MARINUS PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 04/06/17 for the Period Ending 03/31/17

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Telephone	484-801-4670
CIK	0001267813
Symbol	MRNS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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)
March 31, 2017

MARINUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36576**	**20-0198082**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

170 N. Radnor Chester Rd, Suite 250 **Radnor, PA** (Address of principal executive offices)	**19087** (Zip Code)

Registrant's telephone number, including area code: **(484) 801-4670**

(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:

☐ 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))

Item 1.01 . Entry into a Material Definitive Agreement .

On March 31, 2017, we entered into a License Agreement and a Supply Agreement with CyDex Pharmaceuticals, Inc. Under the terms of the License Agreement, CyDex has granted us an exclusive license to use CyDex's Captisol drug formulation system and related intellectual property in connection with the development and commercialization of ganaxolone in any and all therapeutic uses in humans, with some exceptions.

As consideration for this license, we paid an upfront fee and are required to make additional payments in the future upon achievement of various specified clinical and regulatory milestones. We will also be required to pay royalties to CyDex on sales of ganaxolone, if successfully developed, in the low-to-mid single digits based on levels of annual net sales.

Under the terms of the Supply Agreement, we are required to purchase all of our requirements for Captisol with respect to ganaxolone from CyDex, and CyDex is required to supply us with Captisol for such purposes, subject to certain limitations.

A copy of the License Agreement and Supply Agreement, with certain terms omitted, are attached as Exhibits 10.1 and 10.2 to this report and is incorporated herein by reference. Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission. The descriptions of the License Agreement and Supply Agreement are a summary only and are qualified in their entirety by reference to Exhibits 10.1 and 10.2.

Item 9.01 . Financial Statements and Exhibits .

(d) Exhibits

Exhibit No.	Description
10.1	License Agreement by and between Marinus Pharmaceuticals, Inc. and CyDex Pharmaceuticals, Inc., dated March 31, 2017.
10.2	Supply Agreement by and between Marinus Pharmaceuticals, Inc. and CyDex Pharmaceuticals, Inc., dated March 31, 2017.

SIGNATURE

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.

MARINUS PHARMACEUTICALS, INC.

By: /s/ Edward Smith
Edward Smith,
Vice President, Chief Financial Officer,
Secretary and Treasurer

Date: April 6, 2017

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this " **Agreement** ") is made this 31st day of March, 2017 (the " **Effective Date** ") between CyDex Pharmaceuticals, Inc., a Delaware corporation (" **CyDex** "), and Marinus Pharmaceuticals, Inc., a Delaware corporation (" **Company** "). CyDex and Company are hereinafter individually referred to as a " **Party** " and collectively as the "Parties".

RECITALS

WHEREAS , CyDex is engaged in the business of developing and commercializing novel drug delivery technologies designed to enhance the solubility and effectiveness of existing and development-stage drugs;

WHEREAS , CyDex is the exclusive supplier of Captisol®, a patented drug formulation system designed to enhance the solubility and stability of drugs;

WHEREAS , Company desires to obtain an exclusive license to use the Captisol® patented drug formulation system in connection with its development and commercialization of one or more Licensed Products (defined below) and CyDex is willing to grant such an exclusive license to Company under the terms and conditions set forth herein; and

WHEREAS , CyDex desires to sell Captisol® sulfobutylether β (beta) cyclodextrin, sodium salt to Company, and Company desires to purchase Captisol® sulfobutylether β (beta) cyclodextrin, sodium salt from CyDex, in accordance with the terms and conditions of that certain Supply Agreement between the Parties of even date herewith (the " **Supply Agreement** ");

NOW , **THEREFORE** , in consideration of the following mutual promises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS.

For the purposes of this Agreement, the following terms shall have the meanings as defined below:

"Adverse Event" means any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, and the severity thereof, reasonably believed both to be serious and associated with a Study, investigation, test, use and/or marketing of Captisol® or the Licensed Product.

" **Affiliate** " means, with respect to any Party, any entity controlling, controlled by, or under common control with such Party, during and for such time as such control exists. For these purposes, "control" shall refer to the ownership, directly or indirectly, of at least 50% of the voting securities or other ownership interest of the relevant entity or having the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of the relevant entity (e.g.,

by contract or otherwise).

" **Application** " means a 505(b)(2) application, an abbreviated new drug application or a new drug application, pursuant to and/or as defined in the United States Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or similar application filed with an equivalent regulatory body in another country or multinational region.

" **Captisol** " means sulfobutylether β (beta) cyclodextrin, sodium salt. CyDex supplies a uniquely modified form of such material under the Captisol® brand. For avoidance of doubt: the uniquely modified form of sulfobutylether β (beta) cyclodextrin, sodium salt supplied by CyDex under the Captisol® brand shall be deemed to be included among the substances/products which are within the defined term "Captisol."

" **Captisol Data Package** " means (a) all toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates relating to Captisol, including without limitation those provided in the DMF; (b) all toxicology/safety and other relevant scientific data owned, licensed or developed by the licensees or sublicensees of CyDex or its Affiliates or other Third Parties (to the extent permitted in the applicable license or other agreements between CyDex and/or its Affiliates and such licensees, sublicensees or other Third Parties), including without limitation those provided in the DMF; and (c) the open portion of the DMF for Captisol®, in each case to the extent relating to Captisol® alone (and not in conjunction with a product formulation).

" **Captisol Improvement** " means any technology or improvement related to Captisol alone, including without limitation any method of combining or formulating Captisol with an active compound, whether or not patentable, that is developed by Company or its Affiliates or Sublicensees, solely or jointly with a Third Party during the Term; provided, that any such technology or improvement shall, to the extent it involves combining or formulating Captisol with the Compound or is related to the Compound and/or other non-Captisol components of the Licensed Product, shall not to constitute a Captisol Improvement.

" **Claim** " has the meaning specified in **Section 10.1** .

" **Company Indemnitees** " has the meaning specified in **Section 10.1** .

" **Competing Product** " means any product, not covered by any license granted hereunder, that incorporates the Compound as an active pharmaceutical ingredient prepared or combined with or formulated using Captisol as a solubilizing agent for ultimate use in humans within the Field.

" **Compound** " means ganaxolone (i.e., 3β-Methyl-3α-ol-5α-pregnan-20-one or 3α-Hydroxy-3β-methyl-5α-pregnan-20-one).

" **Confidential Information** " has the meaning specified in **Section 8.1** .

" **Contract Manufacturer** " has the meaning specified in **Section 2.4** .

" **CyDex Indemnitees** " has the meaning specified in **Section 10.2** .

" **Designated Executives** " means (a) for CyDex, Matthew Foehr, and (b) for Company,

Christopher Cashman.

" **Disclosing Party** " has the meaning specified in **Section 8.1** .

" **Discovery** " has the meaning specified in **Section 12.1(b)** .

" **Dispute** " has the meaning specified in **Section 14.3(a)** .

" **DMF** " means a Drug Master File (or similar dossier filed with an equivalent regulatory body in another country) for Captisol®, as filed as of the Effective Date, or as hereafter updated from time to time during the Term, by CyDex with the FDA (or equivalent regulatory body in another country).

" **FDA** " means the United States Food and Drug Administration, or any successor thereto.

" **Field** " means any and all therapeutic uses in humans, with the exceptions of the following ***.

" **First Commercial Sale** " means, with respect to a Licensed Product in any country, the first commercial transfer or disposition for value of such Licensed Product in such country to a Third Party by Company, an Affiliate of Company or a Sublicensee of Company. For avoidance of doubt: "IND treatment sales," "compassionate use sales" or "named patient sales" in a country before Marketing Approval in such country shall not be deemed to constitute a First Commercial Sale in such country.

" **Indemnified Party** " has the meaning specified in **Section 10.4** .

" **Indemnifying Party** " has the meaning specified in **Section 10.4** .

" **July 2014 Agreement** " means the Captisol® Use Agreement dated July 2, 2014 between the Parties.

"Know-How" means all scientific and technical information and knowhow, trade secrets, data and technology, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions or products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, that are proprietary or confidential to CyDex and relate to or are directed to Captisol or its manufacture and/or use. Notwithstanding the foregoing, the defined term Know-How (and derivative defined terms thereof) shall not include Licensed Patents or inventions claimed thereby, nor any portion of the DMF not within the definition of Captisol Data Package.

" **Licensed Intellectual Property** " means the Licensed Patents and the Licensed Know-How Rights.

"Licensed Know-How Rights" means, collectively, all trade secret and Know-How rights of CyDex at the Effective Date or during the term of this Agreement as necessary or useful to practice the inventions described in Licensed Patents for the purpose hereof, which relate to the preparation, combination and/or formulation of the Compound with Captisol, including proprietary and confidential information contained in the Captisol Data Package.

" **Licensed Patents** " means all patents and patent applications in the Territory which include Valid Claims (or claims which upon patent issuance would include Valid Claims) that cover Captisol and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisionals, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. Set forth in ***Exhibit A*** attached hereto is a list of the Licensed Patents as of the Effective Date. An updated version of ***Exhibit A*** , if applicable, shall be communicated by CyDex to Company upon request, but no more often than once per year.

" **Licensed Product** " means (a) the Compound prepared or combined with or formulated using Captisol for ultimate therapeutic use in humans within the Field, in any dosage form/formulation, or (b) a pharmaceutical preparation, composition or formulation for ultimate therapeutic use in humans within the Field, in any dosage form/formulation, that includes the Compound and that is covered by or developed through the direct use of any of the Licensed Intellectual Property. For avoidance of doubt: the Licensed Products shall not (without the express written consent of CyDex) include any product the composition of which includes the Compound and any other active pharmaceutical ingredient.

" **Licensed Products Related Uses** " has the meaning specified in **Section 3** .

" **Losses** " has the meaning specified in **Section 10.1** .

" **Major Market** " means any of (a) the United States, (b) Europe (meaning the European Union or any one of France, Germany or the United Kingdom), (c) Japan, or (d) the People's Republic of China.

" **Marketing Approval** " means final approval of an Application by the FDA, or comparable final approval of a comparable document filed with an equivalent health regulatory authority in any other country or in the European Union (using the centralized process, decentralized process or mutual recognition or member state national authorization), without regard to any other marketing approvals such as pricing and reimbursement approvals; provided, that if a First Commercial Sale for use or consumption by a member of the general public of a Licensed Product has occurred in any country in compliance with that country's applicable laws, it shall be conclusively deemed for purposes of this Agreement that such approval in such country has been obtained.

" **Net Sales** " means the gross amount invoiced by Company or any Sublicensee thereof to unrelated Third Parties, excluding to any Sublicensee for resale, for the sale or other disposition of a Licensed Product, less the following deductions to the extent actually allowed or incurred with respect to such sales:

a. Trade, cash and quantity discounts;

b. Discounts, refunds, rebates actually taken, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced), including, without limitation, Medicaid, institutional and governmental rebates (other than such which have already diminished the gross amount invoiced);

c. Credits or allowances granted on returns of Licensed Product actually sold;

d. Amounts invoiced for Licensed Product sales but actually written off in good faith as uncollectible (net of any recoveries on written-off debt);

e. Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced; and

f. Any tax imposed on the production, sale, delivery or use of the Licensed Product, including, without limitation, import, export, sales, use, excise or value added taxes and customs, tariffs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced.

Such amounts shall be determined from the books and records of Company and its Sublicensees, maintained in accordance with United States GAAP, consistently applied, or, in the case of foreign Sublicensees, similar accounting principles, consistently applied. Company further agrees that in determining such amounts with respect to sales and/or expenses not denominated in United States Dollars, conversion from the applicable foreign currency in which such sales and/or expenses were recorded to United States Dollars shall be performed at the exchange rate reported in The Wall Street Journal, Eastern U.S. Edition, for the last trading day of the applicable calendar quarter; based on the resulting Net Sales in U.S. Dollars, the then applicable royalties shall be calculated.

In the event that a Licensed Product is commercialized in combination with one or more services and/or with one or more products which are themselves not Licensed Products for a mutually related price (e.g., buy one and get a discount on or a coupon for the other) or for a single price, the Net Sales for such Licensed Product shall be calculated by multiplying the gross amount invoiced for such combination sale by the fraction A/(A+B) where A is the fair market value of the Licensed Product and B is the fair market value of the other product(s) and/or service(s) in the combination sale, and allocating applicable "Net Sales" deductions in the same proportion. In the case of sale of a product combining (with the express written consent of CyDex) both of the Compound and another active pharmaceutical ingredient(s) prepared or combined with or formulated using Captisol, the Net Sales with respect to such multiple-ingredient product shall be calculated by multiplying the gross amount invoiced for such multiple-ingredient product sale by the fraction A/(A+B) where A is the fair market value of a (Compound-only) Licensed Product of such dosage and B is the fair market value of the multiple-ingredient product; provided, that it is understood that CyDex is entitled to withhold or condition such express written consent in its sole and absolute discretion, and that CyDex expressly reserves the right to condition the giving of any such express written consent on an agreement to vary the foregoing formula.

Resales of Licensed Products between Company, its Affiliates or Sublicensees shall not be included in the calculation for Net Sales.

" **Notice of Termination** " has the meaning specified in **Section 13.3** .

"Pfizer" has the meaning specified in **Section 8.4** .

"Pivotal Trial" means a clinical trial of a Licensed Product in human patients, which trial is designed (a) to establish that the Licensed Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) to be, either by itself or together with one or more other clinical trials having a comparable design and size, the final human clinical trial in support of Marketing Approval of the Licensed Product, and (d) consistent with 21 CFR § 312.21(c) (as hereafter modified or amended) and any of its foreign equivalents. Provided that, and for avoidance of doubt: any pivotal trial, which could be or is used as one of the adequate and well-controlled trials for registration in any jurisdiction, whether or not formally denominated as a Phase III trial, shall be deemed to be a Pivotal Trial. Further for avoidance of doubt: if a clinical trial of a Licensed Product in human patients is not initially designed or presented as a Pivotal Trial but is later re-designed, re-presented or identified as or converted into a trial which could be or is used as one of the adequate and well-controlled trials for registration in any jurisdiction, it shall be deemed to be a Pivotal Trial as of the date of such re-design/re-presentation/identification/conversion, and if the first patient in such trial was dosed before the date of such re-design/re-presentation/identification/conversion, the **Section 4.1(b)(B)** milestone payment shall be payable upon such re-design/re-presentation/identification/conversion.

" **Receiving Party** " has the meaning specified in **Section 8.1** .

" **SEC** " means the United States Securities and Exchange Commission.

" **Study** " has the meaning specified in **Section 6.3** .

" **Sublicense** " has the meaning specified in **Section 2.3** .

" **Sublicensee** " means the sublicensee party to a Sublicense.

" **Supply Agreement** " means that certain Supply Agreement between the Parties of even date herewith, as mentioned in the Recitals.

" **Term** " has the meaning specified in **Section 13.1** .

" **Territory** " means the entire world.

" **Third Party** " means any person or entity or authority other than CyDex or Company or an Affiliate of either of them.

" **Third Party Infringement** " has the meaning specified in **Section 12.3** .

" **Upstream Licensor** " has the meaning specified in **Section 2.6** .

" **Valid Claim** " means a claim which, but for the license granted hereunder, would be infringed by Company's use, manufacture or sale of a Licensed Product in a country in the Territory, and which is covered by an issued and unexpired patent in such country included within the Licensed Patents

which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid, canceled or unenforceable by the owner through re-issue, re-examination or disclaimer, opposition procedure, nullity suit, or otherwise.

2. GRANT OF RIGHTS.

2.1 License Grants from CyDex to Company.

(a) Licensed Intellectual Property . Subject to the terms and conditions of this Agreement, including but not limited to payment of the amounts set forth in **Section 4.1** below, CyDex hereby grants to Company an exclusive, nontransferable (except with respect to the assignment provision in **Section 14.13**) license during the Term under the Licensed Intellectual Property, solely to develop, make, have made (pursuant to **Section 2.4**), use, sell, offer for sale, import and otherwise commercially exploit the Licensed Products in the Territory in and for the Field. (No license, exclusive or non-exclusive, is granted hereunder under the Licensed Intellectual Property, except to so develop, make, have made, use, sell, offer for sale, import or otherwise commercially exploit the Licensed Products in the Territory in and for the Field.) Notwithstanding the foregoing, to the extent that any Licensed Intellectual Property is licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to Company in the foregoing sentence shall be non-exclusive. For clarity, as CyDex is unable to grant Company any rights that it does not have, in the event that CyDex obtains a non-exclusive license from a Third Party (including without limitation being potentially non-exclusive as a result of rights inhering in the United States Government under Chapter 18, Title 35 of the United States Code and regulations thereunder (or otherwise) by virtue of the fact that the licensed invention was funded by the United States Government) for intellectual property within the Licensed Intellectual Property, then CyDex shall pass on such rights to Company hereunder via a license that grants rights that are to such extent non-exclusive. It is understood that all references in this Agreement to "licenses" from CyDex to Company (and other forms of the word "license") include applicable sublicenses from CyDex (as sublicensor) to Company (as sublicensee). Company may not develop, make, have made, use, sell, offer for sale, import or otherwise commercially exploit either the Licensed Intellectual Property or the Licensed Products for any other purposes than those specified in this Agreement. Company may not sublicense the Licensed Intellectual Property, except as expressly set forth in **Sections 2.3** and **2.4** below.

(b) Scope of Licenses . CyDex grants no licenses or rights to use the Licensed Intellectual Property or any other intellectual property other than as expressly set forth herein or as may be expressly set forth in the Supply Agreement. CyDex grants no rights to Company to manufacture, have manufactured, import, sell or offer for sale bulk Captisol; provided, however, that Company may provide Captisol to bona fide collaborators in order to help Company to develop, make, have made (pursuant to **Section 2.4**), use, sell, offer for sale, import or otherwise commercially exploit the Licensed Products in the Territory in the Field. Without prejudice to the provisions of subsection (a) above, Company acknowledges that not all rights of CyDex related to Captisol are included within the rights licensed hereunder, given that CyDex shall supply Company's requirements of Captisol for the Licensed Products. Company shall not attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol except as and to the extent reasonably required to determine an optimal formulation of the Licensed Product, and such structure and composition of

Captisol (as and if so determined) shall be considered a Captisol Improvement. CyDex shall not be liable to Company for violation of Company's exclusive rights hereunder by Third Parties which are not Affiliates or licensees of CyDex except to the extent CyDex has contributed to such violation. Company acknowledges and agrees that except as is expressly set forth in this Agreement (i) CyDex shall not be restricted in making sales of Captisol or licensing intellectual property rights to other persons and/or entities to the extent not expressly inconsistent with the licenses granted to Company under this Agreement and/or the covenants of CyDex in this Agreement, and (ii) CyDex does not warrant or indemnify Company or its Affiliates and Sublicensees against the Licensed Products infringing Third Party rights, except in cases where such infringement results from the incorporation of Captisol in said Licensed Products.

2.2 Grant of License from Company to CyDex. Company hereby grants to CyDex a non-exclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under Company's and its Affiliates' and Sublicensees' rights in and to Captisol Improvements to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol, any Captisol Improvement and products formulated with Captisol or any Captisol Improvement (other than the Licensed Products in the Field or Competing Products during the Term). If during the Term any of (a) Company, (b) Affiliates to whom Company has provided sublicense rights under the licenses granted to Company by CyDex pursuant to **Section 2.1** , or (c) other Sublicensees pursuant to the practice of their respective sublicenses from Company under **Section 2.3** , file any patent application claiming any Captisol Improvement anywhere in the world or are issued any patent thereupon, CyDex shall be deemed automatically to have a non-exclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under the claims relating specifically to any Captisol Improvement to develop, make, have made, use, market, distribute, import, sell, offer for sale and otherwise commercialize Captisol and all products formulated with Captisol (other than the Licensed Products in the Field or Competing Products during the Term). Company shall provide prompt notice of any Captisol Improvement.

2.3 Sublicensing. Company shall have the right to grant sublicenses with terms consistent with those of this Agreement (collectively " **Sublicenses** ") under the licenses granted to Company pursuant to **Section 2.1** ; provided, however, that the granting by Company of a Sublicense shall not relieve Company of any of its obligations hereunder. Any Sublicense shall automatically terminate upon the termination or expiration of this Agreement ***. Company shall ensure that all of its Sublicensees shall comply with the terms and conditions of this Agreement and the Supply Agreement, and Company shall be and remain fully responsible to CyDex for the compliance by such Sublicensees with the terms and conditions of this Agreement and the Supply Agreement as if such Sublicensees were Company hereunder and thereunder; provided, it is not required that a Sublicense include provisions for the Sublicensee to pay royalties or make milestone payments or other payments directly to Licensor or to provide royalty reports directly to Licensor. Company acknowledges that it has no right to, and agrees not to purport to, grant to anyone a sublicense under the Licensed Intellectual Property, other than Sublicenses compliant with the requirements of this Agreement for Sublicenses.

2.4 Contracting. To the extent necessary to engage any one or more Third Party

manufacturers (collectively " **Contract Manufacturers** ") for a Licensed Product, Company shall be permitted under this Agreement to grant any such Contract Manufacturer a sublicense under the licenses granted to Company pursuant to **Section 2.1** solely for such purposes; provided, however, Company warrants and shall procure, as a condition precedent thereto, that (a) any such Contract Manufacturer shall first be advised of the restrictions set forth in this Agreement with respect to the transfer of the rights licensed to Company and its Sublicensees hereunder and (b) any such Contract Manufacturer shall enter into an agreement with Company with terms consistent with those of this Agreement. Company shall ensure that all of its Contract Manufacturers shall comply with the terms and conditions of this Agreement and shall remain fully responsible to CyDex for the compliance by such Contract Manufacturers with the terms and conditions of this Agreement as if such Contract Manufacturers were Company hereunder. Company shall not manufacture bulk Captisol (or contract the manufacture of bulk Captisol with a Contract Manufacturer).

2.5 Bankruptcy Code . All rights and licenses granted under or pursuant to this Agreement by CyDex to Company are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that Company, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by Company to CyDex are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that, as a licensee of such rights under this Agreement, CyDex shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

2.6 Compliance with Upstream Licenses . CyDex shall be solely responsible for paying directly to any and all Third Parties having rights in any of the Licensed Intellectual Property (each an " **Upstream Licensor** ") any royalties or other amounts due to such Upstream Licensors as a result of Company exercising its rights hereunder. In addition, CyDex represents and warrants that it is not in breach of any of its obligations to such Upstream Licensors and covenants that it shall comply with the terms of its agreements with such Upstream Licensors throughout the Term. Furthermore, CyDex covenants and warrants that it shall not amend, modify or supplement the terms of, or waive any rights under any such agreements if the same would have the effect of limiting or further restricting Company's rights or expanding Company's obligations hereunder.

2.7 Negative Covenants by CyDex .

(a) During the Term, neither CyDex nor any of its Affiliates shall directly themselves, nor provide any Third Party any assistance whatsoever, nor grant any Third Party any title, right, claim, interest or license under, in or to any of the Licensed Intellectual Property to, research, develop, modify, make, have made, import, export, use, promote, market, distribute, package, offer for sale, sell, or otherwise commercially exploit Licensed Products or any Competing Products.

(b) During the Term, neither CyDex nor any of its Affiliates shall (other than at Company's express written request) supply Captisol to any Third Party which it knows or should know will use it for a Licensed Product or a Competing Product. If during the Term, any such Third Party utilizes such Captisol (supplied by CyDex or any of its Affiliates) in a Licensed Product or Competing Product, CyDex shall immediately cease and cause its Affiliates and any other Third Party to

immediately cease supplying Captisol to the offending Third Party for the duration of the Term or until (if sooner) assurances reasonably satisfactory to Company that the infringing use has ended and will not resume have been obtained.

(c) During the Term, neither CyDex nor any of its Affiliates shall sue or threaten to sue, or take any similar action against, or aid, abet or enable any Third Party to sue, threaten to sue or take any similar action against, Company, or any Sublicensees, or any of their respective Affiliates, or any customers or end-users of any Licensed Products, claiming that the development, manufacture, use, sale, offer for sale or importation of any Licensed Product infringes any Captisol-related patents or patent applications owned, licensed, sublicensed or otherwise controlled by, now or in the future, CyDex or any of its Affiliates.

3. MANUFACTURE AND SUPPLY OF CAPTISOL.

The provisions of the Supply Agreement shall govern the manufacture and supply of Captisol® sulfobutylether β (beta) cyclodextrin, sodium salt for use in Company's (and its Affiliates' and their Sublicensees') preparation, formulation and production of the Licensed Products, both before and after Marketing Approval (the " **Licensed Products Related Uses** "). Company acknowledges and agrees that CyDex is, during the term of the Supply Agreement, the exclusive manufacturer of sulfobutylether β (beta) cyclodextrin, sodium salt for Company and its Affiliates and Sublicensees for the aforementioned Licensed Products Related Uses. Nothing set forth herein shall be deemed to grant Company or its Affiliates or Sublicensees the right to manufacture Captisol nor the right to contract the manufacture of Captisol to a Third Party, except pursuant to any express provisions of the Supply Agreement. It is understood that it shall be Company's and its Affiliates' responsibility to obtain, at Company's and its Affiliates' sole expense and from sources other than CyDex, all materials (including all quantities of the Compound, but excluding sulfobutylether β (beta) cyclodextrin, sodium salt) needed by Company and its Affiliates for the Licensed Products Related Uses — it being further understood, of course, that Company is to obtain at Company's sole expense and solely from CyDex (pursuant to the Supply Agreement) all sulfobutylether β (beta) cyclodextrin, sodium salt needed by Company and its Affiliates and Sublicensees for the Licensed Products Related Uses. It is of the essence that the only Captisol used in or for any Licensed Product shall be Captisol supplied by CyDex under the Supply Agreement or previously supplied by CyDex under the July 2014 Agreement, and Company hereby covenants and agrees that Company and its Affiliates and Sublicensees shall not use in or for any Licensed Product any other Captisol other than Captisol® and further covenants and agrees that Company and its Affiliates and Sublicensees shall not use in or for any Licensed Product any Captisol® obtained other than directly from CyDex under the Supply Agreement or previously under the July 2014 Agreement.

4. COMPENSATION.

4.1 Payments and Royalties for Licenses.

(a) **One-Time Fee** . Company shall forthwith (but in no event later than 10 days after delivery of the corresponding invoice sent by CyDex after the Effective Date) pay to CyDex a non-refundable, non-creditable, one-time cash fee of $*** in partial consideration of the rights granted to Company under this Agreement.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(b) Milestone Payments. Within 30 days following the achievement of each and any milestone event listed below, Company shall, in further consideration of the rights granted Company hereunder, provide written notice to CyDex of the achievement of such milestone event, accompanied by payment to CyDex of the applicable non-refundable cash milestone fee listed next to such event.

	MILESTONE	MILESTONE PAYMENT
(A)	***	$ ***
(B)	***	$ ***
(C)	***	$ ***
(D)	***	$ ***

Upon achievement of Milestone (B), (C) or (D) with regard to a Licensed Product, the Milestone (A) shall be deemed to be thereby achieved and if such Milestone (A) milestone payment has not previously been paid, it shall thereupon also be paid, forthwith. For clarity, each Milestone shall be paid only once.

(c) Royalties .

(i) In addition to the amounts payable pursuant to **Section 4.1(a)** and **Section 4.1(b)** above, Company shall for all Net Sales within the Term pay to CyDex, on a calendar quarterly basis, ***% royalties on the first $*** of worldwide annual Net Sales, and ***% royalties on the portion of worldwide annual Net Sales which exceeds $***. Notwithstanding the foregoing, as a royalty-rate step-down, for Net Sales (in a country), during the Term, of a Licensed Product which are made after expiry of the last-to-expire Licensed Patent containing a Valid Claim that would in the absence of the license granted herein be infringed by the use, manufacture or sale of such Licensed Product in such country or by the importation of such Licensed Product into such country, Company shall instead pay to CyDex, on a calendar quarterly basis, ***% royalties on the first $*** of worldwide annual Net Sales, and ***% royalties on the portion of worldwide annual Net Sales which exceeds $***.

(ii) Unless this Agreement is earlier terminated pursuant to **Section 13** , royalties shall be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, during the period from the First Commercial Sale of a given Licensed Product in a given country until the later of (a) expiry of the last-to-expire Licensed Patent containing a Valid Claim in such country that would in the absence of the license granted herein be infringed by the use, manufacture or sale of such Licensed Product in such country or by the importation of such Licensed Product into such country; or (b) the 10th anniversary of the First Commercial Sale of such Licensed Product in such country.

(iii) All royalties payable to CyDex pursuant to **Section 4.1(c)** shall be paid on a quarterly basis. These royalties shall be paid together with and in strict compliance with the amounts defined in the final written royalty report sent by Company for the preceding calendar quarter, as set forth in **Section 5.2** below. Within 75 calendar days after the conclusion of its fiscal year, Company may provide notice to CyDex of any adjustments necessary to account for any royalties which were overpaid or underpaid for such prior fiscal year's calendar quarters (as determined from Company's end of fiscal year external audit), and the Parties shall promptly true-up for any such adjustments which are mutually determined in good faith to be correct; provided however, the lapse of

such 75-day period shall not impact the right of a Party to credit or recover any overpayments or underpayments discovered during an audit under **Section 5.3** .

(iv) In establishing the royalty structure hereunder, the Parties recognize, and Company acknowledges, the substantial value of the various obligations being undertaken by CyDex under this Agreement, in addition to the grant of the license under the Licensed Intellectual Property, to enable the rapid and effective market introduction of the Licensed Products. The Parties have agreed to the payment structure set forth herein as a convenient and fair mechanism to compensate CyDex for these obligations.

4.2 Taxes . All amounts due hereunder and under the Supply Agreement exclude and shall, as far as is legally possible, be paid in full to CyDex without reduction for all applicable sales, use, and other taxes and duties, and Company shall be responsible for payment of all such taxes (other than taxes based on CyDex's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement and under the Supply Agreement. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments and other payments made by Company to CyDex under this Agreement and under the Supply Agreement. To the extent Company is required to withhold taxes on any payment to CyDex under this Agreement or under the Supply Agreement, Company shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CyDex may reasonably request, to establish that such taxes have been paid. CyDex shall in due time provide Company any tax forms that may be reasonably necessary in order for Company to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, and Company shall utilize such forms to such effect. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement and under the Supply Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. CyDex shall indemnify and hold Company harmless from and against any penalties, interest or other tax liability arising from any failure by Company (at the express request of CyDex) to withhold or from any Company reduction (at the express request of CyDex) in its withholding.

4.3 Payments. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment. Cumulative with and not exclusive of any and all other available remedies, payments that are not made when due hereunder, and which are not otherwise subject to a good faith dispute, shall accrue interest, from due date until paid, at an annual rate equal to the prime rate, as reported in The Wall Street Journal, Eastern United States Edition, on the date such payment is due, plus an additional 200 basis points (2%). All amounts due hereunder are stated in and shall be paid in United States Dollars.

5. RECORDS; REPORTS; AUDIT.

5.1 Records. During the Term and until the end of the third calendar year after the calendar year during which the Term ends, Company shall, and shall require its Affiliates and Sublicensees to, maintain accurate books and records relating to Net Sales. Without limitation, for three years after the calendar year in which each respective sale of a Licensed Product (whether covered by a Valid Claim

or not) occurs, Company shall keep (and shall ensure that its Affiliates and Sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty calculations hereunder.

5.2 Royalty Reports. Within 25 calendar days after the conclusion of each calendar quarter after a First Commercial Sale and after the conclusion of each successive calendar quarter until the end of the first full calendar quarter after the end of the Term, Company shall deliver to CyDex a verbal or written, non-binding initial estimate of Net Sales and royalties due to CyDex, followed by (within 45 calendar days following the conclusion of each calendar quarter after the First Commercial Sale of the relevant Licensed Product in any country and after the conclusion of each successive calendar quarter until the end of the first full calendar quarter after the end of the Term) a final written royalty report. Each final written royalty report shall provide, on a Licensed Product-by-Licensed Product (and specifying whether covered by a Valid Claim or not, as applicable) and country-by-country basis, (a) gross invoiced (or otherwise charged) amounts of sales, by Company and its Affiliates and Sublicensees, of Licensed Products subject to royalty payments for such calendar quarter, (b) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (c) Net Sales subject to royalty payments for such calendar quarter and calendar year to date, (d) exclusions pursuant to **Section 4.1(c)(i)** , and (e) the corresponding royalty amount due hereunder. Such reports shall be deemed "Confidential Information" of Company and shall be subject to the obligations of **Section 8** of this Agreement.

5.3 Audit. Upon at least 30 days' advance written notice by CyDex, Company shall permit, shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by CyDex (who has not been engaged by CyDex to provide services in any other capacity at any time during the three-year period before such selection), and reasonably acceptable to Company or such Affiliate or Sublicensee, to have access to and to review, during normal business hours on business days upon reasonable prior written notice, the applicable records of Company and its Affiliates or Sublicensees to verify the accuracy of the royalty payments under this **Section 5** . Such review may cover: (a) the records for sales made in any calendar year ending not more than three years before the date of such request, and (b) only those periods that have not been subject to a prior audit. Except as described hereafter, all such audits shall be conducted at the expense of CyDex. Such audits shall be conducted not more than once in each calendar year and not more than once for each audited period. In the event such accountant concludes that additional payments of any kind as required by this Agreement were owed to CyDex during such period, the additional amounts shall be paid within 30 days after the date of the corresponding invoice sent by CyDex and delivered to Company with copy of the aforementioned accountant's written report so concluding, unless Company disputes the results of such audit in accordance with **Section 14.3** . The fees charged by such accountant shall be paid by CyDex, unless the audit discloses that the amounts payable by Company for the audited period are more than *** of the amounts actually paid for such period, in which case Company shall pay the reasonable fees and expenses charged by the accountant for such audit (upon resolution of any dispute initiated by either Party pursuant to **Section 14.3** with respect to the same). In the event such accountant concludes that there was an overpayment by Company to CyDex during such period, at Company's option, the overpayment shall be paid by CyDex to Company within 30 days after the date of the of the corresponding invoice sent by Company to CyDex, unless CyDex disputes the results of such audit in accordance with **Section 14.3** . CyDex shall cause the independent certified public accountant to keep confidential any information obtained during such inspection in accordance with the provisions set forth in **Section 8** hereof and shall report to

CyDex only the amounts of (y) Net Sales that give rise to royalties and (z) royalties payments due and payable. The Parties agree that all information subject to review under this **Section 5.3** or under any Sublicense agreement is the Confidential Information of Company.

5.4 Annual Progress Reports . By November 1 of each calendar year during the Term, Company shall provide CyDex with written reports that describe in reasonable detail Company's progress made toward achievement of the milestones specified in **Section 4.1(b)** above during such calendar year and summarize Company's activities, progress and outlook in developing Licensed Products. Company shall also provide updates regarding any material changes to the expected completion of any such milestones outlined in the annual report or any change that may materially affect the Supply Agreement or orders placed thereunder during such calendar year. The Parties agree that the aforementioned written report is the Confidential Information of Company and shall be subject to the obligations of **Section 8** of this Agreement.

6. DEVELOPMENT AND COMMERCIALIZATION BY COMPANY.

6.1 Development. As between CyDex and Company, from and after the Effective Date Company shall be responsible for all non-clinical and clinical development of the Licensed Products, all commercialization of the Licensed Products, and all storage, handling and use of physical quantities of the Compound and/or the Compound prepared, combined and/or formulated with Captisol.

6.2 Costs and Expenses. Company shall be solely responsible for all decision-making, compliance with law, costs and expenses related to its development, manufacturing and commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Products, and all commercialization of Licensed Products.

6.3 In Vivo Studies. If Company wishes to conduct any in vivo study (preclinical or clinical, in animals or in humans, each a " **Study** ") of a Licensed Product, the following provisions shall apply:

(a) Dosing . Company shall not without the written consent of CyDex exceed the allowable dosing levels of Captisol specified in CyDex's then-current clinical dosing matrix (which shall be provided by CyDex to Company from time to time).

(b) Compliance with Laws . Company represents, warrants and covenants that each Study shall be performed in material compliance with all applicable laws, regulations and requirements. Company shall provide or cause to be provided all appropriate warnings to participants enrolled in each Study and obtain or cause to be obtained appropriate documentation of informed consent from all participants in each such Study.

(c) Adverse Events . Company agrees to promptly inform CyDex if any Adverse Events are observed and ascribed to Captisol in any Study in accordance with **Section 7.4** hereof. Company agrees that, for so long as and to the extent that CyDex is providing supply pursuant to the Supply Agreement, it shall use for each such Study conducted under the scope of this Agreement only Captisol supplied by CyDex under the Supply Agreement or previously supplied by CyDex under the July 2014 Agreement, and shall not use any other Captisol supplied by a Third Party or any Captisol® obtained other than directly from CyDex under the Supply Agreement or previously under the July

2014 Agreement.

(d) Reporting and Study Data . Within three months after receipt of the final Study report for a Study, Company shall provide to CyDex a summary of the data and results of each Study that pertain solely to Captisol, and Company hereby grants to CyDex a non-exclusive, royalty-free license (with the right to sublicense) to use and disclose such data solely as necessary for regulatory purposes, including without limitation to update the DMF for Captisol®.

(e) Responsibility . Company has the freedom to formulate and design each Study, and (as between Company and CyDex) Company is solely responsible for executing each Study; and so it is reasonable that, and the Parties agree that, Company shall be solely responsible therefor and for any effects or consequences of the formulation, design and execution of each Study.

(f) Review of Regulatory Filings and Publications . At least 14 days before a submission of any proposed written publication material or regulatory submission reporting results of a Study where such publication material refers to Captisol (which shall be subject to the restrictions of **Section 8** hereof), Company shall provide to CyDex for CyDex's review and comment a copy of any proposed written publication, material or regulatory submission. Company shall give due consideration to and reasonably incorporate any input that CyDex provides regarding Captisol.

6.4 Global Safety Database. Company shall set up, hold, and maintain (at Company's sole cost and expense) the global safety database for the Licensed Products

6.5 Access to Company's Data. CyDex shall have the right to reference and utilize all toxicology/safety and other relevant scientific data that exclusively relate to Captisol and are developed by Company, its Sublicensees or Affiliates, at no cost to CyDex. Upon request by CyDex, Company shall either provide CyDex, at CyDex's sole expense, with a copy of all such data or shall make such data accessible to CyDex at times and locations reasonably agreeable to CyDex and Company.

6.6 Insurance. During the Term and for three years thereafter, both Parties shall obtain and maintain, at their respective cost and expense, commercial general liability insurance and product liability insurance in amounts that are appropriate with respect to its indemnification obligations hereunder. It is understood and agreed that this insurance shall not be construed to limit each Party's liability with respect to its indemnification obligations hereunder. Each Party shall provide upon request the other Party with a certificate evidencing the insurance it is required to obtain and keep in force under this **Section 6.6** , and shall provide the other Party at least 30 days' prior written notice of any cancellation or material modification of such insurance.

6.7 Patent Marking . Company agrees that with respect to each unit or package of Licensed Products sold in a given country, Company shall comply with the customary patent marking laws and practices of such country as to the applicable Licensed Patents.

6.8 Trademarks . As between CyDex and Company, Company shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks. CyDex does not grant Company the right to use any trademarks of CyDex or its Affiliates.

6.9 No Guaranty of Favorable Outcomes . CyDex does not warrant that Company's preclinical studies and evaluation and/or Company's clinical studies (if any) will produce any

particular results or any favorable results, or that Licensed Products can ever receive Marketing Approval or can ever be successfully or profitably commercialized.

7. REGULATORY MATTERS.

7.1 Right of Reference. Company shall have the right to reference the DMF solely in connection with Company's regulatory filings (including Applications) submitted in connection with obtaining Marketing Approval for a Licensed Product. CyDex shall use commercially reasonable efforts to keep its DMF in good standing throughout the Term.

7.2 Captisol Information Submitted for Regulatory Review. Except as otherwise set forth herein, Company shall be solely responsible for all communications with regulatory agencies in connection with the Licensed Products, provided CyDex shall reasonably cooperate with Company with respect to any interactions with regulatory authorities concerning Captisol. Company shall provide CyDex with copies of the portions of all regulatory submissions containing Captisol data alone (and not in conjunction with any Licensed Product) 14 days before submission and shall allow CyDex to review and comment upon said submissions. The contents of each such submission shall be deemed to be Confidential Information of Company, subject to the terms and provisions of **Section 8** below. Company shall promptly inform CyDex of meetings with the FDA (or other regulatory agencies in the Territory) regarding Captisol. If Company submits written responses to the FDA that include data on Captisol alone, CyDex shall be permitted to review the portions of such written materials relating to Captisol 14 days before submission. If CyDex reasonably objects to the contents of such proposed submissions or written responses relating to Captisol, the Parties agree to cooperate in working toward a reasonable and mutually agreeable submission or response; *provided, however,* that Company shall be entitled to in good faith make the final determination as to the contents of any such materials.

7.3 Material Safety. CyDex shall provide Company, in writing, from time to time, with (a) all relevant material information currently known to it regarding handling precautions, toxicity and hazards with respect to Captisol®, and (b) the then-current material safety data sheet for Captisol®. Notwithstanding the foregoing or anything in this Agreement to the contrary, Company is solely responsible for (x) use of all documentation provided by CyDex, including without limitation, use in any regulatory submission to the FDA or any other regulatory authority in the Territory, (y) document control and retention, and (z) determining the suitability of any documentation provided by CyDex hereunder for use in any regulatory submission.

7.4 Adverse Event Reporting. Company shall adhere, and shall require that its Affiliates, Sublicensees, co-marketers and distributors adhere, to all requirements of applicable law and regulations that relate to the reporting and investigation of any Adverse Event, including without limitation an unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease, whether or not considered Captisol or Licensed Product-related, which occurs or worsens following administration of Captisol or Licensed Product. Each Party shall provide the other with copies of all reports it obtains (either directly or through any Sublicensee or licensee) of any Adverse Event which such Party has reason to believe are associated with Captisol within 14 days following (a) submission of any such report to any regulatory authority, or (b) receipt from such Party's Sublicensee, licensee, co-marketer or distributor of any such report to any regulatory authority. Each Party shall also advise the other Party promptly regarding any proposed labeling or registration dossier changes, of which it becomes aware, which relate specifically to both the Licensed Product and

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Captisol. Reports from Company shall be delivered to the attention of Chief Scientific Officer, CyDex, with a copy to Chief Executive Officer, CyDex, at the address set forth in **Section 14.7** . Reports from CyDex shall be delivered to the attention of Chief Scientific Officer, Company, at the address set forth in **Section 14.7** . The Parties shall mutually cooperate with regard to investigation of any such serious adverse event, whether experienced by Company, CyDex or any Affiliate, Sublicensee, sublicensee, co-marketer or distributor of CyDex or Company.

7.5 Certification under Drug Price Competition and Patent Restoration Act. Each Party shall immediately give written notice to the other Party of any certification of which it becomes aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any Licensed Patents covering the Compound or a Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale in the United States of a Licensed Product or Competing Product by a Third Party.

8. CONFIDENTIALITY.

8.1 Definition. Company and CyDex each recognizes that during the Term, it may be necessary or advisable for a Party (the " **Disclosing Party** ") to provide Confidential Information (as defined herein) to the other Party (the " **Receiving Party** "). Neither Company nor CyDex shall disclose or use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, " **Confidential Information** " means all information disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within 30 days after such oral disclosure, including but not limited to product specifications, data, know-how, formulations, product concepts, sample materials, study results, analyses, protocols, business and technical information, financial data, batch records, inventions, works of authorship, Know-How, trade secrets, processes, techniques, algorithms, programs, designs, drawings, and any other information related to a Party's present or future products, technology, sales, suppliers, customers, employees, investors or business. Without limiting the generality of the foregoing, CyDex's Confidential Information includes all materials provided as part of the Captisol Data Package.

8.2 Obligation. CyDex and Company agree that they will disclose the other Party's Confidential Information to its own (or its Sublicensees' and/or Affiliates') officers, employees, consultants, attorneys, accountants, bankers, Contract Manufacturers, lenders and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or the Supply Agreement, or in accordance with the exercise of their rights under this Agreement or the Supply Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights and provided that such persons or entities are under a written obligation of confidentiality at least as restrictive as this **Section 8** . Except as set forth in the foregoing sentence, neither Party shall disclose Confidential Information of the other to any person or entity without the other's prior written consent. In all events, however, any and all disclosure to any such persons or entities shall also be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this **Section 8** (or, in the case of attorneys, to a duty and obligation of nondisclosure/nonuse

pursuant to the applicable rules of the profession). The Party which disclosed Confidential Information of the other to any such team member or Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such team member or Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. Neither Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each Party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other's request, shall promptly return or destroy (at Disclosing Party's discretion) all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies, embodiments, reflections, analyses and extracts of documents, except for (a) one archival copy (and such electronic copies that exist as part of the Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement and (b) any archival copy that this Party is required to keep by applicable regulations.

8.3 Exceptions. The non-use and non-disclosure obligations set forth in this **Section 8** shall survive the expiration or earlier termination of this Agreement. The non-use and non-disclosure obligations set forth in this **Section 8** shall not apply to any Confidential Information, or portion thereof, that was first disclosed by the Disclosing Party to the Receiving Party after the expiration or earlier termination of this Agreement or that the Receiving Party can demonstrate by competent evidence:

(a) at the time of disclosure is in the public domain;

(b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of and or without violation of any duty of confidentiality of the Receiving Party or its disclosees;

(c) at the time of disclosure is already in the Receiving Party's possession with no duty of confidentiality;

(d) is rightfully received by the Receiving Party from an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's best knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party; or

(e) is independently developed by or expressly for the Receiving Party, in either case solely by personnel without any access to or use of the Disclosing Party's information as shown by Receiving Party's competent, contemporaneous written evidence.

In addition, in the event that the Receiving Party or any of its Representatives is required by law, rule, regulation, court order or in any regulatory, judicial or governmental process having jurisdiction over the Receiving Party to disclose the Confidential Information, the Receiving Party hereby agrees to notify the Disclosing Party of the request or requirement immediately and to make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, confidential treatment or a protective order or any other reasonable measure preventing or limiting the disclosure (to the greatest

possible extent and for the longest possible period), and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued, which the Disclosing Party deems necessary to protect the confidentiality of the Confidential Information (or as much as possible of the Confidential Information). In any event, should the Receiving Party be required by such compulsion to in the end disclose Confidential Information to the requiring authority (and, if so required thereby, to the public), (x) the Receiving Party hereby agrees to take reasonable steps to seek such confidential treatment for the Confidential Information (or as much as possible of the Confidential Information); (y) the Receiving Party may provide the Confidential Information to the appropriate requiring authority (and, if so required thereby, to the public) as ultimately so compelled without such disclosure being deemed a violation of this Agreement; and (z) such disclosure to the requiring authority as ultimately so compelled shall not deprive the disclosed information of Confidential Information status for any other purposes of this Agreement.

8.4 Third Party Information .

(a) Company is generally informed that CyDex's Confidential Information and DMF include information developed by Pfizer Inc. (" **Pfizer** ") that is confidential to both CyDex and Pfizer. Only to the extent that confidential information of Pfizer is either included in the DMF or is specifically identified in a prior written notice by CyDex to Company as being part of CyDex's Confidential Information disclosed to Company hereunder, Pfizer is a limited third party beneficiary of only this **Section 8** of this Agreement and may seek remedies pursuant to it, but only in accordance with its terms.

(b) The Parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party or the Disclosing Party's Affiliates which is in the possession of the Disclosing Party. Both Parties agree not to disclose to the other Party any Confidential Information of a Third Party which is in the possession of such Party, unless the other Party has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

8.5 Public Announcements. The Parties shall mutually agree on any press release to be issued upon execution of this Agreement; such release may include a high-level description of the royalty and milestone payment obligations of this Agreement. Neither Party shall make any subsequent public announcement concerning this Agreement or the terms hereof not previously made public without the prior written approval of the other Party with regard to the form, content, and precise timing of such announcement, except as may be required to be made by either Party in order to comply with applicable law, regulations, court orders, or tax, securities filings, financing arrangements, acquisitions, or sublicenses. Such consent shall not be unreasonably withheld, conditioned or delayed by such other Party. Before any such public announcement, the Party wishing to make the announcement shall submit a draft of the proposed announcement to the other Party sufficiently in advance of the scheduled disclosure to afford such other Party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure, and shall consider all reasonable comments of the other Party regarding such disclosure. (Provided, that neither Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by law or required by the rules of an applicable US national securities exchange or except with the prior

express written permission of such other Party, such permission not to be unreasonably withheld, conditioned or delayed.) Notwithstanding the above, once a public disclosure has been made, either Party shall be free to disclose to Third Parties any information contained in said public disclosure, without further pre-review or pre-approval.

9. REPRESENTATIONS AND WARRANTIES.

9.1 Mutual Representations and Warranties . Each Party represents and warrants to the other that, as of the Effective Date:

(a) it is a corporation duly organized and validly existing under the laws of the state or country of its incorporation;

(b) it has the full power and right to enter into this Agreement and to perform its obligations hereunder;

(c) this Agreement has been duly authorized, executed and delivered by such Party and 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 bankruptcy, insolvency, reorganization, receivership, moratorium, fraudulent transfer, or other similar laws affecting the rights and remedies of creditors generally and by general principles of equity;

(d) the execution, delivery and performance of this Agreement by such Party does not and will not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;

(e) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not and will not violate any order, law or regulation of any court, governmental body or administrative or other agency having authority over such Party;

(f) no person or entity has or will have, as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates or agents, or in addition, with respect to Company, because of any act by its Sublicensees; and

(g) it has not entered and shall not enter into any agreement with any Third Party that is in conflict with the rights granted to the other Party pursuant to this Agreement.

9.2 CyDex Additional Representations and Warranties . CyDex hereby represents and warrants to Company that, as of the Effective Date:

(a) CyDex has no knowledge of any unsettled past or current, and has not received notice of any threatened, patent, trade secret or other intellectual property dispute with any Third Party that actually or is reasonably likely to have a material adverse effect on the Licensed Intellectual Property;

(b) the Licensed Intellectual Property (i) is not subject to any outstanding injunction, judgment, order or ruling, and (ii) to CyDex's knowledge, there is no pending or threatened claim or action, in each instance, which challenges the validity, legality, enforceability or use of the Licensed Intellectual Property;

(c) CyDex has the full right, power and authority to grant all of the licenses granted to Company under this Agreement;

(d) as of the Effective Date, CyDex has not granted to any Third Party any license to any of the Licensed Intellectual Property which conflicts with the exclusive license hereunder and CyDex shall not grant any such license during the Term;

(e) the Licensed Intellectual Property constitutes all Captisol-related rights owned or controlled by CyDex that pertain to Company's development, manufacture, use and commercialization of the Licensed Product as contemplated by this Agreement;

(f) CyDex and its Affiliates are not a debarred entity and have not used and will not use in any capacity the services of any individual or entity known by CyDex to be debarred under 21 U.S.C. §335(a) or (b) of the Federal Food, Drug and Cosmetic Act in connection with its obligations hereunder; and

(g) CyDex has filed and maintained with the appropriate regulatory authorities in all Major Markets all permits, licenses, regulatory filings (including the DMF) and approvals related to Captisol and the manufacture and sale thereof, necessary for CyDex to carry out its obligations and for Company to exercise its rights under this Agreement and the Supply Agreement.

9.3 Disclaimer. Notwithstanding the representations and warranties set forth in this **Section 9** , Company acknowledges and accepts the risks inherent in attempting to develop and commercialize any pharmaceutical product. There is no implied representation that any Licensed Products can be successfully developed or commercialized. The express warranties set forth in this **Section 9** and elsewhere in this Agreement and the Supply Agreement are provided in lieu of, and **EACH PARTY HEREBY DISCLAIMS, all other warranties, express and implied, relating to the subject matter of this Agreement, the subject matter of the Supply Agreement, Captisol, the Licensed Intellectual Property, or the Licensed Products, including but not limited to the implied warranties of merchantability and of fitness for a particular purpose.** Each Party's representations and/or warranties under this Agreement are solely for the benefit of the other Party, and may be asserted only by the other Party and not by any Affiliate, Sublicensee, Permitted Purchaser or other Third Party (including without limitation any customer of the other Party, its Affiliates or Sublicensees) - other than a Company Indemnitee or CyDex Indemnitee with respect to an indemnification claim. Each Party, its Affiliates and Sublicensees shall be solely responsible for all representations and warranties that it, its Affiliates or Sublicensees make to any customer, Affiliates, Sublicensees or other Third Party.

10. INDEMNIFICATION.

10.1 By CyDex. CyDex shall defend, indemnify and hold Company and its Affiliates, and each of their respective directors, officers, managers, employees and agents (collectively, the " **Company Indemnitees** "), harmless from and against any and all judgments, damages, liabilities,

settlements, penalties, fines, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively, " **Losses** "; it being expressly understood, however, that incidental, special, indirect and consequential damages and lost profits, lost savings and interruptions of business are expressly excluded therefrom and from such defined term) incurred by the Company Indemnitees as a result of any claim, demand, action or other proceeding (each, a " **Claim** ") by a Third Party, to the extent such Losses arise out of (a) CyDex's breach of this Agreement or the Supply Agreement, including without limitation any of its covenants, representations and warranties set forth herein or therein; (b) any breach or violation of any applicable law, regulation or court order by CyDex or its Affiliates or contractors, or any of their respective directors, officers, managers, employees or agents, in connection with the activities contemplated by this Agreement including but not limited to those listed in subsections (c) and (d) below, (c) the research, development, manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Captisol by CyDex or its Affiliates or agents (for clarity, such terms shall not include Company in any event); (d) interactions and communications by CyDex, its Affiliates, manufacturers or agents with governmental authorities, physicians or other Third Parties relating to Captisol, including the Captisol Data Package; (e) the grossly negligent or willful misconduct of CyDex or its Affiliates or any of their respective directors, officers, managers, employees or agents; or (f) infringement or unauthorized use by CyDex or its Affiliates or contractors, or any of their respective directors, officers, managers, employees or agents, of any Third Party patents or other intellectual property rights, including in the granting of the rights listed in **Section 2** above, but only to the extent that any such infringement Claim is related to Captisol or the Licensed Intellectual Property; and, for each of subsections (a)-(f), all except to the extent that such Losses are primarily caused by a Company Indemnitee's breach of applicable law, this Agreement or the Supply Agreement, gross negligence or willful misconduct.

10.2 By Company. Company shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers, managers, employees and agents (collectively, the " **CyDex Indemnitees** "), harmless from and against any and all Losses incurred by the CyDex Indemnitees as a result of any Claim by a Third Party, to the extent such Losses arise out of: (a) Company's breach of this Agreement or the Supply Agreement, including without limitation any of its covenants, representations and warranties herein or therein; (b) any breach or violation of any applicable law, regulation or court order by Company, its Affiliates, sublicensees or contractors, or any of their respective directors, officers, managers, employees or agents, in connection with the activities contemplated by this Agreement or the Supply Agreement including but not limited to those listed in subsections (c), (d) and (e) below, (c) any Study conducted by or on behalf of Company; (d) the research, development, manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Licensed Products by Company, its Affiliates, Sublicensees, Contract Manufacturers, distributors or agents (for clarity, such terms shall not include CyDex in any event); (e) interactions and communications by Company, its Affiliates, Sublicensees, distributors or agents with governmental authorities, physicians or other Third Parties relating to Licensed Products and/or Captisol; (f) the grossly negligent or willful misconduct of Company or its Affiliates, Sublicensees, Contract Manufacturers, distributors or agents or any of their respective directors, officers, managers, employees or agents; or (g) actual or alleged infringement of a Third Party's intellectual property rights in the making, having made, using, selling, offering for sale and importing of Licensed Products, but only to the extent that any such infringement Claim is unrelated to Captisol or the Licensed Intellectual Property; and, for each of subsections (a)-(g), all except to the extent that such Losses are primarily caused by a CyDex Indemnitee's breach of applicable law, this Agreement or the Supply Agreement, gross negligence or willful misconduct.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

10.3 Expenses . The indemnification obligation of each Party under this **Section 10** shall include, where applicable, reasonable attorney costs and expenses incurred by the other Party (or an applicable Company Indemnitee or CyDex Indemnitee) to successfully enforce any provision of this **Section 10** .

10.4 Procedure. The Party or other Indemnitee intending to claim indemnification under this **Section 10** (an " **Indemnified Party** ") shall promptly notify the other Party (the " **Indemnifying Party** ") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; *provided, however,* that an Indemnified Party shall have the right to retain its own counsel and to participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party, unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the Indemnifying Party shall pay (as incurred and on demand) the reasonable fees and expenses of counsel retained by the Indemnified Party and all other expenses of investigation and litigation. (Provided, that in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.) If the Indemnifying Party shall fail to timely assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the reasonable fees and expenses of counsel retained by the Indemnified Party and all other expenses of investigation and litigation. The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided , that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld, conditioned or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (a) there is no finding or admission of any violation of law or any violation of the rights of any person or entity by an Indemnified Party, no requirement that the Indemnified Party admit fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (b) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

Regardless of who controls the defense, the other Party hereto shall reasonably cooperate in the defense as may be requested. Without limitation, the Party hereto which is not the Indemnifying Party, and its directors, officers, managers, employees, agents and advisers, and the Indemnified Party, and its directors, officers, managers, employees, agents and advisers, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

10.5 Other Scenarios . Subject to **Section 11** , this **Section 10** shall not be construed to suggest that a Party has no remedy other than under this **Section 10** (or does not have any particular remedy) for Losses and diminutions in value which arise from breaches of this Agreement or of the

Supply Agreement but which are not incurred as a result of a Claim.

11. LIMITATION OF LIABILITY.

EXCEPT FOR (a) INDEMNIFICATION OBLIGATIONS IN CONNECTION WITH THIRD PARTY CLAIMS PURSUANT TO **SECTION 10** HEREOF, AND/OR (b) (DAMAGES ARISING FROM OR IN CONNECTION WITH A BREACH BY CYDEX OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER, AND/OR (c) INTENTIONAL MISCONDUCT OR WILLFUL AND KNOWING BREACH, AND/OR (d) PROVISIONS OF THIS AGREEMENT AND THE SUPPLY AGREEMENT WHICH EXPRESSLY REQUIRE PAYMENTS, THE TOTAL AGGREGATE LIABILITY OF CYDEX FOR DAMAGES UNDER THIS AGREEMENT AND THE SUPPLY AGREEMENT (TOGETHER) IS LIMITED TO A MAXIMUM AMOUNT OF ***.

NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE SUPPLY AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN TWO YEARS AFTER SUCH PARTY HAS KNOWLEDGE OF BOTH THE OCCURRENCE AND THE CONSEQUENCES OF SAID OCCURRENCE THAT GAVE RISE TO THE CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER.

12. MANAGEMENT OF INTELLECTUAL PROPERTY.

12.1 Ownership .

(a) Existing and Acquired Rights . Each Party shall remain the owner of intellectual property rights owned or controlled by such Party before the Effective Date. Each Party shall own any intellectual property acquired by such party outside of this Agreement after the Effective Date.

(b) New Rights . The ownership of discoveries, inventions, improvements and other technology, whether or not patentable (each, a " **Discovery** "), made by Company's and/or CyDex's personnel and related to the subject matter of this Agreement, will be determined in accordance with United States Patent laws and ownership shall follow inventorship. The Party other than the owning Party agrees to cooperate fully in protecting the owning Party's rights and interests in to such Discovery.

12.2 Prosecution and Maintenance .

(a) Existing Rights (Licensed Patents) . During the Term CyDex shall conduct the maintenance, at its sole cost and expense and using reasonable discretion, of the Licensed Patents. CyDex shall have the sole right to control the prosecution of patent applications and the selection of countries where patent applications are filed related to the Licensed Patents.

(b) New Rights . The Parties shall cooperate to take whatever, if any, actions they mutually agree upon in writing and in their respective discretion to prosecute patent applications and maintain patents covering rights which are jointly owned in accordance with **Section 12.1(b)** . Such

agreement shall include actions to be taken by each Party and the allocation of expenses related to such action. Neither Party shall seek patent protection covering such rights without such agreement.

(c) For the avoidance of doubt, subject to **Sections 12.2(a)** and **(b)** each Party shall be solely responsible for all decisions and actions pertaining to the prosecution and maintenance of patent applications and patents owned solely by such Party.

12.3 Infringement by Third Parties .

(a) **Notification of Third Party Infringement** . Each Party shall promptly notify the other Party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Intellectual Property in the Field and in the Territory **("Third Party Infringement")** of which it becomes aware.

(b) **Existing Rights (Licensed Patents)** . CyDex shall have the right (but not the obligation), at its own expense, to initiate and control any action to enforce the Licensed Patents against any Third Party Infringement and may name Company as a party plaintiff solely to the extent required to maintain standing; provided, that CyDex shall reimburse Company for any such costs incurred by Company therefor. Before commencing such an action, CyDex shall consult with Company and give consideration to Company's recommendations regarding the proposed action. Company shall provide to CyDex reasonable assistance in such enforcement, at CyDex's request and expense. CyDex shall control the direction of and any settlement of any such action. Any recoveries resulting from an action relating to a claim of Third Party Infringement of the Licensed Patents (including any recoveries resulting from settlement) shall be retained by CyDex.

(c) **New Rights** . The Parties shall cooperate to take whatever, if any, actions they mutually agree upon in writing and in their respective discretion against the alleged infringer of rights which are jointly owned in accordance with **Section 12.1(b)** . Such agreement shall include actions to be taken by each Party and the allocation of expenses and recoveries related to such action. Neither Party shall take any such action against the alleged infringer without the written consent of the other Party.

(d) **Enforcement Decisions by Owner** . For the avoidance of doubt, subject to **Sections 12.3(a), (b)** and **(c)** , each Party shall be solely responsible for all decisions and actions pertaining to the enforcement of patents owned solely by such Party.

12.4 Alleged Infringement of Third Parties Rights.

(a) Each Party shall promptly notify the other Party in writing of any threat, allegation or claim of infringement received from a Third Party in relation to any of that Third Party's intellectual property rights, in relation with the development, manufacture, use, sale, offer for sale, importation or commercial exploitation of the Licensed Products in the Territory.

(b) Company and/or any of its Affiliates shall control the defense of any litigation mentioned in subsection (a) above, at their own expense and by counsel of their own choice, and CyDex agrees that it will furnish to Company and/or any of Company Affiliates, upon request, all evidence and information in its possession relating to or reasonably necessary for such defense. Provided that, to the extent the litigation concerns (in whole or in part) Captisol, CyDex shall have the right, at its

own expense, to be represented in the legal proceedings by counsel of its own choice, and Company and its Affiliates and their counsels will reasonably cooperate with CyDex and its counsel in strategizing, preparing and presenting the defense.

13. TERM AND TERMINATION.

13.1 Term. The term of this Agreement (the " **Term** ") shall commence on the Effective Date and shall continue in effect thereafter on a country-by-country basis until the later of (a) the final expiration of the last-to-expire of the Licensed Patents that would in the absence of the license granted herein be infringed by the use, manufacture or sale of any Licensed Product in the applicable country or by the importation of such Licensed Product into such country or (b) the 10th anniversary of the First Commercial Sale of any Licensed Product, in each case in the applicable country. In a country (if any) where no Licensed Patent containing a Valid Claim has ever existed nor ever exists, the Term means the period from the First Commercial Sale of a Licensed Product in such country until the 10th anniversary of such First Commercial Sale of a Licensed Product in such country. The Parties confirm that subject to this **Section 13.1** , this Agreement shall not be terminated or invalidated by any future determination that any or all of the Licensed Patents have expired or been invalidated.

13.2 Termination of the Supply Agreement. If the Supply Agreement is terminated in accordance with its terms (except a termination of the Supply Agreement by CyDex for convenience or by Company for CyDex's material breach), CyDex shall have the right to terminate this Agreement with five days' prior written notice to Company.

13.3 Termination for Breach. If either Party should materially breach or violate or fail to perform any material term or covenant of this Agreement or the Supply Agreement, then the other Party may give written notice of such default to the first Party. If such Party should fail to cure such default within 60 days (or 15 days with respect to any payment obligation) of the date of such notice, the other Party shall have the right to terminate this Agreement by a second written notice (a " **Notice of Termination** ") to the first Party. If Notice of Termination is sent to such first Party, this Agreement shall automatically terminate on the effective date of such notice. The Parties agree that any failure by Company to pay when due (subject to the 15-day cure period) 100% of any amount of money owing from Company to CyDex as is not disputed in good faith by Company (or, if some portion of the amount of money owing from Company to CyDex is not disputed in good faith by Company and the remaining portion is disputed in good faith by Company, 100% of the portion which is not disputed in good faith by Company) shall conclusively be deemed to constitute a "material" breach.

13.4 Termination for Bankruptcy. To the extent permitted under applicable laws, either Party may terminate this Agreement in its entirety if, at any time, the other Party: (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, (b) is served with an involuntary petition against it, filed in any bankruptcy or insolvency proceeding, and such petition is not dismissed within 45 days after the filing thereof, (c) commences any dissolution or liquidation, or (d) makes a general assignment for the benefit of its creditors.

13.5 Termination for Convenience . Company may terminate this Agreement at any time upon *** days' prior written notice to CyDex.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

13.6 Survival. Notwithstanding any other provisions of this Agreement, any liability or obligation of either Party to the other (or to the other's Indemnitees) for or arising from acts or omissions before the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated or obviously intended to survive termination or expiration of this Agreement, nor shall any termination or expiration of this Agreement relieve Company of its obligation to pay CyDex, subject to the terms herein, (a) royalties for all Licensed Products sold by Company, its Affiliates or Sublicensees, (b) milestone payments for milestones achieved, or (c) sums due in respect of Captisol shipped, in each case before termination or expiration of this Agreement, or (d) the **Section 4.1(a)** *** payment. **Sections 2.2** (Grant of License from Company to CyDex) [except that this reference to **Section 2.2** shall not apply where the Agreement is terminated by Company pursuant to **Section 13.3**], **4.2** (Taxes), **4.3** (Late Payments), **5** (Records; Reports; Audit), **6.3(d)** (Reporting and Study Data), **6.5** (Access to Company's Data), **7.4** (Adverse Event Reporting), **8** (Confidentiality), **9.3** (Disclaimer), **10** (Indemnification), **11** (Limitation of Liability), **12** (Management of Intellectual Property), **13** (Term and Termination), and **14** (General Provisions) and any other obligations that are expressly indicated or obviously intended to survive shall survive termination or expiration of this Agreement.

13.7 Effect of Termination.

(a) Following the termination by CyDex for Company's breach under **Section 13.3** , all rights granted to Company herein shall immediately terminate and each Party shall promptly return all relevant records and materials in its possession or control containing the other Party's Confidential Information with respect to which the former Party does not retain rights hereunder, except for (i) one archival copy (and such electronic copies that exist as part of the Receiving Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement and (ii) any archival copy that the Receiving Party is required to keep by applicable law or regulations.

(b) The licenses granted in **Section 2.1** shall become perpetual, fully paid-up and royalty-free as to all countries of the Territory if and when (i) the Company terminates this Agreement under **Section 13.3** for CyDex's breach and (ii) either (A) CyDex expressly acquiesces to such termination in writing or (B) the rightfulness of such termination has been confirmed by a final judgment of the appropriate federal or California state court pursuant to **Section 14.3** and no further appeal from such court's final judgment is possible, either because the applicable time for filing any further appeal has expired or because an appellate court of final jurisdiction has affirmed such final judgment.

(c) Upon the natural expiration of the Term as to a country, the licenses granted in **Section 2.1** shall become perpetual, fully paid-up and royalty-free as to such country.

14. GENERAL PROVISIONS.

14.1 Relationship of Parties. Each of the Parties hereto is an independent contractor and nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. Neither Party shall have the right to, and each Party agrees not to purport to, incur any debts or make any commitments or contracts for the

other. During the Term of this Agreement and for a period of one year thereafter, Company shall not solicit, induce, encourage or attempt to induce or encourage any employee of CyDex to terminate his or her employment with CyDex; provided, that this sentence is not meant to encompass general solicitations such as may be found in newspaper advertisements and the like.

14.2 Compliance with Law. Company agrees that in the use of the Licensed Intellectual Property and Captisol by it and its Affiliates and Sublicensees, and the development, study, manufacture, handling, marketing, sale, distribution, importation and use of Licensed Products, it and its Affiliates and Sublicensees shall comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing use and patent, copyright and trade secret protection. CyDex agrees that its manufacture, handling, marketing, sale, distribution, importation and use of Captisol under the Supply Agreement shall comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing use and patent, copyright and trade secret protection.

14.3 Dispute Resolution .

(a) Elevation of Issues for Resolution . In the event of any dispute or disagreement between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party hereunder (each, a " **Dispute** "), the Parties shall endeavor to resolve such Dispute in accordance with the terms of this **Section 14.3(a)** . The Parties shall promptly refer such matter to, as appropriate, the Parties' respective Designated Executives, who shall use good faith efforts to resolve such matter. If agreement on a mutually acceptable resolution of such Dispute is not reached by the Designated Executives within 15 business days after a Party gives written notice to refer such Dispute to them, then such Dispute shall be subject to resolution in accordance with **Section 14.3(b)** .

(b) Dispute Settlement. If any Dispute is not resolved by mutual agreement of the Parties in accordance with **Section 14.3(a)** above within 15 business days of a Party giving notice to refer such Dispute to the Parties' Designated Executives under **Section 14.3(a)** , then either Party may submit such Dispute (and any related claims or other disputes arising out of or relating hereto or to the transactions contemplated hereby or to the inducement of any Party to enter herein or therein, whether for breach of contract, tortious conduct or otherwise and whether predicated on common law, statute or otherwise) for final settlement by the competent federal or state court located in the county of San Diego, California, notwithstanding plurality of defendants, summary proceedings or impleader. Each Party hereby irrevocably consents to the personal jurisdiction of such federal or California state court and agrees that venue is appropriate in such court, and agrees not to assert that such court is an inconvenient forum. The Parties agree that the jurisdiction of such court located in the county of San Diego, California shall be exclusive.

(c) Interim Equitable Relief . Each Party shall, in addition to all other remedies accorded by law (or in equity) and permitted by this Agreement, be entitled to seek interim equitable relief. Neither Party shall commence any court proceeding or action against the other to resolve any dispute, except for such interim injunctive relief or upon compliance with **Section 14.3(a)** and **Section 14.3(b)** .

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

14.4 Costs and Expenses. Except as otherwise expressly provided in this Agreement, each Party shall bear all costs and expenses associated with the performance of such Party's obligations under this Agreement.

14.5 Further Assurances . The Parties hereby covenant and agree, without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and instruments and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

14.6 Force Majeure. Neither Party shall be liable or in breach for failure to perform, or delay in the performance of, its obligations under this Agreement (other than payment obligations) when such failure or delay is caused by an event of force majeure. The corresponding obligations of the other Party shall be suspended to the same extent. For purposes of this Agreement, an event of force majeure means any event or circumstance beyond the reasonable control of the affected Party and not reasonably preventable using industry standard practices, including but not limited to, war, insurrection, riot, fire, flood or other unusual weather condition, explosion, act of God, peril of the sea, sabotage, embargo, act of governmental authority, compliance with governmental order on national defense requirements, or inability due to general industry wide shortages to obtain fuel, power, raw materials, labor or transportation facilities. If, due to any event of force majeure, either Party shall be unable to fulfill its obligations under this Agreement (other than payment obligations), the affected Party shall immediately notify the other Party of such inability and of the period during which such inability is expected to continue, shall use reasonable commercial efforts to cure and remedy such non-performance and the time for performance shall be extended for a number of days equal to the duration of the force majeure, and the Parties shall meet promptly to determine an equitable solution to the effects of such event.

14.7 Notices. Any notice, request, approval or consent required or permitted to be given under this Agreement or the Supply Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, by email or by internationally recognized overnight courier service to the Party to which it is directed at its physical or email address shown below or such other physical or email address as such Party shall have last given by such written notice to the other Party in accordance with this **Section 14.7** :

If to CyDex, to:

CyDex Pharmaceuticals, Inc.
c/o Ligand Pharmaceuticals Incorporated
3911 Sorrento Valley Boulevard, Suite 110
San Diego, California 92121
Attention: Vice President and Secretary
Email: cberkman@ligand.com

If to Company, to:

Marinus Pharmaceuticals, Inc.
170 N. Radnor Chester Road, Suite 250
Radnor, Pennsylvania 19087-5279
Attention: Christopher Cashman
Email: ccashman@marinuspharma.com

With a copy to:

Ligand Pharmaceuticals Incorporated
3911 Sorrento Valley Boulevard, Suite 110
San Diego, California 92121
Attention: General Counsel

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Email: cberkman@ligand.com

If sent by email, the date on which such notice, request, approval or consent shall be deemed delivered is the date of transmission, if such notice, request, approval or consent is sent via email to such email address before 5:00 p.m. at the location of receipt on a business day, or the first business day after the date of transmission, if such notice, request, approval or consent is sent via email to such email address at or after 5:00 p.m. at the location of receipt on a business day or on a day that is not a business day. If sent by internationally recognized overnight courier, the date on which such notice, request, approval or consent shall be deemed delivered is the next business day after the date of deposit with such courier (by the courier's stated time for enabling next-business-day delivery), and if delivered after such stated time shall be deemed to be the second business day after the date of deposit.

14.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California (without giving effect to any conflicts of law principles that require the application of the law of a different state or country). The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods shall be inapplicable to this Agreement and the Supply Agreement and transactions hereunder and thereunder.

14.9 Entire Agreement. This Agreement and the Supply Agreement and all Exhibits attached hereto or thereto contain the entire agreement of the Parties relating to the subject matter hereof and thereof and supersede any and all prior or contemporaneous agreements, written or oral, between CyDex and Company relating to the subject matter hereof and thereof. Notwithstanding the foregoing , it is understood and agreed that neither Party shall be relieved from any liability for any past breach of any previous written agreements. In addition, any confidential information which was disclosed under such previous written agreements shall remain confidential and shall be subject to the nondisclosure and nonuse provisions set forth in **Section 8** of this Agreement. Neither Party has made any promises, representations, warranties, covenants, or undertakings, other than those expressly set forth herein and in the Supply Agreement, to induce the other Party to execute and deliver this Agreement and the Supply Agreement, and each Party acknowledges that it has not executed or delivered this Agreement and the Supply Agreement in reliance upon any such promise, representation, or warranty, covenant or undertaking not contained herein or in the Supply Agreement.

(Specifically with regard to the July 2014 Agreement (which the parties hereby terminate with immediate effect), it is further agreed that any Confidential Information disclosed thereunder shall be deemed to have been disclosed under and shall be governed by this Agreement, the performance of any Studies contemplated thereby shall hereafter be subject to and governed by this Agreement, and any Captisol purchased thereunder shall be deemed to have been purchased and delivered under and shall be governed by this Agreement and the Supply Agreement (except that the price paid for any Captisol ordered thereunder before 2017 shall not be retroactively adjusted). In addition, the Parties agree that all Confidential Information heretofore disclosed under the Mutual Non-Disclosure Agreement entered into in 2014 by Company and CyDex's parent company Ligand Pharmaceuticals Incorporated shall be deemed to have been disclosed (by or on behalf of CyDex, or to CyDex or to a person or entity on behalf of CyDex) under and shall be governed by this Agreement, and all Confidential Information hereafter disclosed shall be deemed to be disclosed under and shall be governed by this Agreement rather than under and by such Mutual Non-Disclosure Agreement.)

14.10 Amendment. This Agreement may not be amended unless agreed to in writing by

both Parties.

14.11 Waiver. No waiver of any breach of a term, provision or condition of this Agreement shall be deemed to have been made by either Party unless such waiver is in writing and signed by an authorized representative of that Party. The failure of either Party to insist upon the strict performance of any of the terms, provisions or conditions of this Agreement, or to exercise any option contained in this Agreement, shall not be construed as a waiver or relinquishment for the future of any such term, provision, condition or option or the waiver or relinquishment of any other term, provision, condition or option. The rights of either Party under this Agreement may be exercised from time to time, singularly or in combination, and the exercise of one or more such rights shall not be deemed to be a waiver of any one or more of the others.

14.12 Severability. This Agreement is severable. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law; but if any provision of this Agreement is determined by a final and binding court or arbitration judgment to be invalid, illegal or unenforceable to any extent, such provision shall not be not affected or impaired up to the limits of such invalidity, illegality or unenforceability; the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any way; and the Parties agree to make a good faith effort to replace such invalid, illegal and unenforceable provision (or portion of provision) with a valid, legal and enforceable provision that achieves, to the greatest lawful extent under this Agreement, the economic, business and other purposes of such invalid, illegal or unenforceable provision (or portion of provision).

14.13 Assignment. Either Party may assign in whole or in part its rights and/or delegate in whole or in part its obligations under this Agreement to an Affiliate or to any Third Party successors, whether by way of merger, exclusive-license or sale of all or substantially all the assets to which this Agreement relates, sale of stock or otherwise, without prior written consent. Provided, however, that as a condition to any such permitted assignment hereunder, the assignor must guarantee the performance of the terms and obligations of this Agreement by any assignee, and the assignee must expressly assume (for the express benefit of the Party hereto which is not the assignor) the performance of the terms and obligations of this Agreement by such assignee. Except as provided herein, neither Party may assign its rights or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Any assignment not in accordance with this **Section 14.13** shall be void.

14.14 Binding Effect. This Agreement shall be binding upon, and the rights and obligations hereof shall apply to CyDex and Company and any successor(s) and permitted assigns. The name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement.

14.15 No Implied License. No right or license is granted to either Party hereunder by implication, estoppel, or otherwise to any Know-How, patent or other intellectual property right now or hereafter owned or controlled by such Party or its Affiliates, except by an express license granted hereunder.

14.16 Third-Party Beneficiaries. Except for the rights of Indemnified Parties pursuant to

Section 10 hereof, and subject to Pfizer's rights under **Section 8.4** hereof, the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CyDex under this Agreement shall only be pursued by Company or a Company Indemnitee, and not by Sublicensees (unless otherwise a Company Indemnitee).

14.17 Remedies Cumulative; Right of Set-Off . Except as provided in **Section 11** , any enumeration of a Party's rights and remedies in this Agreement is not intended to be exclusive, and a Party's rights and remedies are intended to be cumulative to the extent permitted by law and include any rights and remedies authorized in law or in equity. Notwithstanding anything to the contrary in this Agreement or in the Supply Agreement, Company shall not have a right to set-off any royalties, milestone payments or other amounts due to CyDex under this Agreement and/or the Supply Agreement against any damages incurred by Company for a breach by CyDex of this Agreement and/or the Supply Agreement.

14.18 Equitable Relief . Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of **Section 8** and any or all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief), all without need to post any bond or security, and (except as provided in **Section 11**) in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

14.19 Interpretation. The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against any Party because that Party or its attorney drafted the provision.

14.20 Headings. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

14.21 Construction. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause or Exhibit of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, and (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import.

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14.22 Counterparts. This Agreement may be executed and delivered in counterparts (portable document format (.pdf)/electronic transmission included), each of which shall constitute an original document, but both of which shall constitute one and the same instrument.

[Remainder of this page left blank intentionally]

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

CYDEX PHARMACEUTICALS, INC.

By: /s/ Matthew W. Foehr

Name: Matthew W. Foehr

Title: President and Chief Operating Officer

MARINUS PHARMACEUTICALS, INC.

By: /s/ Christopher M. Cashman

Name: Christopher M. Cashman

Title: Chief Executive Officer

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EXHIBIT A

LICENSED PATENTS (13 pages)

[... *** ...]

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SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this " **Agreement** ") is made this 31st day of March, 2017 (the " **Effective Date** ") between CyDex Pharmaceuticals, Inc., a Delaware corporation (" **CyDex** "), and Marinus Pharmaceuticals, Inc., a Delaware corporation (" **Company** ").

RECITALS

WHEREAS , CyDex is engaged in the business of developing and commercializing novel drug delivery technologies designed to enhance the solubility and effectiveness of existing and development-stage drugs;

WHEREAS , CyDex is the exclusive supplier of Captisol®, the uniquely modified form of sulfobutylether β (beta) cyclodextrin, sodium salt;

WHEREAS , CyDex desires to supply and Company desires to purchase Captisol from CyDex, under the terms and conditions set forth herein;

WHEREAS , CyDex and Company are contemporaneously entering into a License Agreement (the " **License Agreement** "); and

NOW , **THEREFORE** , in consideration of the following mutual promises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS.

For the purposes of this Agreement, the following definitions shall apply:

" **Captisol** " means sulfobutylether β (beta) cyclodextrin, sodium salt. CyDex supplies a uniquely modified form of such material under the Captisol® brand, manufactured in accordance with the Specifications, which, for the sake of clarity, includes Clinical Grade Captisol and Commercial Grade Captisol. For avoidance of doubt: the uniquely modified form of such material supplied by CyDex under the Captisol® brand shall be deemed to be included among the substances/products which are within the defined term "Captisol."

" **Clinical Grade Captisol** " means Captisol® brand sulfobutylether β (beta) cyclodextrin, sodium salt which (a) has been manufactured in accordance with the Specifications under GMP conditions, (b) is intended for use in humans, and (c) is intended for clinical trials for the Licensed Products.

" **Commercial Grade Captisol** " means Captisol® brand sulfobutylether β (beta) cyclodextrin, sodium salt which (a) has been manufactured in accordance with the Specifications under GMP conditions, (b) is intended for use in humans, and (c) is intended for commercial sale of the Licensed Products. For the sake of clarity, engineering and regulatory qualification batches of Licensed Products shall be deemed "Commercial Grade Captisol" batches.

"Commercial Grade Shortfall " shall have the meaning defined in **Section 4.2** .

" **Defect** " and " **Defective** " shall have the meanings defined in **Section 3.6(b)** .

" **Detailed Forecast** " shall have the meaning defined in **Section 3.2** .

" **First Commercial Order Date** " shall have the meaning defined in **Section 3.2** .

" **GMP** " means requirements for the quality system under which drug products and their ingredients are manufactured under conditions of current good manufacturing practices for bulk excipients as pursuant to the Federal Food, Drug, and Cosmetic Act and consistent with regulatory guidance, standards or directives, as applicable and as set forth in U.S. Pharmacopeia <1078> as of the Effective Date or any successor thereto.

" **Latent Defect** " shall have the meaning defined in **Section 3.6(c)** .

" **Minimum Remaining Shelf Life** " means with respect to Captisol, a remaining shelf life of at least two years.

" **Permitted Purchaser Requirements** " means the requirements during the Term of all Permitted Purchasers for sulfobutylether β (beta) cyclodextrin, sodium salt in connection with the Licensed Products.

" **Permitted Purchasers** " means, collectively: (a) Company; (b) Affiliates of Company; (c) Sublicensees of Company; and (d) all Contract Manufacturers for Company, Affiliates of Company and Sublicensees permitted in accordance with the License Agreement.

" **Purchase Volume Limitations** " shall have the meaning defined in **Section 3.3** .

" **Q1** ", " **Q2** ", " **Q3** " and " **Q4** shall have the meanings defined in **Section 3.2** .

" **Quality Agreement** " means a formal agreement between CyDex and Company that sets forth the quality expectations, responsibilities, rights (including, as applicable and agreed upon, audit requirements) and quality measures and good manufacturing practices relating to the manufacture and supply of Captisol to assure drug quality, safety and efficacy consistent with FDA guidance or equivalent foreign regulatory authority requirements for Quality Agreements. Any such agreement may be amended from time to time by written agreement between the Parties.

" **Specifications** " means the specifications for Captisol set forth in ***Exhibit B*** hereto, as such may be amended from time to time pursuant to **Section 3.10** .

" **Term** " shall have the meaning defined in **Section 6.1** .

" **Testing Methods** " shall have the meaning defined in **Section 3.6(a)** .

" **Third-Party Manufacturer** " shall have the meaning defined in **Section 2.3** .

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In addition, any capitalized terms not separately defined herein, including " **Affiliate** ", " **Application** ", " **Confidential Information** ", " **Contract Manufacturer** ", " **DMF** ", " **FDA** ", " **Li censed Product** ", " **Major Market** ", " **Party** ", " **Sublicensee** ", " **Study** " and " **Third Party** " shall have the respective meanings defined in the License Agreement.

2. PURCHASE AND SUPPLY OF CAPTISOL.

2.1 Purchase Commitment. Subject to the provisions of this Agreement and during the Term of this Agreement, Company agrees that Company, on behalf of itself and the other Permitted Purchasers, shall purchase from CyDex and CyDex shall supply 100% of the Permitted Purchaser Requirements during the Term. Company and the other Permitted Purchasers shall not have the right to manufacture (or have manufactured on their behalf) under any CyDex intellectual property rights, Captisol, without CyDex's prior written consent.

2.2 Supply Commitment. CyDex agrees that CyDex shall produce (or have produced for it as set forth in **Section 2.3**), sell, supply and deliver to Company and the other Permitted Purchasers 100% of the Permitted Purchaser Requirements during the Term, subject to the provisions of this Agreement. CyDex shall only be required to sell the Permitted Purchaser Requirements for Captisol pursuant to this Agreement. Company shall place orders for Captisol on behalf of itself and/or the other Permitted Purchasers, and shall directly pay to CyDex all amounts payable with respect thereto. CyDex does not grant Company or any other Permitted Purchaser the right to manufacture (or have manufactured on their behalf) under any CyDex intellectual property rights, Captisol.

2.3 Third-Party Manufacturers. Without limiting or relieving CyDex's responsibilities and/or obligations under this Agreement, CyDex may, upon written notice to Company, satisfy its supply obligations to Company hereunder either in whole or in part through arrangements with Third Parties engaged by CyDex to perform services or supply facilities or goods in connection with the manufacture or testing of Captisol (each, a " **Third-Party Manufacturer** "). CyDex shall and hereby does guarantee the performance of all Third-Party Manufacturers and shall promptly notify Company of the name and other relevant information of any Third-Party Manufacturer intended to be used by CyDex to satisfy its supply obligations of Captisol to any Permitted Purchasers hereunder. CyDex shall and hereby does represent and warrant that such Captisol shall meet and satisfy all of the obligations and requirements for supply of Captisol to Company pursuant to this Agreement, including without limitation, meeting the Specifications as set forth in ***Exhibit B*** and the Minimum Remaining Shelf Life and have been manufactured in accordance with all applicable laws and regulations, including under conditions of GMP and under the same DMF and manufacturing processes properly referenced in Company's Applications. The Parties hereby agree that The Hovione Group is an approved Third-Party Manufacturer as of the Effective Date of this Agreement, and unless otherwise instructed by CyDex, Company shall reference The Hovione Group's manufacturing processes with respect to Captisol, and no others, in Company's Applications.

2.4 Restrictions. Company covenants and agrees that: (a) all Captisol supplied by CyDex pursuant to this Agreement shall be used only in Licensed Products, including, without limitation, the development, approval and manufacture of Licensed Products (provided, however, that Company may separately use Captisol for testing, product research, Study and pre-clinical or clinical development of Licensed Products, for such purposes and/or requirements arising under or in

regards to applicable law (including, without limitation, the Food, Drug and Cosmetics Act, in each instance as may be required by Company, Permitted Purchasers and/or the FDA or equivalent foreign regulatory authorities or governmental agencies in connection with Licensed Products); (b) Company shall obtain the written agreement (for the express benefit of CyDex) of each Permitted Purchaser to, among other things, not resell Captisol as a standalone product and only use Captisol in accordance with (a) above; (c) Company shall not make or have made, and shall not permit any other Permitted Purchaser to make or have made, Captisol; and (d) Company and its Affiliates shall not sell, deliver or transfer to anyone any Captisol supplied by CyDex pursuant to this Agreement, except to the extent it is incorporated into a Licensed Product or is otherwise expressly permitted in this Section or elsewhere in this Agreement and/or in the License Agreement.

3. SUPPLY TERMS.

3.1 Long-Term Forecast. Company shall use reasonable efforts to provide to CyDex, at least one year before the date on which Company anticipates issuing its first purchase order to CyDex for Commercial Grade Captisol (the " **First Commercial Order Date** "), a non-binding forecast setting forth Company's estimate of the required quantities of Commercial Grade Captisol for each of the following two years. Such non-binding long-term forecast shall thereafter be updated by Company at least once every 12 months.

3.2 Binding Detailed Forecast. At least one calendar quarter before the First Commercial Order Date, Company shall provide to CyDex a detailed rolling forecast setting forth Company's requirements (inclusive of all Permitted Purchaser Requirements) and anticipated delivery schedules for Commercial Grade Captisol for each calendar quarter during a 12 month period (the " **Detailed Forecast** ") which includes the calendar quarter in which the First Commercial Order Date is to occur and the three following calendar quarters. For purposes of this Agreement, a calendar quarter means the consecutive three month period ending March 31, June 30, September 30, and December 31, respectively. The Detailed Forecast shall thereafter be updated by Company quarterly on a rolling basis, no later than the first day of each calendar quarter, so that in each calendar quarter CyDex shall have been provided with a rolling Detailed Forecast for each calendar quarter during the 12 month period commencing on the first day of the next calendar quarter following the date on which such Detailed Forecast is submitted. The Detailed Forecast shall be firm and binding on Company, subject to the permissible variances set forth in **Section 3.3** below, with respect to the first, second and third calendar quarters covered by such updated Detailed Forecast (**"Q1"** , " **Q2** ", " **Q3** ", respectively, and where the fourth calendar quarter shall be " **Q4** "). Q4 of such Detailed Forecast shall not be binding and shall be provided for the sole purpose of planning; provided, that if Company fails to provide any updated Detailed Forecast in accordance with this **Section 3.2** , the Detailed Forecast last provided by Company shall be deemed to be Company's binding Detailed Forecast (in the subsequent time period when no Detailed Forecast was provided), with the prior Q4 forecasted quantity and timing being the new Q3 forecasted quantity and timing, the prior Q3 forecasted quantity and timing being the new Q2 forecasted quantity and timing and the prior Q2 forecasted quantity and timing being the new Q1 forecasted quantity and timing, and with the same quantity and timing as had been forecasted (or deemed to be forecasted) for the Q4 of the prior Detailed Forecast being repeated as the forecasted quantity and timing for the new Detailed Forecast's Q4.

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3.3 Detailed Forecast Variances. Each updated Detailed Forecast may modify the amount of Commercial Grade Captisol estimated in the previous Detailed Forecast in accordance with the following limitations (the " **Purchase Volume Limitations** "):

(a) for the Q1 covered by such updated Detailed Forecast, no change in excess of a ***% volume increase or decrease may be made to the forecast provided for the Q2 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

(b) for the Q2 covered by such updated Detailed Forecast, no change in excess of a ***% volume increase or decrease may be made to the forecast provided for the Q3 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(c) for the Q3 covered by such updated Detailed Forecast, no change in excess of a ***% volume increase or decrease may be made to the forecast provided for the Q4 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

3.4 Supply.

(a) **Purchase Orders.** Together with each Detailed Forecast provided under **Section 3.2** , Company shall place a firm purchase order with CyDex, for Company's order of Commercial Grade Captisol for Q1 of the concurrent Detailed Forecast for delivery consistent with the Detailed Forecast. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (*i.e.* , Commercial Grade Captisol or Clinical Grade Captisol); (ii) quantities; (iii) delivery dates; and (iv) reasonable shipping instructions and packaging requirements. Any firm purchase order for Captisol, to the extent it does not request more or less than the Purchase Volume Limitations (in the case of Commercial Grade Captisol ordered) nor request a delivery date less than 60 nor more than 100 days after the date of such purchase order (in the case of any grade of Captisol ordered), shall be deemed accepted by CyDex upon receipt by CyDex. With respect to quantities of Commercial Grade Captisol ordered pursuant to such purchase order that exceed the Purchase Volume Limitations, CyDex shall not be obligated to accept the excess portion of such purchase order but nevertheless shall use commercially reasonable efforts to fill such orders for such excess quantities. If CyDex, despite the use of commercially reasonable efforts, is unable to supply as requested such quantities that exceed the Purchase Volume Limitations for Commercial Grade Captisol, such inability to supply shall not be deemed for any purpose to be a breach of this Agreement by CyDex or an inability by CyDex to supply. If CyDex does supply any or all of the excess requested quantity, Company shall be required to take and pay for the entire quantity so supplied. CyDex shall use commercially reasonable Efforts to notify Company as soon as possible, but no less than within 14 days, after its receipt of a purchase order of its expectation regarding its ability to fill any amounts of such order that are in excess of the Purchase Volume Limitation for Commercial Grade Captisol. If any purchase order or other document submitted by a Party hereunder or any other document passing between the Parties contains terms or conditions in addition to or inconsistent with the terms of this Agreement, the terms of this Agreement shall control and prevail and the Parties hereby agree that such additional or inconsistent terms shall simply be ignored and deemed not to exist, unless they are expressly identified as being additional to or inconsistent with this **Section 3.4** and are signed by officers of both Parties.

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(b) **Safety** Stock. CyDex ***. CyDex shall keep Company reasonably informed of the level of inventory identified as the safety stock and shall notify Company in the event any deliveries to Company deplete safety stock levels.

3.5 Delivery. Subject to **Section 3.4(a)** , CyDex shall deliver (or have delivered by any Third-Party Manufacturers approved pursuant to the provisions of **Section 2.3** above) the quantities of Captisol defined in any accepted purchase order. Unless otherwise agreed in writing by the Parties, Captisol shall be delivered CPT (Incoterms 2010) CyDex's production point or storage facilities. Title and risk of loss and/or damage to Captisol shall pass to Company upon delivery of Captisol to Company at CyDex's production point or storage facilities. Company acknowledges the inherent risk that a batch of Captisol may be lost in production or shipment, and Company shall use commercially reasonable efforts to maintain a sufficient inventory of Captisol in the event of late delivery by CyDex. Quantities actually delivered to Company pursuant to an accepted purchase order may vary from the quantities reflected in such purchase order by up to 5% and still be deemed to be in compliance with such purchase order; provided, however, that Company shall only be invoiced and required to pay for the quantities of Captisol that Company actually ordered and CyDex actually delivered to Company. CyDex shall, if requested by Company, include in the next shipment of Captisol to Company, any quantities ordered pursuant to an accepted purchase order but not previously delivered.

3.6 Quality Control; Acceptance and Rejection.

(a) **Quality Control** . The Parties shall, within 180 days after the Effective Date, negotiate in good faith and execute a mutually agreeable Quality Agreement. It is anticipated that the Quality Agreement would clearly describe and set forth the roles and responsibilities of the Parties with respect to quality activities, which shall be consistent with this Agreement. CyDex shall conduct or have conducted quality control testing of Captisol before shipment in accordance with the Quality Agreement, if any, the Specifications, all applicable laws and regulations, including without limitation, GMP and other CyDex-approved quality control testing procedures set forth in the DMF (the " **Testing Methods** "). CyDex shall retain or have retained accurate and complete records pertaining to such testing. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for the relevant lots of Captisol signed and dated by the authorized responsible quality control official of CyDex or its Third-Party Manufacturer.

(b) **Acceptance Testing.** Company shall have a period of *** days from the date of receipt to test or cause to be tested Captisol supplied under this Agreement, with an eye to possible rejection of the shipment. Company or its designee shall have the right to reject by notice to CyDex any shipment of Captisol that does not conform in all material respects with the Specifications, DMF, the Minimum Remaining Shelf Life, applicable laws and regulations, including GMP or is otherwise materially defective or materially not in compliance with the applicable purchase order (including any

packaging instructions set forth therein) or the terms of this Agreement at the time of delivery pursuant to **Section 3.5** when tested in accordance with the Testing Methods (such Captisol thereby having a " **Defect"** and upon proper rejection, deemed " **Defective** "). All shipments of Captisol shall be deemed accepted by Company unless CyDex receives written notice of rejection from Company within such *** day period describing the reasons for the rejection in reasonable detail. Once a delivery of Captisol is accepted or deemed accepted hereunder, Company shall have no recourse against CyDex in the event Captisol is subsequently deemed unsuitable for use for any reason, except as provided in Section 10.1 of the License Agreement or except in circumstances where the Defect is deemed a Latent Defect. In the case of a Latent Defect in a shipment of Captisol, Company shall not be permitted to revoke any prior actual or deemed acceptance of such shipment but shall have the other rights and remedies as set forth in this Agreement. It is understood that the terms "Defect" and "Defective" include matters observed before actual or deemed acceptance and all Latent Defects, but do not include matters falling outside the definition of Latent Defect because, e.g., they arise on or after the 180 th day after actual or deemed acceptance.

(c) **Latent Defects.** As soon as either Party becomes aware of any Defect in any Captisol lot which either (i) existed at the time of actual or deemed acceptance but was not discovered after a reasonable inspection or (ii) arose, before the 180 th day after actual or deemed acceptance, by no fault of any Permitted Purchasers (each such Defect, a " **Latent Defect** "), it shall promptly notify the other Party of such event (including reasonable details and the lot involved). If Captisol accepted by Company becomes non-conforming by virtue of the Latent Defect, Company may place the lot on quality assurance hold pending the further cooperative investigation by CyDex and Company and a final resolution of the claimed Latent Defect. In the event that such Captisol is found to contain a Latent Defect, such Captisol shall be deemed rejected as of the date of the notice, and the rights and obligations of the Parties with respect to the rejected Captisol shall thereafter be governed by the same process as governs acceptance testing set forth below.

(d) **Confirmation.** After its receipt of a notice of rejection or of Latent Defect from Company pursuant to **Section 3.6(b)** or **(c)** above, CyDex shall notify Company as soon as reasonably practical, and in no event later than 10 days after CyDex's receipt of Company's notice of rejection or of Latent Defect, whether it accepts Company's basis for rejection or Latent Defect and Company and CyDex shall cooperate in any further investigation of the rejected or questioned Captisol. If the Parties are unable to agree as to whether a shipment of Captisol supplied by CyDex or its Third-Party Manufacturer hereunder is Defective, such question shall be resolved in accordance with **Section 3.6(f)** .

(e) **Return or Destruction of Defective Shipments.** Company may not return or destroy any batch of Captisol until it receives written notification from CyDex that CyDex does not dispute that the batch or portion thereof is Defective, or independent testing pursuant to **Section 3.6(f)** confirms the Defective Captisol. CyDex shall indicate in its notice either that Company is authorized to destroy the rejected/Latent Defect batch of Captisol or that CyDex requires return of the rejected/Latent Defect Captisol. Upon written authorization from CyDex to do so, Company shall promptly destroy the rejected/Latent Defect batch of Captisol and provide CyDex with written certification of such destruction, or, if the request so states, Company shall promptly return the rejected/Latent Defect batch of Captisol to CyDex. In each case, CyDex shall reimburse Company for the documented, reasonable costs associated with the rejected/Latent Defect Captisol, including without limitation, storage, transport, destruction or return of the rejected/Latent Defect Captisol.

(f) **Independent Testing.** If there is a dispute as to whether any batch is Defective (including, as the case may be, whether it has a Latent Defect) or has been properly rejected, then the Parties shall designate a mutually acceptable Third Party laboratory to make a determination on such matter from a sample obtained from the questioned batch. The decision of the Third Party laboratory shall be binding on all Parties hereto and all expenses related to such Third Party investigation shall be borne by the Party found to have been mistaken. Should such Third Party laboratory confirm Company's claim, the batch shall be deemed to be Defective (including, as the case may be, that it has a Latent Defect) and (if it had been rejected) to have been properly rejected and may be returned or destroyed in accordance with CyDex's instructions.

(g) **Refund or Replacement.** Company shall not be required to pay any invoice with respect to any shipment of Captisol properly rejected or determined finally to have a Latent Defect pursuant to this **Section 3.6** . Nor shall such properly rejected/Latent Defect Captisol count against Company or Company Affiliates or in any way comprise a failure of Company or Company Affiliates to satisfy a Detailed Forecast, minimum purchase or other duties and obligations under this Agreement, the License Agreement or otherwise. Notwithstanding the foregoing, Company shall be obligated to pay in full for any rejected shipment of Captisol that is not subsequently determined to be Defective, irrespective of whether Company has already paid CyDex for a replacement shipment. If Company pays in full for a shipment of Captisol and subsequently properly rejects such shipment (or such shipment is determined finally to have a Latent Defect) in accordance with this **Section 3.6** , Company shall be entitled, upon confirmation that such shipment is Defective, at its election, either: (i) to a refund or credit equal to the purchase price, shipping costs and insurance paid with respect to such rejected shipment; or (ii) to require CyDex to replace such rejected/Latent Defect shipment with non-Defective Captisol at no additional cost to Company. Company acknowledges and agrees that, except for the indemnification obligations set forth in Section 10.1 of the License Agreement (to the extent applicable), Company's rights to a refund or credit for or to receive replacement of properly rejected shipments of Captisol hereunder shall be Company's sole and exclusive remedy, and CyDex's sole obligation, with respect to Defective or non-conforming Captisol delivered hereunder.

(h) **Exceptions.** Company's rights of rejection, return, refund and replacement set forth in this **Section 3.6** shall not apply to any Captisol that is Defective due to damage (i) caused by Company, its Affiliates or Permitted Purchasers or their respective employees or agents, including but not limited to misuse, neglect, improper storage, improper transportation or use beyond any dating provided or (ii) that occurs after delivery of such Captisol to the carrier at the point of delivery, including but not limited to any damage caused thereafter by accident, fire or other hazard; and CyDex shall have no liability or responsibility to Company with respect thereto.

3.7 Facilities and Inspections. CyDex shall permit, and shall use reasonable commercial efforts to induce each Third-Party Manufacturer to permit, a reasonable and limited number of Company's authorized representatives, during normal working hours and upon reasonable prior notice to CyDex but in no event less than 30 days' prior notice (subject to the Third-Party Manufacturer's consent to be reasonably sought by CyDex), to confidentially inspect for a reasonable and limited number of days that portion of all CyDex facilities utilized for the manufacture, preparation, processing, storage or quality control of Captisol or such facilities of any Third-Party Manufacturer, no more frequently than once per calendar year. Company's authorized representatives shall be accompanied by CyDex personnel (and, if the Third-Party Manufacturer so requests, Third-Party Manufacturer personnel) at all times, shall be qualified to conduct such manufacturing audits, and shall

comply with all applicable rules and regulations relating to facility security, health and safety. Company shall ensure that its authorized representatives conduct each manufacturing audit in such a manner as to not interfere with the normal and ordinary operations of CyDex or its Third-Party Manufacturer. Except as expressly set forth in this **Section 3.7** , Company, Permitted Purchasers and their respective employees or representatives shall not have access to CyDex's facilities or the facilities of any Third-Party Manufacturer.

3.8 Inability to Supply.

(a) **Additional Site .** CyDex may in its discretion seek to induce its current Third-Party Manufacturer to undertake and complete validation, qualification and regulatory approvals at its existing secondary site for the manufacture of Captisol (which CyDex confirms is, as of the date of this Agreement, validated and commercially manufacturing Captisol with a typical batch size on the order of 2500 kg) utilizing the same DMF, Specifications and manufacturing processes as utilized at its primary site.

(b) **Notice.** CyDex shall use commercially reasonable efforts to, within 14 days after CyDex's receipt of a purchase order from Company, notify Company if CyDex then knows it will be unable to supply at the scheduled delivery time any quantity of non-Defective Captisol ordered by Company.

(c) **Allocation.** If CyDex is unable to supply to Company and/or its Permitted Purchasers the quantity of non-Defective Captisol that CyDex is required to supply hereunder, CyDex shall (i) first *** safety stock *** (ii) allocate any remaining inventories of Captisol among Company and/or Permitted Purchasers and any other purchasers of Captisol with which CyDex then has an on-going contractual relationship, in proportion to the quantity of Captisol for which each of them has orders pending at such time, (iii) require its Third-Party Manufacturer to utilize both sites discussed in **Section 3.8(a)** (if available) for the supply of any shortfall amounts of Captisol and (iv) use commercially reasonable efforts to minimize supply delays.

3.9 Product Recalls. If any CyDex-supplied Captisol should be alleged or proven to be Defective, Company shall notify CyDex immediately, and both Parties shall cooperate fully regarding the investigation and disposition of any such matter. If (a) Company recalls any Licensed Product, or (b) the FDA or any equivalent Major Market regulatory body requires the recall of any Licensed Product, and in either case such recall is primarily due to any act or omission of CyDex in general or to the CyDex-supplied Captisol being Defective (either at the time of delivery or due to a Latent Defect), then CyDex agrees, upon substantiation thereof, to refund the purchase price for such Captisol and the costs incurred by Company for such recall. Company shall ensure that Permitted Purchasers maintain records of all sales of Licensed Product sufficient to adequately administer any such recall consistent with applicable laws and regulations.

3.10 Regulatory Status and Specifications.

(a) CyDex shall be solely responsible for maintaining the necessary approvals and authorizations for Captisol from applicable regulatory agencies or bodies, including updating and maintaining the DMF.

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(b) CyDex shall promptly notify Company on becoming aware of any matters that are likely to affect adversely the regulatory status of Captisol or the ability of CyDex to supply Captisol in accordance with the terms of this Agreement.

(c) Except as set forth herein, CyDex may, at its sole cost and expense, after at least two months' prior written notice to Company, make reasonable, non-material changes to the Specifications or the manufacturing process for Captisol® without Company's prior written consent, provided such changes do not (i) require Company to conduct additional process validation or stability testing, (ii) require Company to comply with additional clinical study requirements from the FDA or any equivalent Major Market regulatory authority that would be beyond that required for the Licensed Products formulated with Captisol meeting the unmodified Specifications/ manufacturing process, (iii) delay Company's development or the FDA's or equivalent foreign Major Market regulatory authority's approval of a Licensed Product, (iv) negatively affect the solubility, stability, shelf life, safety, or efficacy of a Licensed Product, or (v) in any Major Market affect the regulatory status of any Licensed Product or require any material additional regulatory filings and/or approvals. In addition, CyDex may, after at least *** months' prior written notice to Company, make changes to the Specifications or the manufacturing process for Captisol® without Company's prior written consent, even if such changes (i) require Company to conduct additional process validation or stability testing, (ii) require Company to comply with additional clinical study requirements from the FDA or any equivalent Major Market regulatory authority that would be beyond that required for the Licensed Products formulated with Captisol meeting the unmodified Specifications/ manufacturing process, (iii) delay Company's development or regulatory approval of a Licensed Product, (iv) negatively affect the solubility, stability, shelf life, safety, or efficacy of a Licensed Product, and/or (v) affect the regulatory status of any Licensed Product or any additional regulatory approvals. CyDex shall provide Company with an opportunity to evaluate and comment upon the reasonableness of any proposed change to the Specifications or the manufacturing process for Captisol®. In the event of any permitted change to the Specifications or the manufacturing process for Captisol® effected by CyDex hereunder, CyDex shall nonetheless continue to provide Company with Captisol under the unmodified Specifications and manufacturing process under the terms of this Agreement until such time that Company has obtained any and all required approvals for the Specification change or the manufacturing process, as applicable, for Captisol by the FDA and other equivalent Major Market regulatory agencies or bodies (but only for so long as Company has used commercially reasonable efforts to pursue all required approvals for the Specification change or the manufacturing process, as applicable, from the FDA and other applicable equivalent Major Market regulatory agencies or bodies).

(d) In the event that the FDA or another applicable equivalent Major Market regulatory authority having jurisdiction requires Company to implement any changes to the Specifications or the manufacturing process for Captisol, CyDex shall make all such changes required by the FDA or other applicable Major Market regulatory authority. In the event Company desires to change (including to narrow any ranges within) the Specifications or the manufacturing process for Captisol® and CyDex elects in its sole discretion to accommodate such desire, CyDex shall make all such changes requested by Company. CyDex shall promptly advise Company as to any lead-time changes or other terms that may result from a change to the Specifications or the manufacturing process for Captisol. (In such a case, the Parties shall negotiate in good faith and mutually agree upon amended lead-times and any other provisions which may require amendment as a result of such change, as evidenced by an amendment to this Agreement.) Company shall bear the costs including the costs CyDex actually incurred for materials already purchased expressly for Company, its Affiliates or

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Sublicensees which cannot be sold to a Third Party and are rendered unusable by a change in Specifications or the manufacturing process for Captisol requested by Company and agreed to by CyDex.

(e) The Parties shall use commercially reasonable efforts to cooperate with each other in order to carry out the intent and purposes of this **Section 3.10** . In addition to the rights set forth above, before any change in any of the Specifications or the manufacturing process for Captisol (other than a change required by the FDA or another applicable regulatory authority having jurisdiction), Company shall have the right to make a one-time bulk purchase of Captisol (in addition to any amounts previously forecast) pursuant to a separately issued purchase order and CyDex shall use commercially reasonable efforts to accommodate and deliver the same in a reasonably timely manner.

3.11 Regulatory Authority Inspections . CyDex agrees to reasonably cooperate with all requests by the FDA and any other relevant regulatory authority to conduct inspections of any and all facilities related to the manufacture of Captisol, which the FDA and any other relevant regulatory authority requires and CyDex agrees to reasonably cooperate with the FDA and any other relevant regulatory authority in connection with such inspections.

3.12 Orders of Clinical Grade Captisol . During or before Company's clinical development of any Licensed Product: (a) Company may provide CyDex with purchase orders from time to time as needed for Clinical Grade Captisol, and (b) CyDex shall accept and fulfill all such purchase orders for Clinical Grade Captisol, provided that such purchase order is consistent with the terms of **Section 3.4(a)** . **Sections 3.4, 3.5** and **3.6** shall apply to such order.

4. COMPENSATION.

4.1 Pricing. The purchase prices for Captisol pursuant to this Agreement are as specified in ***Exhibit A*** . CyDex reserves the right to increase such purchase prices set forth in ***Exhibit A*** on each January 1 during the Term, upon not less than 30 days' prior written notice to Company, by a percentage equal to the aggregate percentage increase, if any, in the Producer Price Index, Pharmaceutical Preparation Mfg - pcu325412325412 PCU as reported by the Bureau of Labor Statistics, U.S. Department of Labor, for the 12 month period ending October 31 of the prior year, subject to an annual cap of three percent (3%). In addition, CyDex reserves the right to, upon not less than five days' prior written notice to Company, decrease such purchase prices at any time to any lower price selected by CyDex, provided that if CyDex does so it shall also have the right to at any time, upon not less than 30 days' prior written notice to Company, increase such purchase prices back to the original prices from which the decrease occurred, or to any in-between prices; and in the event of such an increase pursuant to this sentence, CyDex shall have the right to make annual increases thereafter (from such increased price point) pursuant to the preceding sentence.

4.2 Shortfall Reimbursement (Take or Pay). If Company fails to order (pursuant to and in compliance with **Article 3**) for the Q1 of any Detailed Forecast a quantity of Commercial Grade Captisol to be delivered during such Q1 (or within 100 days after the firm purchase order is placed) that is equal to or greater than the quantity of Commercial Grade Captisol Company is obligated to purchase pursuant to the applicable Detailed Forecast (the difference between the quantity of Commercial Grade Captisol Company is obligated to purchase in Q1 pursuant to the applicable

Detailed Forecast and the amount of Commercial Grade Captisol that Company actually orders for delivery in Q1 (or within 60 days after the firm purchase order is placed), the " **Commercial Grade Shortfall** "), then Company shall, at its option upon notice to CyDex, either (a) pay CyDex 60% of the purchase price hereunder for the Commercial Grade Shortfall amount and in such case shall not be entitled to receive delivery of such Commercial Grade Shortfall amount or (b) pay CyDex 100% of the purchase price hereunder for the Commercial Grade Shortfall amount and in such case shall be entitled to receive delivery of such Commercial Grade Shortfall amount upon request during the Term (but such delivery shall not count toward satisfying the Purchase Volume Limitations minimum quantity applicable, at the time of actual delivery, for such subsequent quarter). In either event, such payment must be made within 20 days after the end of the Q1. This **Section 4.2** is based on the time stated for delivery in the original order, as opposed to the time delivery is actually made.

4.3 Payments; Taxes. All amounts due hereunder are stated in, and shall be paid in, U.S. Dollars. Payment of CyDex's invoices shall be made, except to the extent disputed in good faith, within 30 days after Company's receipt of such invoices. The purchase prices for Captisol® specified in ***Exhibit A*** exclude and shall, as far as legally possible, be paid in full to CyDex without reduction for all applicable sales, use, and other taxes and duties applicable to Company and/or in respect of the transactions contemplated by this Agreement, and Company shall be responsible for payment of all such taxes (other than taxes based on CyDex's income), fees, duties, and charges, and any related penalties and interest, arising from the payment of amounts due hereunder. If any amount due hereunder and not subject to a reasonable, good-faith dispute by Company remains outstanding for more than 30 days after its due date, CyDex may, in addition to any other rights or remedies it may have, refuse to ship Captisol hereunder except upon payment by Company in advance.

5. REPRESENTATIONS AND WARRANTIES.

5.1 Limited Warranty. CyDex covenants and warrants solely to Company that:

(a) All Captisol sold to Company pursuant to this Agreement shall conform to the respective Specifications (as applicable for Clinical Grade Captisol or Commercial Grade Captisol), the DMF, the Minimum Remaining Shelf Life and all applicable laws, including GMP, at the time of delivery and shall not, before the 180th day after actual or deemed acceptance, be subject to any Latent Defects;

(b) All Captisol sold to Company pursuant to this Agreement shall, to CyDex's knowledge, not infringe any patent or other proprietary right of any Third Party;

(c) CyDex, its Affiliates and its Third-Party Manufacturers are not a debarred entity and have not used and will not use in any capacity the services of any individual or entity debarred under 21 U.S.C. §335(a) or (b) of the Federal Food, Drug and Cosmetic Act in connection with its obligations hereunder;

(d) To CyDex's knowledge, CyDex, its Affiliates and its Third-Party Manufacturers hold, and are operating in material compliance with, all permits, licenses, franchises, authorizations and clearances of the FDA and/or any other Major Market regulatory authority (including without limitation all applicable health, safety and environmental permits) related to Captisol and the manufacture and sale thereof, necessary for CyDex to carry out its obligations and for Company to exercise its rights under this Agreement and the License Agreement, except where the

failure to so hold or be so operating does not have and would not reasonably be expected to have a material adverse effect on (i) CyDex and/or its ability to supply Captisol to Company hereunder and/or (ii) Company and/or its ability to obtain Captisol hereunder and/or exploit Licensed Products; and

(e) CyDex does not know of any actual or threatened enforcement actions relating to the manufacture and/or supply of Captisol against CyDex, its Affiliates or its Third-Party Manufacturers by the FDA or any other federal, state or Major Market regulatory authority.

5.2 Representations to the Other Party. The provisions of Section 9.1 (Mutual Representations and Warranties) of the License Agreement are incorporated herein by reference as if fully set forth herein, with references therein to "this Agreement" being understood to refer to this Supply Agreement rather than to the License Agreement.

5.3 Representations to Other Persons. Company shall be solely responsible for all representations and warranties that Company or its Affiliates make to any Permitted Purchaser or to any direct or indirect customer of Licensed Products.

6. TERM AND TERMINATION.

6.1 Term. The term of this Agreement (the " **Term** ") shall commence on the Effective Date and, unless terminated earlier as set forth herein, shall continue until the earlier of (a) termination or expiration of the License Agreement; or (b) if CyDex decides to stop the manufacture of Captisol, after CyDex provides one year prior written notice to Company of its intent to terminate this Agreement because it has decided to stop the manufacture of Captisol. In the event of a termination under **Section 6.1(b)** , CyDex shall use good faith efforts in cooperation with Company to enable an alternative supplier of Captisol for the Permitted Purchasers.

6.2 Effect of Termination. Upon the termination of this Agreement, (a) Company shall no longer have any rights to order Captisol from CyDex; and (b) each Party shall promptly return all relevant records and materials in its possession or control containing the other Party's Confidential Information with respect to which the former Party does not retain rights hereunder; *provided, however* , that each Party may retain (i) one archival copy (and such electronic copies that exist as part of the receiving Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement and (ii) any archival copy that this Party is required to keep by applicable regulations.

6.3 Survival . Notwithstanding any other provisions of this Agreement, any liability or obligation of either Party to the other for acts or omissions before the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. **Sections 1** (Definitions) **2.4** (Restrictions), **3.5** (Delivery), **3.6** (Quality Control; Acceptance and Rejection), **3.7** (Facilities and Inspections), **3.9** (Product Recalls), **4.3** (Payments; Taxes), **5.2** (Representations, Warranties), **5.3** (Disclaimer), **6.2** (Effect of Termination), **6.3** (Survival), **6.4** (Accrued Obligations) and **7** (General Provisions) shall survive termination or expiration of this Agreement. In the event that termination of this Agreement is as a result of nonpayment by Company of an obligation owing to CyDex, CyDex shall have the option, in its discretion, either to cancel all outstanding Captisol orders properly made before and pending at the time of termination or to honor and enforce all outstanding Captisol orders properly made before and pending at the time of termination.

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6.4 Accrued Obligations . Termination of this Agreement shall not relieve either Party of any liability which has accrued before the effective date of such termination (e.g., sums due in respect of Captisol supply), nor prejudice either Party's right to obtain performance of any obligations that are expressly indicated or obviously intended to survive termination.

7. GENERAL PROVISIONS.

The following **Sections** of the License Agreement are incorporated into this Agreement by this reference as if fully set forth herein, with references therein to "this Agreement" being understood to refer to this Supply Agreement rather than to the License Agreement: 4.2 (Taxes), 4.3 (Payments), 7.3 (Material Safety), 7.4 (Adverse Event Reporting), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification), 11 (Limitation of Liability), 12 (Management of Intellectual Property), 13.3 (Termination for Breach), 13.4 (Termination for Bankruptcy) and 14 (General Provisions).

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

CYDEX PHARMACEUTICALS, INC.

By: /s/ Matthew W. Foehr

Name: Matthew W. Foehr

Title: President and Chief Operating Officer

MARINUS PHARMACEUTICALS, INC.

By: /s/ Christopher M. Cashman

Name: Christopher M. Cashman

Title: Chief Executive Officer

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EXHIBIT A

PURCHASE PRICES FOR CAPTISOL

All prices are CPT (Incoterms 2010) CyDex's production point or storage facilities.

All prices exclude shipping and insurance .

Grade of Captisol	Price per Kg	
***	$	***
***	$	***

Such prices are subject to adjustment pursuant to ***Section 4.1*** .

All orders are subject to a minimum order size of 20 kg.

* * * * *

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EXHIBIT B: SPECIFICATIONS

[... *** ...]