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

FORM 10-Q/A
Amendment No. 1

☒ **Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**

For the quarterly period ended June 30, 2011

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Transition Period From _____ to _____ .
Commission File Number: 001-33093

LIGAND PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**77-0160744**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3911 Sorrento Valley Boulevard, Suite 110 San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 550-7500
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large Accelerated Filer	☒	Accelerated Filer	☐
Non-Accelerated Filer	☐ (Do not check if a smaller reporting company)	Smaller Reporting Company	☐
Emerging Growth Company	☐		

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 1, 2011, the registrant had 19,673,100 shares of common stock outstanding.

EXPLANATORY NOTE

Ligand Pharmaceuticals Inc. ("Ligand" or the "Company") is filing this Amendment No. 1 on Form 10-Q/A (the "Amendment") to its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2011 (the "Original Form 10-Q"), originally filed with the Securities and Exchange Commission (the "Commission") on August 8, 2011, in response to comments received from the Commission in connection with a request for confidential treatment of certain portions of Exhibit 10.27 to the Original Form 10-Q. Item 6 of Part II of the Original Form 10-Q is hereby amended to include an Exhibit Index and a revised redacted version of Exhibit 10.27, which is being filed herewith. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are filed as exhibits to this Amendment.

Except as described above, no other changes have been made to the Original Form 10-Q. This Amendment speaks as of the original filing date of the Original Form 10-Q and does not reflect any events that occurred at a date subsequent to the filing of the Original Form 10-Q or modify or update those disclosures therein in any way.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description
10.27†	Supply Agreement dated June 13, 2011 by and between CyDex and Merck
31.3	Certification by Principal Executive Officer, Pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.4	Certification by Principal Financial Officer, Pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and submitted separately to the Securities and Exchange Commission.

SIGNATURES

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

Date: November 1, 2017

By: /s/ Matthew Korenberg

Matthew Korenberg
Vice President, Finance and Chief Financial Officer
Duly Authorized Officer and Principal Financial Officer

Exhibit 10.27

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "**Agreement**") is made this 13th day of June, 2011 (the " **Effective Date**") between:

CYDEX PHARMACEUTICALS, INC., a Delaware corporation with offices at 10513 W. 84 th Terrace, Lenexa, Kansas 66214 ("**CyDex**"); and

MERCK SHARP & DOHME CORPORATION , a New Jersey corporation with offices at One Merck Drive, Whitehouse Station, NJ 08889-0100 ("**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 worldwide licensee of Captisol (defined below), a sulfobutylether β-cyclodextrin which is protected by certain patents and designed to enhance the solubility and stability of drugs;

WHEREAS, Company desires to obtain a comprehensive license to use Captisol in connection with its development and commercialization of the Compound (defined below) and CyDex is willing to grant such license to Company under the terms and conditions set forth herein; and

WHEREAS, CyDex desires to sell Captisol to Company, and Company desires to purchase Captisol from CyDex for use in the Licensed Product (defined below), in accordance with the terms and conditions contained herein;

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

DEFINITIONS.

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

"**Affiliate**" means any entity directly or indirectly controlling, controlled by or under common control with a party, control being the direct or indirect ownership of at least fifty percent (50%) of the stock or other equity interest entitled to vote upon election of directors or persons performing similar functions.

"**cGMPs**" means current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packing and holding of pharmaceutical excipients, all as set forth from time to time by the U.S. Pharmacopoeia General Chapter <1078> Good Manufacturing Practices For Bulk Pharmaceutical Excipients and International Pharmaceutical Excipients Council's IPEC/PQG GMP Guide For Pharmaceutical Excipients, and any successors thereto.

"**Captisol**" means a sulfobutylether β-cyclodextrin as specified in ***Exhibit B*** hereto.

"**Captisol Data Package**" means (a) all toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates; and (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), in each case on Captisol alone (and not in conjunction with a product formulation).

"**Captisol Improvement**" means any technology or improvement related to Captisol, whether or not patentable, that is developed during the Term by Company or its Affiliates or Sublicensees, solely or jointly with a third party through use of Captisol supplied hereunder. Captisol Improvement shall not include any Captisol Information. For the avoidance of doubt, Captisol Improvement shall not include any technology or improvement related to Captisol, whether or not patentable, that was developed before the Term by CyDex or its Affiliates, solely or jointly with Company, its Affiliates or a third party.

"**Captisol Information**" means any information solely related to Captisol that is developed during the Term by Company or its Affiliates or Sublicensees, solely or jointly with a third party, that would enhance a drug master file for Captisol if incorporated therein.

"**Captisol Patents**" means the patents and patent applications (until such time as such applications or any of them are denied, abandoned or issued into patents), and any foreign cognates, divisional, continuation, continuation-in-part, reissue, re-examination, extension, renewal, substitution, patent of addition, provisional applications, confirmation patent, registration patent, pipeline protection or supplementary protection certificate related thereto, that include at least one claim relating to the composition, use in the relevant Product or manufacture of a cyclodextrin, which at any time during the Term are owned by CyDex or under which CyDex is licensed with the right to sublicense, *excluding, however,* the Restricted Patent Rights.

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

"**Clinical Grade Captisol**" means Captisol which (a) has been manufactured under conditions of cGMPs, (b) is intended for use in humans, and (c) is intended for clinical trials for

the Licensed Product. For clarity, Clinical Grade Captisol shall meet the specifications set forth in ***Exhibit B***.

"**Commercial Grade Captisol**" means Captisol which (a) has been manufactured under conditions of cGMPs, (b) is intended for use in humans, and (c) is intended for commercial sale of the Licensed Product. For clarity, Commercial Grade Captisol shall meet the specifications set forth in ***Exhibit B***.

"**Commercial Launch Date**" means, in any particular country, the first sale by Company, its Affiliates or Sublicensees of the Licensed Product.

"**Compound**" means that certain pharmaceutical compound known as posaconazole, owned by or licensed to Company and developed and manufactured by or on behalf of Company.

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

"**Detailed Forecast**" has the meaning specified in **Section 3.2(b)**.

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

"**DMF**" means a Drug Master File 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.

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

"**Generic Competition**" has the meaning specified in **Section 4.1(c)(ii)** hereof.

"**IND**" means an Investigational New Drug application, 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.

"**Indemnitee**" has the meaning specified in **Section 10.4**.

"**Indemnitor**" has the meaning specified in **Section 10.4**.

"**LCUA**" means that certain Limited Clinical Use Agreement between CyDex and Schering Corporation effective April 17, 2008, as amended.

"**Laws**" means all applicable federal, state, local or foreign statute or law and shall be deemed also to include all rules and regulations promulgated thereunder by any regulatory authorities in the Territory, unless context requires otherwise. With respect to cGMPs, Laws shall also include guidance documents formally promulgated by the governmental agency with jurisdiction over the manufacture of Captisol. Any reference to a particular law or regulation will be interpreted to include any revision of or successor to such statute, law, rule or regulation regardless of how it is numbered or classified.

"**Licensed Product**" means a human drug product which is formulated as a combination of the active pharmaceutical ingredient posaconazole and Captisol. For clarity, the Licensed Product

shall not include any product which is a combination product incorporating the Compound with any other active pharmaceutical ingredient.

"**Losses**" has the meaning set forth in **Section 10.1**.

"**Marketing Approval**" means final approval of an NDA by the FDA for the United States, or 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 or mutual recognition), including all required marketing, pricing or reimbursement approvals.

"**NDA**" means a New Drug Application, 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.

"**Notice of Default**" has the meaning specified in **Section 13.2**.

"**Notice of Termination**" has the meaning specified in **Section 13.2**.

[***].

"**Purchase Volume Limitations**" has the meaning specified in **Section 3.2(c)**.

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

"**Restricted Patent Rights**" shall mean the [***], as set forth in ***Exhibit D***.

"**Q1**", "**Q2**, "**Q3**", and "**Q4**" have the meanings specified in **Section 3.2(b)**.

"**Research Grade Captisol**" means Captisol which has not been manufactured under required conditions of cGMPs and is not suitable for use in humans, but which meets CyDex's specifications for Research Grade Captisol.

"**SEC**" has the meaning specified in **Section 8.3**.

"**Specifications**" means the specifications for Captisol set forth in ***Exhibit B*** hereto, as such may be amended from time to time pursuant to **Section 3.4**.

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

"**Sublicensees**" means parties to whom Company and/or its Affiliates has sublicensed rights granted to Company and/or its Affiliates under this Agreement, as permitted under this Agreement.

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

"**Testing Methods**" has the meaning specified in **Section 3.5(a)**.

"**Third-Party Manufacturer**" has the meaning specified in **Section 3.6**.

"**Territory**" means the entire world, *excluding, however,* any country during such time that a Restricted Patent Right is valid and enforceable in such country, as follows: [***]

"**Volume Threshold**" has the meaning specified in **Section 3.1**.

GRANT OF RIGHTS.

2.1 License Grants from CyDex to Company.

(a) Licenses. Subject to the terms and conditions of this Agreement, during the Term, CyDex hereby grants to Company and its Affiliates:

(i) an exclusive license in the Territory, even with respect to CyDex, under the Captisol Patents, with right to sublicense (subject to **Sections 2.3** and **2.4)**, to make, use, sell, offer to sell, promote, market, distribute, package, import, export, develop, test, study and otherwise commercially exploit any Licensed Product and otherwise engage in activities relating to the regulatory approval of any Licensed Product; and

(ii) a non-exclusive, worldwide license under CyDex's right in and to:

(A) all Captisol related toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates;

(B) all Captisol related 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); and

(C) any drug master file related to Captisol;

to engage in any activity related to regulatory approval of any Licensed Product. CyDex shall deliver to Company, or provide Company access to, the information and files described in (A), (B) and (C) above at Company's request, which Company may use within the scope of the license.

(b) Scope of Licenses. For the avoidance of doubt, Company shall have no license to the Captisol Patents outside of the Territory and, except for activities deemed non-infringing of patents under national law, Company hereby agrees not to otherwise make, use, sell, offer to sell, promote, market, distribute, package, import, export, develop, test, study and otherwise commercially exploit any Licensed Product or Captisol in [***]. Without limiting the generality of the foregoing, CyDex grants no rights to Company to manufacture, import (except in association with supply of Captisol under this Agreement), sell or offer for sale bulk Captisol. CyDex represents and warrants to Company that the licenses granted under Section 2.1 confer the only rights enforceable by CyDex that are required by CyDex for Company to exploit Captisol purchased under this Agreement within the Territory. Such licenses pursuant to this **Section 2.1** shall be

nontransferable (except with respect to the sublicense provisions of **Sections 2.3** and **2.4** and the assignment provision in **Section 14.15**); Company may not sublicense any rights hereunder except as expressly set forth in **Sections 2.3** and **2.4** below. To the extent that any patent rights are licensed to CyDex or its Affiliates by a third party on a non-exclusive basis, any exclusive license granted to Company shall be exclusive as to CyDex and non-exclusive as to any third party. Other than for investigations relating to quality issues, Company shall not analyze Captisol in an attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol supplied under this Agreement, nor shall the Company develop, test, study or research Captisol supplied under this Agreement other than in combination with the active pharmaceutical ingredient posaconazole for the purpose of making, using, selling, offering to sell, promoting, marketing, distributing, packaging, importing, exporting, and otherwise commercially exploiting any Licensed Product. CyDex shall not be liable to Company for violation of Company's exclusive rights hereunder by parties which are not Affiliates of CyDex except where CyDex or any Affiliate has granted any license or supplied any material in conflict with Company's exclusive rights and/or CyDex's obligations of exclusivity hereunder. Company acknowledges and agrees that (i) CyDex shall not be required to obtain patent rights in the Territory within the scope of the Captisol Patents, (ii) subject to **Section 2.5(a)** hereof, CyDex shall not be restricted in making sales of Captisol or licensing rights to other parties to the extent that such sales and licenses do not conflict with the exclusive license grants and supply exclusivity obligations hereunder.

2.2 Grant of Licenses and Option from Company to CyDex. Company hereby grants to CyDex:

(i) *License for Captisol Information.* A nonexclusive, 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 Information, to use Captisol Information for the sole purpose of incorporation of Captisol Information into any drug master file for Captisol;

(ii) *Option to Negotiate.* An option, exercisable by written notice to Company within [***] after notice of the development of any Captisol Improvement is provided by Company to CyDex pursuant to this Section 2.2, to negotiate with Company for a period of [***] after Company's receipt of the option exercise notice, for a nonexclusive, 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 such Captisol Improvement, to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol and products formulated with Captisol other than products comprising Company proprietary materials (for clarity, Company is under no obligation to grant any license to CyDex under this Section 2.2(ii)); and

Company shall provide prompt notice (within [***]) of the development of any Captisol Information or Captisol Improvement. Information relating to Captisol Improvements shall be deemed Confidential Information of Company.

2.3 Sublicensing. Company shall have the right to grant sublicenses to its Affiliates and licensees of the Licensed Product (such non-Affiliate sublicensees which hold a Marketing Approval for the Licensed Product are collectively referred to herein as "**Sublicensees**") under the licenses granted to Company pursuant to **Section 2.1**; *provided* that Sublicensees shall first enter into an agreement reasonably satisfactory to CyDex (such agreement naming CyDex as an intended third-party beneficiary) with Company pursuant to which such Sublicensee shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this Agreement. Other than as specifically provided in and this **Section 2.3** and **Section 2.4**, Company shall not have the right to grant sublicenses to any third party under the licenses granted pursuant to **Section 2.1,** *provided, however*, that Company may grant to any party in the Licensed Product supply chain (beginning from Company's receipt of Captisol to the end user of the Licensed Product) a sublicense under the licenses granted pursuant to **Section 2.1** to use, sell, offer to sell, promote, market, distribute, package, import or export any Licensed Product.

2.4 Contracting. Company and its Affiliates may manufacture the Licensed Product (but not the bulk Captisol), or contract the manufacture of the Licensed Product (but not the manufacture of bulk Captisol) with non-Affiliate third party manufacturers upon notification to CyDex in writing of Company's or any of its Affiliate's intent to do so (such notice to include the identity and location of the proposed third party manufacturers). To the extent Company or its Affiliates engage a third party manufacturer for the Licensed Product, Company or any of its Affiliates shall be permitted under this Agreement to grant any such third party manufacturer a sublicense under the licenses granted to Company pursuant to **Section 2.1** solely for such purposes; *provided* that any such third party manufacturer shall enter into an agreement reasonably satisfactory to CyDex (such agreement naming CyDex as an intended third-party beneficiary) with Company pursuant to which such third party manufacturer shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this Agreement for the production of Licensed Product.

2.5 Exclusivity.

(a) CyDex Commitment. During the Term, CyDex agrees (i) to supply all of Company's and its Affiliates' requirements of Captisol for the Licensed Product on the terms set forth herein, and (ii) that neither CyDex nor its Affiliates shall sell or otherwise transfer, nor facilitate the sale or other transfer of, any cyclodextrin [***] to [***] for [***] posaconazole, *provided, however,* that CyDex may sell cyclodextrins [***].

(b) Company Commitment. During the Term, Company agrees that Company and its Affiliates shall not, directly or indirectly, [***] posaconazole [***] cyclodextrin [***].

MANUFACTURE AND SUPPLY OF CAPTISOL.

3.1 Purchase of Captisol.

(a) Purchase and Supply of Requirements. Company agrees that, during the Term, Company and its Affiliates and Sublicensees shall purchase one hundred percent (100%) of Company's and its Affiliates' and Sublicensees' requirements for Captisol for use in the formulation of Licensed Product for commercial sale exclusively from CyDex. This Agreement does not grant

Company, its Affiliates or Sublicensees the right under the rights licensed hereunder, to manufacture (or have manufactured on their behalf) Captisol. CyDex agrees that CyDex shall produce (or have produced for it) and sell to Company one hundred percent (100%) of Company's and its Affiliates' and Sublicensees' requirements for Captisol for use in the formulation of Licensed Product for commercial sale, during the Term and subject to the provisions of this Agreement and *provided that*, and notwithstanding anything to the contrary in this Agreement, in no event shall CyDex be obligated to supply to Company or its Affiliates or Sublicensees more than an aggregate quantity of [***] of Captisol per year (the "**Volume Threshold**"). Purchases of Captisol may include Research Grade Captisol, Clinical Grade Captisol and/or Commercial Grade Captisol. Company may place orders for Captisol on behalf of its Affiliates and Sublicensees; *provided, however* that: (a) Company shall instruct CyDex as to the location for the shipment thereof; (b) Company shall guarantee payment to CyDex of all amounts payable with respect thereto; and (c) if Company requests that CyDex deliver such orders to Company for re-delivery thereof by Company to its Affiliates or Sublicensees, Company shall comply with all applicable laws, rules and regulations applicable to the transportation of Captisol from Company to its Affiliates and Sublicensees.

(b) [***]**.** Except for the obligations associated with the Detailed Forecasts that may be issued at Company's sole discretion, the parties acknowledge and agree that Company and its Affiliates are [***].

3.2 Supply Terms.

(a) Long-term Forecast. No later than [***] prior to the anticipated Commercial Launch Date by Company or its Affiliates or Sublicensees of a Licensed Product in any particular country, Company shall provide CyDex with a forecast setting forth Company's estimate of the required quantities of Captisol for each of the following [***]. Such long-term forecast shall thereafter be updated by Company at least once every [***]. It is understood and agreed that such long term forecasts shall not constitute commitments to take delivery of Captisol.

(b) Binding Detailed Forecast. At least [***] prior to the first purchase order submitted by Company for Captisol for formulation of a Licensed Product intended for commercial sale, Company shall deliver to CyDex a detailed rolling forecast setting forth Company's requirements and anticipated delivery schedules for Captisol for each [***] during the [***] period commencing on the first day of the [***] during which the first requested delivery date of Captisol is specified in such purchase order (the "**Detailed Forecast**"). For purposes of this Agreement, a [***] means the [***]. The Detailed Forecast shall thereafter be updated by Company quarterly on a rolling basis, no later than the last day of each [***], so that each [***] CyDex shall have been provided with a rolling Detailed Forecast for each [***] during the [***] period commencing on the first day of the next [***] following the date on which such Detailed Forecast is submitted. The Detailed Forecast shall be firm and binding on Company, subject to permissible variances set forth in **Section 3.2(c)** below. If Company fails to provide any updated Detailed Forecast in accordance with this **Section 3.2(b)**, the Detailed Forecast last provided by Company shall be deemed to be Company's binding Detailed Forecast for the next succeeding [***].

(c) Detailed Forecast Variances.

(i) For the First Year. During the first [***] in which Company orders Captisol for use in Licensed Products intended for commercial sale, each Detailed Forecast may modify the amount of Captisol estimated in the previous Detailed Forecast in accordance with the following limitations (the "**Purchase Volume Limitations**"):

(A) for the [***] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

(B) for the [***] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(C) for the [***] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

(ii) For Subsequent Years. After the first [***] in which Company orders Captisol for use in a Licensed Product intended for commercial sale, the Purchase Volume Limitations shall be determined in accordance with the following:

(A) for the [***] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

(B) for the [***] covered by such updated Detailed Forecast:

(1) if the quantity of Captisol forecasted in the [***] of the immediately preceding Detailed Forecast is less than [***], then no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] of the in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(2) if the quantity of Captisol forecasted in the [***] of the immediately preceding Detailed Forecast is equal to or greater than [***], then no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

(C) for the [***] covered by such updated Detailed Forecast:

(1) if the quantity of Captisol forecasted in the [***] of the immediately preceding Detailed Forecast is less than [***], then no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(2) if the quantity of Captisol forecasted in the [***] of the immediately preceding Detailed Forecast is equal to or greater than [***], then no change in excess of a [***] volume increase or decrease may be made to the forecast provided for the [***] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

In each case where CyDex's consent is required for a change, CyDex's consent may be conditioned on such payment or other terms as CyDex may require.

(d) Purchase Orders. Together with each Detailed Forecast provided under **Section 3.2(b)**, Company shall issue a purchase order to CyDex for Commercial Grade Captisol to be delivered to Company during the next [***] following the date on which such Detailed Forecast is submitted (for [***] delivery to Company consistent with the Detailed Forecast). Notwithstanding any other provision of the Agreement, CyDex shall not be required to deliver Captisol on a date less than [***] from the date that the relevant purchase order is submitted. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (*i.e.*, Commercial Grade Captisol, Clinical Grade Captisol or Research Grade Captisol); (ii) quantities of Captisol to be delivered; (iii) delivery dates; and (iv) shipping instructions. CyDex shall use all commercially reasonable efforts to accommodate the quantities and delivery dates requested in the purchase order; *provided, however*, that (i) the purchase order is received by CyDex at least [***] prior to the requested delivery date for Captisol, and (ii) the quantities are within the Purchase Volume Limitations. No purchase order shall be binding upon CyDex until accepted by CyDex in writing; *provided* that CyDex shall accept or reject Company's purchase order in writing within [***] after CyDex's actual receipt of each purchase order. A failure to reject Company's purchase order within such [***] of actual receipt of the purchase order will be deemed an acceptance by CyDex of the purchase order. Acceptance of the purchase order shall obligate CyDex to comply with the delivery specifications set forth therein, including Captisol quantities, delivery locations and delivery dates. If CyDex rejects a purchase order issued by Company or its Affiliates that (i) is received by CyDex at least [***] prior to the requested delivery date, and (ii) requests quantities of Captisol within the Purchase Volume Limitations, then Company shall bear no responsibility nor liability for any resulting failure to meet Company's obligations associated with the Detailed Forecasts. If any purchase order or other document submitted by Company 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 such additional or inconsistent terms are hereby expressly rejected.

3.3 Delivery. CyDex shall deliver to Company or Company's designee each order of Captisol, packed for shipment in accordance with CyDex's customary practices and the

Specifications, FCA (Incoterms 2000) 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 or Company's designee at CyDex's production point or storage facilities. CyDex will use commercially reasonable efforts to include, in the next shipment of Captisol to Company, any quantities ordered pursuant to an accepted purchase order but not delivered at Company's discretion.

3.4 Modified Specifications. CyDex shall have the right to change the Specifications from time to time during the Term. In such event, CyDex shall provide to Company at least [***] written notice of such change, which shall include information detailing the purpose for and elements of such change. Company shall cooperate with CyDex to have such change approved by all regulatory agencies having jurisdiction in the Territory at CyDex's expense. In addition, if any regulatory agency having jurisdiction requires CyDex to implement any changes to the Specifications, CyDex shall use all reasonable efforts to make such changes. If any change in the Specifications required by a regulatory agency necessitates changes to the terms of this Agreement, the parties shall negotiate such changes in good faith. All direct costs associated with a Specification change shall be borne by CyDex, *provided, however*, if a regulatory agency requires a change to the Specifications where such change is specific to Captisol as implemented in the Licensed Product, then Company shall be responsible for the costs incurred to generate such unique, modified Specifications. At Company's request, and if the change in Specification is discretionary for CyDex and not required by a regulatory agency, CyDex shall continue to supply Captisol meeting the pre-change Specification for up to [***] after Company's receipt of written notice of such change.

3.5 Change Control Notifications. CyDex shall comply with the notification obligations set forth in the External Supplier Process Change Agreement Form and associated instructions attached hereto as ***Exhibit E.***

3.6 Quality Control; Acceptance and Rejection.

(a) Quality Control. CyDex shall conduct or have conducted quality control testing of Captisol prior to shipment in accordance with the Specifications and other CyDex-approved quality control testing procedures (the "**Testing Methods**"). CyDex shall retain or have retained accurate and complete records pertaining to such testing, as well as samples (at least twice the quantity required to perform the full suite of Testing Methods) from each lot of Captisol shipped to Company, for at least through the expiration date of such Captisol [***] or longer if required by Law. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for each lot of Captisol therein.

(b) Acceptance Testing. Company shall have a period of [***] from the date of receipt to test or cause to be tested Captisol supplied under this Agreement ("**Acceptance Testing Period**"). The Acceptance Testing Period may be extended for an additional [***], for a total of [***] from the date of Company's receipt of the Captisol, so long as Company does not subject such Captisol to improper storage conditions that cause material degradation of the Captisol. Company or its designee shall have the right to reject any shipment of Captisol that does not conform with the Specifications at the time of delivery pursuant to **Section 3.3** hereof when tested in accordance with the Testing Methods. All shipments of Captisol shall be deemed accepted by Company unless CyDex receives written notice of rejection from Company within such Acceptance

Testing Period describing the reasons for the rejection. 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 (i) as provided in **Section 10** below, or (ii) in the case of Captisol that is not fit for use in humans after the Acceptance Testing Period due to a latent defect in such Captisol caused by CyDex, its employees or agents.

(c) Confirmation. After its receipt of a notice of rejection from Company pursuant to **Section 3.6(b)** above, CyDex shall notify Company as soon as reasonably practical (but no later than [***] after receipt of Company's rejection notice) whether it accepts Company's basis for rejection and CyDex may perform its own testing at its own cost to evaluate whether such rejection was necessary or justified. If the parties are unable to agree as to whether a shipment of Captisol supplied by CyDex or its Third-Party Manufacturer hereunder meets the Specifications, such question shall be submitted to an independent quality control laboratory mutually agreed upon by the parties. The findings of such independent laboratory shall be binding upon the parties. The cost of the independent quality control laboratory shall be borne by the party whose results are shown by such laboratory to have been incorrect.

(d) Return or Destruction of Rejected 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 fails to meet the Specifications. CyDex will indicate in its notice either that Company is authorized to destroy the rejected batch of Captisol or that CyDex requires return of the rejected Captisol. Upon written authorization from CyDex to do so, Company shall promptly destroy the rejected batch of Captisol and provide CyDex with written certification of such destruction. Upon receipt of CyDex's request for return, Company shall promptly return the rejected batch of Captisol to CyDex. In each case, CyDex will reimburse Company for the documented, reasonable costs associated with the destruction or return of the rejected Captisol.

(e) Refund or Replacement. Company shall not be required to pay any invoice with respect to any shipment of Captisol properly rejected pursuant to this **Section 3.5**. Notwithstanding the foregoing, Company shall be obligated to pay in full for any rejected shipment of Captisol that is subsequently determined to meet the Specifications in all material respects, irrespective of whether Company has already paid CyDex for a replacement shipment. CyDex shall, upon acceptance of Company's basis of rejection or other confirmation that such shipment failed to meet the Specifications, at Company's sole discretion and direction either: (i) issue a refund or credit equal to the purchase price paid, taxes paid and shipping costs with respect to such rejected shipment within [***] of Company's request; or (ii) replace such rejected shipment at no additional cost (beyond the total cost, including delivery, for the rejected shipment paid or owed by Company to CyDex) to Company, with such replacement to be shipped to Company in accordance with Company's instructions and schedule (or, if CyDex in good faith cannot meet Company's schedule, as soon as reasonably practical). Company acknowledges and agrees that, except for the warranty provisions set forth in Section 9.2 below and the indemnification obligations set forth in Section 10 below, 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 non-conforming Captisol delivered hereunder which has not been used in the manufacture of the Licensed Product.

(f) 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 non-conforming due to damage caused by (i) Company, its Affiliates or Sublicensees or their respective employees or agents, including but not limited to, misuse, neglect, improper storage, transportation or use beyond any dating provided or (ii) events subsequent to delivery of such Captisol to the carrier at the point of origin, 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. Without limiting CyDex's responsibility under this Agreement, CyDex shall have the right at any time to satisfy its supply obligations to Company hereunder either in whole or in part through arrangements with third parties engaged to perform services or supply facilities or goods in connection with the manufacture or testing of Captisol (each, a "**Third-Party Manufacturer**"). CyDex shall give Company prior written notice of any such arrangement. The parties hereby agree that [***] is a Third-Party Manufacturer as of the Effective Date of this Agreement. CyDex shall permit no more than [***] of Company's authorized representatives, during normal working hours and upon reasonable prior notice to CyDex but in no event less than [***] prior notice, to inspect 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 [***] per calendar year. If such inspection is of the facilities of a Third-Party Manufacturer, Company shall pay [***]. Company's authorized representatives shall be accompanied by CyDex personnel at all times, shall be qualified to conduct such manufacturing audits, shall comply with all applicable rules and regulations relating to facility security, health and safety, and shall execute a written confidentiality agreement with terms at least as restrictive as those set forth in **Section 8** hereof. In no event shall any such manufacturing audit exceed [***] in duration. 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 3.6**, neither Company nor its Affiliates, Sublicensees or their respective employees or representatives shall have access to CyDex's facilities or the facilities of any Third-Party Manufacturer.

3.8 Inability to Supply.

(a) Notice. CyDex shall notify Company if CyDex is unable to supply the quantity of (i) Commercial Grade Captisol ordered by Company in accordance with the Purchase Volume Limitations set forth in **Section 3.2(c)** or (ii) Research Grade Captisol or Clinical Grade Captisol ordered by Company as set forth in **Section 3.2(d)** above: (1) within [***] after CyDex's receipt of a purchase order from Company as provided in **Section 3.2(d)**; or (2) immediately upon becoming aware of an event of *force majeure* or any other event that would render CyDex unable to supply to Company the quantity of Captisol that CyDex is required to supply hereunder.

(b) Allocation. If CyDex is unable to supply to Company the quantity of Captisol that CyDex is required to supply hereunder, CyDex (i) shall allocate its available Captisol among Company 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 and (ii) shall use commercially reasonable efforts to alleviate supply delays. The supply allocation provided in this **Section 3.8(b)** and the alternative supplier provisions of **Sections 3.8(c)**

and **(d)** below shall be CyDex's sole obligation and Company's sole and exclusive remedy for any supply shortage.

(c) Supply Shortfall and Risk Management. If CyDex believes that it will be unable to supply to Company with the quantity of Captisol respectively specified below, properly forecasted and ordered by Company (and provided such order was within the Purchase Volume Limitations) in accordance with this Agreement, for the continuous period respectively specified below (a "**Supply Shortfall**"):

Period of Time	Quantity that can be Supplied by CyDex
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

then CyDex shall immediately provide written notice to Company of the Supply Shortfall. In the event of a Supply Shortfall:

(i) [***]

(ii) [***]

(iii) [***]

CyDex will use commercially reasonable efforts to develop, update and implement a full risk mitigation plan, including full disaster recovery plan. This plan will be made available to Company, conditional upon subcontractor permitting Company access to risk mitigation plans.

(d) Direct Supply from Third Party Manufacturer. In the event that the supply shortfall is caused by the bankruptcy or other financial distress experienced by CyDex, the parties agree that Company may purchase its requirements of Captisol for the Licensed Product directly from The Hovione Group or other Third Party Manufacturer until the expiration of the Term for use in accordance with the terms of this Agreement.

COMPENSATION.

4.1 **Payments and Royalties for Licenses.**

(a) [***]

(b) [***]

MILESTONE EVENT	Milestone Payment
Upon Company's filing of an NDA with the FDA for a Licensed Product	$200,000
Upon Company's receipt of Marketing Approval in the United States for a Licensed Product	$1,000,000
Upon Company's receipt of Marketing Approval in the European Union for a Licensed Product	$550,000
Upon Company's receipt of Marketing Approval in Japan for a Licensed Product	$200,000

[***]

(c) No Royalties. Company shall not be required to make royalty payments to CyDex during the Term.

4.2 Pricing for Captisol.

(a) Pricing. The purchase prices for Captisol are as specified in ***Exhibit C*** attached hereto. CyDex reserves the right to increase the purchase prices set forth in ***Exhibit C*** on [***], and every [***] thereafter during the Term, by written notice to Company, by a percentage equal to the [***]. The minimum order for Commercial Grade Captisol shall be in [***] increments. Notwithstanding the foregoing, if Company fails to order for any [***] a quantity of Commercial Grade Captisol to be delivered during such [***] 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 [***] pursuant to the applicable Detailed Forecast and the amount of Commercial Grade Captisol that Company actually orders in [***], the "**Shortfall**"), then provided that CyDex has used commercially reasonable efforts to mitigate, Company agrees to reimburse CyDex for the cost of any raw materials and supplies acquired or used in anticipation of supplying Company with such Shortfall to the extent that such raw materials and supplies cannot be redeployed to other projects and any resulting Commercial Grade Captisol cannot be resold to other customers.

(b) Invoicing; Payment. CyDex shall invoice Company upon shipment of each order of Captisol. All invoices shall be sent to the address specified in the applicable purchase order, and each invoice shall state the purchase price for Captisol in such shipment, plus any insurance, taxes, shipping costs or other costs incidental to such purchase or shipment initially paid by CyDex but to be borne by Company hereunder; *provided, however*, that if such insurance, taxes, shipping costs or other costs incidental to such purchase or shipment initially paid by CyDex but to be borne by Company are not known at the time CyDex invoices Company for the purchase price for the Captisol ordered by Company, CyDex may invoice such costs at a later date. Payment of such invoices shall be made within [***] after the date of Company's receipt of an undisputed invoice at the address specified in the applicable purchase order, except in the event of a good faith rejection of a delivery under **Article 3.5** above, in which case payment shall be made within [***] after such order is confirmed to be in compliance with the Specifications in accordance with **Section 3.5(c)** above.

4.3 Currency. All amounts due hereunder are stated in, and shall be paid in, U.S. dollars.

4.4 Taxes. All amounts due hereunder exclude all applicable sales, use, and other taxes, and Company will be responsible for payment of all such taxes (other than taxes based on CyDex's income), arising from the payment of amounts due hereunder.

4.5 Late Payments. Unpaid balances shall accrue interest, from due date until paid, at a rate equal to the lesser of (i) [***], or (ii) the maximum rate permitted under applicable law. If any amount properly invoiced and due hereunder and not subject to a reasonable, good-faith dispute by Company remains outstanding for more than [***] 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.

REPORTS.

Annually, by December 1st of each calendar year during the Term, Company shall provide CyDex with written reports that: (i) describe in reasonable detail Company's progress made toward achievement of the milestones specified in **Section 4.1(b)** above during such calendar year; (ii) summarize Company's communications and meetings involving the FDA related to Captisol during such calendar year; (iii) summarize Company's anticipated preclinical and clinical use of Captisol for the next calendar year; and (iv) set forth such other information regarding Captisol as mutually agreed upon by the parties.

DEVELOPMENT AND COMMERCIALIZATION BY COMPANY.

6.1 Costs and Expenses. Company shall be solely responsible for all costs and expenses related to its development and commercialization of the Licensed Product, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Product.

6.2 [Reserved]

6.3 Right of Reference. Company shall have the right to reference the DMF solely in connection Company's regulatory filings submitted in connection with obtaining Marketing Approval for the Licensed Product.

6.4 Access to Company's Data. CyDex shall have the right to reference and utilize all toxicology/safety and other relevant scientific data developed on Captisol alone (and not in conjunction with a product formulation) by Company, its Sublicensees or Affiliates in connection with CyDex's development and commercialization of Captisol or compounds, at no cost to CyDex. Upon request by CyDex, Company shall either provide CyDex with a copy of all such data or shall make such data accessible to CyDex at such times and locations mutually agreed upon by the parties.

REGULATORY MATTERS.

7.1 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 Product. Notwithstanding the foregoing, CyDex agrees to provide proprietary technical information relating to Captisol directly to global health authorities as reasonably requested by Company during development and/or new product registration. Company shall provide CyDex with copies of the portions of all regulatory submissions containing Captisol data alone (and not in conjunction with any product formulation) [***] prior to submission and shall allow CyDex to review and comment upon said submissions. If CyDex reasonably determines that any such submission would materially adversely affect another product utilizing Captisol, CyDex shall notify Company within [***] of receipt of such submission, and the parties shall discuss and resolve the matter in good faith. Company shall inform CyDex of meetings with the FDA (or other regulatory agencies in the Territory) regarding the Licensed Product [***] prior to such event and shall allow CyDex to participate in any FDA (or other regulatory agency) review that might reasonably include inquiries regarding Captisol. If Company submits written responses to the FDA that include data on Captisol alone, CyDex shall be permitted to review such written materials prior to submission. If CyDex reasonably objects to the contents of such written responses relating to Captisol, the parties agree to cooperate in working toward a reasonable and mutually agreeable response.

7.2 Material Safety. CyDex shall provide Company, in writing, promptly as it becomes available, with (a) relevant 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 (i) use of all documentation provided by CyDex, including without limitation, use in any regulatory submission to the FDA or any other regulatory agency in the Territory (for clarity, CyDex is responsible for the accuracy of the information contained in such documentation), (ii) document control and retention, and (iii) determining the suitability of any documentation provided by CyDex hereunder for use in any regulatory submission.

7.3 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. Company and/or its Affiliates or Sublicensees shall provide CyDex with copies of all reports of any such adverse event which is serious (any such adverse event involving Captisol or the Licensed Product that results in death, is life-threatening, requires or prolongs inpatient hospitalization, results in disability, congenital anomaly or is medically important (i.e., may require other medical or surgical intervention to prevent other serious criteria from occurring)) which Company and/or its Affiliates or Sublicensees has reason to believe are associated with Captisol within [***] days promptly following (i) Company's submission of any such report to any regulatory agency, or (ii) receipt from Company's Sublicensee, co-marketer or distributor of any such report to any regulatory agency. Company shall also advise CyDex regarding any proposed labeling or registration dossier changes affecting Captisol. Reports from Company shall be delivered to the attention of Vice President, Chief Operating Officer, CyDex, with a copy to Vice President, Assistant Secretary, CyDex, at the addresses set forth in **Section 14.6**. By no later than [***] following the Effective Date and not later than the initiation of any clinical studies involving the Licensed Product, the parties shall enter into

a formal safety agreement for the mutual exchange of adverse event reports and safety information associated with Captisol. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed pharmacovigilance agreement between the parties. Company shall be solely responsible for reporting to the regulatory agencies and health authorities, adverse events relating to the Licensed Product and for maintaining the global safety database of such adverse events. The parties shall mutually cooperate with regard to investigation of any such serious adverse event believed to be associated with Captisol supplied under this Agreement, whether experienced by Company, CyDex or any other Affiliate, Sublicensee, co-marketer or distributor of CyDex or Company.

7.4 Product Recalls. In the event that a Licensed Product is recalled or withdrawn, CyDex shall fully cooperate with Company in connection with such recall or withdrawal. If such recall is caused by a breach of any warranty or other obligation of CyDex under this Agreement, CyDex will reimburse Company for [***]. CyDex agrees to abide by all decisions of Company to recall or withdraw Licensed Product.

CONFIDENTIALITY.

8.1 Definition. Company and CyDex each recognizes that during the Term, it may be necessary for a party (the "**Disclosing Party**") to provide Confidential Information (as defined herein) to the other party (the " **Receiving Party**") that is highly valuable, the disclosure of which would be highly prejudicial to such party. The disclosure and use of Confidential Information will be governed by the provisions of this **Section 8**. Neither Company nor CyDex shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "**Confidential Information**" means all scientific, clinical, regulatory, marketing, business, operational, financial or commercial information disclosed by the Disclosing Party to the Receiving Party, including but not limited to product specifications, data, know-how, formulations, product concepts, sample materials, business and technical information, financial data, batch records, trade secrets, processes, techniques, algorithms, programs, designs, drawings, and any other information related to a party's present or future products, 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; nevertheless, Company's and/or its Affiliates disclosure and use of the Captisol Data Package in connection with any activity related to regulatory approval of any Licensed Product shall not constitute a breach of any non-disclosure and/or limited use obligations owed by Company and/or its Affiliates to CyDex or [***] .

8.2 Obligation. CyDex and Company agree that they will disclose the other's Confidential Information to its own officers, employees, consultants, Affiliates and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Neither party shall disclose Confidential Information of the other to any third party without the other's prior written consent, and any such disclosure to a third party shall be pursuant to the terms of a non-disclosure agreement no less restrictive than this **Section 8**. 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). Each party, upon the other's request, will return all the Confidential Information disclosed to the other party pursuant to this Agreement, including all copies and extracts of documents, within sixty (60) days of the request, except that the receiving party may retain (i) one (1) copy for archival purposes and (ii) such electronic copies that exist as part of the party's computer systems, network storage systems and electronic backup systems.

8.3 Exceptions. The use and non-disclosure obligations set forth in this **Section 8** shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by appropriate documentation:

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

(ii) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party;

(iii) at the time of disclosure is already in the Receiving Party's possession, and such prior possession can be properly demonstrated by the Receiving Party, with the exception of Confidential Information exchanged between parties prior to the execution of this Agreement which is subject to an ongoing obligation of confidentiality;

(iv) is made available to the Receiving Party by an independent third party, provided, however, that to the Receiving Party's knowledge, such information was not obtained by said third party, directly or indirectly, from the Disclosing Party hereunder; or

(v) is developed by or on behalf of the Receiving Party or its Affiliates without the aid, application or use of the Disclosing Party's Confidential Information.

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the United States Securities and Exchange Commission (the "**SEC**"), or in the course of litigation, *provided* that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and shall assist the Disclosing Party (at Disclosing Party's request and expense) in obtaining, a protective order preventing or limiting the disclosure 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.

8.4 Injunction. Each party agrees that should it breach or threaten to breach any provisions of this **Section 8**, the Disclosing Party may suffer irreparable damages and its remedy at law may be inadequate. Upon any breach or threatened breach by the Receiving Party of this **Section 8**, the Disclosing Party shall be entitled to seek injunctive relief in addition to any other remedy which it may have.

REPRESENTATIONS AND WARRANTIES.

9.1 **Mutual Representations and Warranties.** Each party represents and warrants to the other as follows:

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

it has the power and authority to enter into this Agreement and to perform its obligations hereunder;

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 as applied by courts of competent jurisdiction or dispute resolution authorities authorized by the parties;

the execution, delivery and performance of this Agreement by such party do not conflict with any agreement, instrument or understanding, oral or written, to which such party is a party or by which such party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over such party;

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;

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 agents, or, with respect to Company, because of any act by its Affiliates or Sublicensees; and

it has not entered 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 Limited Warranty. CyDex warrants solely to Company and its Affiliates that all Captisol sold to Company shall:

(i) conform to the respective Specifications (as applicable for Research Grade Captisol, Clinical Grade Captisol or Commercial Grade Captisol) in all material respects at the time of delivery;

(ii) have been manufactured, stored, packaged and (to the extent CyDex is responsible for shipping) shipped in accordance with cGMPs (Research Grade Captisol excluded) and all other Laws in the country of manufacture and CyDex's site of delivery;

(iii) be delivered to Company (or Company's designated carrier if Company is responsible for shipping) with good and marketable title, free and clear of any liability, pledge, lien, restriction, claim, charge, security interest or other encumbrance; and

(iv) have not less than [***] of remaining shelf life (until re-testing is required) on the date of delivery.

CyDex's sole obligation, and Company's sole and exclusive remedy, for any breach of such warranty shall be as set forth in **Sections 3.5(e)** (Refund or Replacement) and **10.1** (Indemnification by CyDex) hereof.

9.3 Disclaimer. THE WARRANTIES SET FORTH IN THIS **SECTION 9** ABOVE ARE PROVIDED IN LIEU OF, AND EACH PARTY HEREBY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT, CAPTISOL, THE CAPTISOL PATENTS OR THE CAPTISOL DATA PACKAGE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. CYDEX'S WARRANTIES UNDER THIS AGREEMENT ARE SOLELY FOR THE BENEFIT OF COMPANY AND ITS AFFILIATES AND MAY BE ASSERTED ONLY BY COMPANY AND/OR ITS AFFILIATES AND NOT BY ANY SUBLICENSEE OR ANY

CUSTOMER OF COMPANY. COMPANY, ITS AFFILIATES AND SUBLICENSEES SHALL BE SOLELY RESPONSIBLE TO ITS CUSTOMERS FOR ALL REPRESENTATIONS AND WARRANTIES THAT COMPANY, ITS AFFILIATES OR SUBLICENSEES MAKE TO ANY CUSTOMER OF COMPANY, ITS AFFILIATES OR SUBLICENSEES. NOTHING IN THIS SECTION 9.3 SHALL BE DEEMED TO LIMIT OR OTHERWISE ALTER CYDEX'S OBLIGATIONS UNDER ARTICLE 10 (INDEMNIFICATION AND INSURANCE).

INDEMNIFICATION AND INSURANCE.

10.1 By CyDex. CyDex shall defend, indemnify and hold Company and its Affiliates and Sublicensees, and each of their respective directors, officers and employees, harmless from and against any and all losses, damages, liabilities, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively "**Losses**") incurred by Company 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 (i) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Sections 9.1 and 9.2**, (ii) any infringement or alleged infringement of the intellectual property rights of a third party by Captisol alone, but not where the combination of Captisol and any other material is a required element of the alleged or actual infringement, or (iii) CyDex's or CyDex's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement. Notwithstanding the foregoing, CyDex shall have no obligation under this **Section 10.1** to the extent that a third party Claim arises from (i) Company's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Section 9.1**, or (ii) Company's or Company's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement.

10.2 By Company. Company shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers and employees, harmless from and against any and all Losses incurred by CyDex as a result of any Claim by a third party, to the extent such Losses arise out of: (a) the use or sale of the Licensed Product by Company, its Affiliates, Sublicensees, distributors, agents or other parties; (b) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Licensed Products; (c) interactions and communications with governmental authorities, physicians or other third parties; (d) Company's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Section 9.1**, or (e) Company's or Company's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement. Notwithstanding the foregoing, Company shall have no obligation under this **Section 10.2** to the extent that a third party Claim arises from (i) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Sections 9.1 and 9.2**, (ii) any infringement or alleged infringement of the intellectual property rights of a third party by Captisol where a combination of Captisol with a material other than Captisol is a required element of the infringement or alleged infringement, or (iii) CyDex's or CyDex's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement.

10.3 Expenses. As the parties intend complete indemnification, all costs and expenses of enforcing any provision of this **Section 10** shall also be reimbursed by the Indemnitor.

10.4 Procedure. The party intending to claim indemnification under this **Section 10** (an "**Indemnitee**") shall promptly notify the other party (the "**Indemnitor**") of any Claim in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof whether or not such Claim is rightfully brought; *provided, however,* that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, unless Indemnitor does not assume the defense, in which case the reasonable fees and expenses of counsel retained by the Indemnitee shall be paid by the Indemnitor. The Indemnitee, and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigations of any Claim. The Indemnitor shall not be liable for the indemnification of any Claim settled or compromised by the Indemnitee without the written consent of the Indemnitor.

10.5 Insurance. Each party agrees to maintain, during the Term and for [***] thereafter, through policies of insurance or programs of self-insurance, commercial general liability insurance, products liability and products completed operations coverages, with a minimum limitation of [***] per occurrence and [***] annual aggregate upon execution of this Agreement. Each party shall deliver to the other party, prior to the execution of this Agreement and prior to commencing work hereunder, an insurer or insurer's agent signed certificates of insurance, as evidence that policies providing such coverage and limits of insurance are in full force and effect and with insurers, having an AM Best (A-) or higher rating, or similar metric as deemed reasonably acceptable to the other party, or evidence of such self insurance. Thereafter, the certificates of insurance (if applicable) shall be provided annually. These certificates (if applicable) shall provide that not less than [***] advance notice will be given in writing to the other party of any cancellation, termination, or material alteration of said insurance policies to the extent that such provisions are reasonably available. Each party shall name the other party as an additional insured under its policies of commercial general liability insurance. All deductibles or self-insured retentions are the responsibility of CyDex or

Company, as applicable, under the foregoing policies maintained by CyDex or Company, as applicable.

LIMITATION OF LIABILITY.

EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS CONFIDENTIALITY OBLIGATIONS SET FORTH IN **SECTION 8** AND INDEMNIFICATION OBLIGATIONS SET FORTH IN **SECTION 10** ABOVE, THE PARTIES SPECIFICALLY DISCLAIM ALL LIABILITY FOR AND SHALL IN NO EVENT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, LOST SAVINGS, INTERRUPTIONS OF BUSINESS OR OTHER DAMAGES OF ANY KIND OR CHARACTER WHATSOEVER ARISING OUT OF OR RELATED TO THIS AGREEMENT OR RESULTING FROM THE MANUFACTURE, HANDLING, MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCT OR USE OF THE CAPTISOL PATENTS AND CAPTISOL DATA PACKAGE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF A PARTY WERE ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT WITH RESPECT TO PAYMENTS DUE TO CYDEX PURSUANT TO **SECTION 4** OF THIS AGREEMENT AND THE INDEMNIFICATION SPECIFICALLY PROVIDED IN **SECTION 10** ABOVE, IN NO EVENT SHALL EITHER PARTY'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED THE AMOUNTS PAID BY COMPANY TO CYDEX PURSUANT TO **SECTION 4** OF THIS AGREEMENT DURING THE [***] PERIOD IMMEDIATELY PRECEDING THE EVENT GIVING RISE TO LIABILITY. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN [***] AFTER SUCH PARTY HAS KNOWLEDGE OF THE OCCURRENCE THAT GAVE RISE TO THE CAUSE OF SUCH ACTION.

MANAGEMENT OF CAPTISOL PATENTS.

12.1 Prosecution and Maintenance. CyDex shall maintain, at its sole cost and expense and using reasonable discretion, the Captisol Patents set forth on ***Exhibit A***. CyDex shall have the sole right to control the prosecution and maintenance of patent applications and the selection of countries where patent applications are filed related to the Captisol Patents.

12.2 Infringement by Third Parties. If Company becomes aware that a third party may be infringing a Licensed Patent, it will promptly notify CyDex. CyDex shall take whatever, if any, action it deems appropriate, in its sole discretion, against the alleged infringer. If CyDex elects to take action, Company shall, at CyDex's request and expense, cooperate and shall cause its employees to cooperate with CyDex in taking any such action, including but not limited to, cooperating with the prosecution of any infringement suit by CyDex. Company shall not take any such action against the alleged infringer without the written consent of CyDex.

TERM AND TERMINATION.

13.1 Term. The term of the Agreement (the " **Term**") shall commence upon the Effective Date and shall continue in effect thereafter until December 31, 2015, unless extended or earlier

terminated by (i) one of the parties as expressly provided herein, or (ii) written agreement of the parties. The Term may be extended one time, at Company's sole discretion, for an additional period of five (5) years, expiring on December 31, 2020, by Company providing written notice to CyDex on or before December 31, 2014.

13.2 Termination by CyDex. If Company should violate or fail to perform any material term or covenant of this Agreement, then CyDex may give written notice of such default (a "**Notice of Default**") to Company. If Company should fail to cure such default within ninety (90) days of the date of such notice is received by Company or prior to the natural expiration date of this Agreement, whichever is shorter in duration, CyDex shall have the right to terminate this Agreement by a second written notice (a "**Notice of Termination**") to Company. If Notice of Termination is sent to Company, this Agreement shall automatically terminate on the date such notice is received by Company. In addition, CyDex may terminate this Agreement immediately upon written notice to Company in the event Company makes an assignment for the benefit of creditors or has a petition in bankruptcy filed for or against it that is not dismissed within ninety (90) days of such filing.

13.3 Termination by Company. Company shall have the right at any time to terminate this Agreement in whole by giving CyDex at least [***] prior written notice.

13.4 Effect of Termination. Following the termination or expiration of this Agreement for any reason:

(a) All rights granted to Company herein shall immediately terminate. For clarity, the termination of rights means that, except to as provided otherwise in separate agreements, (i) Company and its Affiliates shall not have the right to operate within the scope of any valid and enforceable claim contained in an issued patent within the Captisol Patents or the Restricted Patent Rights in any jurisdiction where such valid and enforceable claim exists; (ii) and Company and its Affiliates shall cease use of non-public Captisol-related toxicology/safety and other relevant non-public scientific safety data provided by CyDex to Company under this Agreement. Company acknowledges that reformulation of and new regulatory approvals for the Product may be required as a result of this provision.

(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 one archival copy of such records and materials solely to be able to monitor its obligations that survive under this Agreement.

13.5 Survival. Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions prior to 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 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 sums due in respect of Captisol ordered by Company and shipped prior to termination or expiration of this Agreement, and subsequently received by Company in good condition meeting all specifications applicable at the time of order.

Sections 2.2 (Grant of Licenses and Option from Company to CyDex), 3.6 (Quality Control; Acceptance and Rejection), 4.1 (Payments and Royalties for Licenses), 4.3 (Currency), 4.4 (Taxes), 4.5 (Late Payments), 7.3 (Adverse Event Reporting), 7.4 (Product Recalls), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification and Insurance), 11 (Limitation of Liability), 13.4 (Effect of Termination), 13.5 (Survival), and 14 (General Provisions) shall survive termination or expiration of this Agreement.

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. No party shall incur any debts or make any commitments for the other.

14.2 Compliance with Law. Company agrees that use of the Captisol Patents and Captisol Data Package by Company and its Affiliates and Sublicensees, and the manufacture, handling, marketing, sale, distribution and use of Licensed Product, will comply with all Laws.

14.3 Arbitration.

(a) Procedure. Any controversy or claim arising out of or relating to this Agreement shall be exclusively and finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association then in effect, in Chicago, Illinois. The arbitration shall be conducted by an arbitrator(s) reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and Company. If CyDex and Company cannot agree on a single arbitrator within [***] after a written demand for arbitration has been made, CyDex shall appoint an arbitrator, Company shall appoint an arbitrator, the two (2) arbitrators shall appoint a third arbitrator, and the three (3) arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within [***] after service of the demand for arbitration, then the arbitrator appointed by the other party shall arbitrate any controversy in accordance with this **Section 14.3(a)**. Except as to the selection of arbitrators, the arbitration proceedings shall be conducted promptly and in accordance with the Commercial Arbitration Rules of the American Arbitration Association in effect at the time the arbitration demand is made. The costs and fees of any arbitration shall be paid by [***]. For purposes of this Agreement, "costs and fees" shall mean all reasonable pre-award expenses of the arbitration, including the fees of the arbitrator(s), administrative fees, travel expenses, out-of-pocket expenses such as copying and telephone, witness fees, and attorney's fees.

(b) Confidentiality of Proceedings. All arbitration proceedings hereunder shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each party’s Confidential Information. Except as required by law, neither a party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both parties.

(c) Interim Equitable Relief. Either party may apply to the arbitrator(s) seeking injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either party may, without waiving any right or remedy under this Agreement, seek from any court

having jurisdiction any interim or provisional relief (including but not limited to interim injunctive relief) that is necessary to protect the rights or property of that party, pending the establishment of an arbitration tribunal or pending the arbitration tribunal's determination of the merits of the controversy. Neither party shall commence any court proceeding or action against the other to resolve any dispute arising out of relating to this Agreement, or the breach

thereof, except (i) to enforce an arbitral award rendered pursuant to this **Section 14.3**, or (ii) under the circumstances set forth in this Section 14.4(c).

(d) Binding Effect. The provisions of this **Section 14.3** shall survive any expiration or termination of this Agreement, and shall be severable and binding on the parties hereto, notwithstanding that any other provision of this Agreement may be held or declared to be invalid, illegal or unenforceable.

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 Force Majeure. Neither party shall be liable 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*. For purposes of this Agreement, an event of *force majeure* means any event or circumstance beyond the reasonable control of the affected party, including but not limited to, war, insurrection, riot, fire, flood or other unusual weather condition, explosion, act of God, peril of the sea, strike, lockout or other industrial disturbance, sabotage, accident, embargo, breakage of machinery or apparatus, injunction, act of governmental authority, compliance with governmental order on national defense requirements, or inability 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.

14.6 Notices. Any notice, request, or communication under this Agreement shall be effective only if it is in writing and personally delivered; sent by certified mail, postage pre-paid; facsimile with receipt confirmed; or by nationally recognized overnight courier with signature required, addressed to the parties at the addresses stated below or such other persons and/or addresses as shall be furnished in writing by any party in accordance with this **Section 14.6**. Unless otherwise provided, all notices shall be sent:

If to CyDex, to:

CyDex Pharmaceuticals, Inc.
10513 W. 84th Terrace
Lenexa, KS 66214
Attention: General Manager
Fax: (913) 685-8856

with a copy to:

Ligand Pharmaceuticals Incorporated
11085 North Torrey Pines Road, Suite 300
La Jolla, CA 92037
Attn: General Counsel
Fax : (858) 550-7272

If to Company, to:

Schering-Plough Brinny Company
Brinny
Innishannon
County Cork
Ireland
Attention: Plant Manager

with a copy to:

Merck Sharp & Dohme Corporation
One Merck Drive
Whitehouse Station, NJ 08889-0100
Attention: VP & Assistant General Counsel, MMD
Fax: (908) 423-4892

If sent by facsimile transmission, [***] shall be deemed to be the date on which such notice, request or communication was given. If sent by overnight courier, [***] after the date of deposit with such courier shall be deemed to be the date on which such notice, request or communication was given. If sent by certified mail, the [***] business day after the date of mailing shall be deemed the date on which such notice, request or communication was given.

14.7 Use of Name. Neither party shall have any right, express or implied, to use in any manner the name or other designation of the other party or any other trade name or trademark of the other party for any purpose, except (i) as may be required by applicable law or regulation, or (ii) as approved in writing by the other party.

14.8 Public Announcements. Upon execution of this Agreement, CyDex or its Affiliate Ligand Pharmaceuticals Incorporated (Ligand) shall have the right to issue a press release so long as such press release has been reviewed and approved in writing by Company prior to issuance (such approval not to be unreasonably withheld) and file a Form 8-K with the SEC summarizing the Agreement. Thereafter, except for such disclosure as is deemed necessary, in the reasonable judgment of a party, to comply with applicable laws or regulations, securities filings or the rules of the NYSE or NASDAQ, no announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, or the terms hereof, will be made without the other party's prior written approval; such prior written approval not to be unreasonably withheld. In the event of a required public announcement, the party making such announcement shall provide the other party with a copy of the proposed text prior to such announcement sufficiently in advance

of the scheduled release of such announcement to afford such other party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure. In the event that Ligand files a copy of the Agreement with the SEC, CyDex shall afford Company a reasonable opportunity to review and comment upon the proposed redactions, if any.

14.9 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York (without giving effect to any conflicts of law principles that require the application of the law of a different state).

14.10 Entire Agreement; Amendment. This Agreement and all Exhibits attached hereto or thereto contain the entire agreement of the parties relating to the subject matter hereof and supersede any and all prior agreements, written or oral, between CyDex and Company relating to the subject matter of this Agreement. This Agreement may not be amended unless agreed to in writing by both parties.

14.11 Binding Effect. This Agreement shall be binding upon, and the rights and obligations hereof shall apply to the 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.

14.12 Waiver. 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. 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 addressed 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.

14.13 Severability. If a final judicial determination is made that any provision of this Agreement is unenforceable, this Agreement shall be rendered void only to the extent that such judicial determination finds such provisions unenforceable, and such unenforceable provisions shall be automatically reconstituted and become a part of this Agreement, effective as of the date first written above, to the maximum extent they are lawfully enforceable.

14.14 Assignment. 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. Notwithstanding the foregoing, either party may assign its rights and delegate its obligations under this Agreement to an Affiliate or to a third party successor, whether by way of merger, sale of all or substantially all of its assets of the business to which this Agreement pertains, sale of stock or otherwise, without the other party's prior written consent. As a condition to any permitted assignment hereunder, the assignor hereby guarantees the performance of any assignee to the terms and obligations of this Agreement. Any assignment not in accordance with this **Section 14.14** shall be void.

14.15 Third Party Beneficiaries. Except for the rights of Indemnitees pursuant to **Section 10** hereof, and subject to Section 8.5 hereof, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective Affiliates, 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, its Affiliates or such Indemnitees, and not Sublicensees.

14.16 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.

14.17 Counterparts. This Agreement may be executed in two counterparts, 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]

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

CYDEX PHARMACEUTICALS, INC.

By: /s/ Matt Foehr

Name: Matt Foehr

Title: Executive Vice President, Chief Operating Officer

MERCK SHARP & DOHME CORPORATION

By: /s/ J.P. Hanthold

Name: J.P. Hanthold

Title: Director of Global Procurement

EXHIBIT A

CAPTISOL PATENTS

[***]				
[***]				
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EXHIBIT B

SPECIFICATIONS

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* * * * *

[***]

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EXHIBIT C

PURCHASE PRICE FOR CAPTISOL

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

* * * * *

EXHIBIT D

RESTRICTED PATENT RIGHTS

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[***]	[***]	[***]	[***]	[***]
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EXHIBIT E

EXTERNAL SUPPLIER PROCESS CHANGE AGREEMENT FORM

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. ("Merck"), is committed to achieving the highest standards of quality and is dedicated to continuous improvement in compliance and quality through our business processes and practices with our suppliers. That said, suppliers are responsible for manufacturing their products in conformance with all laws and regulations that pertain to their specific operations. Suppliers are also responsible for assuring that they have qualified personnel with adequate training to control their own manufacturing processes and ensure consistent quality. Such controls extend to your firm properly evaluating any change in the materials; equipment or processes to ensure your products conform to original specifications.

Sometimes, a change in materials, equipment or process by a supplier may have an unintended impact on the product produced by the supplier and subsequently have an unintended impact on a product being produced by the customer. Merck requires notification of certain changes in materials, equipment or process so as to be able to evaluate whether such change may have an unintended impact on our use of your product. Our requiring this information does not alter your own responsibility in evaluating any and all changes undertaken by your firm.

This agreement will be relevant for any and all products Merck or any of its affiliates, including without limitation Schering Corporation, receives from any of your approved facilities.

Examples of changes that require prior notification and approval by Merck are described in the attached agreement. In the event of uncertainty as to whether or not notification is required, please contact your local Merck procurement office.

Does Require Notification	Does Not Require Notification
[***]	[***]
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[***]	[***]

CyDex agrees to notify local Merck Procurement contact using the External Supplier Process Change Notification Form (next page), or other written notification containing equivalent information, prior to implementing changes in accordance with this Exhibit.

External Supplier Change Notification Form

1. GENERAL INFORMATION:	
Company:	Product Supplied
Address	Date:
	Phone:
	Fax:

2. Target Date for Full Scale Implementation			
3. Will Sample Be Available?	☐ Yes	☐ No	If Yes, Date sample available _____

4. CHANGE DESCRIPTION: **(Attach more info as required)**	
Current:	
Proposed:	

5. TECHNICAL INFO – Describe relevant technical information. (Attach more info as required)

6. SUMMARY CHECKLIST: Impact to supplier

☐ Yes	☐ No	Cleaning Validation Impact? (if yes, technical info must describe cleaning validation plan)
☐ Yes	☐ No	Equipment Qualification Impact? (if yes, technical info must describe equipment validation plan)
☐ Yes	☐ No	Process Validation Impact? (if yes, technical info must describe process validation plan)
☐ Yes	☐ No	Labeling or Artwork Impact? (if yes, technical info must describe labeling/artwork impact)
☐ Yes	☐ No	Packaging or Shipping Impact? (if yes, technical info must describe packaging/shipping impact)
☐ Yes	☐ No	Regulatory Impact? (if yes, technical info must describe regulatory impact)
☐ Yes	☐ No	Change in Quality? (E.g. chemical composition, impurity profile, shelf life)?

Supplier Signature:_____ Title:_____Date:_____
Printed Name _____

☐ ☐

Exhibit 31.3

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John L. Higgins, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q of Ligand Pharmaceuticals Incorporated; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: November 1, 2017

/s/ John L. Higgins

John L. Higgins
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.4

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Korenberg, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q of Ligand Pharmaceuticals Incorporated; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: November 1, 2017

/s/ Matthew Korenberg

Matthew Korenberg
Vice President, Finance and Chief Financial Officer
Duly Authorized Officer and Principal Financial Officer