Current Agreements

Dealdoc

Licensing agreement for Captisol-enabled intravenous formulation of clopidogrel

Ligand Pharmaceuticals
The Medicines Company

Jun 03 2011

Licensing agreement for Captisol-enabled intravenous formulation of clopidogrel

Companies:	Ligand Pharmaceuticals The Medicines Company
Announcement date:	Jun 03 2011
Deal value, US$m:	23.75 : sum of upfront and milestone payments

Details

Announcement date:	Jun 03 2011
Start date:	Jun 01 2011
Industry sectors:	Bigbiotech Pharmaceutical Drug delivery
Therapy areas:	Cardiovascular » Myocardial Infarction Central Nervous System » Stroke Drug delivery » Bioavailability
Technology types:	Drug delivery » Parenteral » Injectable Small molecules
Deal components:	Licensing
Stages of development:	Formulation
Geographic focus:	Worldwide

Financials

Deal value, US$m:	23.75 : sum of upfront and milestone payments
Upfront, US$m:	1.75 : upfront payment
Milestones, US$m:	22.0 : milestone payments
Royalty rates, %:	n/d : up to double digit royalties on annual worldwide net sales

Termsheet

Ligand has licensed exclusive worldwide rights to The Medicines Company for Ligand’s Captisol-enabled intravenous formulation of clopidogrel.

Ligand will receive an upfront payment of $1.75 million plus be eligible to receive up to $22 million in milestones and up to double digit royalties on annual worldwide net sales.

In addition, Ligand will also supply clinical and commercial materials of Captisol for this program, and if the intravenous formulation is approved for commercialization, Ligand will be the exclusive supplier of the product.

Press Release

Ligand Pharmaceuticals Inc. (LGND) and The Medicines Company (MDCO) Agree to Worldwide License for Proprietary Captisol(R); Ligand Eligible to Receive up to $22 Million 6/3/2011

Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) and The Medicines Company (NASDAQ: MDCO) announced today a licensing agreement under which Ligand has licensed exclusive worldwide rights to The Medicines Company for Ligand’s Captisol®-enabled intravenous

formulation of clopidogrel. Clopidogrel is the active ingredient in PLAVIX®, the world's leading anti-platelet medication which is currently only available in an oral formulation. The Captisol-enabled clopidogrel formulation is designed to provide an intravenous option in situations where the administration of oral platelet inhibitors is not feasible or desirable.

"This is a significant transaction for Ligand as it again demonstrates how the Captisol technology can be a powerful tool in reformulating existing compounds, offering clinicians a potentially important new formulation to benefit patients"

Ligand will receive an upfront payment of $1.75 million plus be eligible to receive up to $22 million in milestones and up to double digit royalties on annual worldwide net sales. In addition, Ligand will also supply clinical and commercial materials of Captisol for this program, and if the intravenous formulation is approved for commercialization, Ligand will be the exclusive supplier of the product.

"This is a significant transaction for Ligand as it again demonstrates how the Captisol technology can be a powerful tool in reformulating existing compounds, offering clinicians a potentially important new formulation to benefit patients," said Matt Foehr, Executive Vice President and Chief Operating Officer of Ligand Pharmaceuticals. "The Medicines Company is an excellent partner with their acute and intensive care platform, and we are excited about the efficient 505(b)(2) development plan they have proposed."

"Captisol technology from Ligand has a proven track record with other acute care products," said Clive Meanwell, MD, PhD, Chairman and CEO of The Medicines Company. "Oral clopidogrel is an important, proven drug capable of saving lives and improving outcomes in acute coronary syndromes. We believe that an intravenous form of clopidogrel can provide an important solution in acute medicine worldwide and is highly complementary to our portfolio in acute and intensive care."

Captisol-enabled clopidogrel was originally developed by Ligand's subsidiary, CyDex Pharmaceuticals, Inc. This program is the second to be licensed out of Ligand's proprietary Captisol-enabled pipeline, following the licensing of Nexterone® to Prism Pharmaceuticals (which was recently acquired by Baxter International Inc.). Additional Captisol-enabled programs currently in development are a new ready-to-use intravenous formulation of co-solvent free melphalan and a unique iv formulation of topiramate.

Contingent Value Right

In Ligand's January 2011 acquisition of CyDex Pharmaceuticals, Ligand agreed to share certain future revenue with the former CyDex stockholders for a clopidogrel deal via a contingent value right (CVR). Under such agreement, Ligand will deliver to the CVR holders 50% of all upfront and milestone payments received by Ligand under this licensing agreement from The Medicines Company (when and as received by Ligand) after subtraction of any corresponding milestone payments (potentially up to $5 million) made back to Prism Pharmaceuticals. The program had been previously licensed to Prism Pharmaceuticals Inc., but full rights were returned in 2010 when both parties agreed to terminate the agreement in return for a cash payment and future potential milestone and royalty payments.

About The Medicines Company

The Medicines Company (NASDAQ: MDCO) provides medical solutions to improve health outcomes for patients in acute and intensive care hospitals worldwide. These solutions comprise medicines and knowledge that directly impact the survival and well being of critically ill patients. The Medicines Company's website is www.themedicinescompany.com.

About Ligand Pharmaceuticals

Ligand is a biopharmaceutical company with a business model that is based upon the concept of developing or acquiring royalty revenue generating assets and coupling them to a lean corporate cost structure. Ligand's goal is to produce a sustainably profitable business. By diversifying its portfolio of assets across numerous technology types, therapeutic areas, drug targets, and industry partners, Ligand offers investors an opportunity to invest in the increasingly complicated and unpredictable pharmaceutical industry. In comparison to its size peers, we believe Ligand has assembled one of the largest and most diversified asset portfolios in the industry. These therapies seek to address the unmet medical needs of patients for a broad spectrum of diseases including hepatitis, muscle wasting, Alzheimer's disease, dyslipidemia, diabetes, anemia, COPD, asthma, rheumatoid arthritis and osteoporosis. Ligand has established multiple alliances with the world's leading pharmaceutical companies including GlaxoSmithKline, The Medicines Company, Pfizer, Bristol-Myers Squibb and AstraZeneca. For more information, please visit www.ligand.com. Follow Ligand on Twitter @Ligand_LGND.

Filing Data

Not available.

Contract

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made this 1st day of June, 2011 (the "Effective Date") between:

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

THE MEDICINES COMPANY, a Delaware corporation with offices at 8 Sylvan Way, Parsippany, New Jersey 07054 (“MDCO”).

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®, a patented drug formulation system designed to enhance the solubility and stability of drugs;

WHEREAS, CyDex has developed or obtained certain rights related to the Compound (defined below);

WHEREAS, MDCO desires to obtain a license to use such patented drug formulation system for Captisol and such rights to the Compound for the development and commercialization of the Licensed Product (defined below) and CyDex is willing to grant such license to MDCO under the terms and conditions set forth herein; and

WHEREAS, CyDex desires to sell Captisol® to MDCO or its Contract Manufacturers (defined below), and MDCO desires to obtain supplies of Captisol® from CyDex, for use in the Licensed Product, in accordance with the terms and conditions of that certain Supply Agreement between the parties of even date herewith (the “Supply Agreement”);

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

1. DEFINITIONS.

For the purposes of this Agreement, the following terms whether used in singular or plural form shall have the meanings as defined below:

“Affiliate” means, with respect to any party, any entity controlling, controlled by, or under common control with such party, during and for such time as such control exists. For these purposes, “control” shall refer to the ownership, directly or indirectly, of at [***] of the voting securities or other ownership interest of the relevant entity.

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

“Captisol” means Captisol®, also known scientifically as [***].

“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 safety 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).

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“Captisol Patents” means all patents and patent applications in the Territory which pertain to Captisol, other than the Licensed Product Patents, and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. For avoidance of doubt, all intellectual property pertaining to the Licensed Product generated by MDCO or its Affiliates or their Sublicensees during the Term of this Agreement shall be solely owned by MDCO and shall not be part of the Captisol Patents. Set forth in Exhibit A attached hereto include, without limitation, a list of the Captisol Patents as of the Effective Date. Such Exhibit A may be updated by CyDex from time to time during the Term.

“Claim” has the meaning specified in Section 10.1.

“Clinical Grade Captisol” means [***].

“Commercial Grade Captisol” means [***].

“Commercial Launch Date” means, in any particular country, the first commercial sale by MDCO, its Affiliates or Sublicensees of the Licensed Product to a Third Party (as defined below) in a given regulatory jurisdiction after Marketing Approval has been obtained in such jurisdiction. For avoidance of doubt, any transfer of the Licensed Product to a Third Party for preclinical, clinical or regulatory purposes shall not be deemed as commercial launch.

“Commercially Reasonable Efforts” means those efforts consistent with the exercise of prudent scientific and business judgment as applied by a party to the development and commercialization of its own pharmaceutical products at a similar stage of development and with similar market potential.

“Compound” means that certain pharmaceutical compound known as [***].

“Confidential Information” has the meaning specified in Section 8.1.

“Contract Manufacturer” has the meaning specified in Section 2.4.

“Cover” (including variations thereof such as “Covered,” “Coverage,” or “Covering”) means that the manufacture, use, importation or sale of the Licensed Product which such term is

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being applied would infringe a Valid Claim of a patent in the absence of a grant of rights under such patent. The determination of whether an item or process is Covered by a Valid Claim shall be made on a country–by-country basis.

“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.

“EMEA” means the European Medicines Agency or any successor thereto.

“Expenditure” means the act of paying out funds to a Third Party for development of the Licensed Product. For the avoidance of doubt, Expenditure shall not include any credit for internal MDCO expenses, such as MDCO personnel expenses.

“FDA” means the United States Food and Drug Administration, or any successor thereto.

“Field” means all indications, including without limitation, all dosages, formulations, uses, and routes of administration for the Licensed Product.

“Generic Competing Product” has the meaning specified in Section 4.1(c)(ii) hereof.

“Indemnitee” has the meaning specified in Section 10.4.

“Indemnitor” has the meaning specified in Section 10.4.

“Licensed Patents” means, collectively, the Captisol Patents and the Licensed Product Patents.

“Licensed Product” means a pharmaceutical composition comprising the Compound [***]. For clarity, the Licensed Product shall not include any product which is a combination product incorporating the Compound with any other active pharmaceutical ingredient.

“Licensed Product Patents” means all patents and patent applications in the Territory which Cover the use of Captisol with the Compound, other than the Captisol Patents, and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. Licensed Product Patents further include all other patents and patent applications, other than the Captisol Patents, which are owned or licensed by CyDex before the Effective Date or at any time during the Term of this Agreement, and which are necessary to develop, manufacture, and commercialize the Licensed Product or which are necessary for MDCO to exercise its license under this Agreement. Set forth in Exhibit B attached hereto is a list of the Licensed Products Patents as of the Effective Date. Such Exhibit B may be updated by CyDex from time to time during the Term.

“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.

“MDCO Know-How” means information or data owned, licensed or generated by MDCO and its Affiliates, before and during the Term of this Agreement. For clarity, MDCO Know-How shall not include Product Know-How licensed under this Agreement.

“MDCO Patents” means all patents and patent applications owned now, licensed or developed during the Term of this Agreement by MDCO and its Affiliates, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. For clarity, MDCO Patents shall not include Licensed Patents under this Agreement.

“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.

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“Product Know-How” means information or data related to the Licensed Product owned, licensed or developed by CyDex and its Affiliates, which is not included within the Licensed Product Patents.

“Receiving Party” has the meaning specified in Section 8.1.

“Regulatory Approval” means, with respect to the Licensed Product in any country or jurisdiction, all approvals (including, where required, pricing and reimbursement approvals), registrations, licenses or authorizations from the relevant regulatory authority in a country or jurisdiction that is specific to the Licensed Product and necessary to market and sell such Licensed Product in such country or jurisdiction.

“Royalty Obligation Term” means, for each country within the Territory on a country-by-country basis, the time period commencing on the first Commercial Launch Date of the

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Licensed Product in such country and ending on the date that is the later of (i) the date that a Valid Claim no longer exists under the Licensed Patents in such country, or [***].

“SEC” has the meaning specified in Section 8.3.

“Specifications” means the specifications for Captisol set forth in Exhibit C hereto, as such may be amended from time to time.

“Sublicensees” has the meaning specified in Section 2.3.

“Term” has the meaning specified in Section 13.1.

“Territory” means the entire world.

“Third Party” means any person or entity other than CyDex or MDCO or an Affiliate of either of them.

“Valid Claim” means a claim in any unexpired, issued patent which has not been irrevocably abandoned or held to be invalid or unenforceable by a non-appealed or unappealable decision of a court or other authority of competent jurisdiction, which is not admitted to be invalid through disclaimer or dedication to the public, and which Covers the Licensed Product.

2. GRANT OF RIGHTS.

2.1 License Grants from CyDex to MDCO.

(a) Licensed Patents. Subject to the terms and conditions of this Agreement, CyDex hereby grants to MDCO an exclusive, nontransferable (except with respect to the assignment provision in Section 14.15 and even with respect to CyDex and its Affiliates regarding exclusivity) license during the Term under the Licensed Patents, solely to research, develop, make, have made, import, use, offer for sale and sell the Licensed Product in the Territory in the Field. Notwithstanding the foregoing, to the extent that any Licensed Patents are licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to MDCO in the foregoing sentence shall be exclusive as to CyDex and non-exclusive as to any Third Party. MDCO may not sublicense the Licensed Patents, except as expressly set forth in Section 2.3 below.

(b) Know-How License. Subject to the terms and conditions of this Agreement, CyDex hereby grants to MDCO an exclusive, nontransferable (except with respect to the assignment provision in Section 14.15 and even with respect to CyDex and its Affiliates) license during the Term under CyDex's rights in and to the Captisol Data Package and Product Know-How, solely to research, develop, make, have made, import, use, offer for sale and sell the Licensed Product in the Territory in the Field. Notwithstanding the foregoing, to the extent that any Captisol Data Package and Product Know-How are licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to MDCO in the foregoing sentence shall be exclusive as to CyDex and non-exclusive as to any Third Party. MDCO may not sublicense its rights to the Captisol Data Package or Product Know-How, except as expressly set forth in Section 2.3 below.

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(c) Scope of Licenses. Unless otherwise provided in this Agreement, CyDex grants no rights to MDCO to manufacture, import, sell or offer for sale bulk Captisol.

2.2 Grant of License from MDCO to CyDex. MDCO hereby grants to CyDex a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under MDCO's and its Affiliates' rights in and to Captisol Improvements to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol.

2.3 Sublicensing. MDCO shall have the right to grant sublicenses to any Third Party (collectively "Sublicensees") under the licenses granted to MDCO pursuant to Section 2.1; [***]

2.4 Contracting. MDCO may manufacture the Licensed Product or contract the manufacture of the Licensed Product with reputable FDA-inspected third party manufacturers (each a "Contract Manufacturer"). To the extent necessary to engage a Contract Manufacturer for manufacturing the Licensed Product, MDCO shall be permitted under this Agreement to grant any such Contract Manufacturer a sublicense under the licenses granted to MDCO pursuant to Section 2.1 solely for such purposes. MDCO shall ensure that all of its Contract Manufacturers will comply with the terms and conditions of this Agreement and shall remain fully responsible for the compliance by such Contract Manufacturers with the terms and conditions of this Agreement as if such Contract Manufacturers were MDCO hereunder.

2.5 Technology Transfer. Within [***] after the Effective Date, CyDex shall provide MDCO with a technology transfer package, which shall include the Product Know-How and the Captisol Data Package, related to the formulation, filling and packaging of the Licensed Product. CyDex shall also, for a period of [***] after the Effective Date, make its personnel available to MDCO and its Contract Manufacturers to respond to informational inquiries and provide technical assistance related to the Product Know-How and the Captisol Data Package. Beginning on the earlier of (i) [***] after the first contact by MDCO relating to the technology transfer or (ii) [***] after the Effective Date, MDCO shall compensate CyDex at the rate of [***] for the time of CyDex personnel incurred to provide such services. Such technology transfer shall not include information related to the manufacture of bulk Captisol.

2.6 Negative Covenant. During the Term of this Agreement, CyDex and its Affiliates shall not develop or commercialize any pharmaceutical composition comprising the Compound, and shall not in any way assist any Third Party in developing or commercializing any pharmaceutical composition comprising the Compound.

3. MANUFACTURE AND SUPPLY OF CAPTISOL.

The provisions of the Supply Agreement and any related quality agreement shall govern the manufacture and supply of Captisol for use in the formulation of the Licensed Product.

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4. COMPENSATION.

4.1 Payments and Royalties for Licenses.

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4.2 [***]

4.3 Currency. All amounts due hereunder are stated in, and shall be paid in, U.S. dollars. Net Sales based on foreign revenue [***]. MDCO shall provide CyDex, together with each royalty payment owed pursuant to Section 4.1(c) above, a schedule detailing the calculation of Net Sales resulting from the conversion of foreign revenue to U.S. dollars as set forth herein.

4.4 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement or the Supply Agreement.

(b) Tax Cooperation. The parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by MDCO to CyDex under this Agreement or the Supply Agreement. To the extent MDCO is required to deduct and withhold taxes on any payment to CyDex, MDCO shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex an official tax certificate or other evidence of such withholding sufficient to enable CyDex to claim such payment of taxes. CyDex shall provide MDCO any tax forms that may be reasonably necessary in order for MDCO to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. CyDex shall use reasonable efforts to provide any such tax forms to MDCO at least [***] prior to the due date for any payment for which CyDex desires that MDCO apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or value added tax.

4.5 Late Payments. Payment of CyDex's invoices shall be made within [***] of MDCO's receipt of such invoices. Unpaid balances shall accrue interest, from due date until paid, at a rate equal to the prime rate, [***], unless such unpaid balance is subject to a reasonable, good faith dispute by MDCO.

5. RECORDS; REPORTS; AUDIT.

5.1 Records. During the Term and for a period of [***] thereafter, MDCO shall, and shall require its Affiliates and Sublicensees to maintain accurate records relating to Net Sales of the Licensed Product.

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5.2 Reports. MDCO shall update CyDex annually regarding development and commercial activities with respect to the Licensed Product.

5.3 Audit. Upon reasonable prior notice, such records shall be available during regular business hours for a period [***], and not more often than [***], by an independent certified public accountant selected by CyDex and reasonably acceptable to MDCO, for the sole purpose of verifying the

accuracy of the financial reports furnished by MDCO pursuant to this Agreement. Any such auditor shall not disclose MDCO's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by MDCO or the amount of payments due by MDCO under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [***] from the accountant's report from the original due date, plus interest accrued thereon (from the applicable original due date) at the rate set forth in Section 4.4 above. Any amounts shown to have been overpaid shall be refunded within [***]. CyDex shall bear the full cost of such audit unless such audit discloses an underpayment by MDCO of more than [***] of the amount due, in which case MDCO shall bear the full cost of such audit.

6. DEVELOPMENT AND COMMERCIALIZATION BY MDCO.

6.1 Diligence. MDCO shall (i) use at least Commercially Reasonable Efforts, and shall further require its Affiliates and Sublicensees to use at least Commercially Reasonable Efforts, to develop the Licensed Product, and to commercialize the Licensed Product following Regulatory Approval of the Licensed Product [***].

6.2 Costs and Expenses. Other than those specified in this Agreement, MDCO 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.

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

6.4 Access to MDCO'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 MDCO, its Sublicensees or Affiliates in connection with CyDex's development and commercialization of Captisol or for fulfilling its obligations under this Agreement, at no cost to CyDex. Upon request by CyDex, MDCO 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.

7. REGULATORY MATTERS.

7.1 Captisol Information Submitted for Regulatory Review. Except as otherwise set forth herein, MDCO shall be solely responsible for all communications with regulatory agencies in connection with the Licensed Product. Notwithstanding the foregoing, MDCO shall

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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.

7.2 Material Safety. CyDex shall provide MDCO, in writing, from time to time, 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, MDCO 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, (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. Either party 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. In the event that either party becomes aware of any adverse event relating to either the Licensed Product or Captisol, the party shall timely inform the other party of any such adverse event.

8. CONFIDENTIALITY.

8.1 Definition. MDCO 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 MDCO 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 information disclosed by the Disclosing Party to the Receiving Party and designated in writing by the Disclosing Party as "Confidential" (or equivalent), and all material disclosed orally which is declared to be confidential by the Disclosing Party and confirmed in a writing delivered to the Receiving Party within [***] of such disclosure, 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 and Product Know-How. MDCO's Confidential Information includes MDCO Patents and MDCO Know-How.

8.2 Obligation. CyDex and MDCO agree that they will disclose the other's Confidential Information to its own officers, employees, consultants 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

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customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Unless otherwise specified in this Agreement and subject to terms and conditions in this Agreement, 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 [***] of the request, and in any event, promptly following the termination of this Agreement, except that the receiving party may retain [***] for archival purposes and (ii) [***].

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; or

(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.

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 make a reasonable effort to obtain, or to assist the Disclosing Party 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. MDCO may further disclose CyDex's Confidential Information to extent that such disclosure is necessary to develop, file for Regulatory Approval, or commercialize the Licensed Product, or to seek, prosecute and maintain intellectual property protection for the Licensed Product.

8.4 Injunction. Each party agrees that should it breach or threaten to breach any provisions of this Section 8, the Disclosing Party will suffer irreparable damages and its remedy at law will 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, without need to post any bond or security.

8.5 Third Party Information. MDCO acknowledges that CyDex's Confidential Information includes information developed by [***] that is confidential to both CyDex and [***]. In so far as Confidential Information of [***] is disclosed, [***] is a third-party

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beneficiary of this Section 8 of this Agreement and may enforce it or seek remedies pursuant to it in accordance with its terms.

8.6 Public Announcements. The Parties will mutually agree on a press release to be issued upon execution of this Agreement or reasonably soon thereafter. Neither Party shall make any subsequent public announcement concerning this Agreement or the terms hereof not previously made public without the prior written approval of the other Party with regard to the form, content, and precise timing of such announcement, except as may be required to be made by either Party in order to comply with applicable Law, regulations, court orders, or tax, securities filings,

financing arrangements, acquisitions, or sublicenses. Such consent shall not be unreasonably withheld or delayed by such other Party. Prior to any such public announcement, the Party wishing to make the announcement will submit a draft of the proposed announcement to the other Party in sufficient time to enable such other Party to consider and comment thereon.

9. REPRESENTATIONS AND WARRANTIES.

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

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

(ii) it has the complete and unrestricted power and right to enter into this Agreement and to perform its obligations hereunder;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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; and

(vii) 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 Additional Representations and Warranties of CyDex. CyDex represents and warrants to MDCO that, as of the Effective Date:

(a) it (directly or through its Affiliates) is the owner or licensee of the Licensed Patents and has the right to grant the licenses to MDCO for the Captisol Data Package, Product Know-How, and the Licensed Patents pursuant to this Agreement, and it has not and will not grant such license to any Third Party;

(b) to CyDex's knowledge, it (directly or through its Affiliates) is the owner of all the intellectual property rights necessary to develop, manufacture, and commercialize the Licensed Product, and all such rights have been licensed to MDCO pursuant to this Agreement;

(c) to CyDex's knowledge, other than the intellectual property licensed to MDCO pursuant to this Agreement, no other intellectual property right and interests are required or necessary to develop, manufacture, and commercialize the Licensed Product;

(d) after the Effective Date, it (directly or through its Affiliates) shall provide to MDCO pursuant to Section 2.5 above, all material Confidential Information of CyDex pertaining to the development, manufacture, or commercialization of the Licensed Product;

(e) as of the Effective Date, CyDex or any of its Affiliates has not received any notice from any Third Party asserting or alleging that any research or development of the Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(f) to CyDex's knowledge, there are no actual, pending, alleged or threatened adverse actions, suits, claims, interferences or formal governmental investigations pertaining to the Licensed Product, the Licensed Patents and the Product Know How by or against CyDex or any of its Affiliates in or before any court, governmental or regulatory authority; and

(g) CyDex covenants and agrees that it will not enter into any agreement or other arrangement with any Third Party following the Effective Date that would limit MDCO's right and ability to exploit the rights and licenses granted by CyDex to MDCO under this Agreement.

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 LICENSED PATENTS OR THE CAPTISOL DATA PACKAGE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS.

10. INDEMNIFICATION.

10.1 By CyDex. CyDex shall defend, indemnify and hold MDCO 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

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MDCO as a result of any claim, demand, action or other proceeding (each, a "Claim") by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Capitsol by CyDex and its Affiliates; or (b) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in Sections 9.1 and 9.2, and to the extent that such Losses are not due to MDCO's negligence or misconduct.

10.2 By MDCO. MDCO 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 manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of the Licensed Product by MDCO, its Affiliates and Sublicensees; or (b) MDCO's breach of this Agreement, including without limitation any of its representations and warranties set forth in Section 9.1 and to the extent that such Losses are not due to CyDex's negligence or misconduct.

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.

11. LIMITATION OF LIABILITY.

11.1 Limitation of Remedies. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN SECTION 8.

11.2 [***]

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

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12. MANAGEMENT OF LICENSED PATENTS.

12.1 Prosecution and Maintenance.

(a) CyDex Patents. CyDex shall maintain or abandon, [***].

(b) Licensed Product Patents. MDCO shall maintain [***], provided that (i) CyDex shall be provided with the right and opportunity to give comments and recommendations as to the overall strategy regarding the filing, prosecution and maintenance of the Licensed Product Patents, and (ii) MDCO shall seek to prosecute, obtain and maintain the Licensed Product Patents in [***] (the "Major Markets"). MDCO agrees that, during the Term, it will use best efforts to prosecute, obtain and maintain the Licensed Product Patents in the Major Markets. In the event that MDCO decides not to prosecute and maintain the Licensed Product Patents in a country or countries outside of the Major Markets, MDCO shall provide not less than [***] prior written notice of such decision, and CyDex shall have the option to take over the prosecution and maintenance in such country or countries. For clarity, in the event that MDCO fails to meet such requirements for any Major Market country, CyDex shall have the right to terminate this Agreement pursuant to Section 13.2 hereof with respect to such country (but not other countries within the Territory).

(c) MDCO Patents and MDCO Know-How. MDCO shall be the sole and exclusive owner of MDCO Patents and MDCO Know How. [***].

12.2 Infringement of Captisol Patents by Third Parties. If MDCO becomes aware that a third party may be infringing a Captisol Patent, it will promptly notify CyDex in writing, providing all information available to MDCO regarding the potential infringement. CyDex shall take whatever, if any, action it deems appropriate, in its sole discretion, against the alleged infringer. If CyDex elects to take action, MDCO 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 related to a Captisol Patent. MDCO shall not take any such action against the alleged infringer related to a Captisol Patent without the written consent of CyDex. If either party recovers monetary damages from any Third Party in a suit or action brought for infringement of a Captisol Patent, such recovery shall be allocated [***]. For clarity, this Section 12.2 shall not apply in the event of Product Infringement as defined below in Section 12.3(a). MDCO shall have the right to consent to any settlement concluded by CyDex that would provide the alleged infringer any right to use the Captisol Patents for a product containing the Compound.

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12.3 Infringement of Licensed Product Patents by Third Parties.

(a) Notification. Each party shall promptly notify the other party in writing of any existing or threatened infringement of the Licensed Product Patents through the development or commercialization of a product comprising the Compound as an active ingredient by a Third Party, of which such Party becomes aware, including any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions and of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Licensed Product Patents (collectively "Product Infringement").

(b) Product Infringement.

(i) For any Product Infringement, MDCO shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement. If MDCO fails to institute and prosecute an action or proceeding to abate the Product Infringement within a period of [***] after the first notice under this section to elect to enforce the Licensed Product Patent or otherwise having knowledge of the Product Infringement, then CyDex shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Licensed Product Patent against such third Party perpetrating such Product Infringement at its own cost and expense. In this case, MDCO shall take appropriate actions in order to enable CyDex to commence a suit or take the actions set forth in the preceding sentence.

(ii) Each party shall provide to the party enforcing any such rights under this Section 12.2 reasonable assistance in such enforcement, at such enforcing party's request and expense, including joining such action as a party plaintiff if required by applicable law to pursue such action. The enforcing party shall keep the other party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other party's comments on any such efforts.

(iii) Each party [***].

(iv) The party not bringing an action with respect to Product Infringement under this Section 12.2 shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such party shall at all times cooperate fully with the party bringing such action.

(c) Allocation of Proceeds. If either party recovers monetary damages from any Third Party in a suit or action brought for a Product Infringement, such recovery shall be [***].

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13. TERM AND TERMINATION.

13.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and shall continue in effect thereafter, on a country-by-country basis, until the expiration of MDCO's obligations to pay royalties under Section 4.1(c), unless terminated earlier as set forth herein.

13.2 Termination for Breach.

(a) Notice. If either party believes that the other is in material breach of this Agreement, then the party holding such belief (the "Non-breaching Party") may deliver notice of such breach to the other party (the "Notified Party"). The Notified Party shall have thirty (30) days to cure such breach to the extent involving non-payment of amounts due hereunder, and one hundred twenty (120) days to either cure such breach for all

other material breaches, or, if cure of such breach other than non-payment cannot reasonably be effected within such one hundred twenty (120) day period, to deliver to the Non-breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing but in no event in excess of an additional ninety (90) day period. Following delivery of such a plan, the Notified Party shall diligently carry out the plan and cure the breach and the cure period shall be extended by the time period provided in such plan but in no event to exceed two hundred ten (210) days from the date of any initial breach notice delivered under this Section 13.2.

(b) Failure to Cure. If the Notified Party fails to cure a material breach of this Agreement as provided for in Section 13.2, then the Non-Breaching Party may terminate this Agreement upon written notice to the Notified Party.

(c) Other Termination Rights. CyDex shall additionally have the right to terminate this Agreement either in the United States or Europe, as applicable, in accordance with Section 4.2(d).

(d) Disputes. If a party gives notice of termination under this Section 13.2 and the other Party disputes whether such termination is proper under this Section 13.2, then the issue of whether this Agreement may properly be terminated upon expiration of the notice period (unless such breach is cured as provided in Section 13.2) shall be resolved in accordance with Section 14.4. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to have been effective [***] following the date of the notice of termination (or such other time period applicable pursuant to Section 13.2). If as a result of such dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.

13.3 Termination by MDCO for Convenience. MDCO shall have the right to terminate this Agreement in its entirety without cause by providing CyDex with [***] prior written notice.

13.4 CyDex Rights upon Termination (Other Than for CyDex Breach). In event that MDCO terminates the Agreement without cause pursuant to Section 13.3 or that CyDex

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terminates this Agreement pursuant to Section 13.2, the following shall apply (in addition to any other rights and obligations otherwise under this Agreement with respect to such termination):

[***]

[***]

[***]

[***]

[***]

[***]

13.5 CyDex Rights upon Termination (If for CyDex Breach). In event that MDCO terminates the Agreement due to CyDex's breach pursuant to Section 13.2, the following shall apply (in addition to any other rights and obligations otherwise under this Agreement with respect to such termination):

(a) Termination of Licenses. All rights granted to MDCO or all rights granted to CyDex herein shall immediately terminate, provided, that, in the event that the termination is for one or more countries, the rights granted to MDCO herein and the rights granted to CyDex shall terminate in the country or countries where this Agreement has been terminated.

(b) Regulatory Filings. MDCO shall retain all regulatory filings and data generated by MDCO, its Affiliates and Sublicensees during the Term of this Agreement, including any existing Market Approval for the Licensed Product, and CyDex shall not have rights to use any such regulatory filings, data or Market Approval. In the event that the termination is for one or more countries, this section shall only apply to the country or countries where this Agreement has been terminated.

(c) Return of Records. 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 [***], and (ii) in the event that the termination is for one or more countries, the records to be returned shall be for the country or countries where this Agreement has been terminated.

13.6 MDCO Rights Upon Expiration. On a country-by-country basis, upon the expiration of MDCO's obligations to pay royalties under Section 4.1(c), the license granted to

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MDCO under this Agreement shall become a fully-paid, royalty-free, and perpetual license for the Licensed Product in the Field.

13.7 Termination of the Supply Agreement. For clarity, this Agreement shall terminate if the Supply Agreement is terminated by MDCO without cause, or terminated by CyDex because of any material breach by MDCO.

13.8 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 MDCO of its obligation to pay CyDex royalties for all Licensed Product sold by MDCO, its Affiliates or Sublicensees prior to the effective date of such expiration or termination. Sections 2.2 (Grant of License from MDCO to CyDex), 4.1 (Payments and Royalties for Licenses), 4.3 (Currency), 4.4 (Taxes), 4.5 (Late Payments), 5 (Records; Reports; Audits), 6.4 (Access to MDCO's Data), 7.3 (Adverse Event Reporting), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification), 11 (Limitation of Liability), 13.4 (CyDex Rights Upon Termination (Other Than for CyDex Breach)), 13.5 (CyDex Rights Upon Termination (If for CyDex Breach), 13.6 (MDCO's Rights Upon Expiration), 13.8 (Survival), and 14 (General Provisions) shall survive termination or expiration of this Agreement.

14. GENERAL PROVISIONS.

14.1 Non-Solicitation. During the Term and for a period of [***] thereafter, neither party shall solicit, induce, encourage or attempt to induce or encourage any employee of the other party to terminate his or her employment with such other party or to breach any other obligation to such other party. This section is not meant to encompass general solicitations such as may be found in newspaper advertisements and the like.

14.2 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.

14.3 Compliance with Law. Each of the parties will comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing use and patent, copyright and trade secret protection.

14.4 Arbitration.

(a) Procedure. Except as otherwise expressly set forth in Section 14.4(b) below, any and all disputes or controversies 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 reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and MDCO. If CyDex and MDCO cannot

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agree on a single arbitrator within [***] after a demand for arbitration has been made, CyDex shall appoint an arbitrator, MDCO 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 14.4(a). Except as to the selection of arbitrators, the arbitration proceedings shall be conducted promptly and in accordance with the rules of the American Arbitration Association then in effect. The expenses of any arbitration, including the reasonable attorney fees of the prevailing party, [***].

(b) Short-Form Arbitration. Any dispute subject to short-form arbitration as provided in 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 by a single arbitrator reasonably knowledgeable about the pharmaceutical industry and appointed in accordance with such rules. Such arbitrator shall make his or her determination on the basis of "baseball arbitration" principles. THE FOREGOING REMEDY SHALL BE EACH PARTY'S SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY SUCH DISPUTE. The expenses of any arbitration, including the reasonable

attorney fees of the prevailing party, [***]. In each case, the parties and arbitrator shall use all diligent efforts to complete such arbitration within [***] of appointment of the arbitrator.

(c) 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, no party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other party.

(d) Interim Equitable Relief. Each party shall, in addition to all other remedies accorded by law and permitted by this Agreement, be entitled to equitable relief (including but not limited to interim injunctive relief) in any court having jurisdiction to protect its interests. Neither party shall commence any court proceeding or action against the other to resolve any dispute, except (i) to enforce an arbitral award rendered pursuant to this Section 14.4, or (ii) for such interim injunctive relief.

(e) Binding Effect. The provisions of this Section 14.4 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.

14.5 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.

14.6 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

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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.

14.7 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 14.7. Unless otherwise provided, all notices shall be sent:

If to CyDex, to: CyDex Pharmaceuticals, Inc.

10513 W. 84th Terrace

Lenexa, KS 66214

Attention: President

Fax: (913) 685-8856

With a copy to: General Counsel

Ligand Pharmaceuticals

11085 North Torrey Pines Road

Suite 300

La Jolla, CA 92037

Fax: 858-550-7272

If to MDCO, to: The Medicines Company

8 Sylvan Way

Parsippany, NJ 07054

Attention: [***]

Fax: 862-207-6013

With a copy to: [***]

The Medicines Company

8 Sylvan Way

Parsippany, NJ 07054

Fax: 862-207-6062

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, the [***] 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.

14.8 Use of Name. No party shall use the name, trademark, trade name or logo of the other party, its Affiliates or their respective employee(s) in any publicity, promotion, news

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release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other party, except as may be required by law. The parties agree that a party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in (i) securities filings with the Securities Exchange Commission (“SEC”) (or equivalent foreign agency) to the extent required by law after complying with the procedure set forth in this Section 14.8, or (ii) under conditions of confidentiality in connection with investment and similar corporate transactions. 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.

14.9 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey (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 MDCO 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 MDCO 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, sale of stock or otherwise, without the other party's prior written consent. As a condition to any permitted assignment hereunder, the assignor must guarantee 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 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 MDCO 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

THE MEDICINES COMPANY

By: /s/ Clive A. Meanwell

Name: Clive A. Meanwell

Title: Chairman and CEO

EXHIBIT A: CAPTISOL PATENTS

[***]

[***]

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

[***]

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LICENSE AGREEMENT EXHIBIT A-1

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LICENSE AGREEMENT EXHIBIT A-3

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LICENSE AGREEMENT EXHIBIT A-4

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EXHIBIT B: LICENSED PRODUCT PATENTS

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EXHIBIT C: SPECIFICATIONS

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LICENSE AGREEMENT EXHIBIT C-1

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LICENSE AGREEMENT EXHIBIT D-1

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EXHIBIT E: LIMITATION OF DAMAGES

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LICENSE AGREEMENT EXHIBIT E-1