connection with Licensee's exercise of its rights and performance of its obligations under this Agreement and to permit Licensee to continue to Manufacture Bulk Product so long as such items are reasonably accessible to Somaxon. Somaxon shall reasonably assist Licensee in the implementation of any Manufacturing arrangement in substitution of the Supply Agreement pursuant to Licensee's rights set forth in Article 5. If Somaxon maintains any such Somaxon Know-How in electronic form, Somaxon shall provide such Somaxon Know-How to Licensee in electronic form. Otherwise, Somaxon may provide such Somaxon Know-How in paper form. All Somaxon Know-How shall be in the English language, with any required authenticated translation to be provided by Licensee at no cost to Somaxon.

**2.3.2 Additional FTE Support.** In addition, Somaxon shall, at Somaxon's cost and expense, make certain of its employees who are knowledgeable about the Licensed Product or the Licensed Technology reasonably available to Licensee for scientific and technical explanations, advice and related on-site support, if and to the extent reasonably requested by Licensee and required to seek Regulatory Approval, up to a maximum of 80 hours during the first 12 months following the Effective Date, and up to twenty-four (24) hours per year thereafter during the Term (the "**FTE Support**"). Licensee shall reimburse Somaxon for any documented out-of-pocket costs associated with providing the FTE Support under this Section 2.3.2, including transportation costs associated with any on-site support requested by Licensee and costs incurred by consultants of Somaxon, provided that these costs are mutually agreed upon in writing prior to being incurred. Somaxon shall have no obligation to provide support in excess of the FTE Support limit for the applicable time period without reimbursement by Licensee for costs associated with such excess support; provided however, both Parties shall have a good faith discussion for providing support in excess of the maximum FTE Support if both Parties mutually agree. For further clarification, the details of FTE Support by Somaxon and required reimbursement for Somaxon by CJ shall be discussed and mutually agreed to by the Parties.

## **2.4 Trademarks .**

**2.4.1 Trademarks Ownership.** Licensee hereby acknowledges and agrees that, subject to the license granted to Licensee pursuant to Section 2.4.1(b), as between the Parties, Somaxon shall own all right, title and interest in and to, and shall otherwise Control, all Trademarks (excluding Licensee Trademarks) and that the ownership and all goodwill arising from the use of such Trademarks in the Territory shall vest in and inure to the sole benefit of Somaxon.

- (a) **Designation of Product Marks .** The Parties shall conduct good faith discussions on the Product Marks to be used in connection with Commercialization; provided that Parties shall designate such Product Marks no later than the date the first application for Marketing Approval is filed; provided further that, without Licensee's written consent, the Parties shall not designate any Product Mark for the Licensed Product if such Product Mark (or a derivative thereof that is acceptable to Licensee) is not available in the Territory.

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- (b) **Grant of Trademark License** . Subject to the terms and conditions of this Agreement, Somaxon hereby grants to Licensee, and Licensee hereby accepts, an exclusive license, (a) to use the Trademarks in connection with Commercialization, including the use of the Trademarks in any Licensee website, and (b) to use the Trademarks to perform the obligations and exercise the rights of Licensee in the Field in the Territory under this Agreement. Notwithstanding anything contained herein, Somaxon shall not be deemed to have violated the rights and licenses granted to Licensee pursuant to this Section 2.4.1 or Section 2.1 to the extent that commercialization activities conducted by or on behalf of Somaxon or its Affiliates via the Internet or other global electronic means or methods targeted to Persons outside of the Field and/or outside the Territory may reach Persons within the Field or within the Territory; provided that, Somaxon shall forward orders received for the Territory to Licensee.
- (c) **Trademark Use Guidelines** . Licensee shall use any Trademark hereunder only in connection with the Licensed Products and in compliance with reasonable quality standards and specifications, and shall use any trademark symbols specified under applicable Law for the purpose of identifying the Trademarks as protected under applicable trademark or similar Laws.
- (d) **No Rights in Trademarks**. Licensee acknowledges and agrees that it shall not have any rights in respect of the Trademarks (excluding Licensee Trademarks) except to the extent expressly granted in this Agreement, and that all use of the Trademarks (excluding Licensee Trademarks) in the Territory and all goodwill in the Trademarks (excluding Licensee Trademarks) shall inure to the benefit of Somaxon.
- (e) **Non-Exclusive License to Licensee Trademarks**. Licensee hereby grants to Somaxon a non-exclusive license to use and apply any of the Licensee Trademarks solely in relation to the Licensed Products in the Territory and in the Field and then solely to support Manufacture and Commercialization. Somaxon acknowledges and agrees that it shall not have any rights in respect of the Licensee Trademarks except to the extent expressly granted in this Section 2.4.1 (e), and that all use of the Licensee Trademarks in the Territory and all goodwill in the Licensee Trademarks shall inure to the benefit of Licensee. For further clarification, Somaxon shall neither use nor apply such non-exclusive license without prior written consent of Licensee in the Territory, provided that the printing of the Licensee Trademarks on Manufactured Licensed Products for use in the Territory as required by applicable Law is agreed by the Parties to not require such written consent.

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**2.4.2 Certain Obligations of Licensee** . Licensee shall not use any Mark other than the Trademarks to identify the Licensed Product in connection with Commercialization. Licensee shall not, without Somaxon's prior written consent, directly or indirectly, make any use of the Trademarks, or any Mark which is confusingly similar thereto, as part of a corporate or trade name or in connection with any product or service, other than as permitted under this Agreement.

- (a) As between the Parties, Somaxon shall have the sole right and obligation, at its cost and expense, to obtain and maintain any registration, or other form of protection, for the Trademarks (excluding Licensee Trademarks) for use in connection with Commercialization.
- (b) Licensee, at Somaxon's cost and expense, shall take such actions and provide such assistance as Somaxon may reasonably request from time to time, in connection with Somaxon filing, prosecuting or otherwise in connection with seeking any registration for any of the Trademarks (excluding Licensee Trademarks) for the Licensed Product in the Territory, and as may be reasonably necessary for Somaxon to renew, maintain, protect or enforce, any such Trademark or any pending application for registration or any registration therefor (including the filing of any applications for registration of any Trademark (excluding Licensee Trademarks) for use in connection with the Licensed Product in the Territory).
- (c) Licensee shall be permitted use Licensee Trademarks together with the Trademarks in connection with Commercialization so long as such use is in compliance with Section 2.4.1(c).

**2.4.3 Quality Control** . Upon reasonable prior written notice to the Licensee, Somaxon or its authorized representatives shall have the right to inspect at any time during normal business hours, the business premises of Licensee and its Affiliates to ensure that the character and supply of the goods used or services offered in association with the Trademarks are in compliance with the terms of this Agreement. If and as may be reasonably requested by Somaxon and necessary for it to maintain and exercise quality control over the use of any Trademarks and to protect the goodwill associated therewith, Licensee shall, at Somaxon's cost and expense, provide representative specimens to Somaxon of materials that include any Trademark (including Product Labels and Inserts and Promotional Materials). If after reviewing such representative specimens, Somaxon has a reasonable concern regarding the quality of such materials, Somaxon will notify Licensee in writing and Licensee shall take reasonable steps to address such concern. For the avoidance of doubt, Somaxon's foregoing inspection rights shall be limited to once per Calendar Year other than in the event that any such inspection reveals material concerns which have not been addressed by Licensee.

**2.4.4 Inclusion of Name on Product, Labels and Inserts** . All Product Labels and Inserts (including all packaging) for the Licensed Product shall, if and to the extent permitted by applicable Law, (a) display the name of (i) Somaxon as owner and licensor of any applicable Somaxon Patents, (ii) the applicable manufacturer, (iii) Licensee as exclusive distributor and licensee in the Territory, and (iv) the Licensed Product and Trademarks, and (b) provide that any applicable Somaxon Patents are under license to Licensee by Somaxon, in a form and manner approved by Somaxon in advance (such approval not to be unreasonably withheld, delayed or conditioned). For the avoidance of doubt, the foregoing shall not limit Licensee's obligation to include on any materials bearing the Trademarks (in whatever form or medium), a notice in the form of a brief statement or legend providing that the Trademarks are under license to Licensee by Somaxon, in a form and manner approved by Somaxon in advance (such approval not to be unreasonably withheld, delayed or conditioned) and in compliance with Section 2.4.1(c). In all instances where Licensee requires Somaxon consent under this Section 2.4.4, Licensee shall submit the relevant materials to Somaxon for its approval and Somaxon shall have a period of 10 Business Days following its receipt of such materials to reply, failing which such approval shall be deemed to have been given.

**2.4.5 Survival of Trademark License** . Except as required during the Sell-Off Period, the license to the Trademarks granted pursuant to Section 2.4.1(b) shall automatically terminate upon termination of this Agreement pursuant to ARTICLE 13 and, thereafter, Licensee shall have no right to use any Trademark (excluding Licensee Trademarks) or any Mark that is confusingly similar to any Trademark (excluding Licensee Trademarks) as determined by applicable trademark Law.

## **2.5 No Implied Licenses; Reservation of Rights** .

**2.5.1** Licensee shall have no licenses or other rights other than those expressly granted in this Agreement, and, in particular and without limiting the foregoing, nothing in this Agreement shall be construed to grant Licensee any licenses or other rights in any intellectual property rights, know-how or data owned or Controlled by Somaxon or any of its Affiliates except as provided in Sections 2.1 or 2.4.1(b).

**2.5.2** Somaxon shall have no licenses or other rights other than those expressly granted in this Agreement, and, in particular and without limiting the foregoing, nothing in this Agreement shall be construed to grant Somaxon any licenses or other rights in any intellectual property rights, know-how or data owned or Controlled by Licensee or any of its Affiliates except as provided in Section 13.3.3.

**2.5.3** Notwithstanding the exclusivity of any rights granted under Section 2.1, Somaxon hereby reserves the sublicensable right under the Licensed Technology (i) to make and have made the Bulk Product in the Territory for supply to Licensee or its Affiliates, or to the extent otherwise necessary or appropriate for Somaxon or any of its Affiliates or sublicensees to perform its obligations, under this Agreement or the Supply Agreement, on a non-exclusive basis, (ii) to make and have made the Licensed Product anywhere in the world for import, use, sale and offer for sale outside the Territory on an exclusive basis and (iii) to import, make, have made and use Licensed Product, and to use and practice the Licensed Technology to make, have made and use Licensed Product, in the Territory on a non-exclusive basis for any non clinical or clinical research purpose of Somaxon or its Affiliates, or in support of any regulatory filings or other activities outside the Territory on an exclusive basis; provided however, that Somaxon shall not commence its rights pursuant to Section 2.5.3(iii) in the Territory without the prior written consent of Licensee.

**2.6 Competing Products .** During the Exclusivity Period and except as expressly permitted under this Agreement, neither Licensee nor any of its Affiliates shall, directly or indirectly, promote, distribute, offer for sale, sell or otherwise commercialize any (a) Competing Product in the Territory, or (b) any generic prescription pharmaceutical product or drug treatment containing doxepin 3mg or 6mg as its sole active pharmaceutical ingredient and indicated for use in the treatment of insomnia (a “Generic Competing Product”) in the Territory; provided that if the Exclusivity Period expires as a result of Marketing Approval of a Generic Competing Product in the Territory, during the period beginning as of such expiration and ending five (5) years after the Effective Date, Licensee shall not commercialize any Generic Competing Product utilizing greater efforts than the efforts used to Commercialize the Licensed Products.

**2.7 Right of First Negotiation for Isomers and Metabolites.**

During the Term and for one year thereafter, Somaxon shall notify Licensee before any Third Party in the Territory in writing in the event that Somaxon desires, either alone or with a Third Party, to develop or commercialize a prescription pharmaceutical product for insomnia containing a doxepin isomer or metabolite as one or more active pharmaceutical ingredient in the Territory (a “**ROFN Product**”). If Licensee notifies Somaxon in writing within sixty (60) days after receipt of such notice (the “**Evaluation Period**”) that Licensee is not interested in obtaining rights in and to the ROFN Product in the Territory (such rights, “**ROFN Product Rights**”), or if Licensee fails to notify Somaxon of Licensee’s interest in obtaining the ROFN Product Rights prior to the expiration of the Evaluation Period, then Somaxon shall have no further obligation to Licensee under this Agreement with respect to the applicable ROFN Product and related ROFN Product Rights. If Licensee is interested in obtaining the ROFN Product Rights, it shall so notify Somaxon in writing prior to the expiration of the Evaluation Period, and upon Somaxon’s receipt of such notice Licensee and Somaxon shall promptly commence good-faith negotiations, for a period of up to sixty (60) days (or such longer period as may be mutually agreed upon by the parties in writing in the event the parties have made material progress in the negotiations) (the “**Negotiation Period**”), regarding the commercially reasonable terms of an agreement pursuant to which Licensee shall obtain the ROFN Product Rights. If Somaxon and Licensee have failed to enter into an agreement for the ROFN Product Rights upon the expiration of the Negotiation Period, then Somaxon shall thereafter have the right to negotiate and enter into an agreement with a Third Party granting the ROFN Product Rights to a Third Party. The provisions of this Section 2.7 shall not apply to, and Somaxon shall have no obligation to Licensee under this Section 2.7 in respect of, any acquisition of Somaxon by a Third Party, any merger or consolidation with or involving Somaxon, any acquisition by a Third Party of any material portion of the stock of Somaxon, or any acquisition by a Third Party of a material portion of the assets of Somaxon in addition to the Products (“**Merger Transaction**”). For clarity, the rights set forth in this Section 2.7 shall survive the consummation of any Merger Transaction.

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## 2.8 Future right for OTC Products.

Upon request from Licensee, the Parties shall enter into a good faith discussion relating to a potential business relationship in the Territory for OTC Products.

### ARTICLE 3 REGULATORY MATTERS

#### 3.1 Regulatory Activities .

- 3.1.1 Licensee Regulatory Obligations .** Licensee shall, at its sole cost, subject to the applicable terms and conditions of this Agreement, (i) use Commercially Reasonable Efforts to obtain Marketing Approvals in the Territory, (ii) use Commercially Reasonable Efforts to obtain all required Regulatory Approvals to market the Licensed Product in the Field in the Territory, (iii) conduct all Regulatory Activities related to the Licensed Product in the Territory following Marketing Approval thereof, (iv) keep Somaxon informed regarding the status of regulatory submissions for the Licensed Product in the Territory to the extent that any issues arise which would reasonably be expected to adversely affect Somaxon's Manufacturing or regulatory activities outside the Territory, and (v) notify Somaxon of any actions by KFDA, MHW, HIRA or any other Governmental Body in the Territory that relate to the safety or effectiveness of the Licensed Product.
- 3.1.2 Somaxon Regulatory Obligations .** Subject to Section 2.3.2, Somaxon shall provide reasonably requested information, data, material and any other assistance to Licensee in the development of the materials required for Regulatory Activities in the Territory. Without limiting the generality of the foregoing, Somaxon, at its cost, will (i) provide Licensee with all reasonably required access to Licensed Technology, (ii) reasonably assist Licensee in resolving material issues which may arise after discussions with KFDA, MHW, and HIRA, (iii) keep Licensee informed regarding the status of regulatory submissions for the Licensed Product in jurisdictions outside of the Territory to the extent that any issues arise which would reasonably be expected to materially and adversely affect Licensee's Regulatory Activities in the Territory, (iv) notify Licensee of any changes to chemistry, manufacturing or controls (CMC) that are permitted by the Supply Agreement following receipt of a Marketing Approval for the Licensed Product, and (v) notify Licensee of any actions in jurisdictions outside of the Territory that relate to the safety or effectiveness of the Licensed Product.

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- 3.2 Communications with Governmental Bodies in the Territory.** Except as may otherwise be set forth in this Agreement or required by applicable Law, Licensee shall be responsible for and act as the sole point of contact for communications with KFDA, MHW, HIRA and any other Governmental Body in connection with the Licensed Product in the Field in the Territory, except to the extent Somaxon is required under applicable Law to make any such communications; provided that Somaxon shall be entitled to include one or more representatives of Somaxon in any in-person or other key meetings (whether in-person or telephonic) with KFDA, MHW and HIRA. Licensee shall keep Somaxon reasonably informed of its material contacts and communications (including written and material oral communications) with any Governmental Body in connection with the Licensed Product in the Territory. Licensee shall promptly provide copies to Somaxon of all such material contacts and communications (or, if applicable, minutes of any such oral communication).
- 3.2.2** Except as may otherwise be set forth in this Agreement, the Quality Agreement or the Pharmacovigilance Agreement or required by applicable Law, Licensee shall be responsible for preparing and making all reports, submissions and responses to Governmental Bodies in the Territory concerning the Licensed Product in the Field after receipt of Marketing Approval, including price reporting with respect to any of the foregoing required by applicable Law in the Territory, each in conformance with applicable Law. Licensee will prepare the initial NDA for the Licensed Product, using the Somaxon Know-How, and will file such NDA with any Governmental Body in the Territory after first consulting with Somaxon and incorporating reasonable suggestions made by Somaxon. In addition, following the first filing of the initial NDA for the Licensed Product, any amendment, supplement or other changes to the NDA (including any such amendments, supplements or other changes made following receipt of the applicable Marketing Approval) or any other Regulatory Filing shall be prepared by Licensee but no material Regulatory Filing will be filed with any Governmental Body in the Territory without first consulting with Somaxon and incorporating reasonable suggestions made by Somaxon, if such amendment, supplement or other changes are material to the Licensed Product. Licensee shall submit the relevant materials to Somaxon and Somaxon shall have the following periods of time following its receipt of such materials to reply, failing which Licensee shall be deemed to have fulfilled its consultation obligation: 10 days in the case of the initial NDA for the Licensed Product and five days in all other material instances where Licensee need consult with Somaxon under this Section 3.2.2. Each Party shall immediately inform the other Party in the event that such Party or any of its Affiliates receives any notice from any Governmental Body relating to any finding of deficiency, finding of non-compliance, investigation, penalty for corrective or remedial action or of any other compliance or enforcement action to the extent any of the foregoing could reasonably be expected to have a material adverse effect on the Commercialization, Manufacturing or supply of Licensed Product in the Field in the Territory.
- 3.2.3** All Regulatory Filings and Regulatory Approvals, including any NDA, shall be in the name of Licensee and shall be the property of Licensee.

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**ARTICLE 4**  
**COMMERCIALIZATION**

- 4.1 Cooperation Committee.** A Cooperation Committee (the “CC”) will be formed and remain in existence throughout the Term in order to manage and oversee the seeking, obtaining and maintaining of Regulatory Approvals and Commercialization.
- 4.1.1 Membership .** The CC shall be composed of two members, one member appointed by each Party. The CC member from each Party will be authorized to make decisions with respect to matters before the CC including Commercialization. Promptly following the Effective Date, each Party shall appoint its initial representative to the CC. Each Party may replace its CC representative at any time upon written notice to the other Party. Licensee’s representative will be the Chairperson of the CC. The Chairperson shall be responsible for scheduling meetings, preparing and circulating an agenda in advance of each meeting, preparing and issuing minutes of each meeting within 15 days thereafter, revising such minutes to reflect timely comments thereon, and overseeing the ratification of such revised minutes; provided, that the Chairperson shall call a meeting promptly or include items on any meeting agenda upon the written request of Somaxon and such minutes will not be formalized until the Chairperson and the representative of Somaxon review and confirm the accuracy of such minutes in writing.
- 4.1.2 Meetings .** From and after the Effective Date, the CC shall meet no less than one time per year. The Parties shall endeavour to schedule meetings of the CC at least three months in advance. Meetings for the CC shall be held in person at the primary offices of each Party on an alternating basis, by teleconference or by video conference, or as otherwise agreed by the Parties.
- 4.1.3 Responsibilities.** The CC shall:
- (a) Ensure the complete mutual exchange of all Know-How Controlled by Licensee or Somaxon necessary for the commercialization of the Licensed Product within and outside the Territory, whether such Know-How is derived by Licensee or Somaxon;
  - (b) Review and discuss the status and plan relating to all Regulatory Approvals, including any clinical or non-clinical studies conducted or planned in connection therewith;
  - (c) Oversee the preparation and implementation of the Regulatory Filings and the Commercialization Plan;
  - (d) Discuss the state of the markets for the Licensed Product in the Territory and opportunities and issues concerning the Commercialization, including consideration of marketing and promotional strategy, marketing research plans, labeling, Licensed Product positioning and Licensed Product profile issues;

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- (e) Review and approve post-Regulatory Approval activities in the Field that are proposed by Licensee pursuant to Section 4.1.4, including any trial design and implementation for Phase IV Trials, and thereafter monitor any such approved post-Regulatory Approval activities;
  - (f) Agree on a mechanism to monitor and prevent re-importation of Licensed Product into the U.S. and review the operation of such mechanism (including any needed adjustments) at each meeting of the CC;
  - (g) Discuss optimal Product Marks in the Territory in connection with Somaxon's global branding campaign for the Licensed Product;
  - (h) Discuss any Third Party Patent Rights or Know-How that may be necessary for Commercialization, as provided in Section 9.5;
  - (i) Have authority to establish one or more other committees that report to the CC and assist the CC in carrying out its responsibilities, which other committees shall be subordinate to the CC, shall have such membership and responsibilities as the CC shall determine, and may be disbanded by the CC at any time;
  - (j) Resolve, or attempt to resolve, any disputes not resolved by any subordinate committee created by the CC; and
  - (k) Perform such other functions as allocated to it in writing by the Parties from time to time.

**4.1.4 Licensee Proposals Regarding Post-Regulatory Approval Activities.** Licensee may make a written proposal to the CC regarding post-Regulatory Approval activities (including a Phase IV Trial) for the Licensed Product in the Field in the Territory. Such proposal shall include (a) any Know-How in its possession which may be relevant to the proposed activities, (b) a reasonably detailed outline of the activities including a timeline for performing such activities, (c) an estimated budget for the anticipated costs for such proposed activities, and (d) preliminary information about the expanded Commercialization risks and opportunities for the Licensed Product in connection with such proposed activities. Both Parties shall have a good faith discussion at CC Meetings as provided in Section 4.1.3 or at any other time upon both Parties' mutual agreement before implementing any activities included in such proposal(s).

**4.1.5 Decision Making; Authority .** The CC shall make its decisions by consensus, with each Party's representative having one vote. If the CC is unable to reach consensus regarding a matter before it within 15 days, then:

- (a) Somaxon shall have authority to make the final decision with respect to all issues relating to (i) Manufacturing by Somaxon to the extent conducted under the Supply Agreement, (ii) licensing of Third Party Patent Rights or Know-How, provided that such decision does not, without Licensee's consent, which consent shall not be unreasonably withheld, delayed or conditioned, materially increase Licensee's obligations (including its monetary/budget obligations) under this Agreement; and (iii) the initiation, protocol or conduct of any post-Regulatory Approval clinical trial in the Territory with the potential to materially and adversely affect the market for the Licensed Product in the United States; and

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- (b) Licensee shall have authority to make the final decision with respect to all issues relating to Regulatory Activities and Commercialization, subject to Somaxon's prior review and consultation/consent as set forth in Articles 3 and 4; provided that in all events Somaxon shall be consulted regarding pricing decisions for the Licensed Product in the Territory.

#### **4.2 Licensee Commercialization Responsibilities.**

- 4.2.1 Commercially Reasonable Efforts.** Licensee shall, at its sole cost, use Commercially Reasonable Efforts to Commercialize and shall Commercialize in compliance with applicable Law.
- 4.2.2 Commercial Diligence.** In addition to, and without limiting the foregoing general obligations of Licensee, and subject to Section 15.5, Licensee shall (a) file a Regulatory Filing in the Territory by the first anniversary of the Effective Date; provided that the Parties shall discuss in good faith the extension of such date if reasonably required by the Licensee, including in the event that KFDA, MHW and/or HIRA requires material data in addition to that included in the Regulatory Filing made by Somaxon in the United States for the Licensed Product in the Field; and (b) use Commercially Reasonable Efforts to cause the First Commercial Sale to occur within twelve (12) months of the date on which Regulatory Approval is obtained in the Territory.
- 4.2.3 Commercialization .** Licensee shall keep the CC informed with respect to its activities in support of Commercialization. Licensee shall provide the CC with a copy of its annual marketing plan with respect to the Licensed Product ( "**Commercialization Plan**" ) at least 60 days in advance of its implementation and shall update the CC with respect to any material developments thereto no less than every Calendar Half-Year. Licensee will consider Somaxon's comments on the Commercialization Plan, but, except as set forth in this Agreement, all decisions with respect to the Commercialization shall rest solely with Licensee.
- 4.2.4 Costs .** Licensee will be responsible for all costs associated with obtaining and maintaining Regulatory Approvals and for all costs associated with Commercialization (other than Somaxon's assistance pursuant to Section 3.1.2 above, or as otherwise expressly set forth in this Agreement).
- 4.2.5 Product Labels and Inserts.** Licensee shall be responsible, at its cost and expense, for all aspects of content, design and delivery of all Product Labels and Inserts, as set forth in Section 2.4 of the Supply Agreement, and the Regulatory Approvals required in connection with their use in the Territory

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**4.3 Promotional Materials** . Licensee shall be responsible, at its cost and expense, for developing and producing the Promotional Materials in compliance with all applicable Laws and Section 2.3.1(c); provided, however, that Licensee shall provide copies of all Promotional Materials to Somaxon prior to their use; provided further that Somaxon may object to any aspect of the Promotional Materials based on its inconsistency with Somaxon's global branding for the Licensed Product within 15 calendar days and Licensee shall thereafter use Commercially Reasonable Efforts to promptly resolve the objection prior to use of such Promotional Materials. Subject to the foregoing, Licensee shall use the Promotional Materials in connection with its Commercialization in Licensee's sole discretion. All Promotional Materials shall be the property of Licensee.

**4.4 Inventory Monitoring.** Licensee shall regularly monitor the purchases of Licensed Product by its distributors and sublicensees and data relating to the inventory levels and sales of Licensed Product by such distributors and sublicensees, and Licensee shall cease sales to any such distributor or sublicensee that Licensee reasonably believes, based on such data or other factors, is diverting Licensed Product for sale outside the Territory. Licensee shall notify Somaxon in writing if it becomes aware of any diversion of Licensed Product for sale outside the Territory so that the Parties may discuss actions to be taken in connection with such diversion, including without limitation, the cessation of sales contemplated under this Section 4.4.

**4.5 Certain Representations and Covenants.**

**4.5.1** Licensee has not, directly or indirectly, offered, promised, paid, authorized or given, and will not in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official (as defined below) or Other Covered Party (as defined below) for the purpose of: (i) influencing any act or decision of the Government Official or Other Covered Party; (ii) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

For purposes of this Agreement: (i) "Government Official" means any official, officer, employee or representative of: (A) any federal, state, provincial, county or municipal government or any department or agency thereof; (B) any public international organization or any department or agency thereof; or (C) any company or other entity owned or controlled by any government; and (ii) "Other Covered Party" means any political party or party official, or any candidate for political office.

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- 4.5.2** Licensee maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets, including records of payments to any third parties, Government Officials and Other Covered Parties; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.
- 4.5.3** Subject to the terms and conditions under Section 8.5.1 and upon reasonable prior written notice to the Licensee, Licensee shall permit Somaxon, at Somaxon's expense, to visit and inspect Licensee's properties, to examine its books of account and records and to discuss Licensee's affairs, finances and accounts with its officers for the sole purpose of ensuring Licensee's compliance with the representations and covenants under Sections 4.5.1 and 4.5.2, all at such reasonable times during normal business hours as may be requested by Somaxon; provided, however, Licensee may exclude information (a) if in the opinion of counsel to Licensee, such exclusion is reasonably necessary to preserve attorney-client privilege with respect to a material matter or (b) if there exists, as to Somaxon, an actual or potential conflict of interest between Somaxon and Licensee. For the avoidance of doubt, Somaxon's foregoing inspection rights shall be limited to once per Calendar Year other than in the event that any such inspection reveals material concerns which have not been addressed by Licensee.
- 4.5.4** Anti-Corruption Compliance.
- (a) In performing under this Agreement, Licensee and its Affiliates agree to comply with all applicable anti-corruption laws, including: Foreign Corrupt Practices Act of 1977, as amended ("FCPA"); the anti-corruption laws of the Territory; and all applicable laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.
  - (b) Any third party who represents Licensee or its Affiliates in connection with, or who will be involved in performing, this Agreement or any related activity, shall certify to compliance with all applicable anti-corruption laws and the obligations set forth in this Section prior to any involvement in activities pursuant to this Agreement or any related activity.
  - (c) Licensee is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.
  - (d) No political contributions or charitable donations shall be given, offered, promised or paid at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity, without Somaxon's prior written approval.

- (e) In the event that Licensee violates the FCPA, the anti-corruption laws of the Territory or any applicable anti-corruption law or breaches any provision in this Section 4.5, Somaxon shall have the right to unilaterally terminate this Agreement. In addition, Licensee shall defend, indemnify and hold harmless Somaxon from and against any and all costs, damages, losses, liabilities, expenses, judgments, fines, settlements and any other amounts of any nature, including reasonable attorneys' fees arising from any improper payment made in violation of the FCPA, any applicable anti-corruption laws or this Section 4.5, directly or indirectly, by, on behalf of or with the knowledge of Licensee, in relation to this Agreement.

## **ARTICLE 5 MANUFACTURING AND SUPPLY**

- 5.1 Somaxon Supply Obligations; Supply Agreement** . The Parties will enter into a Supply Agreement concurrently with the execution of this Agreement. The Supply Agreement sets forth the terms and conditions under which Somaxon (or its Third Party manufacturers) will manufacture and supply to Licensee, and Licensee will purchase from Somaxon (or its Affiliates), Licensee's or its Affiliates' requirements for Bulk Product.
- 5.1.2 Quality Agreement.** Within 90 days after the Effective Date, the Parties shall begin to negotiate in good faith a mutually acceptable quality agreement with respect to the Licensed Product (the "**Quality Agreement** "). Each Party shall assign a dedicated representative to ensure that the Quality Agreement is signed and adopted by both Parties within 180 days after the Effective Date. Pending execution of the Quality Agreement, the provisions of the Supply Agreement shall prevail. Upon execution of the Quality Agreement, the terms and conditions of such Quality Agreement shall be incorporated into the Supply Agreement and the terms and conditions of the Supply Agreement with respect to quality shall be superseded by such Quality Agreement.
- 5.1.3 Other Supply Terms.** Somaxon will use good-faith efforts to permit Licensee (i) to Manufacture the Licensed Product for its requirements for Commercialization and (ii) to establish a direct arrangement with its Third Party contract manufacturers of the Licensed Product for direct purchase of Bulk Product for Commercialization. In addition, the Supply Agreement will set forth the terms and conditions under which Licensee may establish a second source of supply from a contract manufacturer of Bulk Product for Commercialization. Any such supply terms shall be subject to the prior written consent of Somaxon, notwithstanding the foregoing, which shall not be unreasonably withheld or delayed, or disadvantageous to Licensee relative to any other licensee of rights to doxepin.
- 5.2 Price and Payment. Transfer Price** . Licensee shall purchase Licensed Product from Somaxon as Bulk Product, at the Transfer Price for each Unit, as set forth in the Supply Agreement.

**5.2.2 Invoicing and Payment** . Somaxon shall submit invoices to Licensee for purchased Bulk Product promptly after delivery of such Bulk Product in accordance with the Supply Agreement. Licensee shall pay Somaxon for each shipment of Bulk Product in the amount invoiced within 30 days after receipt of the applicable invoice, unless such shipment is rejected by Licensee pursuant to the applicable provisions of the Supply Agreement .

## **ARTICLE 6 PHARMACOVIGILANCE AND QUALITY ASSURANCE**

- 6.1 Pharmacovigilance Agreement** . Within 90 days after the Effective Date, the Parties shall begin to negotiate in good faith a process and procedures for sharing Adverse Drug Reaction and Serious Adverse Drug Reaction information which shall be documented in a pharmacovigilance agreement with respect to the Licensed Product (the “**Pharmacovigilance Agreement**”). Each Party shall assign a dedicated representative to ensure that the Pharmacovigilance Agreement is signed and adopted by both Parties within 180 days after the Effective Date. Pending adoption of such agreement, the provisions of this Agreement shall prevail. Upon execution of the Pharmacovigilance Agreement, the terms and conditions of such Pharmacovigilance Agreement shall be incorporated in this Agreement and the terms and conditions of this Article 6 shall be superseded by such Pharmacovigilance Agreement.
- 6.2 Notification** . After receipt of the applicable Marketing Approval, Licensee shall notify KFDA, MHW, HIRA and other appropriate Governmental Bodies in the Territory in accordance with applicable Laws, and shall notify Somaxon promptly (but in all events within five (5) Business Days), in each case after receipt of information with respect to any Adverse Drug Reactions and Adverse Events (including Unexpected Adverse Drug Reactions and Serious Adverse Events or Adverse Drug Reactions) attributable to the use or application of Licensed Product in the Territory. With respect to the use or application of the Licensed Product outside of the Territory, Somaxon shall notify appropriate Governmental Bodies outside the Territory in accordance with applicable Laws, and shall notify Licensee, promptly after receipt of information with respect to any Adverse Drug Reactions and Adverse Events (including Unexpected Adverse Drug Reactions and Serious Adverse Events or Adverse Drug Reactions) attributable to the use or application of Licensed Product outside the Territory.
- 6.3 Reporting** . Licensee shall be responsible for preparing, processing, assessing, and submitting aggregate and periodic reports and expedited reports pertaining to Adverse Drug Reactions and Adverse Events (including Unexpected Adverse Drug Reactions and Serious Adverse Events or Adverse Drug Reactions) attributable to the use or application of the Licensed Product in the Territory as required by Governmental Bodies in the Territory. As between the Parties, Somaxon shall be responsible for preparing, processing, assessing, and submitting aggregate and periodic reports and expedited reports pertaining to Adverse Drug Reactions and Adverse Events (including Unexpected Adverse Drug Reactions and Serious Adverse Events or Adverse Drug Reactions) attributable to the use or application of such Licensed Product outside the Territory as required by Governmental Bodies outside the Territory. At each Party’s request and expense, the other Party shall reasonably cooperate with the requesting Party in connection with the requesting Party’s reporting responsibilities under this Section 6.3.

- 6.4 Literature Reports** . Somaxon shall be responsible for screening published scientific and medical literature for individual case safety reports related to the Licensed Product within and outside the Territory.
- 6.5 Medical Information** . Licensee shall be responsible for responding to all medical information requests in connection with the Licensed Product originating in the Territory. As between the Parties, Somaxon shall be responsible for responding to all medical information requests in connection with the Licensed Product originating outside the Territory. In the event Licensee receives a medical information request originating outside the Territory, Licensee shall forward the medical information request to Somaxon. In the event Somaxon receives a medical information request originating in the Territory, Somaxon shall forward the medical information request to Licensee. Somaxon shall be responsible for maintaining an electronic database for use in responding to medical information requests in connection with the License Product; Somaxon shall permit Licensee to have access to and use of such database at no cost.

**ARTICLE 7  
FINANCIAL CONSIDERATION**

- 7.1 Up-Front Payment** . Within thirty (30) Business Days from the Effective Date, Licensee shall pay or cause to be paid to Somaxon a fee of Six Hundred Thousand US Dollars (US \$600,000), in partial consideration of Somaxon’s grant of the rights and licenses to Licensee in the Licensed Technology in the Territory hereunder.
- 7.2 Milestone Payments** . In partial consideration of Somaxon’s grant of the rights and licenses to Licensee in the Licensed Technology in the Territory hereunder, Licensee shall pay or cause to be paid to Somaxon the following one-time payments upon the first occurrence of each of the following milestones (each, a “**Milestone**”, and each such amount, a “**Milestone Payment**”):

Milestone	Milestone Payment
First Commercial Sale	***
Achieving aggregate Net Sales of Licensed Product of *** in any period of 12 consecutive months in the Territory	***
Achieving aggregate Net Sales of Licensed Product of *** in any period of 12 consecutive months in the Territory	***

\*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 7.2.1 Notice** . Licensee shall provide Somaxon written notice of achievement of the Milestones set forth above within 15 days of the last day of the Calendar Quarter in which any such Milestone is achieved.
- 7.2.2 Payment** . The Milestone Payments to be made under this Section 7.2 shall be due and payable within thirty (30) days after notice that the applicable Milestone has been achieved. Milestone Payments shall be made according to Section 8.1. Each Milestone Payment to be made under this Section 7.2 shall be due and payable only once, if at all.
- 7.3 Additional Payments for Licensed Product** . In addition to the payments due under Sections 5.2, 7.1 and 7.2, as further consideration of Somaxon's grant of the rights and licenses to Licensee in the Licensed Technology in the Territory hereunder, Licensee shall, during the Term, pay or cause to be paid to Somaxon, subject to Section 7.3.2, a transfer fee (" **Royalty** ") equal to \*\*\* of the aggregate annual Net Sales in the Territory; provided, however, that to the extent that Licensee is successful in \*\*\*, then such Royalty percentage shall be \*\*\* .
- 7.3.1 Payments**. The payments of Royalties to be made under this Section 7.3 shall be due and payable within 45 days after the last day of each Calendar Quarter, according to Section 8.1.
- 7.3.2 Reduction of Royalties Upon \*\*\***. Upon \*\*\*, the Royalties shall be \*\*\* for the applicable Calendar Quarter and thereafter; provided that in the case where \*\*\*, such Royalties shall be \*\*\* for the applicable Calendar Quarter and thereafter.
- 7.4 Consideration** . The payment provisions under this Agreement have been negotiated for the convenience of the Parties as a way of estimating the fair value of the rights granted hereunder to Licensee with respect to the Licensed Product.

## ARTICLE 8

### PAYMENT; REPORTING; AUDITING

#### 8.1 Mode of Payment and Conversion .

- 8.1.1 Mode of Payment**. Any payments made by one Party to the other Party under this Agreement shall be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at the paying Party's election, of immediately available funds in the requisite amount to such bank account as the receiving Party may from time to time designate by written notice to the paying Party at least 10 days before the payment is due. The Parties may vary the method of payment set forth herein at any time upon mutual agreement, and any change shall be consistent with the local Law at the place of payment or remittance.

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\*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**8.1.2 Conversion.** Any payments relating to transactions in a foreign currency shall be converted into United States dollars in accordance with applicable accounting standards using a methodology which is consistently applied by Licensee with respect to external reporting (including any annual, regular or periodic reports and registration statements that Licensee may file or be required to file with any Governmental Body pursuant to applicable Laws), or, if Licensee does not report externally, then in a manner consistent with the methodology used by Licensee to present its financials to institutional lenders in the context of financing transactions, applicable to transactions under exchange regulations for the particular currency during the accounting period for which such payment is due.

## **8.2 Reports .**

**8.2.1** Within 35 days after the last day of each Calendar Quarter following the First Commercial Sale, Licensee shall deliver to Somaxon a detailed written report of gross sales of the Licensed Product in the Territory, including the number of Units sold, Net Sales of the Licensed Product, including all permitted deductions from gross sales or reductions to gross sales taken by Licensee in accordance with this Agreement, and the calculation of the Royalties thereof. Such report shall be followed by the payments due pursuant to Section 7.3.

**8.2.2** Within 40 days after the end of each Calendar Quarter, Licensee shall deliver to Somaxon quarterly operation reports of Licensee's activities to register, develop and market the Licensed Product in the Territory, and shall provide to Somaxon copies of all such reports received by Licensee from its licensees or distributors. Each report shall include:

- (a) a monthly compilation of all Licensed Product distributed by Licensee and its licensees and distributors including the revenues derived therefrom and a breakdown of the prices charged to each customer in respect of the Licensed Product; and
- (b) a monthly list of the amount of inventory on hand and, from and after any termination of the Supply Agreement, a monthly list of all Bulk Product ordered by Licensee on its own behalf or on behalf of its licensees or distributors; and
- (c) monthly gross sales and Net Sales in the Territory in local currency and U.S. dollars, using the average exchange rate set forth in Korea Exchange Bank for the preceding month.

**8.2.3** Within 45 days after the end of each Calendar Year, Licensee shall deliver to Somaxon annual statements showing annual sales figures and the amount of inventory on hand as at December 31 of each year, and shall provide to Somaxon copies of all such annual statements received by Licensee from its licensees or distributors. Such annual statements shall also contain (i) a summary of all promotional activities undertaken by Licensee and its licensees and distributors with respect to the Licensed Product during the preceding calendar year, and (ii) a certification that "to Licensee's knowledge no exportation of the Licensed Product outside the Territory has taken place" in the Calendar Year then ended.

**8.3 Records Retention** . For three Calendar Years from the end of the year to which the Milestone Payment or other payments pertains after each sale of each Licensed Product or such longer period as may be required by applicable Laws, Licensee shall (and shall cause its Affiliates, licensees and distributors to) keep and maintain complete and accurate books and records of such sales of the Licensed Product, Net Sales of the Licensed Product including all deductions, and all amounts payable by Licensee to Somaxon hereunder in sufficient detail to confirm the accuracy of the payment calculations or Milestone Payments required hereunder.

**8.4 Interest** . All late payments under this Agreement shall bear interest from the date due until paid at a rate equal to twelve-month LIBOR plus two percent (2%) as set by the British Bankers Association as of the date that such payment was due, or, if lower, the highest rate permitted under applicable Law, calculated on the number of days such payment is delinquent.

**8.5 Rights of Inspection** .

**8.5.1** Without limiting either Party's other inspection and audit rights set forth in this Agreement or the Supply Agreement, during the Term and for three Calendar Years after receiving any report or statement with respect to payments or Milestone Payments, Somaxon shall have the right to appoint an internationally-recognized independent Third Party accounting firm to audit the books and records of Licensee and its Affiliates solely so as to verify the accuracy of the reports, statements, books of accounts and payments made hereunder, as applicable. Such audit shall be conducted upon at least 30 days advanced written notice to Licensee and shall commence on a date reasonably acceptable to both Parties. Such audit shall only be during Licensee's normal business hours. Such audit shall not be more frequent than once per Calendar Year unless a prior audit has revealed material deficiencies, in which case, an additional audit may be conducted within the same Calendar Year if elected by Somaxon. The auditing party shall be required to sign a confidentiality agreement for the benefit of, and in a form reasonably acceptable to, Licensee. Licensee shall be provided the opportunity to discuss any discrepancies of greater than ten percent (10%) found during such audit with the auditors prior to such auditor issuing its final report. In addition, the auditors shall redact any Confidential Information disclosed in the proposed final report identified by Licensee as confidential and, which the auditors agree is not necessary for purposes of calculating the payment(s) owed. The final report shall be shared with both of the Parties. If any audit discloses any underpayments by Licensee to Somaxon, then unless contested by Licensee within 30 days after receipt of the necessary documentation of the amount owed, any underpayment shall be paid by Licensee to Somaxon within 30 days of it being so disclosed. If any audit discloses any overpayments by Licensee to Somaxon, then unless contested by Somaxon within 30 days after receipt of the necessary documentation of the amount owed, Licensee shall have the right to credit the amount of the overpayment against each subsequent quarterly payment due to Somaxon until the overpayment has been fully applied. If the overpayment is not fully applied prior to the final quarterly payment of payments due hereunder, Somaxon shall promptly refund an amount equal to any such remaining overpayment. If Somaxon's audit demonstrates an underpayment of more than ten percent (10%) for the payment due to Somaxon during the audited period, Licensee shall be liable for Somaxon's reasonable cost of the audit that discovered such underpayment. Otherwise, Somaxon shall bear the costs of such audits.

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## **8.6 Taxes .**

- 8.6.1** The Parties shall be responsible for the payment of taxes attributed to any Payments under this Agreement. When required to do so by applicable law, rule or order of a governmental body, Licensee shall withhold taxes required to be paid to a taxing authority in connection with any Payments to Somaxon hereunder, and, upon request of Somaxon, Licensee shall furnish Somaxon with satisfactory evidence of such withholding and payment.
- 8.6.2** The Parties agree to cooperate and produce on a timely basis any tax forms or reports reasonably requested by the other Party in connection with any payment made by Licensee to Somaxon under this Agreement, all at the cost and expense of the requesting Party. Each Party further agrees to provide reasonable cooperation to the other Party, at the other Party's cost and expense, in connection with any official or unofficial tax audit or contest relating to payments made by Licensee to Somaxon under this Agreement.

## **ARTICLE 9**

### **INVENTIONS AND PATENTS**

- 9.1 Notices.** Each Party shall immediately give written notice to the other Party of any Third Party claim that any Somaxon Patents in the Territory are invalid or will not be infringed by the Manufacture, use, sale or commercialization of a product by a Third Party in the Territory.
- 9.2 Somaxon Patents .**
- Somaxon shall undertake prosecution and use Commercially Reasonable Efforts to maintain any Somaxon Patents at Somaxon's expense in an effort to ensure Licensee's right to exclusively sell the Licensed Product in the Territory. Licensee, as holder of the Marketing Approval for the Licensed Product, shall make its best efforts to cooperate and advise Somaxon in a timely manner. Somaxon shall promptly inform Licensee of all material correspondence received in connection with such activities in the Territory.

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- 9.3 New Technology** . All Patent Rights and Know-How (including all associated intellectual property rights): (i) arising directly from or out of the performance of this Agreement (including the exercise of any rights and the performance of any obligations) by either Party, (ii) authored, invented, reduced to practice, developed or otherwise created by one or more employees or independent contractors of either Party, and (iii) required in order to Manufacture or Commercialize the Licensed Product (“ **New Technology** ”) shall, as between the Parties, be the sole property of Somaxon. For the avoidance of doubt, New Technology in the Territory shall be included in the Licensed Technology licensed to Licensee pursuant to Section 2.1. Licensee shall cause each of its employees, consultants, contractors and any Third Parties working on its behalf or their behalf in fulfilling Licensee’s obligations under this Agreement and who may create New Technology to assign to Licensee all of such Person’s right, title and interest in and to any New Technology, and to waive, for the benefit of Licensee and its successors, assigns and licensees (including Somaxon), their respective moral rights in and to any New Technology.
- 9.4 Cooperation** . Each Party shall, and shall cause any Third Parties working on its or their behalf to cooperate with and assist the other Party, if and as may be requested by such other Party, to effect the intent of this ARTICLE 9, including by executing such documents and taking such actions, and making its employees and independent contractors available to execute documents and provide information to such other Party or to such other Party’s authorized lawyers, agents or representatives, as necessary to achieve the foregoing allocation of ownership rights.
- 9.5 Required Third Party Patent Rights or Know-How** . In the event either Party becomes aware of additional Third Party Patent Rights or Know-How that may be necessary for the Commercialization, such technology shall be discussed by the CC and the CC shall determine whether a license shall be taken. In the event the CC determines that a license in such technology shall be taken, Somaxon shall, at its sole cost and expense, use Commercially Reasonable Efforts to negotiate, enter into and comply with such license including the right to sublicense to Licensee.
- 9.6 Filing, Prosecution, Maintenance, Enforcement and Defense of Patents and Trademarks** . Somaxon shall use Commercially Reasonable Efforts to: (a) prosecute and maintain any Somaxon Patents and Trademarks in the Territory; (b) defend the Licensed Technology against claims of infringement in the Territory; (c) enforce the Licensed Technology against infringing Third Parties in the Territory; and (d) file any Patents and Trademarks for Licensed Technology in the Territory that Somaxon later may gain during the Term of this Agreement, to the extent applicable to the Territory and able to be filed under applicable Law. Somaxon shall promptly inform Licensee of all material correspondence received in connection with such activities in the Territory. If either Party becomes aware or reasonably believes that any Licensed Technology or Trademark is being infringed in the Territory by a Third Party or if a Third Party claims that any Somaxon Patent is invalid or unenforceable, or challenges the validity, enforceability, ownership or use of any Trademark, in each case in the Territory, the Party possessing such knowledge or reasonable belief shall promptly, but in all events within 15 days thereof, notify the other Party in writing and provide it with details of such infringement or claim that are known by such Party.

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- 9.7 Third Party Actions Claiming Infringement** . If a Party becomes aware of any claim or action by a Third Party against either Party that claims that the development, Manufacture, advertising, marketing, promotion, distribution, labeling, storage, handling, use, sale, offer for sale or importation of or any other Commercialization activity or the use of any Trademark or Licensed Technology in the Territory infringes such Third Party's intellectual property rights (each, a "**Third Party Action**"), such Party shall promptly, but in all events within fifteen (15) days thereof, notify the other Party in writing and provide it with details of such claim or action that are known by such Party.
- 9.8 Actions Against Third Parties** . In the event of any infringement of Somaxon Patent Rights or the Trademarks in the Territory, which infringement involves a product that could or does compete with the Licensed Product or could adversely affect the Parties' interests in the Licensed Product in the Territory under this Agreement (an "**Infringement**"), Somaxon shall, in its sole discretion, after considering the advice and comments of Licensee, determine to take legal action in the Territory (an "**Enforcement Action**"), if any. In the event such an Enforcement Action is initiated, Somaxon shall use Commercially Reasonable Efforts to prosecute such Enforcement Action. At Somaxon's reasonable request, Licensee shall cooperate fully with Somaxon with respect to any such Enforcement Action, and Somaxon shall reimburse Licensee for its reasonable out-of-pocket costs and expenses (including attorneys' and professionals' fees) incurred in providing such cooperation. Licensee may be represented by counsel of its own selection at its own expense in any such Enforcement Action, but Somaxon shall have the right to control the suit or proceeding and such expenses will not be reimbursed by Somaxon. Any recovery received as a result of any Enforcement Action shall be used first to reimburse Somaxon for its costs and expenses (including attorneys' and professional fees and amounts reimbursed to Licensee) incurred in connection with such Enforcement Action. Of any remaining amounts, the amount (if any) which is required to be paid to any licensors of the applicable Patent Rights or Trademarks under the terms of the respective in-license agreement, if any, shall then be paid to such licensor, if any, and any amounts remaining thereafter shall be paid to Somaxon. If Somaxon elects not to bring an Enforcement Action with respect to an Infringement, it will promptly notify Licensee of such decision, and Licensee shall have the exclusive right to bring such Enforcement Action (a "**Licensee Enforcement Action**"). Costs, recovery thereof, and payments to licensors, if any, under any Licensee Enforcement Action shall be used first to reimburse Licensee for its costs and expenses incurred in connection with such Licensee Enforcement Action. Of any remaining amounts, the amount (if any) which is required to be paid to any licensors of the applicable Patent Rights or Trademarks under the terms of the respective in-license agreement, if any, shall then be paid to such licensor, if any, and any amounts remaining thereafter shall be paid to Licensee.

**9.9 Patent Marking** . All Licensed Product marketed and sold by Licensee under this Agreement shall be marked with appropriate patent numbers or indicia of Somaxon Patents, to the extent required by applicable Laws in the Territory.

**9.10 Licensee Negative Covenant Regarding Somaxon Patent Rights** . Throughout the Term, neither Licensee, any of its Affiliates nor any permitted sublicensees shall commence or otherwise pursue (or voluntarily provide any material assistance to any Third Party to do so, other than as required by applicable Law or legal process), any proceeding seeking to have any of the Somaxon Patent Rights revoked or declared invalid, unpatentable or unenforceable.

## **ARTICLE 10 CONFIDENTIALITY**

**10.1 Confidentiality Obligations** . Each Party shall, and shall ensure that its officers, directors, employees and agents shall, keep and maintain completely confidential and not publish or otherwise disclose and not use for any purpose except as expressly permitted hereunder any Confidential Information disclosed to it by the other Party pursuant to this Agreement or the Supply Agreement. Information disclosed by a Party hereunder shall not constitute Confidential Information for any purpose under this Agreement or the Supply Agreement to the extent that the receiving Party can demonstrate that such Confidential Information:

- (a) Was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;
- (b) Was generally available to the public or otherwise part of the public domain 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 and other than through any direct or indirect act or omission of the receiving Party in breach of this Agreement;
- (d) Was subsequently lawfully disclosed to the receiving Party or its Affiliates by a Third Party without an obligation of confidentiality other than in contravention of a confidentiality obligation of such Third Party known to the receiving Party; or
- (e) Was developed or discovered by employees, consultants, contractors or agents of the receiving Party or its Affiliates independently of the relevant Confidential Information of the disclosing Party.

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**10.2 Permitted Exceptions** . Notwithstanding the above obligations of confidentiality and non-use, a Party may disclose information to the extent that such disclosure is reasonably necessary in connection with:

- (a) prosecuting or defending litigation subject to the terms of ARTICLE 12;
- (b) conducting Phase IV Trials as permitted hereunder;
- (c) seeking Regulatory Approval hereunder; or
- (d) complying with a judicial order, or applicable Law, including securities Law and the rules or requirements of any securities exchange or market on which a Party's securities are listed or traded and the requirements of any regulatory authority.

In making any disclosures set forth in the foregoing clauses of this Section 10.2, the disclosing Party shall, where reasonably practicable, give such advance notice to the other Party of such disclosure requirement as is reasonable under the circumstances, disclose no more of the other Party's Confidential Information than reasonably necessary and will use its reasonable efforts to cooperate with the other Party in order to secure confidential treatment of such Confidential Information required to be disclosed. In addition, in connection with any permitted filing by either Party of this Agreement or the Supply Agreement with any Governmental Body, the filing Party shall endeavor to obtain confidential treatment of economic, trade secret information and such other information as may be requested by the other Party, subject to applicable Law, and shall provide the other Party with the proposed confidential treatment request with reasonable time for such other Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the other Party. With respect to financial and sales information, either Party may also disclose such information, subject to reasonable obligations of confidentiality, at least as stringent as those set forth herein, to actual and prospective acquirers, investors and other sources of finance (and to their respective advisors, agents and representatives) and actual and prospective permitted assignees.

**10.3 Return of Confidential Information** . Upon the request of either Party, upon termination or expiration of this Agreement, each Party shall promptly return to the other Party or destroy and certify destruction of all of the other Party's Confidential Information, including all copies, excerpts or summaries thereof, in whatever form or medium, and thereafter shall not make any use of any such Confidential Information of the other Party, in each case except as expressly permitted hereunder; provided that neither Party shall be obligated to return or destroy Confidential Information that has become integrated with other business records of such Party; provided, further that such Party shall continue to be bound by the confidentiality obligations under this Agreement and the Supply Agreement with respect to any such Confidential Information that is not so returned or destroyed.

**10.4 Press Releases and Disclosure** . The Parties hereby acknowledge and agree that either Party may issue the press release attached as Schedule 10.4. Neither Party shall make any other press release or public announcement regarding the terms of this Agreement, the Supply Agreement or relating to the Licensed Product in the Field in the Territory (including the Commercialization thereof) without the prior written consent of the other Party; provided that (a) Somaxon shall be permitted to make press releases and public announcements about the development, manufacture or commercialization of a Licensed Product outside the Territory or outside the Field in the Territory (provided that Somaxon shall provide Licensee with reasonable advance notice of any press release or public announcement concerning any adverse publicity or other negative news concerning any Licensed Product outside the Territory), (b) each Party shall be permitted to disclose the execution, terms and conditions of this Agreement or the Supply Agreement if and to the extent required by (i) judicial order, or (ii) applicable Laws, including securities Laws and the rules or requirements of any securities exchange or market on which such Party's securities are listed or traded and the requirements of any regulatory authority, provided that, with respect to subsections (i) and (ii), the Party seeking disclosure shall provide each other Party with reasonable advance notice of such disclosure (including the text thereof), disclose no more information relating to the terms of this Agreement or the Supply Agreement or any Licensed Product than reasonably necessary and shall, to the extent practical, use its reasonable efforts to cooperate with such other Party in seeking confidential treatment of such information, (c) each Party shall have the right to disclose the execution, terms and conditions of this Agreement, the Supply Agreement and information relating to any Licensed Product to the extent already disclosed by either Party pursuant to and in accordance with this ARTICLE 10 in connection with any investor calls or presentations (or other similar types of disclosures) in connection with disclosures about such Party's business and (d) each Party shall have the right to disclose information to its attorneys, accountants and other professional advisors who are under an obligation to keep such information confidential.

## **ARTICLE 11 REPRESENTATIONS AND WARRANTIES**

**11.1 Representations and Warranties of Somaxon.** Somaxon hereby represents and warrants to Licensee as of the date hereof as follows:

- 11.1.1 Organization.** Somaxon (i) is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware, and (ii) has all necessary corporate power and corporate authority to own its properties and to conduct its business, as currently conducted.
- 11.1.2 Authorization** . The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby are within the corporate power of Somaxon, have been duly authorized by all necessary corporate proceedings of Somaxon, and this Agreement has been duly executed and delivered by Somaxon.

- 11.1.3 No Conflict** . The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not: (i) conflict with or result in a breach of any provision of Somaxon’s organizational documents; (ii) result in a material breach of any material agreement to which Somaxon is party; (iii) result in a violation of any Law to which Somaxon is subject in any material respect; or (iv) require Somaxon to obtain any material approval or consent from any Governmental Body or Third Party other than those consents and approvals which have been obtained prior to the date hereof.
- 11.1.4 Enforceability** . This Agreement constitutes the valid and binding obligation of Somaxon (assuming the due execution and delivery hereby by Licensee), enforceable against Somaxon in accordance with its terms, subject to bankruptcy, reorganization, insolvency and other similar laws affecting the enforcement of creditors’ rights in general and to general principles of equity (regardless of whether considered in a proceeding in equity or an action at law).
- 11.1.5 Somaxon Intellectual Property** . Except as set forth in Somaxon’s public filings made since December 31, 2010 with the United States Securities and Exchange Commission (the “**SEC Filings**” ), Somaxon has not received any written claim or demand from any Third Party alleging that any infringement, violation, or misappropriation of such Third Party’s intellectual property rights has occurred as a result of or in connection with the manufacture, use, offer for sale, sale or importation of the Licensed Product. Except as set forth in the SEC Filings, Somaxon is not aware of any actual, alleged, or threatened infringement, violation, or misappropriation by a Third Party of any Somaxon intellectual property rights, including the Licensed Technology, covering Silenor<sup>®</sup> (doxepin) in the Field or its manufacture, use, or sale. Except as set forth in the SEC Filings, Somaxon has not received any written claim or demand from any Third Party alleging invalidity or unenforceability of any Licensed Technology. As of the Effective Date, Somaxon warrants that all Somaxon Know-How, to the extent in the form of any tangible items that have been made available to Licensee, are to the best of its actual knowledge, accurate but not necessarily complete.
- 11.1.6 Litigation** . Except as set forth in the SEC Filings, there is no litigation, arbitration proceeding, governmental investigation, action, or claims of any kind, pending or, to the knowledge of Somaxon, threatened, by or against Somaxon or any of its Affiliates relating to the Licensed Product.
- 11.1.7 Right to Grant Licenses**. Somaxon has the right to grant to Licensee the rights that Somaxon purports to grant hereunder, including the right to grant exclusive licenses to the Licensed Technology in connection with the Licensed Product in the Territory and the non-exclusive licenses to Manufacture Licensed Product for Commercialization.
- 11.1.8 Somaxon U.S. Regulatory Filings**. All of the clinical data generated by or on behalf of Somaxon and contained in Somaxon’s Regulatory Filings made in the United States in support of Regulatory Approval of Silenor in the United States were generated in compliance in all respects with cGCP. All of the non-clinical data generated by or on behalf of Somaxon and contained in such Regulatory Filings were generated in compliance in all respects with cGLP. All of the conclusions made by Somaxon relating to such data, and all other information, contained in such Regulatory Filings were submitted by Somaxon in good faith, and Somaxon knows of no inaccuracies in such information. All of such Regulatory Filings complied with all applicable Law.

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**11.2 Representations and Warranties of Licensee** . Licensee hereby represents and warrants to Somaxon as of the date hereof as follows:

- 11.2.1 Organization** . Licensee (i) is a corporation duly organized and validly existing under the laws of the Republic of Korea, and (ii) has all necessary corporate power and corporate authority to own its properties and to conduct its business as currently conducted.
- 11.2.2 Authorization** . The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby are within the corporate power of Licensee, have been duly authorized by all necessary corporate proceedings of Licensee, and this Agreement has been duly executed and delivered by Licensee.
- 11.2.3 No Conflict** . The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not: (i) conflict with or result in a breach of any provision of Licensee's organizational documents; (ii) result in a material breach of any material agreement to which Licensee is party; (iii) result in a violation of any Law to which Licensee is subject in any material respect; or (iv) require Licensee to obtain any material approval or consent from any Governmental Body or Third Party other than those consents and approvals which have been obtained prior to the date hereof.
- 11.2.4 Enforceability** . This Agreement constitutes the valid and binding obligation of Licensee (assuming the due execution and delivery hereby by Somaxon), enforceable against Licensee in accordance with its terms, subject to bankruptcy reorganization, insolvency, and other similar laws affecting the enforcement of creditors' rights in general and to general principles of equity (regardless of whether considered in a proceeding in equity or an action at law).
- 11.2.5 Litigation** . There is no litigation, arbitration proceeding, governmental investigation, action, or claims of any kind, pending or, to the knowledge of Licensee, threatened, by or against Licensee that would reasonably be expected to materially affect Licensee's ability to perform its obligations hereunder.
- 11.2.6 Diligence** . As of the Effective Date, there is no information known to Licensee that would reasonably be expected to materially and adversely affect Commercialization.
- 11.3 DISCLAIMER OF WARRANTY** . EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

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## ARTICLE 12

### INDEMNIFICATION AND INSURANCE

- 12.1 Indemnification by Licensee** . Licensee shall indemnify, defend and hold Somaxon and its Affiliates and each of their respective employees, officers, directors and agents (the “**Somaxon Indemnitees**”) harmless from and against any and all liabilities, obligations, claims, demands, judgments, losses, costs, damages, expenses, fines, royalties, governmental penalties or punitive damages, interest, settlement amounts, awards and judgments (including reasonable legal fees and expenses) (collectively, “**Losses**”) arising out of any Third Party claim, suit or proceeding arising out of or related to: (a) the negligence, reckless or wilful misconduct of any Licensee Indemnitee in performing Licensee’s obligations under this Agreement or otherwise in the seeking, obtaining or maintaining any Regulatory Approval or in Commercialization; (b) any material breach or violation by any Licensee Indemnitee of, or failure to perform by any Licensee Indemnitee of, any representation, warranty, covenant, or other obligation in this Agreement, unless waived in writing by Somaxon; (c) any material violation of applicable Law by any Licensee Indemnitee in connection with performing its obligations under this Agreement or otherwise in the seeking, obtaining or maintenance of any Regulatory Approval or Commercialization; (d) any claim or liability arising from Licensee’s exploitation of the licenses granted under this Agreement; (e) any actions of any Licensee Indemnitee, including a Sales Representative or scientific liaison, including any false or misleading representations to professionals, customers, or others regarding any Somaxon Indemnitee or the Licensed Product; (f) any decision taken hereunder as to which Licensee has final decision-making authority; or (g) the content of the Promotional Materials; excluding, in each case, any Loss for which Somaxon has an obligation to indemnify an Licensee Indemnitee pursuant to Section 12.2 or pursuant to the Supply Agreement, as to which Loss each Party shall indemnify the other to the extent of their respective liability for such Loss.
- 12.2 Indemnification by Somaxon** . Somaxon shall indemnify, defend and hold Licensee and its Affiliates and each of their respective employees, officers, directors and agents (the “**Licensee Indemnitees**”, and together with Somaxon Indemnitees, the “**Indemnitees**”) harmless from and against any and all Losses arising out of any Third Party claim, suit or proceeding arising out of or related to: (a) the negligence, reckless or wilful misconduct of any Somaxon Indemnitee in performing Somaxon’s obligations under this Agreement; (b) any material breach or violation by any Somaxon Indemnitee of, or failure to perform by any Somaxon Indemnitee of, any representation, warranty, covenant, or other obligation in this Agreement, unless waived in writing by Licensee; (c) any material violation of applicable Law by any Somaxon Indemnitee in connection with performing its obligations under this Agreement; or (d) any decision taken hereunder as to which Somaxon has final decision-making authority; excluding, in each case, any Loss for which Licensee has an obligation to indemnify a Somaxon Indemnitee pursuant to Section 12.1 or pursuant to the Supply Agreement, as to which Loss each Party shall indemnify the other to the extent of their respective liability for such Loss.

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- 12.3 NO CONSEQUENTIAL DAMAGES.** IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES, EMPLOYEES, OFFICERS, DIRECTORS OR AGENTS BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES, EMPLOYEES, OFFICERS, DIRECTORS OR AGENTS FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING DAMAGES FOR LOST PROFITS), WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE SUPPLY AGREEMENT, EVEN IF SUCH DAMAGES MAY HAVE BEEN FORESEEABLE; PROVIDED THAT SUCH LIMITATION SHALL NOT APPLY IN THE CASE OF EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 12.
- 12.4 Notification of Claims; Conditions to Indemnification Obligations .** As a condition to an Indemnitee's right to receive indemnification under this ARTICLE 12, it shall: (a) promptly notify the indemnifying Party as soon as it becomes aware of a claim, suit or proceeding for which indemnification may be sought pursuant hereto, provided, that any failure to so notify the indemnifying Party will not relieve the indemnifying Party from any liability that it may have to the indemnified Party under this ARTICLE 12 with respect to such claim or suit, except to the extent that the ability of the indemnifying Party to defend such claim or suit is materially prejudiced by the indemnified Party's failure to give such notice; (b) reasonably cooperate, and cause the individual Indemnitees to reasonably cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. The Party controlling any claim or suit pursuant to this Section 12.4 shall consult with the other Party on all material aspects of such claim or suit. The non-controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such claims and suits. In no event, however, may a Party settle or otherwise compromise any claim or suit (A) in a manner that imposes any obligation on the other Party or its Affiliate or that adversely affects or would reasonably be expected to adversely affect the other Party (including by admitting that any Somaxon Patent or New Technology is invalid or unenforceable or in a manner that admits fault or negligence on the part of any Indemnitee) without the prior written consent of the Indemnitee, which consent shall not be unreasonably withheld, delayed or conditioned, or (B) for which indemnification may be sought pursuant hereto without the other Party's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned).

**12.5 Insurance.** During the Term, each Party shall obtain and maintain, at its sole cost and expense, comprehensive general liability insurance (written on an occurrence basis and including any self-insured arrangements) covering bodily injury (including death) and property damage, and including coverage for product liability in amounts that are reasonable and customary in the Territory or, with respect to Somaxon, the United States, in the pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 12.5. Such certificate will provide that such insurance will not expire or be cancelled or modified without at least 30 days' prior written notice to the other Party. Upon expiration or termination of this Agreement following Commercialization, each Party shall maintain the insurance such Party is required to obtain and keep in force under this Section 12.5 in full force and effect for a period of three years.

## **ARTICLE 13**

### **TERM AND TERMINATION**

**13.1 Term and Expiration .** The term of this Agreement shall commence on and as of the Effective Date, and, unless earlier terminated as provided in this ARTICLE 13 (the date of any such termination, the "**Termination Date**"), shall continue in full force and effect until the date of (a) ten (10) years following First Commercial Sale or (b) the ProCom Term, whichever is the later, unless extended pursuant to this Section 13.1 (the "**Term**"). The Term shall automatically be extended for successive two (2) year periods, unless either the Company or the Licensee gives written notice to the other Party of its intention to terminate this Agreement upon no less than 180 days' prior written notice.

**13.1.1** Pursuant to Section 9.5, the Parties acknowledge that certain Third Party intellectual property may be necessary for Commercialization. Further, the Parties agree that Somaxon may terminate this Agreement in its entirety upon 60 days' prior written notice if, (a) following good faith discussions with a Third Party, Somaxon is unable to license rights to such Third Party's intellectual property necessary for Commercialization as described under Section 9.5 or other proprietary rights in the Territory on terms which are commercially reasonable and (b) the failure of Somaxon to procure such license would reasonably be expected to result in claim(s) from such Third Party alleging infringement or misappropriation in the Territory. Prior to such termination, Somaxon will use Commercially Reasonable Efforts to inform Licensee of all material aspects of discussions with such Third Party relating to the negotiation of such license of rights from such Third Party, including (subject to the approval of such Third Party) having Licensee participate in such discussions; provided that from and after such termination both Parties shall have a good faith discussion with the intent of providing Licensee a license to use the Product Marks, Somaxon Patents and the Somaxon Know-How that are not the cause for the termination of the Agreement under this Section 13.1.1, in the Field in the Territory solely for Manufacture and Commercialization.

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### **13.2 Termination upon Material Breach or an Event of Insolvency.**

**13.2.1** If a Party breaches any of its material obligations under the Agreement (including its obligations under Section 9.10), the Party not in default may deliver to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement if such breach is not curable, or if not cured within 60 days (or 15 days in the event of a breach of its obligations under Section 9.10). If such breach is not curable, or is not cured within 60 (or 15) days after the receipt of such notice, the Party not in default shall be entitled to terminate this Agreement in its entirety, effective immediately upon written notice to the other Party. Any dispute regarding an alleged breach of this Agreement shall be resolved in accordance with ARTICLE 14 hereof. For further clarification, in the event of a termination by Licensee under this Section 13.2.1, Licensee shall have a fully-paid, perpetual license to use the Product Marks and the Somaxon Know-How in the Field in the Territory solely for Manufacture and Commercialization.

**13.3 Effects of Termination.** Survival. The following Articles and Sections of this Agreement shall survive the expiration or termination of this Agreement for any reason: this Section 13.3, Sections, 2.4.1(d), 2.4.5, 6.2, 6.3, 11.3, 13.3.2, 13.3.3(D), 13.4 and 13.5, Articles 8, 12, 14 and 15, and ARTICLE 1 to the extent that any defined terms in ARTICLE 1 are used in the foregoing Sections and Articles. The provision of Article 10 shall survive the termination of this Agreement for five (5) years.

**13.3.2 Accrued Liabilities .** Termination of this Agreement shall not relieve the Parties of any liability that accrued hereunder or under the Supply Agreement prior to the Termination Date. In addition, termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or under the Supply Agreement or at Law or in equity with respect to any breach of this Agreement or the Supply Agreement nor prejudice either Party's right to obtain performance of any obligation.

**13.3.3 Licenses.** Upon termination of this Agreement in its entirety by either Party,

- (A) Except for a termination by Licensee under Section 13.2.1, all licenses granted to Licensee under Sections 2.1 and 2.4.1 shall immediately and automatically terminate;

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- (B) Unless otherwise agreed upon by the parties hereto and except for a termination by Licensee under Section 13.2.1, Licensee shall, at Somaxon's cost and expense, promptly after such termination, but in no event later than 10 Business Days thereafter, (i) assign, convey and transfer to Somaxon (or its designee) ownership of all Regulatory Filings and Regulatory Approvals prepared or obtained by or on behalf of Licensee or its Affiliates in the Territory prior to the Termination Date and execute all documents reasonably necessary to enable Somaxon to have access to and rely on the same, (ii) assign, convey and transfer to Somaxon all of Licensee's and its Affiliates' right, title and interest in and to all regulatory correspondence controlled by Licensee, and if applicable, to transfer and transition to Somaxon (or its designee), if and as may be reasonably requested by Somaxon, the conduct of any ongoing Phase IV Trials in a manner and within such timing as mutually agreed upon by the Parties so as to not disrupt such Phase IV Trials, except that, with respect to each of the foregoing subsections (i) and (ii), Licensee may retain copies of such information, data, reports, records, regulatory correspondence and other materials as may be necessary for Licensee to comply with applicable Law, (iii) assign, convey and transfer to Somaxon (or its designee) ownership of all Promotional Materials (or sufficient rights to permit Somaxon to use the Promotional Materials until Somaxon is able to print its own promotional materials for use with the Licensed Product in the Territory), (iv) cooperate and assist Somaxon at Somaxon's cost and expense in taking such actions and making such filings with the relevant Governmental Bodies as necessary to effect the assignments and transfers contemplated hereunder, (v) assign, convey and transfer to Somaxon all of Licensee's and its Affiliates' right, title and interest in and to all Trademarks used by Licensee in Commercializing the Licensed Product in the Territory (other than Marks owned by Licensee or its Affiliates); and (vi) assign, convey and transfer to Somaxon (or its designee) Licensee's and its Affiliates' right, title and interest in and to the Internet domain name registrations for the Licensed Product website, if any, at Somaxon's cost and expense, and shall cease operation of such website;
- (C) The Supply Agreement shall terminate; and
- (D) Licensee shall have one (1) year (the "**Sell-Off Period**") to sell off any of Licensee's remaining unsold inventory of Licensed Product, including any inventory that it is obliged to purchase under the Supply Agreement or the then applicable supply arrangement for the Licensed Product; and shall continue to pay the Royalties with respect to all sales during the Sell-Off Period in accordance with the provisions of Section 7.3.3 and to comply with all other applicable terms and conditions of this Agreement and the Supply Agreements.

- 13.4 Survival of Licenses in the Event of Somaxon Bankruptcy or Insolvency** . All rights and licenses granted under or pursuant to this Agreement by Somaxon are, and shall otherwise be deemed to be: (i) for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code; and (ii) for the purposes of section 365(n) of the U.S. Bankruptcy Code, licenses of rights to use intellectual property granted to a party to an agreement. The Parties agree that Licensee, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy or insolvency proceeding by or against Somaxon under the U.S. Bankruptcy Code, Licensee shall retain its right to the intellectual property, including its rights to enforce an exclusive license. For greater certainty, in furtherance of Licensee’s rights to use of the intellectual property, Licensee shall be entitled to a duplicate of (or access to, as determined appropriate by Somaxon) embodiments of such intellectual property, which, if not already in Licensee’s possession and requested by Licensee, shall be promptly delivered to it (if and to the extent in Somaxon’s Control and not already provided to Licensee): (a) upon any such commencement of a bankruptcy or insolvency proceeding upon Licensee written request therefor, unless Somaxon elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered under clause (i), following the rejection, disclaimer or rescission of this Agreement by Somaxon upon written request therefor by Licensee.
- 13.5 No Public Statements** . The Parties agree that if this Agreement is terminated, neither Party shall disclose to any Third Party any reason for not proceeding without the express written consent of the other Party, and the Parties shall agree on statements for public disclosure, such agreement not to be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, each Party shall be permitted to make such disclosures if and to the extent required by (a) judicial order, or (b) applicable Laws, including any rules or requirements under any stock exchange on which such Party is listed or may be listed or by any regulatory authorities, provided that, with respect to subsections (a) and (b), the Party seeking disclosure shall provide the other Party with advance notice and shall to the extent practical and requested by the other Party, cooperate with such other Party in seeking confidential treatment of such information.

## **ARTICLE 14 DISPUTE RESOLUTION**

- 14.1 Disputes** . The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party’s rights and/or obligations under this Agreement or the Supply Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement or under the Supply Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this ARTICLE 14 if and when a dispute arises under this Agreement or the Supply Agreement, including any dispute regarding an alleged breach of this Agreement; provided that such procedures shall not apply where this Agreement or the Supply Agreement expressly allocates decision-making authority on an issue to either Party.

**14.2 Escalation** . Disputes between the Parties relating to any matter relating to the subject matter of this Agreement or the Supply Agreement, including in connection with the Manufacture, Regulatory Activities or Commercialization, shall be referred to the CC for resolution. In the event that the CC is, after a period of 10 Business Days, unable to make a decision due to a lack of required unanimity, either Party may, by written notice to the other Party, request that a dispute arising between the Parties under this Agreement or under the Supply Agreement, including in connection with the Manufacture, Regulatory Activities or Commercialization, be referred to the President of Licensee (or an executive of Licensee designated by the President) and the Chief Executive Officer of Somaxon (or an executive of Somaxon designated by the Chief Executive Officer) (the **“Executive Officers”**) for resolution. The Executive Officers shall meet in person or telephonically within 10 Business Days of such other Party’s receipt of written notice of such dispute. If the Executive Officers cannot resolve such dispute within 30 days of written notice of such dispute, then, the Parties irrevocably agree that any dispute arising from or in connection with this Agreement shall be finally settled by arbitration in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce (the **“Rules”**). The arbitration shall proceed in the English language and the arbitration shall be held in the Arbitration Court having jurisdiction over the defendant Party, which shall be San Diego, California, if Somaxon is the defendant Party, or Seoul (the Republic of Korea), if the Licensee is the defendant Party. The number of arbitrators shall be 3 appointed in accordance with the Rules. Notwithstanding the foregoing, nothing in this Section 14.2 shall be construed as precluding a Party from bringing an action for injunctive relief or other equitable relief prior to the initiation or completion of the above procedure.

## **ARTICLE 15 MISCELLANEOUS PROVISIONS**

**15.1 Relationship of the Parties** . Nothing in this Agreement or the Supply Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.

### **15.2 Assignment.**

**15.2.1** Neither this Agreement nor the Supply Agreement nor any interest hereunder or thereunder may be assigned, sold, transferred or otherwise disposed of by either Party without the prior written consent of the other Party, provided, however, that Somaxon may by way of prior written notice to Licensee (a) assign all or any part of its rights or obligations under this Agreement or the Supply Agreement to any Third Party in connection with a Change of Control or sale of all or substantially all of the business or division of which the Licensed Product is a part, or (b) assign all or any part of its rights or obligations under this Agreement or the Supply Agreement to any Affiliate; provided further, Licensee may assign this Agreement and the Supply Agreement (or all of its interests hereunder or thereunder) to any Affiliate, in each case with prior written notice to Somaxon. For the avoidance of doubt, if either Party assigns, sells, transfers or otherwise disposes any or all of its rights or obligations under this Agreement or the Supply Agreement, such Party shall promptly make a written report to the other Party explaining the details of such event and background thereof and shall use Commercially Reasonable Efforts to minimize disruption to the non-assigning Party’s business to which this Agreement relates. For clarity, either Party may assign its right to receive proceeds under this Agreement or the Supply Agreement or grant a security interest in this Agreement or the Supply Agreement or such right to receive proceeds hereunder or thereunder to one or more financial institutions providing financing to such Party pursuant to the terms of a security or other agreement related to such financing. Notwithstanding the foregoing, neither Party shall have the right to assign, delegate or sublicense this Agreement or the Supply Agreement, in whole or in part, to any Person identified as an “excluded person” on the United States Health and Human Services Office of Inspector General and Government Services Administration Websites for excluded persons.

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**15.2.2** Each of this Agreement and the Supply Agreement shall be binding upon the successors and permitted assigns of the Parties.

**15.2.3** Any assignment not in accordance with Section 15.2.1 shall be null and void *ab initio* .

**15.3 Compliance with Laws** . Somaxon shall conduct all activities contemplated under this Agreement and the Supply Agreement in accordance with all applicable Laws and cGMP. Licensee shall conduct all activities contemplated under this Agreement and the Supply Agreement in accordance with the Acts, all applicable Laws and KGMP.

**15.4 Further Actions** . Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement and the Supply Agreement.

**15.5 Force Majeure** . In the event of any failure or delay in the performance by a Party of any obligation under this Agreement or the Supply Agreement due to events reasonably unforeseeable and beyond the reasonable control of such Party (such as, for example, fire, explosion, strike, fuel, or power, accident, act of God, declared or undeclared wars, acts of terrorism, or unforeseen changes in Law or requirements of Law) (a “**Force Majeure Event**” ), then such Party shall have such additional time to perform as shall be reasonably necessary under the circumstances. For clarity, a Force Majeure Event shall not include a failure to commit sufficient resources, financial or otherwise, to the performance of obligations under such agreement or general market or economic conditions not accompanied by circumstances described in the first sentence of this Section 15.5. In the event of such failure or delay, the affected Party will use its diligent efforts, consistent with sound business judgment and to the extent permitted by applicable Law, to correct and mitigate such failure or delay as expeditiously as possible. Provided diligent efforts are made, in the event that a Party is unable to perform by a reason described in this Section 15.5, its obligation to perform under the affected provision of such agreement, as the case may be, shall be suspended during such time of non-performance.

**15.5.2** Neither Party shall be liable hereunder to the other Party nor shall be in breach for failure to perform its obligations under this Agreement or the Supply Agreement caused by a Force Majeure Event except as otherwise set forth in such agreement. In the case of any such Force Majeure Event, the affected Party shall promptly, but in no event later than 10 days after its occurrence, notify the other Party stating the nature of the condition, its anticipated duration, and any action being taken to avoid or minimize its effect. Furthermore, the affected Party shall keep the other Party informed of the efforts to resume performance. After 60 days of such inability to perform, the Parties shall meet and discuss in good faith how to proceed. In the event that the affected Party is prevented from performing its obligations pursuant to this Section 15.5 for a period of 120 days (which period of time shall include the 60 days following which the Parties are to meet pursuant to the previous sentence), the other Party shall have the right to terminate this Agreement (pursuant to the provisions of Section 13.3.1).

**15.6 Entire Agreement of the Parties; Amendments** . This Agreement and the Supply Agreement and the schedules and exhibits hereto and thereto (including the Quality Agreement and the Pharmacovigilance Agreement), constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement or the Supply Agreement shall be valid or effective unless made in a writing referencing such agreement and signed by a duly authorized officer of each Party.

**15.7 Construction** . Except where expressly stated otherwise in this Agreement or the Supply Agreement, the following rules of interpretation apply to this Agreement and the Supply Agreement: (a) “include,” “includes” and “including” are not limiting and shall be deemed to be followed by “without limitation”; (b) definitions contained in this Agreement and the Supply Agreement are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (d) references to a Person are also to its permitted successors and assigns; (e) captions; the plain meaning of defined terms, and other headings to this Agreement or the Supply Agreement are for convenience only, and shall have no force or effect in construing or interpreting any of the provisions of this Agreement or the Supply Agreement or any other legal effect; (f) references to “Parties”, “Article”, “Section”, “Exhibit” or “Schedule” refer to the Parties to, an Article or Section of, or any Exhibit or Schedule to, this Agreement or the Supply Agreement, as the case may be, unless otherwise indicated; (g) the word “will” shall be construed to have the same meaning and effect as the word “shall” and vice versa; and (h) the word “or” has, except where otherwise indicated, the inclusive meaning represented by the phrase “and/or”.

**15.8 Governing Law** . This Agreement and the Supply Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles that would permit or require application of the Law of a jurisdiction outside of the State of New York. The United Nations Convention on Contracts for the International Sale of Goods is specifically excluded from application to this Agreement.

**15.9 Notices and Deliveries** . All notices required or permitted hereunder or under the Supply Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the Party to be notified, (b) when sent by confirmed facsimile if sent during normal business hours of the recipient, and if not during normal business hours of the recipient, then on the next Business Day, or (c) two Business Days after deposit with an internationally recognized overnight courier, with written verification of receipt. All communications shall be sent to the Parties at the following addresses:

(a) if to Somaxon, to:

Somaxon Pharmaceuticals, Inc.  
10935 Vista Sorrento Parkway, Suite 250  
San Diego, CA 92130  
USA  
Attention: General Counsel  
Fax No: +1 (858) 509-1761

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP  
12636 High Bluff Drive, Suite 400  
San Diego, California 92130  
Attention: Faye H. Russell, Esq.  
Fax No: +1.858.523.5450

(b) if to Licensee, to:

CJ CheilJedang Corporation  
CJ Cheiljedang Bldg, 330, Dongho-ro  
Jung-gu, Seoul, 100-400  
Korea  
Attention: Corporate Strategy & Business Development  
Pharmaceutical Business Unit  
Facsimile: +82 (2) 6740 – 2180

or to such other address as the addressee shall have last furnished in writing in accordance with this provision to the addressor.

**15.10 Waiver** . A waiver by either Party of any of the terms and conditions of this Agreement or the Supply Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof or thereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement and the Supply Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

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**15.11 Severability** . Whenever possible, each provision of this Agreement and the Supply Agreement shall be interpreted in such manner as to be effective and valid to the fullest extent permitted under applicable Law, but if one or more provisions of any agreement are held to be unenforceable or invalid under or in contravention of applicable Law by any court of competent jurisdiction, such provision shall be interpreted to the fullest extent permitted by applicable Law, and the Parties shall negotiate in good faith to replace such provision with a provision which effects to the fullest extent possible the original intent of such provision.

**15.12 No Third-Party Beneficiaries.**

Except as provided in Article 12 of this Agreement or Article VII of the Supply Agreement, this Agreement and the Supply Agreement are for the sole benefit of the Parties hereto and thereto and their permitted assigns, and nothing herein or therein expressed or implied shall give or be construed to give to any Person, other than the Parties hereto or thereto and such assigns, any legal or equitable rights hereunder.

**15.13 Expenses.**

Each Party will bear its own costs and expenses in connection with the preparation, negotiation and execution of this Agreement, the Supply Agreement and the other documents related hereto or thereto.

**15.14 Injunctive Relief.**

The Parties agree that if any of the provisions of this Agreement or the Supply Agreement were not performed in accordance with their specific terms or were otherwise breached, irreparable damage would occur, no adequate remedy at law would exist and damages would be difficult to determine, and that the Parties shall be entitled to specific performance of the terms of such agreement and immediate injunctive relief, without the necessity of proving the inadequacy of money damages as a remedy, in addition to any other remedy at law or in equity.

**15.15 Counterparts** . This Agreement and the Supply Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or other electronic copy of this Agreement and the Supply Agreement, including the signature pages, will be deemed an original.

*[Remainder of this page intentionally left blank; signature page follows]*

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*[Signature Page to License Agreement]*

**IN WITNESS WHEREOF** , the Parties have caused this License Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written, each copy of which shall for all purposes be deemed to be an original.

**SOMAXON PHARMACEUTICALS, INC.**

Per: /s/ Richard W. Pascoe

Name: Richard W. Pascoe

Title: President & CEO

**CJ CHEILJEDANG CORPORATION**

Per: /s/ Seok-Hee Kang

Name: Seok-Hee Kang

Title: Executive Vice President

Head of Pharmaceutical Business

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Schedule 1.21  
Restrictions Under Existing Agreements  
The ProCom Agreement

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Schedule 1.57  
ProCom Agreement

[Note: The Amended and Restated License Agreement between Somaxon Pharmaceuticals, Inc. and ProCom One, Inc. dated September 15, 2010 is incorporated by reference from Exhibit 10.5 to the Form 10-Q filed with the SEC on November 10, 2010.]

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Schedule 1.73  
Somaxon Patents  
(as of the Effective Date)

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\*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Schedule 1.81  
Initial Transfer Price

Silenor 3mg  
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Silenor 6mg  
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\*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Schedule 10.4  
Press Release