# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

**CURRENT REPORT** 

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

Date of Report (Date of earliest event reported): January 3, 2019

# CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware001-3734846-4348039(State or other jurisdiction of incorporation)(Commission (IRS Employer Identification No.)

500 River Ridge Drive, Norwood, MA (Address of principal executive offices)

02062 (Zip Code)

Registrant's telephone number, including area code: (617) 963-0100

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):
[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company [X]
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [X]

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

On January 3, 2019, Corbus Pharmaceuticals Holdings, Inc. ("Corbus" or the "Company") through its wholly-owned subsidiary, Corbus Pharmaceuticals, Inc., entered into a Collaboration and License Agreement (the "Agreement") with Kaken Pharmaceutical Co., Ltd., a company organized under the laws of Japan ("Kaken"), effective January 3, 2019. Pursuant to the Agreement, Corbus granted Kaken an exclusive license to commercialize pharmaceutical preparations containing lenabasum (the "Licensed Products") for the prevention or treatment of dermatomyositis and systemic sclerosis (together, the "Initial Indications") in Japan (the "Territory").

Pursuant to the terms of the Agreement, Corbus will bear the cost of, and be responsible for, among other things, conducting the clinical studies and other developmental activities for the Licensed Products in the Initial Indications in the Territory, and Kaken will bear the cost of, and be responsible for, among other things, preparing and filing applications for regulatory approval in the Territory and for commercializing Licensed Products in the Territory, and will use commercially reasonable efforts to commercialize Licensed Products and obtain pricing approval for Licensed Products in the Territory.

In consideration of the license and other rights granted by Corbus, Kaken will pay Corbus, within 30 days of the date of the Agreement, a \$27,000,000 upfront cash payment and is obligated to pay potential milestone payments to Corbus totaling up to approximately \$173,000,000 for the achievement of certain development, sales and regulatory milestones, with part of the milestone payments being calculated in Japanese Yen, and therefore subject to change based on the conversion rate to U.S. Dollars in effect at the time of payment. In addition, during the Royalty Term (as defined below), Kaken is obligated to pay Corbus royalties on sales of Licensed Products in the Territory, under certain conditions, in the double digits, which royalty shall be reduced in certain circumstances. In particular, for so long as Corbus supplies Licensed Products to Kaken pursuant to a supply agreement to be entered into by the parties, royalty payments shall be payable for each unit of Licensed Product that Corbus supplies as a percentage of the Japanese National Health Insurance price of the Licensed Product. During any time in which a supply agreement is not in effect, royalty payments shall be changed to a rate to be agreed upon by the parties in good faith.

The Agreement will remain in effect on a Licensed Product-by-Licensed product basis and will expire upon the expiration of the Royalty Term for the final Licensed Product. The "Royalty Term" means the period beginning on the date of the first commercial sale of the Licensed Product in Japan and ends on the latest of (i) the expiration of the last valid claim of the royalty patents covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product for such Initial Indication in Japan, or (iii) ten (10) years after the first commercial sale of such Licensed Product for such Initial Indication in Japan. The Agreement may be terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern or clinical failure, or at its convenience following the second anniversary of the first commercial sale of a Licensed Product in either of the Initial Indications in the Territory, with 180 days' notice.

Pursuant to the Agreement, the parties agreed to develop a joint steering committee to provide strategic oversight of the parties' activities under the Agreement, as well as a joint development committee to coordinate the development of Licensed Products in Japan. Additionally, the parties will establish a joint commercialization committee to review and confirm commercialization activities with respect to Licensed Products in Japan upon regulatory approval of such Licensed Product.

The Agreement also contains customary representations, warranties and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

The foregoing description of the terms of the Agreement is qualified in its entirety by reference to the full text of the Agreement, which is filed as Exhibit 10.1 hereto, and is incorporated by reference herein.

#### Item 7.01. Regulation FD Disclosure.

On January 3, 2019, the Company issued a press release announcing the entry into the Agreement. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

#### Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Collaboration and License Agreement, dated January 3, 2019, between Corbus Pharmaceuticals, Inc. and Kaken Pharmaceutical Co., Ltd.#
99.1	Press Release issued by Corbus Pharmaceuticals Holdings, Inc., dated January 3, 2019.

# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

# **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.

# CORBUS PHARMACEUTICALS HOLDINGS, INC.

Dated: January 3, 2019 By: <u>/s/ Yuval Cohen</u>

Name: Yuval Cohen

Title: Chief Executive Officer

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## **CONFIDENTIAL TREATMENT**

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED AS TO CERTAIN PORTIONS OF THIS DOCUMENT. EACH SUCH PORTION, WHICH HAS BEEN OMITTED HEREIN AND REPLACED WITH AN ASTERISK [\*], HAS BEEN FILED SEPERATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

#### COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this "Agreement"), dated as of January 3, 2019 (the "Effective Date"), is entered into by and between Corbus Pharmaceuticals, Inc., a Delaware corporation ("Corbus"), and Kaken Pharmaceutical Co., Ltd., a company organized under the laws of Japan ("Licensee"). Corbus and Licensee are referred to in this Agreement individually as a "Party" and collectively as the "Parties".

#### **RECITALS:**

- **WHEREAS**, Corbus is a clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat inflammatory and fibrotic diseases;
- WHEREAS, Licensee possesses expertise in developing, manufacturing, marketing and selling pharmaceutical products worldwide; and
- **WHEREAS**, Corbus and Licensee desire to collaborate to Develop and Commercialize the Licensed Products in the Field for the Licensee Territory (as such capitalized terms are defined herein), as more fully described in this Agreement.
- NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

#### 1. **DEFINITIONS**

#### 1.1. Definitions.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, will have the respective meanings set forth below:

- 1.1.1. "Abbreviated New Drug Application" or "ANDA" has the meaning set forth in the FD&C Act 21 U.S.C. § 355(b)(2), 21 U.S.C. § 355(j) and 21 C.F.R. § 314.3 as amended, or such analogous provisions of applicable Law outside the United States.
- **1.1.2.** "Accounting Standards" means, GAAP, with respect to Corbus and IFRS or GAAP, as applicable, with respect to Licensee and its Related Parties, in each case, as generally and consistently applied throughout the Party's organization. Each Party will promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained; <u>provided</u>, <u>however</u>, that each Party may only use internationally recognized accounting principles (e.g. IFRS, GAAP, etc.).
- 1.1.3. "Acquirer" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.
- **1.1.4. "Additional Indication"** means a human disease or pathological condition intended to be treatable by a therapeutic product other than either of the Initial Indications.

- 1.1.5. "Additional Indication Japan License" has the meaning set forth in Section 10.6.
- 1.1.6. "Affiliate" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with, such Person, whether now or in the future. For purposes of this Agreement, a Person will be deemed to control another Person if it owns or controls, directly or indirectly, more than fifty percent (50%) of the equity securities of such other Person entitled to vote in the election of directors (or, in the case that such other Person is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to direct the management and policies of such other Person. The Parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management and policies of such entity. For clarity, a Person may be or become an Affiliate of another Person and may cease to be an Affiliate of such Person, in each case, during the Term of this Agreement.
  - **1.1.7.** "Agreement" has the meaning set forth in the preamble.
  - 1.1.8. "Alliance Manager" has the meaning set forth in Section 2.1.
  - 1.1.9. "Alternate Trademark" has the meaning set forth in Section 12.11.1.3.
  - **1.1.10.** "Anti-Corruption Laws" has the meaning set forth in Section 10.2.17.
  - **1.1.11.** "Auditor" has the meaning set forth in Section 8.7.3.
  - 1.1.12. "Bankrupt Party" has the meaning set forth in Section 7.4.
  - 1.1.13. "Bankruptcy Code" has the meaning set forth in Section 13.5.
  - **1.1.14.** "Bioequivalency" has the meaning set forth in Schedule 1.1.14.
  - 1.1.15. "Bioequivalency Failure" has the meaning set forth in Section 8.2.2.1.
  - **1.1.16.** "Brief" has the meaning set forth in Section 14.3.4.2(b).
- 1.1.17. "Business Day" means a day other than a Saturday, Sunday or a bank or other public holiday in Massachusetts, United States or in Tokyo, Japan.
- **1.1.18.** "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of each Calendar Year.
- **1.1.19. "Calendar Year"** means each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.1.20. "CDISC" means the Clinical Data Interchange Standards Consortium which is an interdisciplinary nonprofit organization that establishes international standards for data collection, interchange, application, and storage for the purpose of promoting interoperation of clinical research data.
- 1.1.21. "Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets. Notwithstanding the foregoing, any transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Party or changing the form or jurisdiction of organization of such Party will not be deemed a "Change of Control" for purposes of this Agreement.

- 1.1.22. "Clinical Failure" means the occurrence of either, (a) the Parties mutually agreeing through the JSC (i) [\*] and (ii) [\*], or (b) [\*].
- 1.1.23. "Clinical Study" means, with respect to any product, a Phase 1 Study, Phase 2 Study, Phase 3 Study, Post-Marketing Study, Supplemental Study or other study (including a non-interventional study) in humans to obtain information regarding such product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such product.
- **1.1.24.** "CMC" means chemistry, manufacturing and controls with respect to a product, which includes (a) Manufacturing process development records for such product, (b) all chemistry, Manufacturing and control procedures necessary for the Manufacture of such product, and (c) sourcing and testing of all raw materials and components used in the Manufacture of such product.
  - **1.1.25.** "CMC Activities" has the meaning set forth in Section 3.5.
- **1.1.26. "CMC Work Plan"** means the work plan detailing the CMC Activities to be undertaken as mutually agreed by the Parties and attached hereto as Schedule 1.1.26.
- **1.1.27.** "Collaboration" means the collaboration of the Parties under this Agreement for the Development, Manufacture and Commercialization of Licensed Products in the Field in the Licensee Territory.
- 1.1.28. "Combination Product" means any and all pharmaceutical preparations containing (a) Lenabasum (or any deuterated formulations, hydrates, solvates, salts, polymorphs, esters, prodrugs, metabolites, isomers, stereoisomers, diastereomers, enantiomers and racemates thereof) and (b) one or more additional agents (other than any of the compounds of clause (a)) having a meaningful therapeutic effect (whether coformulated or copackaged with any of the compounds of clause (a)). For the avoidance of doubt, equipment used to administer any of the foregoing will not be deemed an "additional therapeutic agent" for the purposes of the definition of "Combination Product."
- **1.1.29.** "Commercialization" or "Commercialize" means, with respect to any product, any and all activities directed to marketing, promoting, distributing, importing, exporting, using, offering to sell, or selling or otherwise commercializing such product, and any and all activities directed to obtaining any Pricing Approvals for such product, as applicable.
- 1.1.30. "Commercially Reasonable Efforts" means, with respect to the efforts and resources to be expended by a Party with respect to any objective, the reasonable, diligent, good faith efforts to accomplish such objective typically used by biotechnology or pharmaceutical companies similar in size and scope to such Party to accomplish a similar objective under similar circumstances, which efforts and resources will be those efforts and resources made with respect to products at a similar stage in development or product life and of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of Regulatory Approval given the Regulatory Authority involved, and the profitability and commercial potential of the product (including amounts due under this Agreement and any amounts payable to other licensors of patent or other Intellectual Property rights).

- 1.1.31. "Committee" means the Joint Steering Committee, the Joint Development Committee or the Joint Commercialization Committee.
- **1.1.32. "Competing Product**" means, other than any Licensed Product, any pharmaceutical product in the Licensee Territory that (a) [\*], and (b) [\*], excluding from clauses (a) and (b) Licensee's products existing on the Effective Date and set forth on <u>Schedule 1.1.32</u>.
- 1.1.33. "Competitive Infringement" means, on a Licensed Product-by-Licensed Product and country-by-country basis, where the making, using, selling, offering for sale, or importing, by any Third Party (other than any Sublicensee or authorized purchaser or other authorized transferee of such Licensed Product by either Party), of any pharmaceutical product is Covered by a Valid Claim of any Corbus Licensed Patent or a Licensee Controlled Patent. For clarity, filing of an Abbreviated New Drug Application with any applicable Regulatory Authority with respect to a Licensed Product as the reference product by any such Third Party will be deemed to be Competitive Infringement.
- **1.1.34. "Competitive (Corbus) Infringement"** means any Competitive Infringement with respect to any Licensed Product in the Corbus Territory, but does not include any Competitive (Licensee) Infringement.
- **1.1.35. "Competitive (Licensee) Infringement"** means any Competitive Infringement with respect to any Licensed Product in the Licensee Territory, but does not include any Competitive (Corbus) Infringement.
- 1.1.36. "Confidential Information" means any and all confidential or proprietary information and data and all other scientific, pre-clinical, clinical, regulatory, Manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is or has been provided by one Party or any of its Affiliates to the other Party or any of its Affiliates in connection with this Agreement.
- 1.1.37. "Contract" means any contract, agreement, lease, sublease, license, sales order, purchase order, loan, credit agreement, bond, debenture, note, mortgage, indenture, guarantee, undertaking, instrument, arrangement, understanding or other commitment, whether written or oral, that is or was binding on any Person or any part of its property under applicable Law, whether in effect or if expired or terminated solely with respect to any provisions surviving such expiration or termination as of the Effective Date, including all amendments related to any of the foregoing.
- 1.1.38. "Control" means, with respect to any Patents or Know-How, the possession (whether by ownership, license or sublicense, other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) by a Party of the ability to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Patents or Know-How as provided for in this Agreement, without (a) violating the terms or conditions of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access and use, and (b) paying any consideration to any Third Party, except for that which a Party in-licenses and under which the other Party elects to take a sublicense and agrees to make the associated payments pursuant to Section 7.2.2 or 7.2.4, as applicable, which will be considered under the Control of such Party. Notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any Patents or Know-How that are owned or in-licensed by an Acquirer except (a) with respect to any such Patents or Know-How arising from active participation by employees or consultants of the Acquirer in the Collaboration after such Change of Control, (b) to the extent that any such Patents or Know-How are included in or used in furtherance of the Collaboration by the Acquirer after such Change of Control, or (c) for Know-How and Patents constituting improvements (or direct improvements to such improvements) to the Corbus Licensed Technology, the Licensee Background Technology or Program IP (as applicable) in existence prior to such Change of Control developed or conceived by any employees or consultants of the Acquirer.

- 1.1.39. "Controlling Party" has the meaning set forth in Section 12.6.4.
- **1.1.40.** "Corbus" has the meaning set forth in the preamble.
- 1.1.41. "Corbus Indemnitees" has the meaning set forth in Section 11.1.
- 1.1.42. "Corbus Licensed Know-How" means any and all Know-How Controlled by Corbus or its Affiliates (solely or jointly with a Third Party) (a) in existence as of the Effective Date, or (b) arising during the Term, including that comprising New Corbus IP, comprising New Lenabasum IP, or within Corbus' interest in the Joint Program IP, that, in each case of (a) and (b), is necessary or useful for the Exploitation of any Licensed Products in the Field.
- 1.1.43. "Corbus Licensed Patents" means any and all Patents Controlled by Corbus or its Affiliates (solely or jointly with a Third Party) (a) in existence as of the Effective Date, or (b) arising during the Term, including those comprising New Corbus IP, comprising New Lenabasum IP, or within Corbus' interest in the Joint Program IP, that, in each case of (a) and (b), are necessary or useful for the Exploitation of any Licensed Products in the Field. The Corbus Licensed Patents existing as of the Effective Date are set forth on Schedule 1.1.43.
  - 1.1.44. "Corbus Licensed Technology" means, collectively, the Corbus Licensed Know-How and the Corbus Licensed Patents.
  - 1.1.45. "Corbus Territory" means all countries, territories and possessions of the world, except Japan.
- 1.1.46. "Cover", "Covering" or "Covered" means that, with respect to a Licensed Product under this Agreement or a product of a Third Party, but for a license granted to any Person under any claim included in a Patent, the manufacture, use, sale, offer for sale or importation of such Licensed Product or such product, as applicable, in the Field in the relevant Territory by such Person would infringe such claim, where the reference to "claim" in this definition includes the claims of any pending Patent application as if issued.
- 1.1.47. "Develop" and "Development" means, with respect to any product, any and all nonclinical, preclinical and clinical drug development activities conducted before or after obtaining Regulatory Approval for such product that are reasonably related to or leading to the development, preparation, or submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting or expanding Regulatory Approval of such product, together with all activities related to pharmacokinetic profiling, design and conduct of Nonclinical Studies and Clinical Studies (including Post-Marketing Studies) of such product, and regulatory affairs, statistical analysis, report writing, and regulatory filing creation and submission related to the foregoing (including the services of outside advisors and consultants in connection therewith).

- 1.1.48. "Development Costs" means, with respect to a Licensed Product, those costs and expenses directly incurred in connection with the performance of any Development activities, including as set forth under the Initial Indications Development Plan, for such Licensed Product, including costs for full-time scientific or technical persons, fees charged by Third Party service providers, and other Out-of-Pocket Costs, any and all costs and expenses incurred in connection with the performance of any Clinical Study for such Licensed Product, including the cost to manufacture the supply of drug product for such Licensed Product for any Clinical Studies, and costs related to preparing and filing applications for Regulatory Approval or submissions to Regulatory Authorities (including associated filing fees, translation expenses and legal and other professional service fees).
  - **1.1.49.** "Disputes" has the meaning set forth in Section 14.3.1.
  - **1.1.50.** "**DM**" means the disease or pathological indication Dermatomyositis.
  - **1.1.51.** "Dollars" or "\$" means the legal tender of the United States.
  - **1.1.52.** "Effective Date" has the meaning set forth in the preamble.
- **1.1.53. "Efficacy Concern"** means that a reasonable person would conclude that a Clinical Failure is likely based on the efficacy data from Clinical Studies with respect to a Licensed Product.
- 1.1.54. "Executive Officer" means, for Corbus, its Chief Executive Officer or another senior executive designee with responsibilities and seniority comparable thereto, and for Licensee, its Chief Executive Officer or another senior executive designee with responsibilities and seniority comparable thereto; provided that any of the foregoing individuals may designate the Chief Financial Officer as his/her designee for financial related matters. In the event that the position of any of the Executive Officers identified in this Section 1.1.54 no longer exists due to a Change of Control, corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable Executive Officer will be replaced with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.
  - 1.1.55. "Existing In-Licensing Agreements" has the meaning set forth in Section 7.2.1.
  - 1.1.56. "Existing Trademark" has the meaning set forth in Section 12.11.1.1.
  - 1.1.57. "Expedited Arbitration" has the meaning set forth in Section 14.3.4.1.
  - **1.1.58.** "Expedited Dispute" has the meaning set forth in Section 14.3.4.1.
  - 1.1.59. "Exploit" means, collectively, research, Develop, Manufacture, Commercialize, register or otherwise exploit.
  - 1.1.60. "FDA" means the United States Food and Drug Administration or any successor agency thereto.
  - 1.1.61. "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as amended.
  - 1.1.62. "Field" means the prevention or treatment of either of the Initial Indications in human patients.

- 1.1.63. "First Commercial Sale" means, on a Licensed Product-by-Licensed Product basis, the first commercial sale in an arms' length transaction of a Licensed Product to a Third Party by Licensee or any of its Related Parties in the Licensee Territory following receipt of applicable Regulatory Approval of such Licensed Product in the Licensee Territory.
  - **1.1.64.** "First Regulatory Milestone" has the meaning set forth in Section 8.2.1.
- 1.1.65. "GAAP" means (a) with respect to Corbus, generally accepted accounting principles as practiced in the United States, as consistently applied and (b) with respect to Licensee and its Related Parties, generally accepted accounting principles as practiced in Japan, as consistently applied.
- **1.1.66.** "GCP" means the then current standards for clinical trials for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by Regulatory Authorities in the Licensee Territory.
- 1.1.67. "Generic Competition" means, with respect to the Licensee Territory, as assessed on a Licensed Product-by-Licensed Product and Calendar Quarter-by-Calendar Quarter basis, a fraction (expressed as a percentage), the numerator of which shall be the aggregate number of units of specific Generic Products (for such applicable Licensed Product) sold in the Licensee Territory during such Calendar Quarter, and the denominator of which shall be the aggregate number of units of such specific Generic Products (for such applicable Licensed Product) sold in the Licensee Territory during such Calendar Quarter plus the aggregate number of units of such applicable Licensed Product sold in the Licensee Territory during such Calendar Quarter, based on IMS Market Data obtained by Licensee for such Generic Product, or if such data is not available, such other reliable data source as is reasonably determined by Licensee.
- 1.1.68. "Generic Product" means a Third Party product containing an active ingredient that is the same or substantially the same chemical structure as that contained in a Licensed Product (whether approved under an ANDA, or other applicable abbreviated or expedited approval process), and where bioequivalence of such Third Party product to such Licensed Product has been asserted in the application for approval to a Regulatory Authority, and where such Third Party product is approved by the applicable Regulatory Authority based upon or in reliance upon safety and efficacy data generated by Corbus, Licensee or any licensee or sublicensee (or any of their respective Affiliates) for such Licensed Product.
  - 1.1.69. "Global Development Plan" has the meaning set forth in Section 3.2.1.
- 1.1.70. "GLP" means the then current standards for laboratory activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good laboratory practice as are required by Regulatory Authorities in the Licensee Territory.
- 1.1.71. "GMP" means the then current standards for Manufacturing for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are required by Regulatory Authorities in the Licensee Territory.
- 1.1.72. "Governmental Authority" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof, or (c) any supranational body.

- 1.1.73. "Harmonization Principle" means the principle that the Development and Commercialization of the Licensed Products in the Licensee Territory, including such activities as clinical indication selection, clinical trial design (including dosing), Regulatory Approval strategy (including labelling), CMC, and marketing and commercialization strategy, (a) will be conducted so as to harmonize with the Development and Commercialization of the Licensed Products by or on behalf of Corbus in the Corbus Territory, and (b) in no event will be conducted in a manner that would materially adversely affect the Development or Commercialization of the Licensed Products by or on behalf of Corbus in the Corbus Territory.
  - **1.1.74.** "ICC" has the meaning set forth in <u>Section 14.3.3</u>.
  - 1.1.75. "IFRS" means International Financial Reporting Standards, as consistently applied.
  - **1.1.76.** "In-License Agreements" has the meaning set forth in Section 7.2.3.
- 1.1.77. "IND" means any Investigational New Drug Application, as defined in 21 C.F.R. § 312, or any corresponding application in any country or jurisdiction other than the United States.
  - **1.1.78.** "Indemnified Party" has the meaning set forth in Section 11.3.
  - 1.1.79. "Indemnifying Party" has the meaning set forth in Section 11.3.
  - 1.1.80. "Initial Indications" mean SSc and DM.
  - 1.1.81. "Initial Indications Development Plan" has the meaning set forth in Section 3.2.2.
- 1.1.82. "Intellectual Property" means, in any and all jurisdictions throughout the world, all (a) Patents, (b) trademarks, service marks, trade dress, slogans, logos, symbols, trade names, brand names or other identifiers of source or goodwill recognized by any Governmental Authority, including registrations and applications for registration thereof and including the goodwill symbolized thereby or associated therewith, (c) Internet domain names and associated uniform resource locators and social media addresses and accounts, (d) copyrights, whether in published and unpublished works of authorship, registrations, applications, renewals and extensions therefor, mask works, and any and all similar rights recognized in a work of authorship by a Governmental Authority, (e) any trade secret rights in any inventions, discoveries, improvements, trade secrets and all other confidential or proprietary information (including know-how, data (including data), formulas, processes and procedures, research records, records of inventions, test information, and market surveys), and all rights to limit the use or disclosure thereof, (f) registered and unregistered design rights, (g) rights of privacy and publicity and (h) any and all other intellectual property rights recognized by any Governmental Authority under the Laws of any country throughout the world.
  - 1.1.83. "JCC Communication Plan" has the meaning set forth in Section 2.4.3.
  - 1.1.84. "JDC Communication Plan" has the meaning set forth in Section 2.3.3.
  - 1.1.85. "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 2.4.1.

- 1.1.86. "Joint Development Committee" or "JDC" has the meaning set forth in Section 2.3.1.
- 1.1.87. "Joint Program IP" has the meaning set forth in Section 12.2.3.
- 1.1.88. "Joint Program IP Patents" means all Patents within the Joint Program IP.
- 1.1.89. "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.2.1.
- 1.1.90. "JRA Exception" has the meaning set forth in Section 12.1.2.
- 1.1.91. "Know-How" means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, Manufacturing and quality control data and know-how, including regulatory data, study designs and protocols), and Materials, in all cases, whether or not confidential, proprietary, patented or patentable, in written, electronic or any other form now known or hereafter developed.
- 1.1.92. "Knowledge" means with respect to Corbus, the actual knowledge as of the Effective Date of any of Yuval Cohen, Mark Tepper, Barbara White, Robert Discordia or Ross Lobell as, respectively, the Chief Executive Officer, Chief Science Officer, Chief Medical Officer, Vice President, CMC, or Vice President, Regulatory Affairs of Corbus and such knowledge as would be imputed to such Persons upon due inquiry (including to their direct reports and the patent attorneys and agents involved in the filing, prosecution or maintenance of any of the Corbus Licensed Patents).
- 1.1.93. "Laws" means all applicable laws, statutes, rules, regulations, orders, judgments, injunctions, ordinances or other pronouncements having the binding effect of law of any Governmental Authority, including if either Party is or becomes subject to a legal obligation to a Regulatory Authority or other Governmental Authority (such as a corporate integrity agreement or settlement agreement with a Governmental Authority).
  - 1.1.94. "Lenabasum" means the molecule described on Schedule 1.1.94.
- 1.1.95. "Licensed Products" means any pharmaceutical product consisting of or containing Lenabasum, or any deuterated formulations, hydrates, solvates, salts, polymorphs, esters, prodrugs, metabolites, isomers, stereoisomers, diastereomers, enantiomers and racemates thereof, in any strengths, forms, formulations, and modes of administration and delivery. For clarity, a Licensed Product includes any Combination Product.
  - 1.1.96. "Licensee" has the meaning set forth in the preamble.
  - 1.1.97. "Licensee Additional Development Activities" has the meaning set forth in Section 3.4.2.
  - 1.1.98. "Licensee Additional Development Proposal" has the meaning set forth in Section 3.4.2.
  - 1.1.99. "Licensee Background Patents" means the Patents within the Licensee Background Technology.

- 1.1.100. "Licensee Background Technology" means any and all Patents and Know-How Controlled by Licensee or its Affiliates (solely or jointly with a Third Party) (a) in existence as of the Effective Date or (b) arising during the Term but independently from this Agreement, that, in each case of (a) and (b), (i) are necessary for the Development, Manufacture or Commercialization of any Licensed Products in the Field, or (ii) are reasonably useful for the Development, Manufacture or Commercialization of any Licensed Products in the Field and is also used by Licensee or any of its Affiliates in connection with the Development, Manufacture or Commercialization of Licensed Products in the Field in the Licensee Territory, and, for clarity, excluding the Licensee Program IP and Licensee's interest in the Joint Program IP.
  - 1.1.101. "Licensee Controlled Patents" has the meaning set forth in Section 12.5.1.1.
  - **1.1.102.** "Licensee Indemnitees" has the meaning set forth in Section 11.2.
- **1.1.103.** "Licensee Licensed Technology" means, collectively the Licensee Background Technology, the Licensee Program IP, and Licensee's interest in the Joint Program IP.
  - 1.1.104. "Licensee Program IP" has the meaning set forth in Section 12.2.2.
  - 1.1.105. "Licensee Program IP Patents" means all Patents within the Licensee Program IP.
  - 1.1.106. "Licensee Territory" means Japan.
  - 1.1.107. "Licensee Territory Commercialization Plan" has the meaning set forth in Section 4.2.
- 1.1.108. "Lien" means any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, adverse claim, option, right of first refusal, preemptive right, community property interest or other restriction of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).
  - **1.1.109.** "Losses" has the meaning set forth in Section 11.1.
- 1.1.110. "Manufacturing" or "Manufacture" means, with respect to any product, all activities related to the manufacture of such product, including, but not limited to, manufacturing active pharmaceutical ingredient and drug product for Development or Commercialization, packaging, in-process and finished product testing, release of such product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of such product, ongoing stability tests, storage, shipment, and regulatory activities related to any of the foregoing.
  - 1.1.111. "Manufacturing Price" means [\*]% of the cost of manufacturing (as such cost is defined in the Supply Agreement).
  - 1.1.112. "Material Communications" has the meaning set forth in Section 5.1.2.
- **1.1.113.** "Materials" means all tangible compositions of matter, devices, articles of manufacture, assays, biological, chemical or physical materials and other similar materials.

- 1.1.114. "MHLW" means the Japanese Ministry of Health, Labour and Welfare or any successor agency thereto.
- **1.1.115.** "Narcotics and Psychotropics Control Act" means the Japanese Narcotics and Psychotropics Control Act (Act No. 14 of March 17, 1953).
- **1.1.116.** "NDA" means any New Drug Application as described in 21 C.F.R. § 314, or any corresponding application for Regulatory Approval in any country or jurisdiction other than the United States.
  - **1.1.117.** "Negotiation Period" has the meaning set forth in Section 10.6.
- 1.1.118. "Net Sales" means, with respect to a Licensed Product, the gross amounts invoiced or received by or on behalf of Licensee or any of its Related Parties for any Licensed Product sold to Third Parties (other than Sublicensees, but including wholesalers and distributors) in bona fide, arms-length transactions, as determined in accordance with Accounting Standards consistently applied less the following permitted deductions:
  - (a) trade, quantity and cash discounts, rebates, allowances or credits actually given on such Licensed Product sold;
  - (b) amounts repaid or credited by reason of defect, rejection, recall, or return of Licensed Product previously sold;
  - (c) distribution, transportation, importation, shipping, insurance, and other handling expenses directly chargeable to sales of such Licensed Product;
    - (d) retroactive price reductions or billing corrections for Licensed Product previously sold;
  - (e) amounts previously included in Net Sales of such Licensed Product that are adjusted or written-off by Licensee or its Related Parties as bad debt or otherwise uncollectible in accordance with the standard practices of Licensee or its Related Parties for writing off uncollectible amounts consistently applied; *provided*, *however*, that if any such written-off amounts are subsequently collected, then such collected amounts will be included in Net Sales in the period in which they are subsequently collected; and
  - (f) import taxes, export taxes, excises, sales taxes, value added taxes, consumption taxes, duties or other taxes imposed upon and paid (excluding income or franchise taxes of any kind) allocated to sales of such Licensed Product in accordance with Licensee's or such Related Party's standard policies and procedures consistently applied across its products, as applicable.

In the case of any sale or other disposal of a Licensed Product between or among Licensee and any of its Related Parties for resale, Net Sales will be calculated only on the value charged or invoiced on the first arm's-length sale thereafter to a Third Party (other than a Sublicensee, but including wholesalers and distributors). In the case of any sale or other disposal for value, such as barter or countertrade, of any Licensed Product, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales will be calculated on the value of the non-cash consideration received or the fair market price (if higher) of such Licensed Product(s) in the country of sale or disposal. In addition, in the case of any sale to a distributor or other Third Party other than in an arm's length transaction or in a transaction under which Licensee or any of its Related Parties receives cash consideration other than or in addition to that metered on units of Licensed Product, then for purposes of the calculation of Net Sales associated with such transaction, all amounts paid and other value provided by the distributor or other Third Party to Licensee or such Related Party will be equitably apportioned between the purchased units of Licensed Product and any other products or services provided by Licensee or such Related Party to the distributor or other Third Party and the amount apportioned to units of Licensed Product will be included in the calculation of Net Sales. Licensee will promptly deliver to Corbus a written report setting forth such apportionment. In the event Corbus disagrees with such apportionment, Corbus will so notify Licensee and the Parties will meet to discuss and resolve such disagreement in good faith. If the Parties are unable to agree in good faith on such apportionment within thirty (30) days, the matter will be submitted to Expedited Arbitration.

Notwithstanding the foregoing, the following will not be included in Net Sales: (i) samples of Licensed Product used to promote additional Net Sales, in amounts consistent with normal business practices of the selling party; and (ii) disposal or use of Licensed Products in Clinical Studies or under compassionate use, patient assistance, named patient use, or non-registrational studies or other similar programs or studies where the Licensed Product is supplied without charge.

If a Licensed Product is sold as part of a Combination Product, Net Sales will be the product of (A) Net Sales of the Combination Product calculated as above (i.e., calculated as for a Licensed Product that is not a Combination Product) and (B) the fraction (A/(A+B)), where:

"A" is the gross invoice price in such country of a Licensed Product having as its sole therapeutically active ingredient Lenabasum (or any deuterated formulations, hydrates, solvates, salts, polymorphs, esters, prodrugs, metabolites, isomers, stereoisomers, diastereomers, enantiomers and racemates thereof); and

"B" is the gross invoice price in such country of the other component having a meaningful therapeutic effect contained in such Combination Product.

If "A" or "B" cannot be determined by reference to the sales of a Licensed Product that is not a Combination Product, or sales of the other component, as applicable, as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation will be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variations in dosage units and the relative fair market value of each therapeutically active component in the Combination Product. If the Parties are unable to reach such an agreement prior to the end of the applicable accounting period, the Parties will refer such matter to a jointly selected Third Party with expertise in the pricing of pharmaceutical products that is not, and has not in the past five (5) years been, an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party for resolution.

- 1.1.119. "New-Controlling Party" has the meaning set forth in Section 12.6.5.1.
- 1.1.120. "New Corbus IP" has the meaning set forth in Section 12.2.1.
- 1.1.121. "New Lenabasum IP" has the meaning set forth in Section 12.2.1.2.
- 1.1.122. "NHI" means the National Health Insurance in Japan.
- **1.1.123.** "NHI Price" means the NHI price in Japan (yakka).

- 1.1.124. "Non-Bankrupt Party" has the meaning set forth in Section 7.4.
- 1.1.125. "Nonclinical Studies" means all non-human studies, including preclinical studies and toxicology studies, of Licensed Products.
  - 1.1.126. "Non-Controlling Party" has the meaning set forth in Section 12.6.4.
  - 1.1.127. "Notice" has the meaning set forth in Section 10.6.
- 1.1.128. "Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties and specifically identifiable and incurred to conduct such activities for a Licensed Product, including payments to contract personnel (including contractors, consultants and subcontractors).
  - **1.1.129.** "Parties" has the meaning set forth in the preamble.
  - 1.1.130. "Party" has the meaning set forth in the preamble.
- 1.1.131. "Patent" means all patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts and equivalents of any of the foregoing in any country or jurisdiction.
  - 1.1.132. "Patent Challenge" has the meaning set forth in Section 13.6.
- 1.1.133. "Patent Costs" means the Out-of-Pocket Costs and expenses paid to outside legal counsel and other Third Parties (including to any licensor pursuant to any in-license), and filing and maintenance expenses, incurred in Prosecuting and Maintaining Patents and enforcing and defending them.
- 1.1.134. "Person" means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or Governmental Authority, or any other similar entity.
- 1.1.135. "Phase 1 Study" means a clinical study of an investigational product in patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. § 312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.
- 1.1.136. "Phase 2 Study" means a clinical study of an investigational product in patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. § 312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. § 312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. § 312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Study (e.g., a phase 1/2 trial).

- 1.1.137. "Phase 3 Study" means a clinical study of an investigational product in patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. § 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.
  - 1.1.138. "PMDA" means Japan's Pharmaceuticals and Medical Devices Agency or any successor agency thereto.
- **1.1.139. "PMDA-Required Supplemental Study"** means a Supplemental Study, the completion of which is a condition to issuance of Regulatory Approval by the MHLW for a Licensed Product in an Initial Indication in the Licensee Territory.
- **1.1.140.** "Post-Marketing Study" means a non-human or human clinical study of a Licensed Product initiated after receipt of Regulatory Approval for such Licensed Product in a country or territory, that is required by the Regulatory Authority in such country or territory to maintain the Regulatory Approval for such Licensed Product in such country or territory, but excluding any Supplemental Study.
- **1.1.141.** "**Pricing Approval**" means such governmental approval, agreement, determination or decision establishing prices for a Licensed Product that can be charged or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price or reimbursement of pharmaceutical products.
- 1.1.142. "Pricing Matters" means all issues and decisions regarding (a) price, price terms and other contract terms with respect to Licensed Product sales, including discounts, rebates, other price concessions and service fees to payors and purchasers and (b) reimbursement programs applicable to a Licensed Product.
  - **1.1.143.** "Proceeding" means an action, suit or other proceeding before a governmental tribunal.
  - 1.1.144. "Program IP" has the meaning set forth in Section 12.2.3.
  - 1.1.145. "Program IP Patents" means all Patents within the Program IP.
  - **1.1.146.** "Promotional Materials" has the meaning set forth in <u>Section 4.4.</u>
- 1.1.147. "Prosecution and Maintenance" means, with respect to a particular Patent, the preparation, filing, prosecution and maintenance of such Patent, as well as re-examinations, reissues and the like with respect to that Patent, together with the conduct of interferences, the defense of oppositions and other similar proceedings with respect to that Patent (and the foreign equivalents of any of the foregoing). "Prosecute and Maintain" and "Prosecuting and Maintaining" have corresponding meanings.
- 1.1.148. "Qualified Assignee" means an entity engaged in the pharmaceutical or biotechnology industry (a) that has an investment grade credit rating with respect to such entity's unsecured indebtedness (or whose ultimate parent's unsecured indebtedness is so rated), or (b) (i) whose securities are then listed upon a United States securities exchange or a national securities exchange in France, Germany, Italy, Spain, the United Kingdom or Japan and (ii) has a market capitalization of greater than or equal to U.S. \$[\*] at the time of the assignment contemplated under Section 14.1.1.

- 1.1.149. "Regulatory Approval" means all approvals by Regulatory Authorities necessary for the manufacture, marketing, importation and sale of a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but not including any Pricing Approvals. If the MHLW requires that any of Licensed Products be scheduled in the Narcotics and Psychotropics Control Act, Regulatory Approval will include any approvals required under the Narcotics and Psychotropics Control Act for the manufacture, marketing, importation and sale of such Licensed Products in Licensee Territory.
  - 1.1.150. "Regulatory-Approval Trigger Date" has the meaning set forth in Section 14.1.1.
- **1.1.151.** "Regulatory Authority" means any Governmental Authority involved in granting approvals for the Development, Manufacturing, Commercialization, Pricing Approval of pharmaceutical products, including the FDA, the European Medicines Agency, the European Commission, the MHLW and the PMDA.
- **1.1.152.** "Regulatory Exclusivity" means, with respect to any product, any exclusive marketing rights or data exclusivity rights with respect to such product (other than provided by Patents Covering such product) conferred for the Licensee Territory by any Regulatory Authority of the Licensee Territory.
- 1.1.153. "Regulatory Filing" means any submission to a Regulatory Authority, including all applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals), together with any related correspondence and documentation submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to a product and all data contained in any of the foregoing, including all INDs, NDAs, regulatory drug lists, advertising and promotion documents, clinical data, adverse event files and complaint files, and includes any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment to any of the foregoing.
- 1.1.154. "Regulatory Materials" means any regulatory notification, communication, correspondence, Regulatory Filings, Regulatory Approvals and other filings made to, received from or otherwise conducted with a Regulatory Authority related to Developing, Manufacturing, obtaining marketing authorization, marketing, selling or otherwise Commercializing a pharmaceutical product in a particular country or jurisdiction.
  - 1.1.155. "Regulatory Milestone Event" has the meaning set forth in Section 8.2.1.
  - 1.1.156. "Regulatory Milestone Payment" has the meaning set forth in Section 8.2.1.
- 1.1.157. "Related Party(ies)" means (a) with respect to Licensee, Licensee's Affiliates and Sublicensees, and (b) with respect to Corbus, Corbus' Affiliates and Sublicensees.
- **1.1.158.** "Representatives" means, with respect to a Party, the Affiliates of such Party, and each of such Party's and its Affiliates' respective officers, directors, managers, employees, consultants, and contractors.
- 1.1.159. "Royalty Patents" means the Corbus Licensed Patents excluding (i) all Patents that are part of the New Lenabasum IP and (ii) Corbus' interest in the Joint Program IP Patents.
  - 1.1.160. "Royalty Term" has the meaning set forth in Section 8.5.

- 1.1.161. "Safety Concern" means, with respect to any Licensed Product, (a) any safety concern required to be reported under 21 C.F.R. § 312.32 or Article 273 of the Enforcement Regulations of the Law on Securing Quality, Efficacy and Safety of Drugs of Japan (or any equivalent Law in any other country or jurisdiction outside the United States or Japan) if an IND with respect to such Licensed Product was open at the time of the observation (or that would be so reportable if an IND was open at such time), or (b) a toxicity or drug safety issue or a Serious Adverse Event reasonably related to or observed in connection with Development or Commercialization activities with respect to a Licensed Product.
  - **1.1.162.** "Sales Milestone Event" has the meaning set forth in Section 8.3.1.
  - 1.1.163. "Sales Milestone Payment" has the meaning set forth in Section 8.3.1.
  - 1.1.164. "SDEA" has the meaning set forth in Section 5.5.
  - **1.1.165.** "Securitization Transaction" has the meaning set forth in Section 14.1.2.
- 1.1.166. "Serious Adverse Event" means an adverse drug experience or circumstance that results in any of the following outcomes: (a) death, (b) life-threatening condition, (c) inpatient hospitalization or a significant prolongation of existing hospitalization, (d) persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, (e) congenital anomaly/birth defect, or (f) significant intervention required to prevent permanent impairment or damage.
- **1.1.167. "Significant Trial"** means, with respect to a Licensed Product, a human clinical trial that, at the time of commencement, is reasonably expected to cost in excess of U.S. \$[\*].
  - 1.1.168. "SSc" means the disease or pathological indication Systemic Sclerosis.
- **1.1.169.** "Sublicensee" means a Third Party to which a Party or its Affiliate has granted or grants rights, as permitted under this Agreement, to Develop, Manufacture or Commercialize any Licensed Products, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights).
- **1.1.170.** "Supplemental Study" means any Clinical Study (other than any Post-Marketing Study) for a Licensed Product beyond what is contemplated in the Initial Indications Development Plan.
  - **1.1.171.** "Supply Agreement" has the meaning set forth in Section 6.1.
  - **1.1.172.** "Supply Transfer Price" has the meaning set forth in Section 8.4.1.1.
  - **1.1.173.** "Technology Transfer Plan" has the meaning set forth in <u>Section 3.8.1</u>.
  - 1.1.174. "Term" has the meaning set forth in Section 13.1.
- **1.1.175.** "Territory" means (a) with respect to Corbus, the Corbus Territory and (b) with respect to Licensee, the Licensee Territory.
  - 1.1.176. "Third Party" means any Person other than Licensee, Corbus or their respective Affiliates.

- 1.1.177. "Third Party Action" has the meaning set forth in Section 12.6.3.
- 1.1.178. "Third Regulatory Milestone" has the meaning set forth in Section 8.2.1.
- **1.1.179.** "Trademark" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.
  - 1.1.180. "United States" or "U.S." means the United States of America and its territories, possessions and commonwealths.
- 1.1.181. "Valid Claim" means a claim of a Patent that (a) has not been rejected, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken, or (b) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer. In order to be a Valid Claim, any claim being prosecuted in a pending patent application must be prosecuted in good faith and not have been pending for more than five (5) years from the filing date of the first utility patent application (or equivalent concept in any such country) in the patent application family of such patent application in the country in question, in which case it will cease to be considered a Valid Claim until the patent issues and recites said claim.
  - 1.1.182. "Withdrawing Party" has the meaning set forth in Section 12.6.5.1.
  - 1.1.183. "Yen" or "JPY" means the legal tender of Japan.

#### 2. GOVERNANCE

2.1. Alliance Manager. Promptly following the Effective Date, each Party will designate an individual to facilitate communication and coordination of the Parties' activities under this Agreement relating to Licensed Products in the Licensee Territory (each, an "Alliance Manager"). Each Alliance Manager may also serve as a representative of its respective Party on one or more Committees. For clarity, unless an Alliance Manager is a representative of its respective Party on a particular Committee, each Alliance Manager will have no voting right on any Committee unless otherwise agreed to in writing by the Parties.

#### 2.2. Joint Steering Committee.

**2.2.1.** Formation; Composition; Dissolution. Within thirty (30) days after the Effective Date, the Parties will establish a committee (the "Joint Steering Committee" or "JSC") to provide strategic oversight of the Parties' activities under the Collaboration. Each Party will initially appoint three (3) representatives to the JSC, with each representative having knowledge and expertise in the Development and Commercialization of molecules and products similar to the Licensed Products, and having sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibility. The JSC may change its size from time to time by mutual consent of the Parties, provided that the JSC will consist at all times of an equal number of representatives of each of Corbus and Licensee. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC, provided that such participants have no voting authority at the JSC and are bound under written obligations of confidentiality and non-use no less protective of the Parties' Confidential Information than those set forth in this Agreement. The JSC will be chaired on a Calendar Year basis by a chairperson alternately designated by Corbus or Licensee. The initial chairperson of the JSC for the period commencing on the Effective Date and ending on January 1, 2020 will be a Corbus designated chairperson, who will then be replaced by a Licensee designated chairperson on January 1, 2020, and so forth. The JSC chairperson's responsibilities will include conducting meetings, including, when feasible, ensuring that objectives for each meeting are set and achieved. The JSC will exist for so long as the JDC or JCC exists or there is at least one Licensed Product being Commercialized under this Agreement.

- 2.2.2. Specific Responsibilities of the JSC. The JSC will have the following responsibilities in connection with the Collaboration:
  - **2.2.2.1.** reviewing, discussing and approving any amendments to the Initial Indications Development Plan, including the proposed addition thereto of any PMDA-Required Supplemental Study or Licensee Additional Development Activities;
    - **2.2.2.2.** approving any amendments to the CMC Work Plan;
  - **2.2.2.3.** approving any Licensee Additional Development Proposals and corresponding Licensee Additional Development Activities proposed to be conducted;
    - **2.2.2.4.** determining or approving that a Clinical Failure has occurred;
    - 2.2.2.5. approving any proposed Post-Marketing Studies for any Licensed Product in the Licensee Territory;
  - **2.2.2.6.** approving the commercial positioning with respect to target patients of the Licensed Products in the Licensee Territory and approving any proposed material changes thereto;
  - **2.2.2.7.** approving the key promotional message with respect to the Licensed Products in the Licensee Territory and approving any proposed material changes thereto;
  - 2.2.2.8. approving the Licensee Territory Commercialization Plan for each Licensed Product, including, in each case, any amendments thereto;
  - **2.2.2.9.** reviewing, discussing and providing input on the strategy with respect to Pricing Matters, including the price negotiation strategy with Regulatory Authorities for the Licensed Products in the Licensee Territory and other communications with Regulatory Authorities, and approving such strategy with respect to Pricing Matters (including the price bands for purposes of such strategy) for the Licensed Products in the Licensee Territory;
  - **2.2.2.10.** providing a forum for Corbus to raise for discussion and resolution of any decision regarding the Development or Commercialization of the Licensed Products in the Licensee Territory perceived by Corbus to be deviating from the Harmonization Principle;
    - **2.2.2.11.** coordinating the filing of Joint Program IP Patent applications;
    - 2.2.2.12. resolving any issues escalated by, or disputes within, the JDC or JCC; and
  - **2.2.2.13.** establishing such additional joint subcommittees of the JSC as it deems necessary to oversee activities relating to the Licensed Products in the Licensee Territory to achieve the objectives and intent of the Collaboration.

- **2.2.2.14.** determining in its reasonable discretion whether the Existing Trademark is suited for use in the Licensee Territory and if it is not, or if use of the Existing Trademark with the Licensed Products in the Licensee Territory is rejected by the PMDA or the MHLW, reviewing and approving an alternate Trademark to be used with the Licensed Products in the Licensee Territory as contemplated by Section 12.11.1.3.
- 2.2.3. Meetings. The JSC will meet at least twice per Calendar Year, unless the Parties mutually agree in writing to a different frequency. The JSC may meet in person, by videoconference, or by teleconference, provided that at least one meeting of the JSC per Calendar Year will be in person. In-person JSC meetings will be held at locations in the United States and in Japan alternately selected by Corbus and by Licensee, or at any other location mutually agreed by the members of the JSC. The first JSC meeting shall be held within ninety (90) days of the Effective Date. Meetings of the JSC will be effective only if at least one (1) representative of each Party is present or participating in such meeting. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. No later than five (5) Business Days prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the Alliance Managers together will prepare and circulate an agenda for such meeting; provided, however, that either Party will be free to propose additional topics to be included on such agenda, either prior to or in the course of such meeting, and any Party which will be presenting to the JSC at any meeting as part of such agenda will prepare and provide detailed materials to the JSC representatives to support discussion. Either Party may also call a special meeting of the JSC (by videoconference, teleconference or in person) by providing at least ten (10) Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the Alliance Managers to provide the members of the JSC no later than three (3) Business Days prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision. The JSC chairperson will be responsible for preparing reasonably detailed written minutes of JSC meetings that reflect all decisions made and action items identified at such meetings. The JSC chairperson will send meeting minutes to each member of the JSC for review and approval within ten (10) Business Days after each JSC meeting. Minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) Business Days of receipt. Any material changes proposed to any meeting minutes by either Party's members of the JSC will be promptly circulated by the JSC chairperson to each member of the JSC for review and approval within ten (10) Business Days of receipt, with such process repeating until the meeting minutes are approved by all JSC members. Minutes will be officially endorsed by the JSC at the next JSC meeting, and will be signed by the Alliance Managers.
- **2.2.4.** *Decision-Making*. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. Approvals of the JSC will require unanimous agreement. If the JSC cannot reach unanimous agreement on an issue that comes before the JSC within fifteen (15) days of the meeting where such issue was raised and over which the JSC has oversight, the Parties will refer such issue for resolution in accordance with <u>Section 2.5</u>.

#### 2.3. Joint Development Committee.

**2.3.1.** Formation; Composition; Dissolution. Within thirty (30) days after the Effective Date, the Parties will establish a committee to coordinate the Development of Licensed Products (the "Joint Development Committee" or "JDC") in the Licensee Territory. Each Party will initially appoint three (3) representatives to the JDC, with each representative having knowledge and expertise in the Development of molecules and products similar to the Licensed Products and having sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of the Parties, provided that the JDC will consist at all times of an equal number of representatives of each of Corbus and Licensee. Each Party may replace its JDC representatives at any time upon written notice to the other Party. The JDC may invite non-members to participate in the discussions and meetings of the JDC, provided that such participants have no voting authority at the JDC and are bound under written obligations of confidentiality and non-use no less protective of the Parties' Confidential Information than those set forth in this Agreement. The JDC will be chaired by a chairperson designated by Corbus, whose responsibilities will include conducting meetings, including, when feasible, ensuring that objectives for each meeting are set and achieved. The JDC will exist for so long as at least one Licensed Product is being Developed under this Agreement.

- **2.3.2.** Specific Responsibilities of the JDC. The JDC will have the following responsibilities in connection with the Collaboration:
  - **2.3.2.1.** overseeing and reviewing the Development of each Licensed Product in the Licensee Territory, including the conduct of any Post-Marketing Study;
  - **2.3.2.2.** reviewing and providing input on any amendments to the Initial Indications Development Plan, including the proposed addition of any PMDA-Required Supplemental Study or Licensee Additional Development Activities thereto, for approval by the JSC of any such amendments;
  - **2.3.2.3.** reviewing and providing input on any Licensee Additional Development Proposals and corresponding Licensee Additional Development Activities proposed to be conducted, for approval thereof by the JSC;
  - **2.3.2.4.** reviewing and providing input on any proposed Post-Marketing Studies for any Licensed Product in the Licensee Territory, for approval thereof by the JSC;
  - **2.3.2.5.** creating and implementing the overall strategy regarding Regulatory Approval of Licensed Products in the Licensee Territory, including content of label or other prescribing information;
    - **2.3.2.6.** reporting on subcontracting services pursuant to <u>Section 3.6</u>;
  - **2.3.2.7.** without limiting <u>Section 2.3.2.5</u>, reviewing and providing input on any material Regulatory Filings to Regulatory Authorities for Regulatory Approval of Licensed Products in the Licensee Territory;
  - **2.3.2.8.** determining and overseeing a reasonable and expeditious process to identify, and under which Corbus will provide to Licensee, any submissions, filings or other material communications with a Regulatory Authority with respect to a Licensed Product in the Corbus Territory to which Licensee needs access to support obtaining or maintaining a Regulatory Approval for a Licensed Product in the Licensee Territory;
  - **2.3.2.9.** without limiting <u>Sections 2.3.2.5</u> and <u>2.3.2.7</u>, providing a forum to facilitate the flow of information between the Parties with respect to the Development and Regulatory Approval of the Licensed Products in the Licensee Territory, including the reporting of and discussion of communications with Regulatory Authorities; and
  - **2.3.2.10.** reviewing and providing input on any proposed amendments to the CMC Work Plan for approval by the JSC of any material such amendments.

2.3.3. Meetings. The JDC will meet at least four (4) times per Calendar Year, unless the Parties mutually agree in writing to a different frequency. The JDC may meet in person, by videoconference, or by teleconference, provided that at least two (2) meeting of the JDC per Calendar Year will be in person. In-person JDC meetings will be held at locations in the United States and in Japan alternately selected by Corbus and by Licensee, or at any other location mutually agreed by the members of the JDC. Meetings of the JDC will be effective only if at least one (1) representative of each Party is present or participating in such meeting. Each Party will bear the expense of its respective JDC members' participation in JDC meetings. No later than fifteen (15) days prior to the first meeting of the JDC and in each Calendar Year thereafter while the JDC exists, the Alliance Managers will prepare a communication plan setting forth a schedule of the dates of each JDC meeting for that Calendar Year and a proposed agenda for each such meetings ("JDC Communication Plan"). No later than five (5) Business Days prior to any meeting of the JDC (or such shorter time period as the Parties may agree), the Alliance Managers together will prepare and circulate an agenda for such meeting based on the agenda previously included for such meeting in the JDC Communication Plan; provided, however, that either Party will be free to propose additional topics to be included on such agenda, either prior to or in the course of such meeting, and any Party which will be presenting to the JDC at any meeting as part of such agenda will prepare and provide detailed materials to the JDC representatives to support discussion. Either Party may also call a special meeting of the JDC (by videoconference, teleconference or in person) by providing at least ten (10) Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the Alliance Manager to provide the members of the JDC no later than three (3) Business Days prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision. The JDC chairperson will be responsible for preparing reasonably detailed written minutes of JDC meetings that reflect all decisions made and action items identified at such meetings. The JDC chairperson will send meeting minutes to each member of the JDC for review and approval within ten (10) Business Days after each JDC meeting. Minutes will be deemed approved unless one or more members of the JDC objects to the accuracy of such minutes within ten (10) Business Days of receipt. Any material changes proposed to any meeting minutes by either Party's members of the JDC will be promptly circulated by the JDC chairperson to each member of the JDC for review and approval within ten (10) Business Days of receipt, with such process repeating until the meeting minutes are approved by all JDC members. Minutes will be officially endorsed by the JDC at the next JDC meeting, and will be signed by the Alliance Managers.

**2.3.4.** *Decision-Making*. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. Approvals of the JDC shall require the unanimous agreement. If the JDC cannot reach unanimous agreement on an issue that comes before the JDC within ten (10) days of the meeting where such issue was raised and over which the JDC has oversight, the Parties will refer such issue for resolution to the JSC.

#### 2.4. <u>Joint Commercialization Committee</u>.

**2.4.1.** Formation; Composition; Dissolution. Within three (3) months of Licensee making a Regulatory Filing in respect of the first Licensed Product for either of the Initial Indications with any Regulatory Authority of the Licensee Territory or such earlier time as decided by the JSC, the Parties will establish a committee to review and confirm Commercialization activities with respect to Licensed Products in the Licensee Territory (the "**Joint Commercialization Committee**" or "**JCC**"). Each Party will initially appoint three (3) representatives to the JCC, with each representative having knowledge and expertise in the Commercialization of products similar to the Licensed Products and having sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JCC's responsibilities. The JCC may change its size from time to time by mutual consent of the Parties, provided that the JCC will consist at all times of an equal number of representatives of each of Corbus and Licensee. Each Party may replace its JCC representatives at any time upon written notice to the other Party. The JCC may invite non-members to participate in the discussions and meetings of the JCC, provided that such participants have no voting authority at the JCC and are bound under written obligations of confidentiality and non-use no less protective of the Parties' Confidential Information than those set forth in this Agreement. The JCC will be chaired by a chairperson designated by Licensee, whose responsibilities will include conducting meetings, including, when feasible, ensuring that objectives for each meeting are set and achieved. The JCC will exist for so long as at least one Licensed Product is being Commercialized under this Agreement.

- **2.4.2.** Specific Responsibilities of the JCC. Subject to any limitations under applicable Law, the JCC will have the following responsibilities in connection with the Collaboration:
  - **2.4.2.1.** discussing and providing input on the Licensee Territory Commercialization Plan for each Licensed Product, including, in each case, any amendments thereto, for approval by the JSC;
  - **2.4.2.2.** facilitating the flow of information between the Parties with respect to the Commercialization of Licensed Products in the Licensee Territory, including information as to pricing for the Licensed Products;
    - 2.4.2.3. reviewing Promotional Materials pursuant to the provisions of Section 4.4; and
  - **2.4.2.4.** discussing strategies for abating a Competitive Infringement of any Licensed Product within either Party's respective Territory as contemplated by Section 12.6.1.
- 2.4.3. Meetings. The JCC will meet at least twice per Calendar Year, unless the Parties mutually agree in writing to a different frequency. The JCC may meet in person, by videoconference, or by teleconference, provided that at least one (1) meeting of the JCC per Calendar Year will be in person. In-person JCC meetings will be held at locations in the United States and in Japan alternately selected by Corbus and by Licensee, or at any other location mutually agreed by the members of the JCC. Meetings of the JCC will be effective only if at least one (1) representative of each Party is present or participating in such meeting. Each Party will bear the expense of its respective JCC members' participation in JCC meetings. No later than fifteen (15) days prior to the first meeting of the JCC in the stub-Calendar Year in which it is formed and in each Calendar Year thereafter while the JCC exists, the Alliance Managers will prepare a communication plan setting forth a schedule of the dates of each JCC meeting for that Calendar Year and a proposed agenda for each such meetings ("JCC Communication Plan"). No later than five (5) Business Days prior to any meeting of the JCC (or such shorter time period as the Parties may agree), the Alliance Managers together will prepare and circulate an agenda for such meeting based on the agenda previously included for such meeting in the JCC Communication Plan; provided, however, that either Party will be free to propose additional topics to be included on such agenda, either prior to or in the course of such meeting, and any Party which will be presenting to the JCC at any meeting as part of such agenda will prepare and provide detailed materials to the JCC representatives to support discussion. Either Party may also call a special meeting of the JCC (by videoconference, teleconference or in person) by providing at least ten (10) Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the Alliance Managers to provide the members of the JCC no later than three (3) Business Days prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision. The JCC chairperson will be responsible for preparing reasonably detailed written minutes of JCC meetings that reflect all decisions made and action items identified at such meetings. The JCC chairperson will send meeting minutes to each member of the JCC for review and approval within ten (10) Business Days after each JCC meeting. Minutes will be deemed approved unless one or more members of the JCC object to the accuracy of such minutes within ten (10) Business Days of receipt. Any material changes proposed to any meeting minutes by either Party's members of the JCC will be promptly circulated by the JCC chairperson to each member of the JCC for review and approval within ten (10) Business Days of receipt, with such process repeating until the meeting minutes are approved by all JCC members. Minutes will be officially endorsed by the JCC at the next JCC meeting, and will be signed by the Alliance Managers.

**2.4.4.** *Decision-Making*. The representatives from each Party have, collectively, one (1) vote on behalf of that Party. If the JCC cannot reach unanimous agreement on an issue that comes before the JCC within ten (10) days of the meeting where such issue was raised and over which the JCC has oversight, the Parties will refer such issue for resolution by the JSC. For clarity, any and all such communications or strategy involving Commercialization activities will be limited to those permitted under applicable Law.

#### 2.5. Resolution of Committee Disputes.

- **2.5.1.** Referral to Executive Officers and Executive Management. The JSC may refer any matter as to which the JSC cannot reach a consensus decision to the Executive Officers for resolution. If the JSC does so, the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. Such Executive Officers will use good faith efforts, in compliance with this Section 2.5.1, to resolve promptly such matter, which good faith efforts will include at least one meeting between such Executive Officers within five (5) Business Days after the JSC's submission of such matter to them. If the Executive Officers are unable to reach unanimous agreement on any such matter within fifteen (15) days of the matter being presented to them, then:
  - (a) if the matter escalated by the JSC relates to the Exploitation of the Licensed Products in the Field in the Licensee Territory, Licensee will have final decision-making authority over such matter (other than with respect to the matters covered by (c)); provided, however, that Licensee shall not have final decision-making authority over matters relating to (i) the Manufacture of the Licensed Products in the Field in the Licensee Territory unless and until the Parties agree that Licensee will Manufacture the Licensed Products and (ii) the Global Development Plan;
  - (b) if the matter escalated by the JSC relates to (i) the Global Development Plan or (ii) any amendment of the Initial Indications Development Plan, to the extent not covered by clause (a) (other than with respect to the matters covered by (c)), Corbus will have final decision-making authority over such matter; and
  - (c) if the matter escalated by the JSC relates to (i) whether a decision, strategy or implementation of a strategy is consistent with the Harmonization Principle, (ii) whether or not there has been a Clinical Failure or (iii) if the matter otherwise does not fall within those specified in either clause (a) or clause (b), the Executive Officers will submit their respective positions on such matter to be resolved by Expedited Arbitration. Notwithstanding anything herein to the contrary, no exercise of a Party's decision-making authority on any matters may, without the other Party's prior written consent, (i) result in a material increase in the other Party's or its Related Parties' obligations, costs or expenses, including expenditure of such Party's resources, under this Agreement, the Initial Indications Development Plan, or the Licensee Territory Commercialization Plan, (ii) unilaterally modify, amend or waive its own compliance with the terms or conditions of this Agreement, or (iii) otherwise conflict with this Agreement.

- **2.5.2.** *Good Faith.* In conducting themselves on Committees, and in exercising their rights under this Section 2.5, all representatives of both Parties will consider diligently, reasonably and in good faith all input received from the other Party, and will use reasonable efforts to reach unanimous agreement on all matters before them. In exercising any decision-making authority granted to it under this Section 2.5, each Party will act based on its good faith business judgment.
- **2.6.** General Committee Authority. Each Committee has solely the powers expressly assigned to it in this Section 2. No Committee will have any power to amend, modify, or waive the terms or conditions of this Agreement or compliance with the terms and conditions of this Agreement.

#### 3. DEVELOPMENT

#### 3.1. Responsibility; Costs.

- 3.1.1. Corbus. Subject to the responsibilities of the JDC and the other terms and conditions of this Section 3 and this Agreement, Corbus will be responsible for conducting or having conducted, in accordance with the Initial Indications Development Plan and the Harmonization Principle, the Development of the Licensed Products in the Initial Indications for purposes of obtaining and maintaining Regulatory Approval of Licensed Products in the Initial Indications in the Licensee Territory and in support of Commercializing such Licensed Products in the Initial Indications, including conducting Clinical Studies pursuant to the Initial Indications Development Plan. Such activities to be conducted by Corbus include the preparation of electronic data that meets CDISC compliance in the Licensee Territory. Subject to Section 3.4.2 and the rest of this Section 3.1.1, Corbus will bear one hundred percent (100%) of the Development Costs incurred in connection with the foregoing Development activities; provided, however, that, the portion of Development Costs in connection with the foregoing activities that are costs related to preparing and filing applications for Regulatory Approval or submissions to Regulatory Authorities (including associated filing fees, translation expenses and legal and other professional service fees) will be borne entirely by Licensee.
- **3.1.2.** *Licensee.* Subject to the responsibilities of the JDC and the other terms and conditions of this <u>Section 3</u> and this Agreement, Licensee will be responsible for conducting or having conducted, in accordance with the Harmonization Principle, any other Development of the Licensed Products, beyond what is contemplated in <u>Section 3.1.1</u>, including the preparing and filing applications for Regulatory Approval in the Field in the Licensee Territory based upon data from Clinical Studies conducted by Corbus pursuant to the Initial Indications Development Plan for purposes of obtaining and maintaining Regulatory Approval of Licensed Products in the Initial Indications in the Licensee Territory and post-Regulatory Approval clinical research in support of Commercializing such Licensed Products in the Initial Indications in the Licensee Territory not covered by the terms of <u>Sections 3.1.1</u> and <u>3.4</u>. Licensee will bear one hundred percent (100%) of the Development Costs and any other costs and expenses incurred in connection with the foregoing Development activities.
- **3.1.3.** Retained Rights. Corbus retains the exclusive right, and will have sole discretion and control over the Development of the Licensed Products for purposes of obtaining and maintaining Regulatory Approval for Commercialization of such Licensed Products anywhere in the world, other than in the Field in the Licensee Territory. Corbus will bear one hundred percent (100%) of the Development Costs incurred in connection with the foregoing Development activities.

#### 3.2. Development Plans.

- **3.2.1.** *Global Development Plan.* Corbus' worldwide plan for the Development of the Licensed Products is attached hereto as <u>Schedule 3.2.1</u> (as may be updated by Corbus from time to time so long as such update (i) does not materially adversely impact the rights or increase the obligations of Licensee and (ii) is reported to the JDC at the next JDC meeting) (the "Global Development Plan").
- **3.2.2.** *Initial Indications Development Plan.* Corbus' plan setting forth the Development activities that are necessary to be undertaken for the Licensed Product to support obtaining Regulatory Approval for each of the Initial Indications in the Licensee Territory is attached hereto as <u>Schedule 3.2.2</u> (the "**Initial Indications Development Plan**"). The JDC will review and provide input on any amendments to the Initial Indications Development Plan submitted to it in accordance with <u>Section 2.3.2.2</u>, and the JSC will approve all such amendments to the Initial Indications Development Plan in accordance with <u>Section 2.2.2.1</u>.
- **3.3.** <u>Diligence: Standards of Conduct.</u> Corbus will use Commercially Reasonable Efforts to perform the Development activities specified in the Initial Indications Development Plan.

#### 3.4. Supplemental Studies.

- **3.4.1.** *PMDA-Required Supplemental Studies*. Corbus will be responsible for conducting or having conducted, any PMDA-Required Supplemental Study. Corbus will bear one hundred percent (100%) of the Development Costs incurred in connection with the performance of any PMDA-Required Supplemental Study.
- 3.4.2. Licensee Additional Development Proposals. If Licensee desires Corbus to conduct or have conducted a Supplemental Study (other than a PMDA-Required Supplemental Study) for a Licensed Product for the purpose of seeking Regulatory Approval to market such Licensed Product in the Field in the Licensee Territory, Licensee will submit to the JDC a proposal to add such Supplemental Study to the Initial Indications Development Plan (a "Licensee Additional Development Proposal"). Each Licensee Additional Development Proposal will describe in reasonable detail the applicable Supplemental Study(ies) that Licensee desires Corbus to conduct or have conducted, including a synopsis of the trial or activities, the proposed enrollment criteria, number of patients to be included, endpoints to be measured, and statistical design and powering (the "Licensee Additional Development Activities"), as well as a proposed timeline and an analysis of the business opportunity and revenue potential for such Licensee Additional Development Activities.
- **3.4.3.** JSC Decision Regarding Licensee Additional Development Proposals/Activities. The JDC will review and provide input on any Licensee Additional Development Proposal and corresponding Licensee Additional Development Activities submitted to it in accordance with Section 2.3.2.3, and the JSC will approve all such Licensee Additional Development Proposals and corresponding Licensee Additional Development Activities in accordance with Section 2.2.2.3. The JSC will approve or reject a Licensee Additional Development Proposal and corresponding Licensee Additional Development Activities within forty-five (45) days after receipt thereof from the JDC.
  - **3.4.3.1.** If the JSC approves a Licensee Additional Development Proposal and corresponding Licensee Additional Development Activities, (a) upon such an approval, the Initial Indications Development Plan will be amended to include such Licensee Additional Development Activities, including the proposed timeline for such Licensee Additional Development Activities set forth in such Licensee Additional Development Proposal (as may be amended by the JSC); (b) the conduct of such Licensee Additional Development Activities will be subject to the responsibilities of the JSC and the JDC; and (c) any costs and expenses incurred in the performance of such Licensee Additional Development Activities will be deemed Development Costs and will be borne solely by Licensee.

- **3.4.3.2.** If the JSC does not approve a Licensee Additional Development Proposal and corresponding Licensee Additional Development Activities, then the same will not be undertaken whether by Corbus or Licensee under this Agreement.
- 3.5. CMC Development. All Development relating to CMC (other than activities related to the active pharmaceutical ingredient (API) of the Licensed Products) required to be conducted to support obtaining and maintaining Regulatory Approval in the Licensee Territory for any Licensed Product in the Initial Indications that is the subject of the Initial Indications Development Plan, including all CMC activities related to all phases of Manufacturing the Licensed Product through and including the packaging of Licensed Product in the format determined by the JSC to be preferable for the Japanese market (such as aluminum blister packs) for Commercialization in the Licensee Territory (the "CMC Activities") will be conducted by Corbus in accordance with the Harmonization Principle and the CMC Work Plan. Any and all costs and expenses incurred in connection with the CMC Activities will be borne solely by Licensee, except for such costs and expenses incurred for CMC Activities the completion of which is a condition to issuance of Regulatory Approval by the MHLW for a Licensed Product in an Initial Indication in the Licensee Territory, which costs and expenses will be borne by Corbus; provided, that with respect to any such costs and expenses borne by Licensee, [\*].
- **3.6.** Third Parties. Subject to Section 7.1.1.4 and the rest of this Section 3.6, a Party will be entitled to subcontract to Third Parties, and to utilize the services of Third Parties to perform, its Development activities, if any, under this Section 3. provided that (a) such Party requires under any such agreement executed on or after the Effective Date that such Third Party operate in a manner consistent with this Agreement and reasonably acceptable to the other Party, (b) such Party remains at all times fully liable to the other Party for its Development responsibilities under this Agreement, and (c) such Party submits at every other regularly scheduled meeting of the JDC a list of its then-current Third Party subcontractors performing any Development activities on its' behalf. Such Party will be solely responsible for direction of and communications with such Third Party service provider, but such Party will provide the other Party with reasonably detailed updates regarding any such activities from time to time through the JDC.
- **3.7. Scientific Records.** Each Party will maintain scientific records, in sufficient detail and in sound scientific manner appropriate for Patent and regulatory purposes and in compliance with GLP, GCP and GMP, as applicable, with respect to activities intended to be submitted in regulatory filings, which will fully and accurately reflect all work done and results achieved in the performance of the Development activities, Clinical Studies, and Supplemental Studies with respect to Licensed Products by such Party.

#### 3.8. Technology Transfer.

3.8.1. The Parties will negotiate in good faith and enter into a technology transfer plan so that transfer of the technology (i.e., transfer of the physical or electronic documents or other tangible manifestations) can occur within six (6) months of the Effective Date (as such period may be extended by mutual written agreement of the Parties), pursuant to which Corbus, [\*], will complete a transfer to Licensee of the Corbus Licensed Know-How in existence as of the date of such transfer that is reasonably useful for the Exploitation of Licensed Products in the Field, including (a) the then-current Manufacturing process, manufacturing data and any other information as is necessary for Manufacturing Licensed Products in the Field as and to the extent consistent with Licensee's Manufacturing rights in Section 7.1.1.3 and (b) Nonclinical Study and Clinical Study data, CMC data, study reports, batch records, vendor information, validation documentation, analyses and applicable reference standards used in analytical testing of the Licensed Products in the Initial Indications, which plan will set forth the details of such Corbus Licensed Know-How to be transferred in a format compliant with the CDISC and the timing of such transfer to be completed (the "Technology Transfer Plan"). Corbus has disclosed or will disclose to Licensee all of the Corbus Licensed Know-How that is required to be disclosed pursuant to this Section 3.8.1.

- 3.8.2. Corbus will provide any information, data and other assistance reasonably requested by Licensee to enable Licensee to carry out its obligations under this Agreement, including providing Licensee with (a) data from Corbus' Phase 3 Study sufficient to obtain Regulatory Approval for the Licensed Products in the Initial Indications, (b) Know-How Controlled by Corbus generated for Exploitation and pricing activities related to the Licensed Products worldwide, to the extent such Know-How is reasonably useful for such Exploitation and pricing activities and available and accessible to Corbus, and (c) Nonclinical Studies and other pre-clinical data, Clinical Studies data (including clinical data and other related information generated in compliance with CDISC standards), CMC data, a complete copy of any dossier for the Licensed Products, minutes of meetings with Regulatory Authorities, and any information necessary for Licensee to obtain Regulatory Approval in the Licensee Territory. Notwithstanding the foregoing, Corbus shall have no obligations under this Section 3.8.2 if providing such information, data or assistance would [\*], unless the requested information, data or assistance is required by Regulatory Authorities for Licensee to obtain Regulatory Approval in the Licensee Territory.
- 3.8.3. In the event that the Parties agree that Licensee will Manufacture Licensed Products, Corbus shall, to facilitate such transfer, (a) make available to Licensee Corbus' or its Third Party manufacturer's technical personnel with appropriate skill and experience during mutually agreeable times, [\*], (b) provide Licensee with assistance (other than financial assistance) and disclose and allow access to the Corbus Licensed Know-How necessary or reasonably useful for such Manufacturing, including Know-How related to formulating and/or packaging Licensed Products in the Field, and (c) transfer to Licensee and/or its designee all agreements with Third Parties Manufacturing, formulating and/or packaging Licensed Product in the Field for distribution of Licensed Product in the Licensee Territory (or otherwise facilitate separate agreements between Licensee and such Third Parties enabling Licensee to use such Third Parties for such activities), in each case, as and to the extent consistent with Licensee's Manufacturing rights in Section 7.1.1.3. The Manufacture of the Licensed Products by Licensee will be subject to a manufacturing agreement to be entered into by the Parties.

#### 4. COMMERCIALIZATION

#### 4.1. Responsibility, Costs.

**4.1.1.** *Licensee.* Subject to the oversight of the JSC and JCC and to the other terms and conditions of this <u>Section 4.1</u> and of this Agreement, on a Licensed Product-by-Licensed Product basis, Licensee will be responsible for all Commercialization activities relating to the Licensed Products in the Field in the Licensee Territory, at its sole cost and expense, in accordance with the Licensee Territory Commercialization Plan and the Harmonization Principle.

- **4.1.2.** Corbus. Corbus, at its sole cost and expense, will have sole responsibility and control of all Commercialization activities relating to the Licensed Product, other than in the Field in the Licensee Territory.
- **4.2.** <u>Licensee Territory Commercialization Plan.</u> No later than six (6) months following the Effective Date, Licensee will prepare and deliver to the JCC for review and input and approval by the JSC a reasonable written plan that summarizes the Commercialization activities (including any pre-Regulatory Approval activities in preparation for commercial launch) to be undertaken with respect to the Licensed Products in the Field in the Licensee Territory, where such plan will include marketing and promotional activities for the Licensed Products in the Field in the Licensee Territory aligned with the commercial positioning and the key message approved by the JSC and consistent with the Harmonization Principle (the "Licensee Territory Commercialization Plan"). Updates and modifications of the Licensee Territory Commercialization Plan may be proposed by Licensee for approval by the JSC, from time to time and no less frequently than once per Calendar Year, based upon, among other things, Licensee's Commercialization activities with respect to the Licensed Products in the Field in the Licensee Territory.
- **4.3.** Diligence: Standards of Conduct. Licensee will use Commercially Reasonable Efforts to (a) perform the Commercialization activities specified in the Licensee Territory Commercialization Plan, (b) subject to the provisions of Section 5.2, obtain Pricing Approval for a Licensed Product in the Licensee Territory within a reasonable time after having received approval from the MHLW to Commercialize such Licensed Product in each Initial Indication that is the subject of the corresponding Regulatory Approval, and (c) begin to Commercialize such Licensed Product in such Initial Indication in the Licensee Territory within [\*] of having obtained Pricing Approval for such Licensed Product in the Licensee Territory; provided, however, in the event that Corbus breaches any terms of this Agreement and such breach impedes Licensee's ability to perform its obligations under Section 3.1.2, this Section 4.3 or Section 5.2, then Licensee shall be relieved of performing such obligations to the extent that such breach impedes such performance (and will not be precluded from seeking legal and equitable remedies to such breach by Corbus), but only for so long as such breach continues. Except as set forth in Section 3.1.2, this Section 4.3 and Section 5.2, Licensee will not have any obligations to conduct Development or Commercialization of Licensed Products, including any fiduciary obligations or implied duties.
- 4.4. Advertising and Promotional Materials. Licensee will be responsible for the creation, preparation, production, reproduction and filing with the applicable Regulatory Authorities, of relevant written sales, promotion and advertising materials relating to each Licensed Product ("Promotional Materials") for use in the Field in the Licensee Territory. All such Promotional Materials will be compliant with applicable Law, consistent in all material respects with the Licensee Territory Commercialization Plan, and with the Harmonization Principle. Licensee will submit representative samples of its Promotional Materials developed by it for use in the Licensee Territory to the JCC at least annually thereafter (or more frequently if reasonably requested by Corbus). Licensee will consider in good faith any timely comments Corbus may have with respect to any such Promotional Materials, but will have final decision-making authority in the Licensee Territory with respect to such Promotional Materials. Notwithstanding the foregoing, Licensee will incorporate any changes to Promotional Materials requested by Corbus in a timely fashion in cases where Corbus indicates that it believes in good faith that such change is necessary to enable Corbus to comply with any applicable Law.
- **4.5.** Reporting Obligations. Licensee will report to the JCC in writing, on an annual basis in the first Calendar Quarter of each Calendar Year, beginning with the Calendar Year following the first Regulatory Approval of a Licensed Product in the Field in the Licensee Territory (for the period ending December 31 of the prior Calendar Year), summarizing in reasonable detail Licensee's Commercialization activities for such Licensed Product performed to date (or updating such report for activities performed since the last such report was given hereunder, as applicable). In addition, Licensee will provide Corbus with written notice of the First Commercial Sale of each Licensed Product in the Field in the Licensee Territory as soon as reasonably practicable after such event; provided, however, that, Licensee will inform Corbus of such event prior to public disclosure of such event by Licensee. Licensee will provide such other information to the JCC as Corbus may reasonably request with respect to Commercialization of Licensed Products in the Field in the Licensee Territory and will keep the JCC reasonably informed of Licensee's Commercialization activities with respect to Licensed Products.

#### 4.6. Booking of Sales and Handling of Returns.

- **4.6.1.** Corbus will be responsible for booking sales of the Licensed Products sold in the Corbus Territory. Licensee will be responsible for booking sales of the Licensed Products sold in the Field in the Licensee Territory. Each Party may warehouse Licensed Products both inside and outside of such Party's Territory, *provided* that any sales with respect to such Licensed Products occur and are booked in such Party's Territory.
- **4.6.2.** Moreover, Licensee will be solely responsible for handling all returns of any Licensed Product sold in the Licensee Territory, as well as all aspects of Licensed Product order processing, invoicing and collection, distribution, inventory and receivables of Licensed Products sold in the Licensee Territory.
- 4.7. Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product in a Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of a Licensed Product in its Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, will as promptly as possible, notify the other Party's Alliance Manager and JCC representatives thereof by telephone or e-mail, and will discuss with the other Party the reasons for the recall, market withdrawal or similar action. Each Party will decide whether to conduct a recall of a Licensed Product in its own Territory and the manner in which any such recall will be conducted (except in the case of a government mandated recall, when such Party may act without such advance notice, but will notify the other Party as soon as possible thereafter). Except as may otherwise be agreed to by the Parties, each Party will bear the expense of any such recall in its own Territory. Each Party will make available all of its pertinent records that may be reasonably requested by the other Party in order for a Party to effect a recall of a Licensed Product in its Territory. The Parties' rights and obligations under this Section 4.7 will be subject to the terms and conditions of any supply agreement(s), including any SDEA or quality related agreements entered into between the Parties. In the event of a conflict between the provisions of any such supply agreement, SDEA or quality related agreements and this Section 4.7, the provisions of such supply agreement, SDEA or quality related agreements will govern.

### 4.8. Ex-Territory Sales; Export Monitoring.

**4.8.1.** *Ex-Territory Sales.* Subject to applicable Law, neither Party will engage in any advertising or promotional activities relating to any Licensed Product directed primarily to customers or other buyers or users of such Licensed Product located outside of its Territory or accept orders for Licensed Products from or sell Licensed Products into such other Party's Territory for its own account, and, if a Party receives any order for any Licensed Product in the other Party's Territory, it will refer such orders to the other Party, to the extent it is not prohibited from doing so under applicable Law. For clarity, but subject to Licensee's rights under Section 10.6, nothing in this Section 4.8.1 will prevent Corbus and its Related Parties from undertaking, or having undertaken, any of the foregoing activities with respect to any Licensed Product outside of the Field in the Licensee Territory.

**4.8.2.** Export Monitoring. Each Party will use reasonable efforts to monitor and prevent exports of Licensed Products from its own Territory for Commercialization in the other Party's Territory using methods permitted under applicable Law that are commonly used in the industry for such purpose (if any), and will promptly inform the other Party of any such exports of Licensed Products from its Territory, and any actions taken to prevent such exports. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with applicable Law to prevent exports of Licensed Products from its Territory for Commercialization in the other Party's Territory. For clarity, but subject to Licensee's rights under Section 10.6, nothing in this Section 4.8.2 will prevent Corbus and its Related Parties from exporting Licensed Products from the Corbus Territory for Commercialization of such Licensed Products outside of the Field in the Licensee Territory.

#### 5. REGULATORY

#### 5.1. Regulatory Filings and Interactions.

#### **5.1.1.** *Responsibilities*.

**5.1.1.1.** Corbus. Corbus, at its sole cost and expense, will be solely responsible for all regulatory matters relating to a Licensed Product, and will solely and exclusively own all Regulatory Materials with respect thereto, other than in the Field in the Licensee Territory, including any drug master files maintained by or on behalf of Corbus. Corbus, at its sole cost and expense, will have the sole and exclusive right to (a) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority with respect to each Licensed Product, (b) interface, correspond and meet with each Regulatory Authority with respect to each Licensed Product, and (c) seek and maintain all Regulatory Filings with respect to each Licensed Product, in each case of (a), (b) and (c), other than in the Field in the Licensee Territory. Corbus will provide to Licensee all Nonclinical Study and Clinical Study data in its possession that is reasonably required by Licensee to apply for Regulatory Approval for each Licensed Product for the Initial Indications in the Licensee Territory.

**5.1.1.2.** *Licensee*. Licensee, at its sole cost and expense, will be solely responsible for all regulatory matters relating to a Licensed Product for the Initial Indications in the Licensee Territory, and will solely and exclusively own all Regulatory Materials with respect to such Licensed Product for the Initial Indications in the Licensee Territory, including any drug master files maintained by or on behalf of Licensee solely with respect thereto. Licensee, at its sole cost and expense, will have the sole and exclusive right to (a) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority in the Licensee Territory with respect to each Licensed Product for the Initial Indications, (b) interface, correspond and meet with each Regulatory Authority in the Licensee Territory with respect to each Licensed Product for the Initial Indications, and (c) seek and maintain all Regulatory Filings in the Licensee Territory with respect to each Licensed Product for the Initial Indications.

- **5.1.2.** Communications with Regulatory Authorities. Licensee will notify the JDC, including a brief description in English, of the principal issues raised in each Material Communication with Regulatory Authorities with respect to each Licensed Product for the Initial Indications in the Licensee Territory within fifteen (15) Business Days after receipt thereof. Upon Corbus' request, Licensee will provide to Corbus, at Corbus' expense: (a) a summary translation of such Material Communications in English, (b) complete copies of the original correspondence with such Regulatory Authorities in their native language, or (c) a complete translation of such Material Communications in English, in each case of (a) through (c) within a reasonable period of time following such request. For the purposes of this <u>Section 5.1.2</u>, "**Material Communications**" with Regulatory Authorities include meetings with Regulatory Authorities and Regulatory Authority questions or concerns with respect to significant issues, including any of the following: key product quality attributes (e.g., purity), safety findings affecting the platform (e.g., Serious Adverse Events, emerging safety signals), clinical or nonclinical findings affecting patient safety, lack of efficacy or receipt or denial of Regulatory Approval.
- **5.1.3.** Regulatory Meetings. Licensee will provide Corbus with reasonable advance notice of all substantive meetings with the Governmental Authorities in the Licensee Territory pertaining to each Licensed Product for the Initial Indications, or with as much advance notice as practicable under the circumstances. Licensee will use Commercially Reasonable Efforts, to the extent reasonably practicable, to permit Corbus to have, at Corbus' expense, mutually acceptable representatives of Corbus attend, solely as a non-participating observer, material, substantive meetings with any Governmental Authorities within the Licensee Territory pertaining to such Licensed Product for the Initial Indications; <u>provided</u>, <u>however</u>, that (a) if required by the Governmental Authority, attendance by Corbus will be permitted, (b) attendance by the representatives of Corbus will not prevent participation of a representative of Licensee due to restrictions imposed by Regulatory Authorities on the number of attendees; and (c) Licensee will not be obligated to change the schedule of such meeting in order to accommodate the schedule of Corbus' representatives.
- **5.1.4.** Submissions. Licensee will provide Corbus with written notice of each of the following events with regard to each Licensed Product for the Initial Indications in the Licensee Territory, within a reasonable period of time following the occurrence thereof, (a) the submission of any filings or applications for Regulatory Approval of such Licensed Product for the Initial Indications in the Licensee Territory to any Regulatory Authority, and (b) receipt or denial of Regulatory Approval for such Licensed Product for the Initial Indications in the Licensee Territory, <u>provided</u>, <u>however</u>, that Licensee will inform Corbus such event under (a) or (b) prior to public disclosure of such event by Licensee. Licensee, within a reasonable period of time following Corbus' written request, will provide to Corbus, at Corbus' cost and expense, a complete copy of any of the filings or applications of clause (a).
- **5.1.5.** *Coordination*. The activities of Licensee and its Related Parties under this <u>Section 5.1</u> will be subject to the coordination and other responsibilities of the JDC and JSC and the Harmonization Principle.
- **5.2.** <u>Diligence</u>: <u>Standards of Conduct</u>. Licensee or any of its Related Parties will use Commercially Reasonable Efforts to obtain Regulatory Approval for one Licensed Product in each of the Initial Indications in the Licensee Territory; <u>provided</u>, <u>however</u>, that in the event Licensee fails to obtain such Regulatory Approval for either Initial Indication as a result of a breach of its obligations under this <u>Section 5.2</u>, (a) [\*] and (b) [\*].
- **5.3.** Costs of Regulatory Affairs. Except as otherwise indicated in this Agreement, each Party will be responsible for all costs and expenses incurred in connection with its efforts to apply for, obtain and maintain Regulatory Approval with respect to Licensed Products in its Territory, and its related regulatory affairs activities.

5.4. Right of Reference. Each Party, on behalf of itself and its Related Parties, hereby grants to the other Party, and at the request of the other Party will grant to the other Party's Related Parties, a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including all CMC information as well as data made, collected or otherwise generated in the conduct of any Clinical Studies or of any Supplemental Studies or early access/named patient programs for the Licensed Products) included in or used in support of any regulatory filing, Regulatory Approval, drug master file or other Regulatory Materials maintained on behalf of such Party (or its Related Parties) that relates to any Licensed Product, to the extent necessary to obtain Regulatory Approval of a Licensed Product in the Licensee Territory or the Corbus Territory, as applicable, and such Party will provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous Law outside of the United States). In addition, upon the reasonable request of either Party (on behalf of itself or any of its Related Parties), the other Party will, and will cause its Related Parties to, obtain and provide to the requesting Party certificates or other formal or official attestations concerning the regulatory status of the Licensed Products in the Licensee Territory or the Corbus Territory, as applicable (e.g., Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments), at the requesting Party's request and cost, and provided further that such attestations are reasonably necessary for the requesting Party to exercise its rights under this Agreement. For clarity, Licensee's rights under this Section 5.4 may be exercised solely as is necessary to support filing for, obtaining and maintaining Regulatory Approval for any Licensed Product in the Initial Indications in the Licensee Territory. Notwithstanding anything to the contrary in this Agreement other than for Safety Concerns, neither Party nor any of its Related Parties will withdraw or inactivate any Regulatory Filing that the other Party or the other Party's Related Parties references or otherwise uses pursuant to this <u>Section 5.4</u>.

**5.5.** Pharmacovigilance. The Parties will cooperate with regard to the reporting and handling of safety information involving the Licensed Products in accordance with applicable regulatory Laws and regulations on pharmacovigilance and clinical safety, with Corbus being responsible, [\*], for maintaining a global safety database, and Licensee being responsible, [\*], for pharmacovigilance reporting in the Licensee Territory. Within ninety (90) days from the Effective Date (as such period may be extended by mutual written agreement of the Parties, but within such time to ensure that all regulatory requirements are met), the Parties will negotiate in good faith and enter into a Safety Data Exchange Agreement ("SDEA"), which will define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures to enable each Party (and their respective related Third Parties, if any) to comply with all of its legal and regulatory obligations related to the Licensed Products.

# 6. MANUFACTURE

**6.1.** Supply Agreement and Quality Agreement. Prior to validation of the commercial supply process for Licensed Products (as such period may be extended by mutual written agreement of the Parties), the Parties will negotiate in good faith and enter into (a) a supply agreement pursuant to which Corbus will supply Licensee's and its Related Parties' commercial requirements of finished drug product for the Licensed Products for the Licensee Territory on the material terms set forth in Schedule 6.1 (the "Supply Agreement") and (b) a quality agreement, where such agreements will include customary commercial terms such as, by way of non-limiting examples, the right to receive a fair allocation of supply relative to Corbus and its Affiliates and other licensees, sublicensees and distributors in the event of supply shortfall, and the right to require a second or alternative source of supply.

#### 7. LICENSES

### 7.1. License Grants.

### 7.1.1. License Grants to Licensee.

- 7.1.1.1. Development License. Subject to the terms and conditions of this Agreement, Corbus hereby grants Licensee a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Sections 3.6 and 7.1.1.4) exclusive (even as to Corbus and its Affiliates) license under the Corbus Licensed Technology to Develop Licensed Products in the Field anywhere in the world; provided, however, that such license grant for Development will be limited in each case solely as and to the extent permitted under this Agreement, and in each case, solely for purposes of obtaining Regulatory Approval of Licensed Products in the Field in the Licensee Territory and Commercializing Licensed Products in the Field in the Licensee Territory. Notwithstanding the foregoing exclusive grant, Corbus retains the right under the Corbus Licensed Technology, with the right to grant licenses through multiple tiers in accordance with Section 7.1.2.4, which will apply mutatis mutandis, (a) (i) to Develop Licensed Products anywhere in the world for obtaining Regulatory Approval of Licensed Products in any indications in the Corbus Territory, and (ii) to Develop Licensed Products anywhere in the world for obtaining Regulatory Approval of Licensed Products outside of the Field in the Licensee Territory and Commercializing Licensed Products outside of the Field in the Licensee Territory, but subject to Licensee's rights under Section 10.6, and (b) to perform, and have performed, its obligations under the Initial Indications Development Plan.
- **7.1.1.2.** Commercialization License in the Licensee Territory. Subject to the terms and conditions of this Agreement, Corbus hereby grants Licensee a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.1.4), exclusive (even as to Corbus and its Affiliates) license under the Corbus Licensed Technology to Commercialize Licensed Products in the Field in the Licensee Territory.
- 7.1.1.3. Manufacturing Licenses. Subject to the terms and conditions of this Agreement, and exercisable only as permitted under the terms of the Supply Agreement between the Parties, Corbus hereby grants Licensee a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.1.4), exclusive (even as to Corbus and its Affiliates) license under the Corbus Licensed Technology to Manufacture and have Manufactured Licensed Products anywhere in the world solely for (a) Development solely for purposes of obtaining Regulatory Approval of Licensed Products in the Field in the Licensee Territory; and (b) Commercialization of Licensed Products in the Field in the Licensee Territory; provided, however, that, in no event whether pursuant to rights under this Agreement or the Supply Agreement, will Licensee or any of its Related Parties have the right to [\*]. Notwithstanding the foregoing exclusive grant, Corbus retains the right under the Corbus Licensed Technology, with the right to grant licenses through multiple tiers in accordance with Section 7.1.2.4, which will apply mutatis mutandis, to Manufacture and have Manufactured Licensed Products anywhere in the world (i) (A) for Development of Licensed Products and Commercialization of Licensed Products in any indications in the Corbus Territory, (B) for Development of Licensed Products and Commercialization of Licensed Products outside of the Field in the Licensee Territory, but subject to Licensee's rights under Section 10.6, and (C) for Development of Licensed Products in the Field in the Licensee Territory, and (ii) to supply (or have supplied) Licensed Products to Licensee pursuant to any supply agreement agreed to between the Parties.

### **7.1.1.4.** Sublicensing Terms.

- (a) In addition to its subcontracting rights pursuant to <u>Section 3.6</u>:
- (i) Licensee will have the right to sublicense any of its rights under <u>Sections 7.1.1.1</u>, <u>7.1.1.2</u> and <u>7.1.1.3</u>, to any of its Affiliates without the prior consent of Corbus, but subject to the requirements of this <u>Section 7.1.1.4</u>; and
- (ii) Licensee will have the right to sublicense any of its rights under <u>Sections 7.1.1.1</u>, <u>7.1.1.2</u> and <u>7.1.1.3</u> to any Third Party with Corbus' prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), subject to the requirements of this <u>Section 7.1.1.4</u>; <u>provided</u>, <u>however</u>, that, for clarity, Licensee's appointment of a Third Party distributor will not constitute a sublicense of Licensee's rights under <u>Section 7.1.1.2</u> requiring Corbus' prior written consent, but any other sublicensing of Commercialization activities relating to Licensed Products in the Licensee Territory will be a sublicense requiring such Corbus' prior written consent in accordance with the foregoing sentence.
- (b) Without limiting Section 7.1.1.4(a)(i), each sublicense granted by Licensee pursuant to this Section 7.1.1.4, and sublicense or subcontracting agreement entered into by Licensee pursuant to Section 3.6, will be subject and subordinate to this Agreement and will contain provisions consistent with the terms and conditions of this Agreement. Licensee will as soon as reasonably practicable thereafter, provide Corbus with a copy of any executed sublicense agreement covering a material sublicense granted hereunder (which copy may be redacted to remove financial provisions and other provisions which are not necessary to monitor compliance with this Section 7.1.1.4). Each such sublicense agreement will contain the following provisions: (i) a requirement that the Sublicensee comply with the confidentiality and non-use provisions of Section 9.1 with respect to Corbus' Confidential Information, (ii) if such sublicense agreement contains a sublicense of rights granted under Section 7.1.1.2, such sublicense agreement will also contain the following provisions: (A) a requirement that the Sublicensee submit applicable sales or other reports to Licensee to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement, and (B) the audit requirement set forth in Section 8.7.3, (iii) a requirement that the Sublicensee comply with the applicable provisions under any in-license agreement of Corbus under which Licensee elects to take a sublicense pursuant to Section 7.2.1, and (iv) provisions whereby Licensee obtains ownership of, or a fully sublicensable non-exclusive (or exclusive) license (or an option to obtain such license) under and to, any Know-How and Patents that are developed by the Sublicensee in the performance of such agreement and are reasonably necessary or useful to the Development, Manufacture or Commercialization of Licensed Products in the Field; provided that the foregoing requirement to obtain ownership of, or a fully sublicensable nonexclusive (or exclusive) license (or an option to obtain such license) will not apply to any improvements unless such improvements are reasonably necessary to the Development, Manufacture or Commercialization of those Licensed Products in the Field.

(c) Notwithstanding any sublicense granted pursuant to this Section 7.1.1.4, Licensee will (i) remain primarily liable to Corbus for the performance of all of Licensee's obligations under, and Licensee's compliance with all provisions of, this Agreement and (ii) be liable for any act or omission of any such Sublicensee that is a breach of any of Licensee's obligations under this Agreement as though the same were a breach by Licensee, and Corbus shall have the right to proceed directly against Licensee without any obligation to first proceed against such Sublicensee. Each (sub)license by Licensee and its Affiliates will be subject to the applicable terms and conditions of this Agreement. For clarity, Licensee grants no rights hereunder to permit Corbus to proceed directly against a Sublicensee.

### 7.1.2. License Grants to Corbus.

- **7.1.2.1.** Development Licenses. Subject to the terms and conditions of this Agreement, Licensee hereby grants Corbus a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.2.4), terminable (pursuant to the provisions of Section 13), nonexclusive license under the Licensee Background Technology and Licensee Program IP (a) to Develop Licensed Products anywhere in the world solely for obtaining Regulatory Approval of Licensed Products in any indications in the Corbus Territory and Commercializing Licensed Products in any indications in the Corbus Territory, and (b) to Develop Licensed Products anywhere in the world solely for obtaining Regulatory Approval of Licensed Products outside of the Field in the Licensee Territory and Commercializing Licensed Products outside of the Field in the Licensee Territory, but subject to Licensee's rights under Section 10.6.
- **7.1.2.2.** Commercialization Licenses in the Corbus Territory. Subject to the terms and conditions of this Agreement, Licensee hereby grants Corbus a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.2.4), terminable (pursuant to the provisions of Section 13), nonexclusive license under the Licensee Background Technology and Licensee Program IP (a) to Commercialize Licensed Products in any indications in the Corbus Territory, and (b) to Commercialize Licensed Products outside of the Field in the Licensee Territory, but subject to Licensee's rights under Section 10.6.
- **7.1.2.3.** *Manufacturing Licenses.* Subject to the terms and conditions of this Agreement and any applicable supply agreement between the Parties, Licensee hereby grants Corbus a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.2.4), terminable (pursuant to the provisions of Section 13), nonexclusive license under the Licensee Background Technology and Licensee Program IP to Manufacture and have Manufactured such Licensed Product anywhere in the world solely (a) for Development of Licensed Products and Commercialization of Licensed Products outside of the Field in the Licensee Territory, but subject to Licensee's rights under Section 10.6.

# **7.1.2.4.** Sublicensing Terms.

- (a) Corbus will have the right to sublicense any of its rights under  $\frac{\text{Sections } 7.1.2.1}{7.1.2.2}$  and  $\frac{7.1.2.2}{7.1.2.2}$  to any of its Affiliates or to any Third Party (which sublicensed rights may be further sublicensable through multiple tiers) without the prior consent of Licensee, subject to the requirements of this  $\frac{\text{Section } 7.1.2.4}{1.2.2}$ .
- (b) Each sublicense granted by Corbus pursuant to this <u>Section 7.1.2.4</u> will be subject and subordinate to this Agreement and will contain provisions consistent with the terms and conditions of this Agreement. Each such sublicense agreement will contain the following provisions: (i) a requirement that the Sublicensee comply with the confidentiality and non-use provisions of <u>Section 9.1</u> with respect to Licensee's Confidential Information, and (ii) a requirement that the Sublicensee comply with the applicable provisions under any in-license agreement of Licensee under which Corbus elects to take a sublicense pursuant to <u>Section 7.2.4.</u>

(c) Notwithstanding any sublicense granted pursuant to this Section 7.1.2.4, Corbus will (i) remain primarily liable to Licensee for the performance of all of Corbus' obligations under, and Corbus' compliance with all provisions of, this Agreement and (ii) be liable for any act or omission of any such Sublicensee that is a breach of any of Corbus' obligations under this Agreement as though the same were a breach by Corbus, and Licensee shall have the right to proceed directly against Corbus without any obligation to first proceed against such Sublicensee. Each (sub)license by Corbus and its Affiliates will be subject to the applicable terms and conditions of this Agreement. For clarity, Corbus grants no rights hereunder to permit Licensee to proceed directly against a Sublicensee.

# 7.2. Third Party In-Licenses Payments.

- **7.2.1.** Existing In-Licensing Agreements. Corbus will be responsible for all payments associated with any agreements related to the Corbus Licensed Technology that exist as of the Effective Date ("Existing In-Licensing Agreements"), except as otherwise agreed by Licensee in writing.
- 7.2.2. Additional In-Licensing Agreements. Subject to the provisions of Section 7.2.3, in the event that, after the Effective Date, Corbus in-licenses Corbus Licensed Technology that is Controlled for purposes of any of the licenses granted to Licensee under Section 7.1.1 but for which Corbus owes payments under the agreement for such in-licensed Corbus Licensed Technology on account of any sublicense granted thereunder to Licensee or its Affiliates or its Sublicensees, Corbus will notify Licensee of the existence, and anticipated amounts, of such payments and Licensee will have the right to decline a sublicense to such in-licensed Corbus Licensed Technology or take such sublicense, in which case Licensee agrees to comply, and will cause its Affiliates and Sublicensees to comply, with any obligations under such agreement of Corbus that apply to Licensee, its Affiliates or its Sublicensees and of which Licensee was informed by Corbus, including any obligation to make such payments. In the event Licensee elects to take such sublicense, Licensee will make such payments to Corbus within thirty (30) days of receiving an invoice from Corbus for the same.
- 7.2.3. Required In-License Agreements. In the event it becomes necessary during the Term to enter into an agreement with a Third Party to in-license any Intellectual Property rights controlled by such Third Party that are necessary for the Exploitation by Licensee of the Licensed Product in the Field in the Licensee Territory where such Intellectual Property rights, but for such in-license, would be infringed, misappropriated or otherwise violated by the Licensed Product or its Exploitation, as such Licensed Product (including the Manufacturing process therefor) existed on the Effective Date and was disclosed by Corbus to Licensee in accordance with the technology transfer pursuant to the terms of Section 3.8, Corbus, or with Corbus' permission (not to be unreasonably withheld), Licensee, will enter into an agreement with such Third Party to in-license such Intellectual Property rights and any payments under such in-license shall be Corbus' responsibility (whether Corbus or Licensee executes such agreement) (such in-licenses, together with the Existing In-Licensing Agreements, the "In-License Agreements"). Without the prior written consent of Licensee, Corbus will not terminate or amend an In-License Agreement or fail to exercise its rights or comply with its obligations under an In-License Agreement if such termination, amendment or failure would adversely impact the rights of Licensee hereunder. Corbus shall furnish Licensee with copies of all notices received by Corbus relating to any alleged breach or default by Corbus under the In-License Agreements as soon as reasonably practicable after Corbus' receipt thereof. If Corbus cannot or chooses not to cure or otherwise resolve any alleged breach or default under an In-License Agreement, Corbus shall so notify Licensee no less than ten (10) Business Days prior to the expiration of the cure period under the In-License Agreement. Licensee, in its sole discretion, shall be permitted to cure any breach or default under the In-License Agreement in accordance with the terms and conditions of the In-License Agreement or otherwise resolve such breach directly with the licensors under the In-License Agreement; and, if Licensee pays the licensors under any In-License Agreement any amounts owed by Corbus, Licensee may deduct such amounts from payments Licensee is required to make to Corbus hereunder.

- 7.2.4. Licensee In-License Agreements. Licensee will be responsible for all payments associated with any agreements related to the Licensee Background Technology that exist as of the Effective Date, except as otherwise agreed by Corbus in writing. In the event that, after the Effective Date, Licensee in-licenses Licensee Background Technology that is Controlled for purposes of any of the licenses granted to Corbus under Section 7.1.2 but for which Licensee owes payments under the agreement for such in-licensed Licensee Background Technology on account of any sublicense granted thereunder to Corbus or its Affiliates or its Sublicensees, Licensee will notify Corbus of the existence, and anticipated amounts of, such payments and Corbus will have the right to decline a sublicense to such in-licensed Licensee Background Technology or take such sublicense, in which case Corbus agrees to comply, and will cause its Affiliates and Sublicensees to comply, with any obligations under such agreement of Licensee that apply to Corbus, its Affiliates or its Sublicensees and of which Corbus was informed by Licensee, including any obligation to make such payments. In the event Corbus elects to take such sublicense, Corbus will make such payments to Licensee within thirty (30) days of receiving an invoice from Licensee for the same.
- **7.3.** <u>Combinations</u>. Notwithstanding any other provision of this Agreement, for purposes of the license grants under <u>Section 7.1</u> with respect to any Licensed Product that is a Combination Product, such license will only include a license with respect to the Lenabasum component of such Combination Product.
- 7.4. Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, a license of a right to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties acknowledge and agree that the Parties and their respective Sublicensees, as Sublicensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign counterpart thereto. The Parties further agree that upon commencement of a bankruptcy proceeding by or against a Party (the "Bankrupt Party") under the Bankruptcy Code, the other Party (the "Non-Bankrupt Party") will be entitled to a complete duplicate of, or complete access to (as the Non-Bankrupt Party deems appropriate), all such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments of such intellectual property will be promptly delivered to the Non-Bankrupt Party (a) upon any such commencement of a bankruptcy proceeding and upon written request by the Non-Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party and upon written request by the Non-Bankrupt Party. The Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) agree not to interfere with the exercise by the Non-Bankrupt Party or its Related Parties of its rights and licenses to such intellectual property and such embodiments of intellectual property in accordance with this Agreement, and agrees to assist the Non-Bankrupt Party and its Related Parties in obtaining such intellectual property and such embodiments of intellectual property in the possession or control of Third Parties as are reasonably necessary or desirable for the Non-Bankrupt Party to exercise such rights and licenses in accordance with this Agreement. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the Bankruptcy Code or other Laws.

7.5. No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license or other right (whether by implication, estoppel or otherwise) in or to any Know-How, Patents or other Intellectual Property rights of the other Party or any of such other Party's Affiliates, including tangible or intangible items owned, controlled or developed by the other Party or any of such other Party's Affiliates, or provided by the other Party or any of its Affiliates to the receiving Party or any of its Affiliates at any time, pursuant to this Agreement. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

### 8. PAYMENTS

**8.1.** <u>Upfront Fee.</u> Within thirty (30) days following the Effective Date, Licensee will pay to Corbus a one-time, non-refundable, non-creditable payment of Twenty-Seven Million Dollars (U.S. \$27,000,000).

## 8.2. Regulatory Milestone Payments.

**8.2.1.** Regulatory Milestones. Subject to Section 8.2.2, Licensee will make one-time, non-refundable, non-creditable milestone payments to Corbus (each, a "Regulatory Milestone Payment") upon the first achievement of each of the regulatory events set forth in this Section 8.2.1 (each, a "Regulatory Milestone Event") by Licensee or its Related Parties.

Regulatory Milestone Event	Regulatory Milestone Payment
[*]	[*]
[*]	[*]
[*]	[*]

- **8.2.2.** Additional Regulatory Milestone Terms. Notwithstanding the foregoing, for the purpose of construing the Regulatory Milestone Payments specified in the table in <u>Section 8.2.1</u>:
  - **8.2.2.1.** In the event that Bioequivalency between the investigational product used for the Phase 3 Study and the Licensed Products to be Commercialized is not demonstrated by Corbus or any of its Related Parties on or prior to (a) [\*], then [\*] shall be reduced to [\*] (in each case (a) -([\*]), a "Bioequivalency Failure").
  - **8.2.2.2.** The [\*] shall be equal to [\*] unless the NHI Price per [\*] is less than [\*], in which case the [\*] shall be equal to [\*] *multiplied* by the quotient of (a) the NHI Price per [\*] and (b) [\*]; *provided*, that in no event shall the [\*] be less than [\*]. For example, if the NHI Price per [\*] is [\*], the [\*] shall be [\*].
- **8.2.3.** Payment Terms for Regulatory Milestone Payments. Licensee will notify and pay to Corbus the amounts set forth in the table of Section 8.2.1 within [\*] days after the achievement of the applicable Regulatory Milestone Event by Licensee or its Related Parties; provided, however, that if the applicable NHI Price has not been established at the time the [\*] is achieved, Licensee will (a) pay to Corbus [\*] within [\*] days after the achievement of the [\*] and (b) notify and pay to Corbus any amount calculated under Section 8.2.2.2 in excess of [\*] within [\*] days after the applicable NHI Price is established.

### 8.3. Sales Milestone Payments.

**8.3.1.** Sales Milestones. Subject to Section 8.3.2, Licensee will make one-time, non-refundable, non-creditable milestone payments to Corbus (each, a "Sales Milestone Payment") when aggregate Net Sales of all Licensed Products in the Initial Indications in the Licensee Territory in a given Calendar Year first reach the Dollar threshold values indicated below (each, a "Sales Milestone Event") during the Term:

Sales Milestone Event (based on [*])	Sales Milestone Payment
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

For clarity, the Sales Milestone Payments will each be paid only once, such that, the maximum total amount payable by Licensee to Corbus under this <u>Section 8.3</u> is [\*] (it being understood that the Sales Milestone Payments will be additive).

**8.3.2.** Payment Terms for Sales Milestone Payments. Licensee will notify and pay to Corbus the amounts set forth in the table of Section 8.3.1 within [\*] days after the achievement of the any Sales Milestone Event; provided, however, if more than one Sales Milestone Event set forth in the table above is achieved in the same Calendar Year and no such Sales Milestone Events have been achieved in any prior Calendar Year, [\*].

## 8.4. Supply Transfer Price; Back-Up Royalties.

## 8.4.1. Supply Transfer Price.

- **8.4.1.1.** During Royalty Term. During the applicable Royalty Term for such Licensed Product and subject to Sections 8.4.2 and 8.5, Licensee will make non-refundable, non-creditable payments to Corbus, on a Licensed Product-by-Licensed Product basis, in an amount, payable in [\*] at the time of such supply, equal to [\*] percent ([\*]%) of the tax-excluded NHI Price then in effect for such Licensed Product (other than with respect to a Combination Product, the tax-excluded NHI Price for which shall be calculated as described in the definition of Net Sales), for each unit of such Licensed Product that Corbus supplies to Licensee under the Supply Agreement (the "Supply Transfer Price").
- **8.4.1.2.** *Post-Royalty Term.* On a Licensed Product-by-Licensed Product basis, after the Royalty Term expires for such Licensed Product and for so long as Corbus continues to supply commercial quantities of such Licensed Product pursuant to the Supply Agreement, Licensee will pay Corbus the Manufacturing Price for each unit of such Licensed Product.

- **8.4.2.** *Back-Up Royalties.* If, at any time during the applicable Royalty Term for a Licensed Product in an Initial Indication, the Supply Agreement is terminated or is otherwise no longer in effect, then, with respect to such Licensed Product, Licensee will make non-refundable, non-creditable royalty payments in [\*] to Corbus at a royalty rate to be agreed upon by the Parties in good faith and which shall be set forth in the Supply Agreement.
- **8.5.** Royalty Term. On a Licensed Product-by-Licensed Product basis, the royalties due under Section 8.4.2 if applicable, will be payable on annual Net Sales of such Licensed Product in the Licensee Territory from the First Commercial Sale of such Licensed Product for such Initial Indication in the Licensee Territory until the latest of (a) the expiration of the last Valid Claim of the Royalty Patents Covering such Licensed Product in the Licensee Territory, (b) the expiration of Regulatory Exclusivity for such Licensed Product for such Initial Indication in the Licensee Territory, and (c) ten (10) years after the First Commercial Sale of such Licensed Product for such Initial Indication in the Licensee Territory (the "Royalty Term").

## 8.6. Additional Supply Transfer Price and Back-Up Royalty Terms.

- **8.6.1.** Only One Royalty. In the event <u>Section 8.4.2</u> applies, only one royalty will be due thereunder with respect to the sale of the same unit of Licensed Product. Only one royalty will be due under <u>Section 8.4.2</u> on the sale of a Licensed Product even if the manufacture, use, sale, offer for sale or importation of such Licensed Product infringes more than one claim of the Royalty Patents.
- **8.6.2.** Reduction for Loss of Patent Protection. On a Licensed Product-by-Licensed Product basis, upon the expiration of the last Valid Claim of the Royalty Patents which are either a [\*] Patent or a [\*] Patent which Cover such Licensed Product in the Licensee Territory (i) the Supply Transfer Price will be reduced from [\*] percent ([\*]%) to [\*] percent ([\*]%) or (ii) if applicable, the royalties payable to Corbus under Section 8.4.2 will be reduced by [\*] percent ([\*]%); <u>provided</u>, that no such reduction shall apply under this Section 8.6.2 if any reduction under Section 8.6.3 applies.
- **8.6.3.** Royalty Reduction for Generic Competition. On a Licensed Product-by-Licensed Product basis, Initial Indication-by-Initial Indication basis, and Calendar Quarter-by-Calendar Quarter basis:
  - (a) if the Generic Competition in the Licensee Territory with respect to such Licensed Product for such Initial Indication during such Calendar Quarter equals or exceeds [\*] percent ([\*]%) but is less than or equal to [\*] percent ([\*]%), then Licensee shall have the right to reduce (i) the Supply Transfer Price by [\*] percent ([\*]%) or (ii) if applicable, the royalties on annual Net Sales payable to Corbus under Section 8.4.2 by [\*] percent ([\*]%);
  - (b) if the Generic Competition in the Licensee Territory with respect to such Licensed Product for such Initial Indication during such Calendar Quarter exceeds [\*] percent ([\*]%) but is less than or equal to [\*] percent ([\*]%), then Licensee shall have the right to reduce (i) the Supply Transfer Price by [\*] percent ([\*]%) or (ii) if applicable, the royalties on annual Net Sales payable to Corbus under Section 8.4.2 by [\*] percent ([\*]%); and
  - (c) if the Generic Competition in the Licensee Territory with respect to such Licensed Product for such Initial Indication during such Calendar Quarter exceeds [\*] percent ([\*]%), then Licensee shall have the right to reduce (i) the Supply Transfer Price by [\*] percent ([\*]%) or (ii) if applicable, the royalties on annual Net Sales payable to Corbus under <u>Section 8.4.2</u> by [\*] percent ([\*]%).

- **8.6.4.** Reduction for Narcotics Scheduling. On a Licensed Product-by-Licensed Product basis, Licensee will have the right to reduce (i) the Supply Transfer Price from [\*] percent ([\*]%) to [\*] percent ([\*]%) or (ii) if applicable, the royalties payable to Corbus under Section 8.4.2 by [\*] percent ([\*]%) if, and for so long as, the MHLW requires that such Licensed Product be scheduled in the Narcotics and Psychotropics Control Act.
- **8.6.5.** *Minimum Floor.* In no event will the Supply Transfer Price or, if applicable, the royalties payable to Corbus under Section 8.4.2 be reduced in any given Calendar Quarter by more than [\*] percent ([\*]%) of the amount that otherwise would have been due and payable to Corbus in such Calendar Quarter but for the reductions set forth in Sections 8.6.2, 8.6.3 and 8.6.4, and in no event will the Supply Transfer Price (whether during or after the Royalty Term) be reduced to below the Manufacturing Price. Licensee may not carry over any reductions that are not applied against the royalties payable to Corbus as a result of the foregoing floor.
- **8.6.6.** *Transfer Price Revisions*. In the event that the tax-excluded NHI Price for a Licensed Product is less than [\*], the Parties will negotiate in good faith to agree on a new supply transfer price; *provided*, that, until the Parties mutually agree on a new supply transfer price, the Supply Transfer Price will continue to apply.
- **8.6.7.** Other Amounts Payable. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified herein, within thirty (30) days after the end of each Calendar Quarter, each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed amounts within [\*] days of receipt of the invoice, and any disputed amounts owed by a Party will be paid within [\*] days of resolution of the dispute.
- **8.6.8.** Payments to be made under Sections 8.1 and 8.2 by Licensee to Corbus (a) prior to obtaining Regulatory Approval, specifically the payments to be made under Section 8.1 and [\*], are made in consideration for the license to Develop the Licensed Product granted by Corbus to Licensee pursuant to Section 7.1.1.1 and (b) on or after Regulatory Approval has been obtained, specifically the payments to be made under [\*], are made in consideration for the license to Commercialize the Licensed Product granted by Corbus to Licensee pursuant to Section 7.1.1.2.

## 8.7. Payment Terms.

- **8.7.1.** *Manner of Payment.* All payments to be made by Licensee hereunder will be made in Dollars or Yen, as the same has been specified in the applicable provision of this Agreement, by wire transfer to such bank account as Corbus may designate.
- **8.7.2.** Reports and Back-Up Royalty Payments. All amounts payable to Corbus pursuant to Section 8.4.2, if applicable, will be paid in [\*] within [\*] days after the end of each Calendar Quarter. Each such payment of royalties due to Corbus will be accompanied by a written report showing in Yen the amount of annual Net Sales of Licensed Products and the royalty due for such Calendar Quarter. The report will include, at a minimum, the following information for the applicable Calendar Quarter, each listed by Licensed Product: (a) the number of units of each Licensed Product on which royalties are owed to Corbus hereunder sold either by Licensee or its Related Parties, (b) the gross amount received for such sales, (c) Net Sales (including all permitted deductions taken or applied), and (d) the royalties owed to Corbus. All such reports will be treated as Confidential Information of Licensee.

8.7.3. Records and Audits. Licensee will keep, and will cause its Related Parties to keep, complete, true and accurate books and records in accordance with its Accounting Standards in relation to this Agreement, including in relation to Net Sales and royalties. Licensee will keep, and will cause its Related Parties to keep, such books and records for at least three (3) years following the Calendar Year to which they pertain. Corbus may, upon written request, cause an internationally-recognized independent accounting firm (the "Auditor"), which is reasonably acceptable to Licensee, to inspect the relevant records of Licensee and its Affiliates to verify the payments made by Licensee and the related reports, statements and books of accounts, as applicable. Before beginning its audit, the Auditor will execute an undertaking reasonably acceptable to Licensee by which the Auditor agrees to keep confidential all information reviewed during the audit. The Auditor will have the right to disclose to Corbus only its conclusions regarding any payments owed under this Agreement. Licensee and its Affiliates will make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from Corbus. The records will be reviewed solely to verify the accuracy of Licensee's royalties and other payment obligations and compliance with the financial terms of this Agreement. Such inspection right will not be exercised more than once in any Calendar Year and not more frequently than once with respect to records covering any specific period of time. In addition, Corbus will only be entitled to audit the books and records of Licensee for the three (3) Calendar Years prior to the Calendar Year in which the audit request is made. Corbus agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any Law or judicial order. The Auditor will provide its audit report and basis for any determination to Licensee at the time such report is provided to Corbus before it is considered final. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment by Licensee, the underpaid or overpaid amount will be settled promptly. Corbus will pay for such inspections, as well as its expenses associated with enforcing its rights with respect to any payments hereunder, except, if an underpayment of more than five percent (5%) of the total payments due hereunder for the applicable year is discovered, then the fees and expenses charged by the Auditor will be paid by Licensee.

#### 8.7.4. Taxes.

**8.7.4.1.** Licensee may withhold from payments due to Corbus amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. Licensee will provide Corbus all relevant documents and correspondence, and will also provide to Corbus any other cooperation or assistance on a reasonable basis as may be necessary to enable Corbus to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Licensee will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include (a) Licensee making payments from a single source in the U.S., where possible and necessary for enabling Corbus to claim deductions, (b) Corbus confirming that it is entitled to exemption from withholding tax on the royalties under this Agreement under the U.S.-Japan income tax convention, (c) if it is entitled to that exemption, Corbus preparing and submitting to Licensee the applicable application form for the above income tax convention and any other attachment thereto so that Licensee for the benefit of Corbus will file them with the relevant taxation office in Japan prior to the payment from Licensee to Corbus pursuant to this Agreement, (d) Licensee making such filing in a timely manner, and (e) if such withholding tax is payable, Licensee filing the application for certification of tax payment that is duly prepared and submitted to Licensee by Corbus with the relevant taxation office in Japan in a timely manner.

- **8.7.4.2.** Apart from any taxes withheld by Licensee pursuant to the provisions of <u>Section 8.7.4.1</u> and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies.
- **8.7.5.** *Blocked Payments.* In the event that, by reason of applicable Law in the Licensee Territory, it becomes impossible or illegal for Licensee to transfer, or have transferred on its behalf, payments owed to Corbus hereunder, Licensee will promptly notify Corbus of the conditions preventing such transfer and such payments will be deposited in local currency in the Licensee Territory to the credit of Corbus in a recognized banking institution designated by Corbus or, if none is designated by Corbus within a period of thirty (30) days, in a recognized banking institution selected by Licensee, as the case may be, and identified in a written notice given to Corbus pursuant to Section 14.10.
- **8.7.6.** Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in Yen or any other foreign exchange calculations required hereunder shall be calculated based on currency exchange rates for the Calendar Year for which remittance is made. For each month, such exchange rate shall equal [\*]. Each daily exchange rate shall be obtained from [\*] or, if not so available, as otherwise agreed by the Parties. For purposes of calculating the Net Sales thresholds set forth in Section 8.3.1, the aggregate Net Sales with respect to each Calendar Quarter within a Calendar Year shall be calculated based on the currency exchange rates for the Calendar Quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in this Section 8.7.6.
- **8.7.7.** *Interest Due.* If a Party does not receive payment of any sum due to it on or before the due date therefor, [\*] interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of [\*] percent ([\*]%) [\*], or the maximum rate allowable by applicable Law, whichever is less.
- **8.8.** <u>Mutual Convenience</u>. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Corbus.

## 9. CONFIDENTIALITY AND PUBLICATION

### 9.1. Nondisclosure and Non-Use Obligations.

- **9.1.1.** All Confidential Information disclosed by one Party to the other Party under this Agreement will be maintained in confidence by the receiving Party and will not be disclosed to a Third Party or used for any purpose except pursuant to the licenses granted under this Agreement as otherwise set forth herein, without the prior written consent of the disclosing Party, except to the extent that such Confidential Information:
  - (a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
  - (b) is known to the public before its receipt from the disclosing Party, or thereafter becomes generally known to the public through no breach of this Agreement by the receiving Party;

- (c) is subsequently disclosed to the receiving Party by a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party; or
- (d) is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.

For clarity, all information and data relating to the inventions claimed by Patents within the New Lenabasum IP, New Corbus IP and the Corbus Licensed Technology and the Know-How specific thereto, will be Confidential Information of Corbus, and all information and data relating to the inventions claimed by Patents within the Licensee Licensed Technology and the Know-How specific thereto, will be Confidential Information of Licensee. Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is encompassed by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

The existence and terms and conditions of this Agreement are hereby deemed to be the Confidential Information of each Party.

9.1.2. Notwithstanding the obligations of confidentiality and non-use set forth above in Section 9.1.1, a receiving Party may provide Confidential Information disclosed to it and disclose the existence and terms and conditions of this Agreement, in each case, as may be reasonably required in order to perform its obligations or to exercise its rights under this Agreement, and specifically to (a) Related Parties, and their employees, directors, agents, consultants, or advisors to the extent necessary for the performance of its obligations or exercise of its rights under this Agreement, in each case who are under an obligation of confidentiality with respect to such information that is no less stringent than the terms of this Section 9; (b) Governmental Authorities or Regulatory Authorities in order to obtain Patents or perform its obligations or exercise its rights under this Agreement, <u>provided</u> that such Confidential Information will be disclosed only to the extent reasonably necessary to do so, and where permitted, subject to confidential treatment; (c) the extent required by Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; (d) with respect to the terms and conditions of this Agreement only, any bona fide actual or prospective acquirers, underwriters, investors, lenders or other financing sources and any bona fide actual or prospective collaborators, licensors, Sublicensees, licensees or strategic partners and to employees, directors, agents, consultants or advisers of such Third Party, in each case who are under obligations of confidentiality and non-use with respect to such information that are no less stringent than the terms of this Section 9 (but of duration customary in confidentiality agreements entered into for a similar purpose); and (e) to any Third Party to the extent a Party is required to do so pursuant to the terms and conditions of an in-license agreement with such Third Party relating to the intellectual property rights sublicensed by such Party hereunder. If a Party is required by Law to disclose Confidential Information of the other Party that is subject to the confidentiality or non-disclosure provisions of this Section 9, such Party will promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure. Notwithstanding Section 9.1, Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of this Section 9. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, such Party will, a reasonable time prior to any such filing, provide the other Party with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration before filing such agreement and use reasonable efforts to have terms identified by such other Party afforded confidential treatment by the applicable regulatory agency.

### 9.2. Publication and Publicity.

**9.2.1.** *Publication.* Except for disclosures permitted pursuant to <u>Sections 9.1</u> and <u>9.3.3</u>, if a Party wishes to make a publication or public presentation that contains the Confidential Information of the other Party or any results of Development activities under this Agreement in the Licensee Territory or mentions Licensee, this Agreement or any activities in the Licensee Territory, such Party will deliver to the other Party a copy of the proposed written publication or presentation at least thirty (30) days prior to submission for publication or presentation. The other Party will have the right (a) to propose modifications to the publication or presentation for patent reasons or trade secret reasons or to remove Confidential Information of the other Party, and such Party will remove all Confidential Information of the other Party if so requested by the other Party and otherwise will incorporate the other Party's reasonable comments, or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the other Party requests a delay, such Party will delay submission or presentation for a period of ninety (90) days (or such shorter period as may be mutually agreed by the Parties) to enable the other Party to file patent applications protecting the other Party's rights in such information. With respect to any proposed publications or disclosures by investigators or academic or non-profit collaborators, such materials will be subject to review under this <u>Section 9.2.1</u> to the extent that such Party has the right and ability (after using Commercially Reasonable Efforts to obtain such right and ability) to do so. Such Party will not submit or publish any article or other publication to or with any scientific journal or other publisher that requires, as a condition of publication, that such Party agree to make available to the publisher or Third Parties any Materials which are the subject of the publication.

**9.2.2.** Publicity. Except as set forth in Section 9.1, 9.2.1 or 9.3, the terms and conditions of this Agreement may not be disclosed by either Party, and neither Party will use the name or any other Trademarks of the other Party or the name of its employees in any publicity, news release or other disclosure relating to this Agreement, its subject matter, or the activities of the Parties under the Collaboration without the prior express written permission of the other Party, except (a) as may be required by applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in any country other than the United States or of any stock exchange or listing entity, provided that the Party making such disclosure or use of the name or other Trademarks of the other Party or the name of its employees, gives the other Party reasonable prior notice and otherwise complies with Section 9.1.2, or (b) as expressly permitted by the terms and conditions of this Agreement.

## 9.3. Press Release.

9.3.1. The Parties will issue the press releases in Schedule 9.3.1 on January 3, 2019, or such other mutually agreed date.

- **9.3.2.** Except as provided in <u>Section 9.2.2</u> or this <u>Section 9.3</u>, neither Party will issue a press release or public announcement relating to this Agreement without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed), except that a Party may (a) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (b) issue a press release or public announcement as required by applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity, *provided* that the Party issuing such press release gives reasonable prior notice to the other Party of and the opportunity to comment on the press release or public announcement, and otherwise complies with this <u>Section 9</u>. In addition, Corbus may with Licensee's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed, issue a press release regarding the payment or receipt of any milestone payments under this Agreement with respect to any Licensed Products, *provided*, that such press release complies with this <u>Section 9.3</u>.
- **9.3.3.** Notwithstanding anything in this <u>Section 9.3</u> to the contrary, either Party may issue a press release or make a public disclosure relating to such Party's Development, Manufacturing or Commercialization activities under this Agreement with respect to Licensed Products in such Party's Territory, <u>provided</u> that such press release or public disclosure does not disclose Confidential Information of the other Party. Prior to making any such disclosure under this <u>Section 9.3.3</u>, however, the disclosing Party will provide the other Party with a draft of such proposed disclosure within a reasonable time (but at least five (5) Business Days) prior to disclosure for the other Party's review and comment, and the disclosing Party will consider in good faith any timely comments provided by the other Party.

## 10. REPRESENTATIONS, WARRANTIES AND COVENANTS

- 10.1. Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:
- **10.1.1.** such Party is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation;
- **10.1.2.** such Party has all requisite corporate power and corporate authority to enter into this Agreement and to carry out its obligations under this Agreement;
- 10.1.3. all requisite corporate action on the part of such Party, its directors and stockholders required by applicable Law for the authorization, execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken;
- 10.1.4. the execution, delivery and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and will not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, or adversely affect any rights under, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound (including, in the case of Corbus, the Corbus Licensed Technology and the Licensed Products), or (c) violate or conflict with any of the provisions of such Party's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents); and

- **10.1.5.** no consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement.
- 10.1.6. This Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as enforceability may be limited by applicable equitable principles or bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally.
- **10.2.** <u>Additional Representations and Warranties of Corbus</u>. Corbus represents and warrants to Licensee that, as of the Effective Date in the Licensee Territory, except as set forth on <u>Schedule 10.2</u>:
- **10.2.1.** Corbus or one of its Affiliates is the sole and exclusive owner, or has exclusive rights to, the Corbus Licensed Technology existing as of the Effective Date. All of the Corbus Licensed Technology is free and clear of any Liens. No Person has alleged in writing to Corbus or any of its Representatives that any Third Party owns, in whole or in part, any of the Corbus Licensed Technology, and to the Knowledge of Corbus, there is no reasonable basis for any such allegation.
- 10.2.2. None of the issued Corbus Licensed Patents existing as of the Effective Date has been adjudged invalid, unenforceable or unpatentable by any Governmental Authority of competent jurisdiction, and, to the Knowledge of Corbus, all such issued Corbus Licensed Patents existing as of the Effective Date are valid and enforceable.
- 10.2.3. To the Knowledge of Corbus, (a) the Exploitation of Licensed Products based upon the Corbus Licensed Technology as it exists on the Effective Date does not infringe any issued Patent or any pending Patent (were its claims to issue in their form as of the Effective Date) of any Person and (b) the use of the Corbus Licensed Technology by Licensee pursuant to the terms of this Agreement, and Licensee's exercise of its rights hereunder in connection therewith, does not infringe, misappropriate or otherwise violate the trade secret rights or copyrights of any other Person. No written claim or demand of any Third Party has been made, or to the Knowledge of Corbus, is threatened against Corbus or any of its Affiliates and there is no Proceeding, or action, claim (including regarding infringement of Intellectual Property), complaint, demand, suit, proceeding, or arbitration brought by a Third Party, pending, or, to the Knowledge of Corbus, threatened, as of the Effective Date, against Corbus or any of its Affiliates, and in each case involving any of the Corbus Licensed Technology or Licensed Products existing as of the Effective Date or the Exploitation of the foregoing and (i) challenging any rights of Corbus or any of its Affiliates in any such Corbus Licensed Technology or Licensed Products, (ii) alleging that any issued Patent within such Corbus Licensed Technology is invalid or unenforceable, (iii) alleging that the use of any Corbus Licensed Technology existing as of the Effective Date infringes any issued Patent of a Third Party or infringes, misappropriates or otherwise violates the Intellectual Property rights of any Person, (iv) challenging the transactions contemplated by this Agreement or (v) asserting that the manufacture, use, sale, offer for sale or importation of Licensed Products or the processes used to make Licensed Products is or was infringing or otherwise violates or violated any Intellectual Property of any Person; provided, however, that, "Proceeding" for purposes of the representations and warranties of this Section 10.2.3 includes any notice of non-compliance, summons, subpoena, inquiry or investigation by a Governmental Authority, of any nature, whether civil, criminal, regulatory, or otherwise, in law or in equity, but excludes office actions or similar communications issued by any patent office or comparable registration authority in the ordinary course of prosecution of any patent application within the Corbus Licensed Patents.

- 10.2.4. Each of Corbus and its Affiliates is and has been in compliance in all material respects with all applicable Laws applicable to and in connection with the Exploitation of the Corbus Licensed Technology and the Licensed Products, except to the extent any non-compliance would not reasonably be expected to have a material adverse effect on the ability of Licensee to Exploit the Licensed Products in the Field in the Licensee Territory in compliance with all applicable Laws. There are no, and there have not been any issued judicial orders, writs, injunctions, decrees, judgments or stipulations in force against Corbus or its Affiliates with respect to the Corbus Licensed Technology or Licensed Products that would reasonably be expected to have a material adverse effect on the ability of Licensee to Exploit the Licensed Products in the Field in the Licensee Territory in compliance with all applicable Laws.
- **10.2.5.** To the Knowledge of Corbus, no Third Party has infringed, misappropriated or otherwise violated any Corbus Licensed Technology.
- 10.2.6. The Corbus Licensed Patents owned by Corbus or both Controlled by and prosecuted by Corbus and, to the Knowledge of Corbus, the Corbus Licensed Patents Controlled but not prosecuted by Corbus have been filed and diligently Prosecuted and Maintained in accordance with all applicable Laws, including disclosure of all prior art to the relevant patent authority to the extent required by applicable Laws, and with all applicable fees due with respect thereto having been paid.
- 10.2.7. To the Knowledge of Corbus, the scientific, technical and other information relating to the Corbus Licensed Technology and Licensed Products disclosed or made available by Corbus or any of its Representatives to Licensee in writing in the electronic data room has been true and correct in all respects. Any experimental data therein that purports to be the result of work conducted by or on behalf of Corbus or its Affiliates is based upon actual experimentation conducted by or on behalf of Corbus or its Affiliates.
- **10.2.8.** Except as set forth on <u>Schedule 10.2.8</u>, no IND has been filed by Corbus with any Regulatory Authority in the Licensee Territory with respect to the Licensed Products. Corbus is not currently assisting any Third Party in preparation for or in connection with filing an IND with respect to the Licensed Products.
- 10.2.9. Corbus has the unrestricted right to grant to Licensee the rights in the Corbus Licensed Technology in the Licensee Territory that are being granted to Licensee under this Agreement upon the terms set forth herein. Neither Corbus nor any of its Affiliates has granted any license or sublicense to any rights in the Corbus Licensed Technology in the Licensee Territory to any Third Party that are in conflict with the rights granted to Licensee in this Agreement.
- 10.2.10. Schedule 1.1.43 sets forth, with the countries, application numbers and application dates indicated, as applicable, all Corbus Licensed Patents that have issued or that have been applied for and are pending issuance with any Governmental Authority. To the Knowledge of Corbus, there is no information that, in Corbus' reasonable judgment, would likely render any of the granted Corbus Licensed Patents invalid or unenforceable and that is not part of the publicly available file history, except to the extent such invalidity or unenforceability would not reasonably be expected to have a material adverse effect on the ability of Licensee to Exploit the Licensed Products in the Field in the Licensee Territory in compliance with all applicable Laws.
- 10.2.11. Corbus and its Affiliates have taken reasonable and customary measures to maintain and protect, as applicable, the confidentiality of its or their owned Confidential Information within the Corbus Licensed Technology. Notwithstanding the foregoing, Corbus and its Affiliates have disclosed Confidential Information to (a) Third Parties under an obligation of confidentiality with respect to such information, (b) Governmental Authorities or Regulatory Authorities in order to obtain Patents or develop or submit Regulatory Filings for products, and (c) the extent required by Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

- 10.2.12. All employees, consultants, contractors and other persons who have contributed to the design, creation, conception, reduction to practice or invention of any Intellectual Property in the Corbus Licensed Technology or the Corbus Licensed Patents have entered into written agreements with Corbus assigning to Corbus all rights relating to such design, conception, reduction to practice, invention or Corbus Licensed Technology.
- 10.2.13. Schedule 10.2.13, which shall be provided by Corbus to Licensee within fifteen (15) days after the Effective Date, sets forth a true and complete list of all Contracts to which Corbus or any of its Affiliates is a party and under which Corbus or its Affiliates have in-licensed Intellectual Property of a Third Party that comprises Corbus Licensed Technology or is otherwise material to the Exploitation of the Licensed Products in the Field in the Licensee Territory. Except as described in Schedule 10.2.13, none of such Contracts prevent Corbus from licensing or sublicensing rights to Licensee or require royalties to be paid in connection with a sublicense. True and correct copies of the Contracts set forth on Schedule 10.2.13 have been provided to Licensee, and such Contracts are in full force and effect and have not been modified or amended. Neither Corbus or its Affiliates nor, to the Knowledge of Corbus, the other party to such Contracts is in default with respect to a material obligation under, and none of such parties has claimed or, to the Knowledge of Corbus with respect to such counterparty's claims against Corbus or any of its Affiliates, has grounds upon which to claim that the other party is in default with respect to a material obligation under, such Contracts. None of Corbus and its Affiliates has received any written notice of breach under any of the Contracts listed in Schedule 10.2.13. None of Corbus and its Affiliates has waived or allowed to lapse any of its rights under any Contracts listed in Schedule 10.2.13 with respect to Licensed Products, and no such rights have lapsed or otherwise expired or been terminated.
- 10.2.14. To the Knowledge of Corbus, there are no Safety Concerns, adverse events or Efficacy Concerns in relation to Clinical Studies of the Licensed Products or issues with any Governmental Authorities in relation to the Regulatory Approval of the Licensed Products for either of the Initial Indications, other than as has previously been made available as of the Effective Date to Licensee in writing in the electronic data room, that would reasonably be expected to have a material adverse effect on the ability of Licensee or Corbus to Exploit the Licensed Products in the Field in the Licensee Territory in compliance with all applicable Laws. Without limiting the foregoing, to the Knowledge of Corbus, Corbus has made available to Licensee prior to the Effective Date in writing in the electronic data room all material adverse information in its possession with respect to the Safety Concerns, adverse events or Efficacy Concerns in relation to the Development of the Licensed Products or issues with any Governmental Authorities in relation to the Regulatory Approval of the Licensed Products for either of the Initial Indications.
- 10.2.15. To the Knowledge of Corbus, all Clinical Studies and Nonclinical Studies sponsored by Corbus relating to Licensed Products have been and are being conducted in material compliance with applicable Laws, including GCP requirements, and federal, national, state and local Laws, rules, regulations and guidance restricting the use and disclosure of individually identifiable health information. Corbus has not received any written notices or other written correspondence from the FDA or any other Governmental Authority performing functions similar to those performed by the FDA with respect to any ongoing Clinical Studies and Nonclinical Studies relating to the Licensed Products requiring the termination, suspension or material modification of such Clinical Studies and Nonclinical Studies.

- 10.2.16. The inventions Covered by the owned Corbus Licensed Patents: (1) were not conceived, discovered, developed or otherwise made, in whole or in part, using funds provided by the federal government of the U.S. or any agency thereof or any other Governmental Authority; (2) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f); and (3) are not otherwise subject to the provisions of the Bayh-Dole Act (35 U.S.C. §§ 200-212, as well as any regulations promulgated pursuant thereto, including 37 C.F.R. Part 401).
- 10.2.17. In connection with the Exploitation of the Licensed Products conducted by Corbus, Corbus has maintained as of the Effective Date internal procedures and policies that comply in all material respects with the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, et seq.) and any other applicable anti-bribery or anti-corruption laws (collectively "Anti-Corruption Laws") and the Physicians' Payment Sunshine Act.
- 10.2.18. Corbus has not, to its Knowledge (a) made an untrue statement of a material fact or fraudulent statement to the FDA or any Governmental Authority with respect to any of the Licensed Products, (b) failed to disclose a material fact required to be disclosed to the FDA or any Governmental Authority, or (c) committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy or for any other state or foreign Governmental Authority to invoke any similar policy with respect to any of the Licensed Products. Corbus is not the subject of any pending or, to the Knowledge of Corbus, any threatened investigation by the FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy. Neither Corbus, nor any of its Affiliates has been convicted of any crime or engaged in any conduct which has resulted or, to Corbus' Knowledge, is reasonably likely to result in debarment, exclusion or disqualification by the FDA or any other Governmental Authority. To the Knowledge of Corbus, none of its collaborators, agents or subcontractors it has used in the Development of the Licensed Products has been convicted of any crime or engaged in any conduct which has resulted in debarment, exclusion or disqualification by the FDA or any other Governmental Authority.
- 10.3. Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY PATENTS, KNOW-HOW, MATERIALS, LICENSED PRODUCT, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

# 10.4. Certain Covenants.

**10.4.1.** *Compliance*. Each Party and its Related Parties will conduct the Collaboration and the Development and Commercialization of the Licensed Products in the Field in the Licensee Territory in accordance with all applicable Laws.

- 10.4.2. No Debarment. Each Party will use reasonable efforts to not use, in any capacity in connection with the Collaboration or the performance of its obligations under this Agreement, any Person that has been debarred pursuant to Section 306 of the FD&C Act, as amended, or that is the subject of a conviction described in such section, or, in the case of Licensee, such equivalent Laws applicable in the Licensee Territory. Each Party agrees to inform the other Party in writing immediately if it or any Person that is performing activities in the Collaboration or under this Agreement, is debarred or is subject to debarment or is the subject of a conviction described in Section 306 of the FD&C Act or, in the case of Licensee, such equivalent Laws applicable in the Licensee Territory, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the notifying Party's knowledge, is threatened, relating to the debarment or conviction of the notifying Party or any Person or entity used in any capacity by such Party or any of its Affiliates in connection with the Collaboration or the performance of its other obligations under this Agreement.
- 10.4.3. Conflicting Transactions. During the Term, Corbus will not, and will cause its Affiliates not to, enter into any agreement granting a license or other right or interest under the Corbus Licensed Technology that is inconsistent with this Agreement or that would conflict with or otherwise impair the licenses to Licensee as purported to be granted pursuant to this Agreement. During the Term, Licensee will not, and will cause its Affiliates not to, enter into any agreement granting a license or other right under the Licensee Licensed Technology that is inconsistent with this Agreement.
- **10.4.4.** *SSc Priority.* Without limiting Licensee's diligence obligations under <u>Sections 4.3</u> and <u>5.2</u>, Licensee will prioritize and first pursue obtaining Regulatory Approval for and commencing Commercialization of a Licensed Product for SSc in the Licensee Territory.
- 10.4.5. Internal Procedures and Policies. Corbus will maintain and enforce in all material respects throughout the Term appropriate internal procedures and policies that comply with the Anti-Corruption Laws and the Physicians' Payment Sunshine Act (and any equivalent Law in any other country or jurisdiction outside the United States), including: (A) an applicable code of conduct and (B) provisions for monitoring, training and obtaining certifications of compliance from all Third Parties involved with the Exploitation of the Licensed Products. Corbus shall provide such assistance and documentation as may be reasonably necessary for Licensee and its Affiliates to comply with the Anti-Corruption Laws, the Physicians' Payment Sunshine Act (and any equivalent Law in any other country or jurisdiction outside the United States).

## 10.5. Exclusivity.

- **10.5.1.** Subject to <u>Section 10.5.2</u>, during the Term, Licensee will not, and will cause its Affiliates not to, without the prior written consent of Corbus, (a) alone or with any Affiliates or Third Parties, conduct Clinical Studies on or Commercialize a Competing Product, or (b) enter into an agreement or other arrangement with any Third Party pursuant to which Licensee or one of its Affiliates grants such Third Party any license or other rights to Develop, Manufacture or Commercialize a Competing Product; <u>provided, however</u>, this <u>Section 10.5.1</u> shall no longer apply with respect to Competing Products in an Initial Indication in the event that [\*].
- 10.5.2. Licensee will not be in breach of the restrictions set forth in Section 10.5.1 if Licensee undergoes a Change of Control with an Acquirer that was (either directly or through an Affiliate) Developing, Manufacturing or Commercializing a Competing Product that would violate the restrictions of Section 10.5.1 prior to the closing of such Change of Control transaction and thereby becomes an Affiliate of such Acquirer, and such Acquirer may continue to Develop, Manufacture and Commercialize such Competing Product after such Change of Control transaction; provided, however, that (a) no Licensee Licensed Technology is used by or on behalf of such Acquirer or its Affiliates in more than a de minimis fashion in connection with such subsequent Development, Manufacture or Commercialization of such Competing Product, (b) no Corbus Licensed Technology is used by or on behalf of such Acquirer or its Affiliates in connection with such subsequent Development, Manufacture or Commercialization of such Competing Product, and (c) such Acquirer and Licensee institute commercially reasonable technical and administrative safeguards to ensure the same, including by creating "firewalls" between the personnel teams charged with such Development, Manufacture, and Commercialization of such Competing Product.

10.6. Licensee Right of First Negotiation for Additional Indications in the Licensee Territory. Corbus hereby grants to Licensee a right of first negotiation during the Term of this Agreement to obtain a license under the Corbus Licensed Technology to Develop, Manufacture and Commercialize Licensed Products in any Additional Indication in the Licensee Territory (an "Additional Indication Japan License") in the event that Corbus intends to grant an Additional Indication Japan License to any Third Party. Licensee will have a right of first negotiation to obtain any such Additional Indication Japan License for a period of [\*] days after Licensee's receipt of a written notice from Corbus (the "Negotiation Period") that Corbus intends to grant an Additional Indication Japan License to a Third Party, which notice will set out the Additional Indication at issue and the proposed commercial and other terms of such Additional Indication Japan License (the "Notice"). Licensee will have [\*] Business Days from its receipt of such a Notice to notify Corbus in writing either of its desire to commence negotiations or its rejection of such proposal. If Licensee notifies Corbus of its rejection of such proposal, or if Licensee fails to respond to Corbus in writing during such [\*] Business Days period, Corbus will have no further obligations to Licensee under this Section 10.6 with respect to the Additional Indication Japan License that was the subject of the applicable Notice. If Licensee notifies Corbus of its desire to commerce negotiations during such [\*] Business Days period, Corbus will not, and will ensure that its Affiliates will not, during the Negotiation Period engage in negotiations with any Third Party other than Licensee's designee(s) for such negotiations) with respect to the Additional Indication Japan License that is the subject of such a Notice from Corbus. During the Negotiation Period, each Party will negotiate with the other in good faith towards executing a license agreement for such Additional Indication Japan License on commercially reasonable terms during the Negotiation Period, where such license agreement can instead be an amendment to this Agreement if so mutually agreed by the Parties during the Negotiation Period. Upon the expiration of the Negotiation Period, unless Licensee and Corbus have executed a license agreement (or an amendment to this Agreement, if so agreed by the Parties) covering such Additional Indication Japan License, Corbus will be free to enter into negotiations with any Third Party for such Additional Indication Japan License and enter into any agreement for the same, provided that the terms of such agreement are not in the aggregate more favorable to such Third Party than the terms offered to Licensee.

## 11. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

11.1. General Indemnification by Licensee. Licensee will indemnify, hold harmless and defend Corbus, its Related Parties, and their respective directors, officers, employees and agents ("Corbus Indemnitees") from and against any and all liabilities, damages, costs, fees and expenses (including reasonable attorneys' fees and litigation expenses) (collectively, "Losses") incurred in connection with Third Party claims or suits to the extent arising out of or resulting from: (a) any breach of, or inaccuracy in, any representation or warranty made by Licensee in this Agreement, or any breach or violation of any covenant or agreement of Licensee in, or in the performance of, this Agreement, (b) the gross negligence or willful misconduct by or of Licensee or any of its Related Parties, or any of their respective directors, officers, employees or agents in the performance of Licensee's obligations under this Agreement, or (c) the Development or Commercialization of Licensed Products by or on behalf of Licensee or any of its Related Parties. Licensee will have no obligation to indemnify the Corbus Indemnitees to the extent that the Losses arise out of or result from any matters for which Corbus is obligated to indemnify Licensee under Section 11.2.

- 11.2. General Indemnification by Corbus. Corbus will indemnify, hold harmless, and defend Licensee, its Related Parties and their respective directors, officers, employees and agents ("Licensee Indemnitees") from and against any and all Losses incurred in connection with Third Party claims or suits to the extent arising out of or resulting from: (a) any breach of, or inaccuracy in, any representation or warranty made by Corbus in this Agreement, or any breach or violation of any covenant or agreement of Corbus in, or in the performance of, this Agreement, (b) the gross negligence or willful misconduct by or of Corbus or any of its Related Parties, or any of their respective directors, officers, employees or agents in the performance of Corbus' obligations under this Agreement, or (c) the Development or Commercialization of Licensed Products by or on behalf of Corbus or any of its Related Parties. Corbus will have no obligation to indemnify the Licensee Indemnitees to the extent that the Losses arise out of or result from any matters for which Licensee is obligated to indemnify Corbus under Section 11.1.
- 11.3. Indemnification Procedure. The Party entitled to indemnification under this Section 11 (an "Indemnified Party") will notify the Party potentially responsible for such indemnification (the "Indemnifying Party") in writing promptly upon being notified of or having actual knowledge of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, that the failure to give such notice will not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party. If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending a claim, the Indemnifying Party will have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings; provided, that the Indemnifying Party may not enter into any compromise or settlement unless (a) such compromise or settlement imposes only a monetary obligation on the Indemnifying Party and includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; or (b) the Indemnified Party consents to such compromise or settlement, which consent will not be unreasonably withheld, conditioned or delayed unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 11.3 and will bear its own costs and expenses with respect to such participation; provided that the Indemnifying Party will bear such costs and expenses if counsel for the Indemnifying Party will have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense, in the Indemnified Party's reasonable opinion, is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party will have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed); provided that the Indemnified Party will keep the Indemnifying Party apprised of all material developments with respect to such claim. The Indemnified Party may not enter into any compromise or settlement without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.
- 11.4. <u>Limitation of Liability</u>. NEITHER PARTY WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT, OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF (A) A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR (B) A BREACH OF <u>SECTION 9</u>. NOTHING IN THIS <u>SECTION 11.4</u> IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS <u>SECTION 11</u>.

11.5. <u>Insurance</u>. Each Party will obtain and maintain insurance during the Term and for a period of at least two (2) years after the last commercial sale of any Licensed Product for which it is responsible, with a reputable, solvent insurer in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement. Specifically, each Party will maintain product liability insurance and clinical trial liability insurance with limits of at least [\*]. Upon request, each Party will provide the other Party with evidence of the existence and maintenance of such insurance coverage.

### 12. INTELLECTUAL PROPERTY

# 12.1. Inventorship.

- **12.1.1.** *Determination of Inventorship.* Inventorship for inventions and discoveries (including Know-How) first made during the course of the performance of activities pursuant to the Collaboration will be determined in accordance with United States patent Laws for determining inventorship.
- 12.1.2. JRA Exception. Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the America Invents Act Joint Research Agreement exception codified at 35 U.S.C. § 102(c) (the "JRA Exception") when exercising its rights under this Agreement, but only with prior written consent of the other Party in its sole discretion. In the event that a Party intends to invoke the JRA Exception, once agreed to by the other Party if required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined 35 U.S.C. § 100(h).

### 12.2. Ownership.

### 12.2.1. Corbus.

- **12.2.1.1.** As between the Parties, Corbus will own the entire right, title and interest in and to all Know-How (and Patents claiming inventions therein) first developed or conceived solely by Corbus in the performance of the Collaboration ("**New Corbus IP**").
- 12.2.1.2. As between the Parties, Corbus will own the entire right, title and interest in and to all Know-How (and Patents claiming inventions therein) first developed or conceived, whether solely by or on behalf of Licensee or its Related Parties or jointly by the Parties, in the performance of the Collaboration that relates to (a) any new use or mode of action of Lenabasum, (b) any new formulation for the active pharmaceutical ingredient of Lenabasum that is an improvement to the Corbus Licensed Patents or to the subject matter taught in the Corbus Licensed Know-How, or any new mode of administration for Lenabasum, or (c) any compound whose principal mode of action is to modulate the cannabinoid receptor type 2 (CB2) and that is derived from subject matter claimed in the Corbus Licensed Patents or taught in the Corbus Licensed Know-How (collectively, the "New Lenabasum IP"). If Licensee holds any right, title, or interest in any New Lenabasum IP, then Licensee hereby does, and agrees to, assign any and all such right, title and interest to any such New Lenabasum IP to Corbus together with the right to file and own applications for any Patent and any Patent issuing thereon.

- **12.2.2.** *Licensee.* As between the Parties, Licensee will own the entire right, title and interest in and to all Know-How (and Patents claiming inventions therein) first developed or conceived solely by Licensee in the performance of the Collaboration that is neither New Corbus IP nor New Lenabasum IP (the "**Licensee Program IP**").
- 12.2.3. Joint Ownership. The Parties will jointly own all Know-How (and Patents claiming inventions therein) developed or conceived in the performance of the Collaboration that is not New Corbus IP, New Lenabasum IP or Licensee Program IP first developed or conceived jointly by (a) Licensee or any of its Related Parties and (b) Corbus or any of its Related Parties (the "Joint Program IP" and, together with the Licensee Program IP, the "Program IP").

# 12.3. Covenants in Support of IP Ownership Allocation.

- 12.3.1. Each Party will have an equal and undivided joint ownership interest in and to the Joint Program IP. Each Party will have the right to exercise its ownership in and to such Joint Program IP, including, upon prior written notice to the other Party, the right to license and sublicense or otherwise to exploit, transfer or encumber its ownership interest, without any accounting or obligation to, or consent required from, the other Party, but subject to the licenses under this Agreement and the other terms and conditions of this Agreement. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Program IP. Each Party, for itself and on behalf of its Affiliates, licensees and sublicensees, and employees, subcontractors, consultants and agents of any of the foregoing, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to the other Party an equal and undivided joint ownership interest in and to all Joint Program IP.
- 12.3.2. Each Party will provide the other Party (at such other Party's cost and expense) with all further cooperation to give effect to the allocation of ownership, as between the Parties, of the New Corbus IP, New Lenabasum IP, Licensee Program IP and Joint Program IP (including with respect to rights of priority), in each case, as contemplated by Section 12.2, including executing and delivering further assignments, consents, releases and other commercially reasonable documentation, and providing good faith testimony by affidavit, declaration, deposition, in person or other proper means and otherwise assisting such other Party in support of its efforts to establish, perfect, defend, or enforce its rights in its respective intellectual property.
- **12.4.** <u>Disclosure of Inventions</u>. The Parties will promptly disclose to each other any New Corbus IP, New Lenabasum IP or Program IP developed or conceived during the Term, but no later than thirty (30) days after the applicable Party's intellectual property department receives notice of such development or conception.

# 12.5. Prosecution and Maintenance of Patents.

### 12.5.1. Licensee.

12.5.1.1. General. Subject to the remainder of this Section 12.5.1, as between the Parties, Licensee will have sole control of and responsibility for the Prosecution and Maintenance (and all applicable Patent Costs therefor), in Licensee's name, all Joint Program IP Patents within the Licensee Territory, Licensee Program IP Patents and all Licensee Background Patents (collectively, the "Licensee Controlled Patents"). Licensee will furnish to Corbus, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining the Licensee Controlled Patents in the Corbus Territory, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to the Licensee Controlled Patents in the Corbus Territory, and such other material documents related to the Prosecution and Maintenance of the Licensee Controlled Patents in the Corbus Territory, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Corbus. Licensee will consider in good faith timely comments and recommendations made by Corbus in connection with such review.

12.5.1.2. Licensee Controlled Patents Abandonment. In the event that Licensee elects not to Prosecute and Maintain (or continue to Prosecute and Maintain, including filing a Patent claiming priority to a Patent prior to its issuance), any Licensee Controlled Patent, Licensee will notify Corbus at least ninety (90) days before any such Licensee Controlled Patent would become abandoned, no longer available or otherwise forfeited, whereupon, at the written request of Corbus, the Parties will meet to discuss any such decision by Licensee. Subject to, if applicable, the provisions of any in-license agreement of Licensee applicable to such Licensee Controlled Patent, Corbus will have the right (but not the obligation), at its sole discretion, to assume the Prosecution and Maintenance (and all applicable Patent Costs therefor) of such Licensee Controlled Patent in the name of Licensee (which right will include the right to file additional Patents claiming priority to such Patent). Corbus will consult reasonably with Licensee on its strategy for the Prosecution and Maintenance of all such assumed Licensee Controlled Patents. Corbus will furnish to Licensee, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining such assumed Licensee Controlled Patents, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such assumed Licensee Controlled Patents, and such other material documents related to the Prosecution and Maintenance of such assumed Licensee Controlled Patents, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Licensee. Corbus will consider in good faith timely comments and recommendations made by Licensee in connection with such review. Licensee will sign, or will use Commercially Reasonable Efforts to have signed, all legal documents as are reasonably necessary for Corbus to assume the Prosecution and Maintenance of such assumed Licensee Controlled Patent.

#### 12.5.2. Corbus.

12.5.2.1. General. Subject to remainder of this Section 12.5.2, as between the Parties, Corbus will have sole control of and responsibility for the Prosecution and Maintenance (and all applicable Patent Costs therefor), in Corbus' name, all Patents within the New Corbus IP, all Patents within the New Lenabasum IP, all Joint Program IP Patents within the Corbus Territory, and all other Corbus Licensed Patents other than Joint Program IP Patents within the Licensee Territory. Corbus will furnish to Licensee, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining the Corbus Licensed Patents other than the Joint Program IP Patents in the Licensee Territory, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such foregoing Patents in the Licensee Territory, and such other material documents related to the Prosecution and Maintenance of such foregoing Patents in the Licensee Territory, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Licensee. Corbus will consider in good faith timely comments and recommendations made by Licensee in connection with such review.

12.5.2.2. Corbus Licensed Patents Abandonment. In the event that Corbus elects not to Prosecute and Maintain (or continue to Prosecute and Maintain, including filing a Patent claiming priority to a Patent prior to its issuance), any Corbus Licensed Patent (other than Joint Program IP Patents within the Licensee Territory), Corbus will notify Licensee at least ninety (90) days before any such Corbus Licensed Patent would become abandoned, no longer available or otherwise forfeited, whereupon, at the written request of Licensee, the Parties will meet to discuss any such decision by Corbus. Subject to, if applicable, the provisions of any in-license agreement of Corbus applicable to such Corbus Licensed Patent, Licensee will have the right (but not the obligation), at Licensee's sole discretion, to assume the Prosecution and Maintenance (and all applicable Patent Costs therefor) of such foregoing Patent in the name of Corbus (which right will include the right to file additional Patents claiming priority to such Patent). Licensee will consult with Corbus on its strategy for the Prosecution and Maintenance of all such assumed foregoing Patents. Licensee will furnish to Corbus, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining such assumed foregoing Patents, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such assumed foregoing Patents, and such other material documents related to the Prosecution and Maintenance of such assumed foregoing Patents, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Corbus. Licensee will consider in good faith timely comments and recommendations made by Corbus in connection with such review. Corbus will sign, or will use reasonable efforts to have signed. all legal documents as are reasonably necessary for Licensee to assume the Prosecution and Maintenance of such assumed foregoing Patents.

12.5.3. Patent Miscellaneous. Each Party hereby agrees: (a) to use Commercially Reasonable Efforts to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake any Prosecution and Maintenance described in this <u>Section 12.5</u>; and (b) to reasonably cooperate in any such Prosecution and Maintenance by the other Party.

## 12.6. Third Party Infringement and Defense.

12.6.1. Notices. Each Party will promptly report in writing to the other Party any Competitive Infringement of which such Party (or any of its Affiliates or Sublicensees) becomes aware, and will provide the other Party with all available evidence of such Competitive Infringement in such Party's control; provided, however, that (a) for cases of Competitive Infringement under Section 12.6.2.3 below, such written notice will be given within five (5) calendar days, and (b) for cases of infringement as described in Section 12.6.2.4 below, such written notice will be given as specified in Section 12.6.2.4. Without limiting the last sentence of the definition of "Competitive Infringement," a notice under 21 U.S.C. § 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) (however those sections may be amended) or any equivalent provision under applicable Law outside of the United States with respect to any Patents that are the subject of this Agreement will be deemed to describe an act of Competitive Infringement, regardless of its content. Subject to the rest of this Section 12.6, the JCC will discuss in good faith strategies for abating such Competitive Infringement of any Licensed Product within each of the Party's respective Territory.

### 12.6.2. Rights to Enforce.

- **12.6.2.1.** Competitive (Licensee) Infringement. As between the Parties, Licensee will have the first right (but not the obligation), at Licensee's sole discretion, through counsel of its choosing reasonably acceptable to Corbus, to seek to abate any Competitive (Licensee) Infringement by enforcing any Corbus Licensed Patents or any Licensee Controlled Patents, in each case, solely in the Licensee Territory. Licensee will pay all Patent Costs incurred by Licensee for such enforcement. If Licensee does not take steps to abate such Competitive (Licensee) Infringement, within six (6) months of becoming aware, or receiving written notice from Corbus, of such Competitive (Licensee) Infringement (or such shorter period of time as is required to comply with applicable Law to not waive any statutory rights), Licensee will provide Corbus with written notice of such decision and Corbus will have the rights set forth in Section 12.6.5.1 with respect to enforcing the Corbus Licensed Patents and the Licensee Controlled Patents in the Licensee Territory to abate such Competitive (Licensee) Infringement.
- 12.6.2.2. Competitive (Corbus) Infringement. As between the Parties, Corbus will have the first right (but not the obligation), at Corbus' sole discretion, through counsel of its choosing reasonably acceptable to Licensee, to seek to abate any Competitive (Corbus) Infringement by, as applicable, (a) enforcing any Patents within the New Corbus IP or the New Lenabasum IP that are not also Corbus Licensed Patents anywhere in the world and (b) enforcing any Licensee Program IP Patents or any Corbus Licensed Patents solely in the Corbus Territory. Corbus will pay all Patent Costs incurred by Corbus for such enforcement. If Corbus does not take steps to abate such Competitive (Corbus) Infringement, within six (6) months of becoming aware, or receiving written notice from Licensee, of such Competitive (Corbus) Infringement (or such shorter period of time as is required to comply with applicable Law to not waive any statutory rights), Corbus will provide Licensee with written notice of such decision and Licensee will have the rights set forth in Section 12.6.5.1 with respect to enforcing the Licensee Controlled Patents in the Corbus Territory to abate such Competitive (Corbus) Infringement.
- **12.6.2.3.** 35 U.S.C. § 271(e)(2) Infringement. Notwithstanding anything to the contrary in this Section 12.6.2, for a Competitive Infringement under 35 U.S.C. § 271(e)(2), the time period set forth in Section 12.6.2.1 or 12.6.2.2, as applicable, during which a Party will have the initial right to bring a Proceeding will be shortened to a total of twenty-five (25) days, so that, to the extent the other Party has the right, pursuant to such Section 12.6.2.1 or 12.6.2.2, as applicable, to initiate a Proceeding, if the first Party does not initiate a Proceeding, then such other Party will have such right if the first Party does not initiate a Proceeding within such twenty-five (25) days after such first Party's receipt of written notice of such Competitive Infringement.
- **12.6.2.4.** *Notification of Patent Certification.* If either Party becomes aware of any allegations of alleged patent invalidity, unenforceability or non-infringement of any Patent licensed under this Agreement Covering a Licensed Product (including methods of use thereof) pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application, or other similar patent certification by a Third Party, and any foreign equivalent thereof, for a Generic Product, such Party will notify and provide the other Party with copies of such allegations. Such notification and copies will be provided to such other Party as soon as practicable and at least within five (5) calendar days after such Party receives such certification, and will be sent by facsimile and overnight courier to the address set forth in Section 14.10.

- 12.6.3. Defense. As between the Parties, the Party controlling the Prosecution and Maintenance of any Patent under Section 12.5 will have the right (but not the obligation), at its sole discretion, to defend against a declaratory judgment action or other action (such as a revocation proceeding or an opposition) challenging any such Patent (a "Third Party Action"), other than with respect to (a) any counterclaims in any enforcement action brought by the other Party pursuant to Section 12.6.2 or (b) any action by a Third Party in response to an enforcement action brought by the other Party, which in both cases ((a) and (b)) will be controlled by such other Party. If the Party controlling such Prosecution and Maintenance of Patents under Section 12.5 does not provide notice to the other Party of such Party's intent to defend such Patent under this Section 12.6.3 within thirty (30) calendar days (or such shorter period of time as is required to not waive any statutory rights), or elects not to initiate or continue any such defense (in which case it will promptly provide notice thereof to the other Party), then (i) in the case of any of the foregoing done by Corbus with respect to any Patent under this Agreement for which Corbus is responsible for the Prosecution and Maintenance thereof at such time in the Licensee Territory, Licensee will have the right (but not the obligation), at its sole discretion, to defend any Corbus Licensee with respect to any Patent under this Agreement for which Licensee is responsible for the Prosecution and Maintenance thereof at such time in the Corbus Territory, Corbus will have the right (but not the obligation), at its sole discretion, to defend any Licensee Controlled Patent against any such Third Party Action in the Corbus Territory, in each case of (i) and (ii), as further set forth in Section 12.6.5.
- 12.6.4. Cooperation Regarding Enforcement or Defense. With respect to any Competitive Infringement action or Third Party Action identified above in Sections 12.6.2 and 12.6.3 and subject to the terms and conditions of this Section 12.6.4, the Party controlling any such Competitive Infringement action or Third Party Action (the "Controlling Party") will keep the other Party (the "Non-Controlling Party") reasonably informed of the status and progress of such enforcement or defense efforts, and will reasonably consider the Non-Controlling Party's comments on any such efforts. The Non-Controlling Party will provide the Controlling Party with all reasonable assistance in the enforcement or defense of the applicable Patents, as the Controlling Party may request, at such Controlling Party's expense, including by signing or executing any necessary documents and consenting to it being named a party to any applicable Proceedings. Where the Non-Controlling Party is named a party or joins any applicable Proceeding, the Non-Controlling Party will have the right to be represented by counsel of its choice at the Controlling Party's expense.
- **12.6.5.** *Withdrawal, Cooperation and Participation*. With respect to any Competitive Infringement action or Third Party Action identified above in <u>Sections 12.6.2</u> and <u>12.6.3</u> and subject to the terms and conditions of this <u>Section 12.6.5</u>:
  - 12.6.5.1. If the Controlling Party ceases to pursue or withdraws from such action (the "Withdrawing Party"), it will promptly notify the other Party (in sufficient time to enable such other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and (a) if Corbus is the Withdrawing Party, then Licensee will have the right (but not the obligation) to substitute itself for Corbus in any Competitive Infringement action or Third Party Action identified above in <a href="Section 12.6.2.2">Section 12.6.2</a> or <a href="12.6.3">12.6.3</a> involving the Licensee Controlled Patents in the Corbus Territory and proceed under the terms and conditions of this <a href="Section 12.6.5">Section 12.6.5</a>, and (b) if Licensee is the Withdrawing Party, then Corbus will have the right (but not the obligation) to substitute itself for Licensee in any Competitive Infringement action identified above in <a href="Section 12.6.2.1">Section 12.6.2</a>. I or <a href="12.6.3">12.6.3</a> relating to the Corbus Licensee Patents or the Program IP Patents in the Licensee Territory, and proceed under the terms and conditions of this <a href="Section 12.6.5">Section 12.6.5</a> (Licensee or Corbus, as applicable, under (a) or (b), the "New-Controlling Party").

- 12.6.5.2. The Withdrawing Party will cooperate with the New-Controlling Party controlling any such action (as may be reasonably requested by the New-Controlling Party), including, at the New-Controlling Party's sole cost and expense, (a) providing access to relevant documents and other evidence, (b) using reasonable efforts to make its Affiliates and its Affiliates' licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (c) if reasonably necessary, by being joined as a party, subject to, for this clause (c), the New-Controlling Party agreeing to indemnify such Withdrawing Party for its involvement as a named party in such action and paying those Patent Costs incurred by such Withdrawing Party in connection with such joinder. The New-Controlling Party controlling any such action will keep the Withdrawing Party reasonably updated with respect to any such action, including providing copies of all materials documents received or filed in connection with any such action.
- 12.6.5.3. The Withdrawing Party will have the right to consult with the New-Controlling Party regarding any such action controlled by such New-Controlling Party, in each case at such Withdrawing Party's sole cost and expense. If the Withdrawing Party elects to so be involved, the New-Controlling Party will provide such Withdrawing Party and its counsel with an opportunity to consult with the New-Controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any material correspondence, legal papers or other documents related thereto), and the New-Controlling Party will take into account reasonable and timely requests and comments of the Withdrawing Party regarding such enforcement or defense. However, nothing in this Section 12.6.5.3 will limit the New-Controlling Party's ability to prosecute any such action.
- 12.6.6. Settlement. With respect to any Competitive Infringement or Third Party Action identified above in this Section 12.6, the Controlling Party of such action will have the right to settle or otherwise dispose of such action on such terms and conditions as such Party will determine in its sole discretion, including by granting a license or sublicense to a Third Party under the rights granted to such Party in Section 7; provided that, notwithstanding the foregoing, no such settlement or other disposition will (a) impose any monetary restriction or obligation on or admit fault of the other Party, or (b) adversely affect the other Party's rights under this Agreement to any such Patent then being enforced or defended, in each case ((a) and (b)) without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed.
- **12.6.7.** *Damages*. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in this <u>Section 12.6</u> will be used first to reimburse the Controlling Party for its Patent Costs arising from the action, with the balance of any such recovery to be divided as follows:
  - **12.6.7.1.** for any applicable action initiated in the Controlling Party's Territory, (a) if Corbus was the Controlling Party, [\*], and (b) if Licensee was the Controlling Party, [\*]; and
  - **12.6.7.2.** for any applicable action <u>not</u> initiated in the Controlling Party's Territory, then the balance of any such recovery will be allocated [\*] percent ([\*]%) to the controlling Party and [\*] percent ([\*]%) to the other Party.

- 12.7. Patent Extensions. With respect to any election for patent term restoration or extension, supplemental protection certificate or any of their equivalents, (a) Licensee will have the sole and exclusive right to make any such decision relating to any Licensee Controlled Patents that are not Joint Program IP Patents, (b) Corbus will have the sole and exclusive right to make any such decision relating to any Patents within the Corbus Licensed Technology that are not Joint Program IP Patents, and (c) Licensee and Corbus together will make such decision relating to any Joint Program IP Patents, in each case of (a), (b) and (c) with respect to any Licensed Product, provided that notwithstanding the foregoing clauses (a) and (b), each Party will use reasonable efforts to obtain any such patent term restoration or extension, supplemental protection certificate or any of their equivalents available for the Patents subject to the enforcement rights specified in Section 12.6.2 with respect to any Licensed Product; and further provided, however, that no Party will be required to use any such reasonable efforts in a manner inconsistent with any term or condition of this Section 12.7 if any such item could impair the applicable Patent (including its enforcement potential) or the ability to obtain any such patent term restoration or extension, supplemental protection certificate or any of their equivalents for any other pharmaceutical product. Upon the written request by a Party, the other Party will reasonably cooperate with the implementation of such requesting Party's decisions made in a manner consistent with this Section 12.7.
- 12.8. Patent Listings. With respect to any filings of Patents made with Regulatory Authorities for any Licensed Product, including as required or allowed in connection with, in the United States, the FDA's Orange Book, or, outside of the United States, other international equivalents, but subject to Section 12.6.2.3. (a) the Parties will list any such Patents as may be required by applicable Laws with respect to any such filings for Licensed Products made with Regulatory Authorities in their respective Territory, and (b) otherwise (i) Licensee will have the sole and exclusive right to make any such decision whether to list any Licensee Background Patents, Licensee Program IP Patents and Joint Program IP Patents with respect to any Licensed Product in filings made with Regulatory Authorities in the Licensee Territory, and (ii) Corbus will have the sole and exclusive right to make any such decision whether to list any Joint Program IP Patents and any Corbus Licensed Patents that are not Joint Program IP Patents with respect to any Licensed Product in filings made with Regulatory Authorities in the Corbus Territory, provided that notwithstanding the foregoing clauses (b)(i) and (ii), each Party will use Commercially Reasonable Efforts to make any such listing if available for the Patents subject to the enforcement rights specified in Section 12.6.2 with respect to any Licensed Product; and further provided, however, that no Party will be required to use any such Commercially Reasonable Efforts in a manner inconsistent with any term or condition of this Section 12.8 if any such item could impair the applicable Patent (including its enforcement potential) or the ability to list such Patent for any other pharmaceutical product. Upon the request by a Party, such other Party will reasonably cooperate in the implementation of such requesting Party's decisions made in a manner consistent with this Section 12.8.
- 12.9. <u>Third Party Rights</u>. Notwithstanding the foregoing provisions of this <u>Section 12</u>, each Party's rights and obligations with respect to any Patent under this <u>Section 12</u> will be subject to any Third Party rights and obligations (including under any in-license of a Party applicable to such Party's licensed intellectual property rights hereunder).
- 12.10. Common Interest. All information exchanged between the Parties regarding the Prosecution and Maintenance, and enforcement and defense, of Patents under this Section 12 will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such Prosecution and Maintenance, and enforcement and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patents under this Section 12, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Section 12 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

### 12.11. Trademarks.

#### 12.11.1. Licensed Products Trademarks.

12.11.1.1. Subject to <u>Section 12.11.1.3</u>, the Parties agree to use Commercially Reasonable Efforts to use the trademark EMPRELVIA® (the "Existing Trademark") with each Licensed Product being Commercialized in the Licensee Territory and the Corbus Territory. As between the Parties, Corbus will own all right, title, and interest in and to the Existing Trademark and all goodwill associated therewith worldwide. Further, as between the Parties, Corbus will own all rights to any Internet domain names incorporating the Existing Trademark or any variation or part of such Existing Trademark used as its URL address or any part of such address.

12.11.1.2. If the JSC determines that the Existing Trademark is suited for use in the Licensee Territory, Corbus shall at its own cost and expense apply for the registration of the Japanese character (katakana) mark corresponding to the English character mark (EMPRELVIA®; International registration Number 1363931) in the Licensee Territory. Corbus shall be responsible for the registration, maintenance and defense of the Existing Trademark for use in connection with the sale or marketing of Licensed Products in the Field in the Licensee Territory, and the fees and expenses incurred in connection therewith for the Existing Trademark applicable to Licensed Products in the Licensee Territory shall be the responsibility of Corbus. Corbus and Licensee will enter into a separate trademark license agreement containing commercially reasonable and customary terms and conditions pursuant to which Corbus will grant to Licensee an exclusive, royalty-free, sublicensable (in accordance with Section 7.1.1.4) license to use the Existing Trademark(s) with the Licensed Products to Commercialize such Licensed Products in the Licensee Territory.

12.11.1.3. In the event that (a) the PMDA or the MHLW rejects the use of the Existing Trademark with the Licensed Products in the Licensee Territory or (b) the JSC determines in its reasonable discretion that the Existing Trademark is not suited for use in the Licensee Territory, the Parties, promptly and working together, will develop and propose, and the JSC will review and approve, the use of an alternative Trademark with the Licensed Products to Commercialize such Licensed Products in the Licensee Territory (the "Alternate Trademark"). The Alternate Trademark may be a Trademark developed by one Party with respect to the Commercialization of Licensed Products in such Party's Territory, but may not include other Trademarks Controlled by such Party unless otherwise agreed by the JSC. Following the JSC's approval of the Alternate Trademark, and except where such approved Alternate Trademark is a Trademark Controlled by Corbus, in which case, the Parties will enter into the same license arrangement described in Section 12.11.1.2, as between the Parties, Licensee will own all right, title, and interest (including all applications for registration and registrations) in and to the Alternate Trademark, but subject to Corbus' rights under Sections 13.7.2.3 and 13.7.3.4 and all goodwill associated therewith worldwide, and Licensee will own also all rights to any Internet domain names incorporating the Alternate Trademark or any variation or part thereof used as its URL address or any part of such address.

- 12.11.2. Trademark Infringement. In the event either Party becomes aware of any infringement of the Existing Trademark or the Alternate Trademark, as applicable, by a Third Party, such Party will promptly notify the other Party, and the Parties will consult with each other and jointly determine the best way to prevent such infringement, including by the institution of legal proceedings against such Third Party. Notwithstanding the foregoing, the Party owning such Trademark retains the sole and exclusive right (but not obligation) to seek to abate any such infringement.
- **12.11.3.** *No Other Trademark Rights.* For the avoidance of doubt, except as expressly permitted by this Agreement or as otherwise agreed in writing by the Parties, neither Party will have any right to use the other Party's or the other Party's Affiliates' Trademarks, corporate names or logos in connection with Development, Manufacturing, or Commercialization of Licensed Products.

#### 13. TERM AND TERMINATION

- 13.1. <u>Term</u>. This Agreement will be effective as of the Effective Date and, unless terminated earlier, this Agreement will continue on a Licensed Product-by-Licensed Product basis until the date on which the Royalty Term has expired in the Licensee Territory for such Licensed Product and will finally expire upon the expiration of the Royalty Term for the final Licensed Product (the "Term"). Upon expiration of the Royalty Term for a Licensed Product in the Licensee Territory or upon expiration of this Agreement, all licenses granted from one Party to the other Party in <u>Section 7</u> with respect to such Licensed Product will become fully-paid, irrevocable and perpetual.
- 13.2. <u>Termination by Licensee for Convenience</u>. At any time following the second (2<sup>nd</sup>) anniversary of the date of the First Commercial Sale of the first Licensed Product in either of the Initial Indications in the Licensee Territory, Licensee may terminate this Agreement in its entirety, for any reason or no reason upon one hundred and eighty (180) days' prior written notice to Corbus.
- **13.3.** <u>Termination by Licensee for Safety Concern or Clinical Failure</u>. At any time, Licensee will have the right to terminate this Agreement in its entirety in the event of (a) a Safety Concern or (b) a Clinical Failure, in each case of (a) or (b), upon ninety (90) days' prior written notice to Corbus, <u>provided</u> that, during such ninety (90) day period, Licensee will consult with Corbus in respect of measures to overcome the Safety Concern or Clinical Failure, as applicable, and avoid termination of this Agreement.

### 13.4. Termination for Material Breach.

### 13.4.1. Material Breach.

13.4.1.1. Subject to Section 13.4.2, Corbus will have the right to terminate this Agreement in its entirety upon delivery of written notice to Licensee in the event of any material breach by Licensee of any material terms and conditions of this Agreement, provided that such termination will not be effective if such breach has been cured within thirty (30) days after written notice thereof is given by Corbus to Licensee specifying the nature of the alleged breach (or, if such default cannot be cured within such thirty (30) day period, within ninety (90) days after such notice if Licensee commences actions to cure such default within such thirty (30) day period and thereafter diligently continues such actions, but fails to cure the default by the end of such ninety (90) days); provided, however, that to the extent such material breach involves the failure to make a payment when due, such breach must be cured within thirty (30) days after written notice thereof is given by Corbus to Licensee.

- 13.4.1.2. Subject to Section 13.4.2, Licensee will have the right to terminate this Agreement in its entirety upon delivery of written notice to Corbus in the event of any material breach by Corbus of any material terms and conditions of this Agreement, provided that such termination will not be effective if such breach has been cured within thirty (30) days after written notice thereof is given by Licensee to Corbus specifying the nature of the alleged breach (or, if such default cannot be cured within such thirty (30) day period, within ninety (90) days after such notice if Corbus commences actions to cure such default within such thirty (30) day period and thereafter diligently continues such actions, but fails to cure the default by the end of such ninety (90) days); provided, however, that to the extent such material breach involves the failure to make a payment when due, such breach must be cured within thirty (30) days after written notice thereof is given by Licensee to Corbus.
- **13.4.2.** Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 13.4.1 and such alleged breaching Party provides the other Party notice of such dispute within such thirty (30) day period, as applicable, then the non-breaching Party will not have the right to terminate this Agreement under Section 13.4.1 unless and until the dispute resolution process set forth in Section 14.3 has been completed (including the tolling and cure periods set forth therein).
- 13.5. <u>Termination for Insolvency</u>. If, at any time during the Term (a) a case is commenced by or against either Party under Title 11, United States Code, as amended, or analogous provisions of applicable Law outside the United States (the "Bankruptcy Code") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within sixty (60) days after the commencement thereof, (b) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) either Party assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for either Party's business, or (e) a substantial portion of either Party's business is subject to attachment or similar process; then, in any such case ((a), (b), (c), (d) or (e)), the other Party may terminate this Agreement upon written notice to the extent permitted under applicable Law.
- 13.6. Patent Challenge. Either Party has the right to terminate this Agreement upon written notice to the other Party in the event that the other Party or any of its Affiliates or Sublicensees directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Patents within the Corbus Licensed Technology (with respect to a challenge brought by Licensee), any Patents within the Licensee Licensed Technology (with respect to a challenge brought by Corbus), or any Joint Program IP Patents (with respect to a challenge brought by either Party ), as the case may be (each, a "Patent Challenge"); provided that (a) this Section 13.6 will not apply to any such Patent Challenge that is first made by a Party or any of its Affiliates or Sublicensees in defense of a claim of patent infringement brought by the other Party under the applicable Patent, (b) with respect to any Third Party that becomes an Affiliate of a Party during the Term as a result of a Change of Control of such Party or acquisition by such Party, this Section 13.6 will not apply to any Patent Challenge involving such Third Party if such proceeding was initiated before the signing of the definitive document(s) whereby such Third Party becomes such an Affiliate, and (c) with respect to any non-Affiliate Sublicensee, a Party will not have the right to terminate this Agreement under this Section 13.6 if the other Party (i) causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (ii) terminates such Sublicensee's sublicense to the Patents being challenged by the Sublicensee, in each case, within ninety (90) days of the terminating Party's notice to the other Party under this Section <u>13.6</u>.

- **13.7.** <u>Consequences of Termination or Expiration</u>. Upon termination or expiration of this Agreement, the following shall apply (in addition to any other rights and obligations under this <u>Section 13.7</u> or otherwise under this Agreement with respect to such termination):
- 13.7.1. Winding Down of Activities. If there are any on-going Development or Commercialization activities at termination or expiration of this Agreement, the Parties shall negotiate in good faith and adopt a plan to wind-down such activities in an orderly fashion or, at the continuing Party's election, promptly transition such activities from the non-continuing Party to the continuing Party or its designee, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Studies of the Licensed Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable Laws.
- **13.7.2.** *Termination for Breach or Insolvency*. In the event that this Agreement is terminated by a Party pursuant to <u>Section 13.4</u> or <u>13.5</u>:
  - 13.7.2.1. any and all rights and licenses granted by the non-terminating Party to the terminating Party under this Agreement shall remain in effect and, if necessary, be converted into transferable, fully paid, perpetual, royalty-free license, with the right to sublicense, and any licenses granted by the terminating Party to the non-terminating Party will terminate,
  - **13.7.2.2.** to the extent permitted by applicable Laws, Licensee (if it is the non-terminating Party), shall transfer to Corbus its entire right, title and interest in all Regulatory Materials in the Licensee Territory,
  - 13.7.2.3. Licensee (if it is the non-terminating Party) shall assign to Corbus all right, title and interest in and to those trademarks used exclusively with Licensed Products in the Licensee Territory (excluding any such trademarks that include, in whole or part, any corporate name or logo of Licensee or its Affiliate or Sublicensee), and
    - 13.7.2.4. the Right of Reference granted to the non-terminating Party in Section 5.4 will terminate.
- **13.7.3.** *Termination by Licensee for Convenience or Safety Concern or Clinical Failure.* In the event this Agreement is terminated by Licensee pursuant to <u>Section 13.2</u> or <u>13.3</u>, Licensee will:
  - 13.7.3.1. if Corbus so requests, and to the extent permitted under Licensee's or such Affiliate's obligations to such Third Parties, transfer to Corbus any Third Party agreements relating to the Development, Manufacture or Commercialization of the Licensed Products to which Licensee or any of its Affiliates is a party, subject to any required consents of such Third Party,
  - 13.7.3.2. transfer to Corbus any inventory of the Licensed Products owned by Licensee or its Affiliates as of the effective date of termination at the actual price paid by Licensee for such supply,
  - **13.7.3.3.** to the extent permitted by applicable Laws, transfer to Corbus its entire right, title and interest in all Regulatory Materials in the Licensee Territory, and

- 13.7.3.4. assign to Corbus all right, title and interest in and to those trademarks used exclusively with Licensed Products in the Licensee Territory (excluding any such trademarks that include, in whole or part, any corporate name or logo of Licensee or its Affiliate or Sublicensee).
- **13.7.4.** Return of Confidential Information. Upon expiration or termination of this Agreement, except to the extent that the either Party retains a license under this Agreement, each Party will promptly return all records and materials in its possession or control containing or comprising the other Party's Confidential Information. Each Party shall have the right to maintain one copy of such records in its files for archive purposes; provided that such copy is maintained in accordance with the surviving confidentiality obligations of this Agreement.
- 13.8. Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.
- **13.8.1.** Dissolution of Committees. All Committees will be dissolved as of the effective date of such termination, provided that, for any surviving provisions requiring action or decision by any of the Committees or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable.
- **13.8.2.** *Termination of Rights and Obligations*. Except as set forth in this <u>Section 13.8</u> and <u>Section 13.9</u>, all rights and obligations of the Parties under this Agreement will terminate as of the effective date of such termination.

# 13.9. Effect of Expiration or Termination; Survival.

- 13.9.1. Expiration or termination of this Agreement for any reason will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity, with respect to any breach of this Agreement. For the avoidance of doubt, termination of this Agreement will not affect any SDEA, which will continue to survive so long as any Licensed Products thereunder are being Commercialized.
- 13.9.2. Subject to the termination consequences set forth in <u>Sections 13.7</u> and <u>13.8</u> and any Sections referenced therein), the following provisions will survive expiration or termination of this Agreement for any reason: <u>Sections 5.4, 7, 8.7.3</u> (until the third anniversary of such expiration or termination), <u>9</u> (until the fifth anniversary of such expiration or termination), <u>11, 12, 13</u> and <u>14</u>.

### 14. MISCELLANEOUS

### 14.1. Assignment.

- 14.1.1. General. Except as provided in this Section 14.1.1, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding anything in this Section 14.1.1 to the contrary, Licensee may assign this Agreement and its rights and obligations hereunder in whole or in part (a) to an Affiliate without Corbus' prior written consent, or (b) to a party that acquires, by or otherwise in connection with, a merger, sale of assets, reorganization or otherwise, all or substantially all of the business of Licensee to which the subject matter of this Agreement relates (i) with Corbus' prior written consent for any such assignment occurring before the first Regulatory Approval by the MHLW for a Licensed Product for either of the Initial Indications has been obtained (the "Regulatory-Approval Trigger Date"), and (ii) with Corbus' prior written consent for any such assignment occurring after the Regulatory-Approval Trigger Date unless such party is a Qualified Assignee. In addition, Corbus' prior written consent, not to be unreasonably withheld, shall be required for any assignment of this Agreement by Licensee to an Affiliate that is not a Japanese legal entity. Notwithstanding anything in this Section 14.1.1 to the contrary, Corbus may, without Licensee's prior written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or to a party that acquires, by or otherwise in connection with, a merger, sale of assets, reorganization or otherwise, all or substantially all of the business of Corbus to which the subject matter of this Agreement relates. Any permitted successor or assignee of any rights or obligation under this Agreement must expressly assume the performance thereof. Notwithstanding any permitted assignment, the assigning Party will remain responsible for the performance by its assignee of any obligation hereunder so assigned. An assignment to an Affiliate will terminate, and all rights so assigned will revert to the assigning Party, if and when such Affiliate ceases to be an Affiliate of the assigning Party. Any purported assignment in violation of this Section 14.1.1 will be void.
- **14.1.2.** Securitization. Notwithstanding anything to the contrary in Section 14.1.1 or elsewhere in this Agreement, Corbus may assign to a Third Party its right to receive the milestone payments and the royalty payments owed under Section 8 (such assignment, a "Securitization Transaction") without the prior written consent of Licensee. Further, in connection with a contemplated Securitization Transaction, Corbus may disclose to such Third Party the Confidential Information of Licensee (including the royalty reports contemplated under Section 8.7.2), without the prior written consent of Licensee, to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (provided that such Third Party is under obligations of confidentiality and non-use with respect to such Confidential Information that are no less stringent than the terms of Section 9.1), and to allow such Third Party to exercise its rights under this Section 14.1.2. As part of any consummated Securitization Transaction, Corbus may assign, without the prior written consent of Licensee, its right to receive the royalty reports and to conduct audits under Section 8.7.3 to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such Sections.
- **14.2.** Governing Law. The Agreement will be construed and the respective rights of the Parties determined in accordance with the substantive Laws of the State of New York, USA, notwithstanding any provisions of New York Law or any other Law governing conflicts of laws to the contrary.

## 14.3. Arbitration.

- **14.3.1.** *Disputes*. Except as otherwise expressly set forth in this Agreement, including <u>Section 2.5.1</u>, disputes of any nature arising under, relating to, or in connection with this Agreement ("**Disputes**") will be resolved pursuant to this <u>Section 14.3</u>.
- **14.3.2.** Dispute Escalation. In the event of a Dispute between the Parties, the Parties will first attempt to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within twenty (20) days from receipt of the written notice of a Dispute, any Party may, by written notice to the other, have such Dispute referred to the Executive Officers (or their designee, which designee is required to have decision-making authority on behalf of such Party), who will attempt to resolve such Dispute by negotiation and consultation for a twenty (20) day period following receipt of such written notice.

14.3.3. Full Arbitration. Except as otherwise expressly set forth in this Agreement, in the event the Parties have not resolved such Dispute within twenty (20) days of receipt of the written notice referring such Dispute to the Executive Officers, either Party may at any time after such twenty (20) day period submit such Dispute to be finally settled by arbitration administered in accordance with the procedural rules of the International Chamber of Commerce (the "ICC") in effect at the time of submission, as modified by this Section 14.3. The arbitration will be governed by the Laws of the State of New York. The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the pharmaceutical and biotechnology industry, each of whom will be impartial and independent. Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within thirty (30) days following appointment of the second arbitrator, by the ICC. Such arbitration will take place in San Francisco, California, USA. The arbitration award so given will, absent manifest error, be a final and binding determination of the Dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 11.4. Fees, costs and expenses of arbitration are to be divided by the Parties in the following manner: Licensee will pay for the arbitrator it chooses, Corbus will pay for the arbitrator it chooses, and the Parties will share payment for the third arbitrator. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties.

### 14.3.4. Expedited Arbitration.

**14.3.4.1.** If a Party exercises its right under this Agreement to refer a dispute to expedited arbitration (an "**Expedited Dispute**"), then the Parties will follow the expedited dispute resolution process in this <u>Section 14.3.4</u> (and not the dispute resolution process in <u>Section 14.3.3</u> of this Agreement) ("**Expedited Arbitration**"). The Parties agree and acknowledge that any good faith dispute under Expedited Arbitration will not be deemed to be a material breach of this Agreement.

14.3.4.2. The Expedited Dispute will be submitted to fast-track, binding arbitration in accordance with the following:

(a) Arbitration will be conducted in San Francisco, California, USA, under the rules of the ICC for the resolution of commercial disputes in the most expedited manner permitted by such rules. The Parties will appoint a single arbitrator to be selected by mutual agreement. If the Parties are unable to agree on an arbitrator, the Parties will request that the ICC select the arbitrator. The arbitrator will be a professional in business or licensing experienced in the valuation of biopharmaceutical products with at least ten (10) years of experience in the pharmaceutical and life sciences industries, including the conduct of development and commercialization collaborations. The cost of the arbitration will be borne equally by the Parties. Except in a proceeding to enforce the results of the arbitration or as otherwise required by applicable Laws, neither Licensee nor Corbus nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written agreement of Licensee and Corbus.

- (b) Within thirty (30) days after such matter is referred to arbitration, each Party will provide the arbitrator with a proposal and written memorandum in support of its position regarding the Expedited Dispute, as well as any documentary evidence it wishes to provide in support thereof (each a "**Brief**") and the arbitrator will provide each Party's Brief to the other Party after it receives it from both Parties. The Parties agree and acknowledge that the Harmonization Principle will serve as a guiding principle for each Party's Brief and for the arbitrator's determination.
- (c) Within thirty (30) days after a Party submits its Brief, the other Party will have the right to respond thereto. The response and any material in support thereof will be provided to the arbitrator and the other Party.
- (d) The arbitrator will have the right to meet with the Parties as necessary to inform the arbitrator's determination and to perform independent research and analysis. Within thirty (30) days of the receipt by the arbitrator of both Parties' responses (or expiration of the thirty (30) day period if any Party fails to submit a response), the arbitrator will deliver his/her decision regarding the Expedited Dispute in writing; <u>provided</u> that the arbitrator will select one of the resolutions proposed by the Parties.
- 14.3.5. Injunctive Relief. Notwithstanding the dispute resolution procedures set forth in this Section 14.3, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder. Any claim for such equitable relief shall be submitted to the United States District Court for the Southern District of New York or any New York State court sitting in New York City so long as one of such courts has subject matter jurisdiction over such claim, and each Party hereby irrevocably consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any proceeding with respect to any such claim and irrevocably waives, to the fullest extent permitted by Law, any objection that it may now or hereafter have to the laying of the venue of any such proceeding in any such court or that any such proceeding brought in any such court has been brought in an inconvenient forum. Process in any such proceeding may be served on either Party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each Party agrees that service of process on such Party in accordance with Section 14.10 shall be deemed effective service of process on such Party. Each of the Parties hereby irrevocably waives any and all right to trial by jury in any such proceeding.
- 14.3.6. Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches), as well as all time periods in which a Party must exercise rights or perform obligation hereunder, will be tolled once the dispute resolution procedures set forth in this Section 14.3 have been initiated and for so long as they are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result. In addition, during the pendency of any Dispute under this Agreement initiated before the end of any applicable cure period, including under Section 13.4, (a) this Agreement will remain in full force and effect, (b) the provisions of this Agreement relating to termination for material breach with respect to such Dispute will not be effective, (c) the time periods for cure under Section 13.4 as to any termination notice given prior to the initiation of arbitration will be tolled, (d) any time periods to exercise rights or perform obligations will be tolled, and (e) neither Party will issue a notice of termination pursuant to this Agreement based on the subject matter of the arbitration, until the arbitral tribunal has confirmed the material breach and the existence of the facts claimed by a Party to be the basis for the asserted material breach; provided, that if such breach can be cured by (i) the payment of money, the defaulting Party will have an additional ten (10) days within its receipt of the arbitral tribunal's decision to pay such amount or (ii) the taking of specific remedial actions, the defaulting Party will have a reasonably necessary period to diligently undertake and complete such remedial actions within such reasonably necessary period or any specific timeframe established by such arbitral tribunal's decision before any such notice of termination can be issued. Further, with respect to any time periods that have run during the pendency of the dispute, the applicable Party will have a reasonable period of time or any specific timeframe established by such arbitral tribunal's decision to exercise any rights or perform any obligations affected by the running of such time periods.

- 14.4. Entire Agreement; Amendments. This Agreement, together with any applicable supply agreement (and related quality agreements) between the Parties, and SDEA, contains the entire understanding of the Parties with respect to the subject matter hereof, and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral, including, effective as of the Effective Date, the Mutual Nondisclosure Agreement between Corbus and Licensee, dated as of June 19, 2018 (provided that all information disclosed or exchanged under such agreement will be treated as Confidential Information disclosed hereunder). This Agreement may be amended, or any term or condition hereof modified, only by a written instrument duly-executed by authorized representatives of both Parties. Any term or condition of this Agreement may be waived if, but only if, such waiver is in writing and signed by an authorized representative of the Party against whom the waiver is to be effective. The Schedules attached hereto may be amended, or any term or condition hereof modified, only by a written instrument duly-executed by authorized representatives of both Parties.
- 14.5. Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable nature of one or several provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.
- **14.6.** <u>Headings</u>. The captions to the Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Sections hereof.
- **14.7.** Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.
- 14.8. Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation" and will not be interpreted to limit the provision to which it relates; (c) the word "shall" will be construed to have the same meaning and effect as the word "will"; (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any Person will be construed to include the Person's successors and assigns; (f) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in each of their entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto and any capitalized terms used but not defined in any Schedules shall have their respective meanings as defined in this Agreement; (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging); (j) references to any specific Law or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor Law thereof; and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or".

- 14.9. No Implied Waivers; Rights Cumulative. No failure on the part of Corbus or Licensee to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at Law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.
- **14.10.** <u>Notices</u>. All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Corbus, to: Corbus Pharmaceuticals, Inc.

500 River Ridge Drive, Second Floor

Norwood, MA 02062, USA Attention: Yuval Cohen Ph.D. Facsimile No.: 1-617-963-0102

With a copy to (which will not constitute

notice):

Goodwin Procter LLP 100 Northern Avenue

Boston, Massachusetts 02210, USA

Attention: Stuart Cable and Karen A. Spindler

Facsimile No.: 1-617-523-1231

If to Licensee, to: Kaken Pharmaceutical Co., Ltd.

20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome,

Bunkyo-ku, Tokyo 113-8650, Japan Attention: Kiyoshi Inoguchi, Ph. D. Head of Business Development Facsimile No.: 81-3-5977-5131

With a copy to (which will not constitute

notice):

Jones Day

Kamiyacho Prime Place

1-17, Toranomon 4-chome, Minato-ku

Tokyo 105-0001, Japan

Attention: Scott Jones and Benjamin Lang

Facsimile No.: 81-3-5401-2725

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day of receipt if sent by overnight courier or facsimile; or (c) on the Business Day of receipt if sent by mail.

- **14.11.** Compliance with Export Regulations. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export Laws and regulations.
- 14.12. Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, earthquakes, floods, or other acts of God. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical, and will promptly undertake all reasonable efforts necessary to cure such force majeure circumstances and resume performance of its obligations hereunder.
- **14.13.** <u>Independent Parties</u>. It is expressly agreed that Corbus and Licensee will be independent contractors and that the relationship between Corbus and Licensee will not constitute a partnership, joint venture or agency. Corbus will not have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on Licensee, without the prior written consent of Licensee, and Licensee will not have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on Corbus, without the prior written consent of Corbus.
- **14.14.** Expenses. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby will be paid by the Party hereto incurring such fees, costs and expenses.
- **14.15.** Counterparts. The Agreement may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which will be deemed an original, but all of which together will constitute one and the same instrument.
- **14.16.** <u>Binding Effect; No Third Party Beneficiaries</u>. As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and permitted assigns. Except as expressly set forth in this Agreement, no Person other than the Parties and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- 14.17. <u>Further Assurances</u>. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken in furtherance of their respective obligations under this Agreement, including (a) furnishing to each other such further information; (b) executing and delivering to each other such other documents; and (c) doing such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Corbus Pharmaceuticals, Inc.

Kaken Pharmaceutical Co., Ltd.

BY: /s/ Yuval Cohen, Ph. D. NAME: Yuval Cohen, Ph. D. BY: /s/ Tetsuo Onuma

NAME: Tetsuo Onuma

TITLE: CEO TITLE: President and Representative Director

[Signature Page to the Collaboration and License Agreement]

# Schedule 1.1.32 <u>Licensee's products that would be deemed "Competing Products" existing on the Effective Date</u>

# Schedule 3.2.2 <u>Initial Indications Development Plan</u>

# Schedule 6.1 Supply Agreement Material Terms

- 1. Corbus shall supply, and Licensee agrees to purchase from Corbus, [\*] under the terms and conditions provided in the Supply Agreement.
- 2. Licensee shall secure and maintain the Marketing Authorization and other regulatory registration and/or approval necessary for Corbus to sell and distribute the Licensed Products in the Territory. Licensee shall be responsible for performing all requirements and duties under all laws, rules, orders and regulations including but not limited to, the Pharmaceutical Affairs Law, the Antitrust Law and any anti-corruption related regulations in the Territory and the promotion code prevailing in the pharmaceutical industry.

3. [\*]

- 4. Any Licensed Product supplied by Corbus shall be received by Licensee subject to inspection and performance testing by Licensee, in accordance with Licensee's quality assurance program in effect at the time of delivery, to ensure that the Licensed Product meets the specifications and otherwise complies with the warranties provided in the Supply Agreement. In regard to any defect, shortage or delay of the Licensed Product as delivered, Licensee shall make a claim against Corbus within thirty (30) days after receipt by Licensee of the Licensed Product. Notwithstanding the previous sentence, Licensee shall notify Corbus of latent defects within thirty (30) days of discovery.
- 5. In the event of a claim pursuant to the previous paragraph, Licensee and Corbus agree to mutually investigate all rejects to establish root cause, determine appropriate disposition of the material, and make mutually agreeable arrangements for the return, replacement, or disposal as applicable. [\*].
- 6. Corbus and Licensee shall determine any packaging and/or package design and wording Licensee intends to use in connection for the Commercialization of the Licensed Products in the Territory and stated in the Supply Agreement.
- 7. Audit Rights. Licensee shall have the right to audit, on an annual basis (once per Year) and at its expense (except as provided below), the records maintained by Corbus and its Affiliates related to the calculation of the Manufacturing Price (excluding, for clarity, any records not in Licensee's possession or control) and the accuracy of the Supply Transfer Price charged by Corbus to Licensee hereunder.
- 8. Back-Up Royalties. If, at any time during the applicable Royalty Term for a Licensed Product in an Initial Indication, the Supply Agreement is terminated or is otherwise no longer in effect, then, with respect to such Licensed Product, Licensee will make non-refundable, non-creditable royalty payments in [\*] to Corbus at a royalty rate to be agreed upon by the Parties.

9. [\*].

## Schedule 9.3.1 Press Release of Each Party

[See following pages]

# Schedule 10.2 Exceptions to Representations and Warranties



# Corbus Pharmaceuticals Announces Strategic Collaboration with Kaken Pharmaceutical Co., Ltd. to Develop and Commercialize Lenabasum in Japan for Systemic Sclerosis and Dermatomyositis

- Collaboration in-line with Corbus vision to become the global leader in the treatment of inflammatory and fibrotic diseases by targeting the endocannabinoid system
- Advances strategy to partner lenabasum commercial rights outside US and EU
- Japan presents important market with 28,000 SSc patients and 9,000 DM patients and no currently approved drugs

Norwood, MA, and Tokyo, Japan, January 3, 2019 – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company") announced today that they have entered into a strategic collaboration with Kaken Pharmaceutical Co., Ltd. ("Kaken") for the development and commercialization in Japan of Corbus' investigational drug lenabasum for the treatment of systemic sclerosis ("SSc") and dermatomyositis ("DM"), two rare and serious autoimmune diseases.

Under the terms of the agreement, Kaken receives an exclusive license to commercialize and market lenabasum in Japan for systemic sclerosis and dermatomyositis. Kaken will make an upfront payment to Corbus of \$27 million. Corbus will be eligible to receive in addition up to \$173 million upon achievement of certain regulatory, development and sales milestones as well as double- digit royalties.

Current patient numbers for systemic sclerosis and dermatomyositis in Japan are 28,000 and 9,000, respectively.

"We are honored to collaborate with Kaken, a company that shares our passion and dedication to working together to bring to market novel therapies targeting serious rare inflammatory diseases," said Yuval Cohen, PhD., Chief Executive Officer of Corbus. "Kaken is a well-regarded leader in rare autoimmune diseases in Japan with a proud history of scientific and medical innovation. By working together, we believe we can expand the Japanese footprint for lenabasum alongside Corbus' ongoing efforts in the U.S. and E.U. This collaboration is an important next step in achieving our vision of becoming the global leader in treating inflammatory diseases by focusing on the endocannabinoid system."

"It is my pleasure to start a collaboration with Corbus, a company with a strong passion toward developing novel therapeutics for rare autoimmune diseases," said Tetsuo Onuma, President and Representative Director of Kaken. "With this collaboration, we hope we can further contribute for the better lives of patients with rare autoimmune disease in Japan."

### About Lenabasum

Lenabasum is a rationally-designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2). CB2 is preferentially expressed on activated immune cells, fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to-date, lenabasum has induced the production of Specialized Pro-resolving lipid Mediators ("SPMs") that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Lenabasum is also believed to have a direct effect on fibroblasts to limit production of fibrogenic growth factors and extracellular connective tissue that lead to tissue fibrosis (scarring). Data from animal models and human clinical studies suggest that lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. Lenabasum has demonstrated promising activity in animal models of skin and lung inflammation and fibrosis in systemic sclerosis (SSc). Lenabasum is also active in animal models of lung infection and inflammation in cystic fibrosis and joint inflammation and scarring in rheumatoid arthritis.

<sup>&</sup>lt;sup>1</sup> Health Advances, LLC; Lenabasum Commercial Market Assessment



Lenabasum has demonstrated favorable safety and tolerability profiles in clinical studies to date. Lenabasum improved multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and skin-predominant dermatomyositis. Lenabasum also reduced pulmonary exacerbations in a Phase 2 cystic fibrosis study. Additional clinical studies are being conducted and/or planned to confirm these results and support applications for regulatory approval.

#### **About Corbus**

Corbus Pharmaceuticals Holdings, Inc. is a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat inflammatory and fibrotic diseases by leveraging its pipeline of endocannabinoid system-targeting synthetic drug candidates. The Company's lead product candidate, lenabasum, is a novel, synthetic, oral, selective cannabinoid receptor type 2 (CB2) agonist designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis, and systemic lupus erythematosus.

Corbus licensed the exclusive worldwide rights to develop, manufacture and market drug candidates from more than 600 novel compounds targeting the endocannabinoid system from Jenrin Discovery LLC. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to eliminate blood-brain barrier penetration and subsequent brain CB1 receptor occupancy that mediates the neuropsychiatric adverse events associated with first-generation CB1 inverse agonists. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction and acute interstitial nephritis, among others. Corbus plans to enter a Phase 1 study of CRB-4001 in 2019, intended to be followed by a National Institutes of Health (NIH)-funded proof-of-concept Phase 2 study.

For more information, please visit www.CorbusPharma.com and connect with the Company on Twitter, LinkedIn, and Facebook.

### About Kaken

Kaken (Tokyo Stock Exchange: 4521) is a specialty pharmaceutical company in Japan with strong experience in developing and commercializing novel pharmaceuticals and medical devices in the fields of orthopedics, dermatology and surgery. Kaken concentrates its R&D resources in inflammation/immunology (dermatitis, rheumatoid arthritis and osteoarthritis), pain relief and fungal infection areas. For more information, please visit http://www.kaken.co.jp/english/



### Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential, "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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