Confidential Draft No. 2 submitted on December 19, 2013.
As filed with the Securities and Exchange Commission on , 2013.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
Under
THE SECURITIES ACT OF 1933

ALDEXA THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	2834	20-1968197
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

15 New England Executive Park
Burlington, MA 01803
Telephone: (781) 270-0630

(Address, including zip code and telephone number, including area code, of registrant's principal executive offices)

Todd C. Brady, M.D., Ph.D.
President and Chief Executive Officer
Aldexa Therapeutics, Inc.
15 New England Executive Park
Burlington, MA 01803
Telephone: (781) 270-0630

(Name, address, including zip code and telephone number, including area code, of agent for service)

	Copies to:	
Jay K. Hachigian **Keith J. Scherer** **Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP** **850 Winter Street** **Waltham, MA 02451** **Telephone: (781) 890-8800** **Telecopy: (781) 622-1622**	**Scott L. Young** **Chief Operating Officer** **15 New England Executive Park** **Burlington, MA 01803** **Telephone: (781) 270-0630**	**Ivan K. Blumenthal** **Avisheh Avini** **Mintz Levin Cohn Ferris Glovsky and Popeo PC** **666 Third Avenue** **New York, NY 10017** **Telephone: (212) 935-5000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 the 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 ☐ Smaller reporting company ☒

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee (3)
Common Stock, $0.001 par value per share(4)	$	$
Representative's Warrant to Purchase Common Stock(5)	-	-
Common Stock Underlying Representative's Warrant(4)(6)	$	$
TOTAL REGISTRATION FEE	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the offering price of shares of common stock that the underwriters have the option to purchase to cover over-allotments, if any.
(3) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
(4) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares of common stock registered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.
(5) No registration fee pursuant to Rule 457(g) under the Securities Act, as amended.
(6) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 125% of the public offering price. As estimated solely for the purpose of recalculating the registration fee pursuant to Rule 457(g) under the Securities Act, the proposed maximum aggregate offering price of the representative's warrant is $ (which is equal to 4% of $).

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

Explanatory Note

This Draft Registration Statement No. 2 is being submitted solely for the purposes of filing Exhibit 10.10 and amending the disclosures in Item 16 of Part II of the Draft Registration Statement. No changes or additions are being made hereby to the Prospectus constituting Part I of the Draft Registration Statement (not included herein) or to Items 13, 14, 15 or 17 of Part II of the Draft Registration Statement.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and The NASDAQ Capital Market listing fee.

SEC registration fee	*
FINRA filing fee	*
Listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue sky fees and expenses	*
Custodian and transfer agent fees	*
Miscellaneous fees and expenses	*
Total	*

***** To be completed by amendment

Item 14. Indemnification of Directors and Officers.

In connection with the completion of this offering, the Registrant's amended and restated certificate of incorporation will contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of the Registrant's directors for monetary damages for breach of their fiduciary duties as directors. The Registrant's amended and restated bylaws to be in effect immediately prior to the completion of this offering provide that the Registrant must indemnify its directors and officers and may indemnify its employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

Prior to the consummation of this offering, the Registrant expects to enter into indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its amended and restated bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Underwriting Agreement, the form of which is attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the underwriters, for certain liabilities, including liabilities arising under the Securities Act, and affords certain rights of contribution with respect thereto.

See also "Undertakings" set out in response to Item 17 herein.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding the shares of common stock and preferred stock and the warrants issued, and options granted, by us in the three years preceding the filing of this registration statement that were not registered under the Securities Act of 1933.

(1) Under the 2004 Employee, Director and Consultant Stock Plan, we granted stock options to purchase shares of our common stock to certain of our employees, officers, consultants and advisors, as follows: (a) from August 13, 2004 to July 1, 2005, we granted stock options to purchase an aggregate of 465,000 shares of our common stock at an exercise price of $0.001 per share; (b) in 2008, we granted stock options to purchase an aggregate of 215,000 shares of our common stock at an exercise price of $0.10 per share; (c) in 2008, we granted stock options to purchase an aggregate of 25,000 shares of our common stock at an exercise price of $0.10 per share; (d) in 2009, we granted stock options to purchase 750,137 shares of our common stock at an exercise price of $0.27 per share; and (e) in 2010, we granted stock options to purchase 1,274,082 shares of our common stock at an exercise price of $0.27 per share.

(2) Under the 2010 Employee, Director and Consultant Equity Incentive Plan, we granted stock options to purchase shares of our common stock to certain of our employees, officers, consultants and advisors, as follows: (a) in 2010, we granted a stock option to purchase an aggregate of 175,000 shares of our common stock at an exercise price of $0.27 per share, (b) in 2012, we granted stock options to purchase 344,350 shares of our common stock at an exercise price of $0.27 per share, (c) in 2013, we granted stock options to purchase an aggregate of 5,358,833 shares of our common stock at an exercise price of $0.046 per share and (d) in 2013 we granted stock options to purchase an aggregate of 1,152,504 shares of our common stock at an exercise price of $0.38 per share.

(3) In 2008, we issued and sold an aggregate of 8,784,950 shares of Series A convertible preferred stock to investors for an aggregate purchase price of $9.0 million.

(4) In 2010, we issued and sold an aggregate of 2,979,756 shares of Series A convertible preferred stock to investors for an aggregate purchase price of $3.0 million.

(5) In 2013, we issued and sold an aggregate of 15,800,191 shares of Series B convertible preferred stock to investors for an aggregate purchase price of $6.8 million.

(6) In 2012, as consideration for entering into a debt facility, we issued a warrant to Square 1 Bank exercisable for an aggregate of 24,510 shares of our Series A convertible preferred stock at an initial exercise price of $1.02 per share. This warrant will become exercisable for an aggregate of 58,153 shares of our common stock immediately prior to the closing of this offering. This warrant terminates seven years after the date issued.

(7) In 2012, in connection with our Series B financing, we issued warrants to investors exercisable for an aggregate of 1,163,062 shares of our Series B convertible preferred stock at an initial exercise price of $0.4299 per share. These warrants will become exercisable for an aggregate of 1,163,062 shares of our common stock immediately prior to the closing of this offering. This warrant terminates five years after the date issued.

(8) In 2013, in connection with our Series B financing, we issued warrants to investors exercisable for an aggregate of 1,163,060 shares of our Series B convertible preferred stock at an initial exercise price of $0.4299 per share. These warrants will become exercisable for an aggregate of 1,163,060 shares of our common stock immediately prior to the closing of this offering. This warrant terminates five years after the date issued.

(9) In 2013 we sold an aggregate of 155,377 shares of our common stock to Todd C. Brady, M.D., Ph.D. pursuant to a restricted stock grant under our 2010 Employee, Director and Consultant Equity Incentive Plan.

(10) In 2013 we issued a convertible promissory note in the principal amount of $170,000 to Domain Partners VI, L.P. convertible into shares of our common stock in connection with this offering. The note accrues interest at a rate of 6% per annum and will be convertible into shares of our common stock at the price per share of the common stock listed on the cover page of the prospectus contained in this registration statement.

(11) In 2013 as consideration for the amendment to our debt facility, we issued a warrant to Square 1 Bank exercisable for an aggregate of 116,306 shares of our Series B convertible preferred stock at an initial exercise price of $0.4299 per share. This warrant will become exercisable for an aggregate of 116,306 shares of our common stock immediately prior to the closing of this offering. This warrant terminates ten years after the date issued.

The offers, sales, grants and issuances of the securities described in paragraph (1), (2) and (9) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701. The recipients of such securities were our employees, officers, bona fide consultants and advisors and received the securities under our 2004 Employee, Director and Consultant Stock Plan and our 2010 Employee, Director and Consultant Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us

The offer, sale, and issuance of the securities described in paragraphs (3), (4), (5), (6), (7), (8), (10) and (11) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act in that the issuance of the security to the accredited investor did not involve a public offering. The recipients of the securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in this transaction. The recipient of the securities in this transaction was an accredited investor under Rule 501 of Regulation D.

Item 16. Exhibits and Financial Statement Schedules.

Exhibit	Description
1.1*	Form of Underwriting Agreement
3.1#	Restated Certificate of Incorporation, as amended (currently in effect)
3.2#	Bylaws (currently in effect)
3.3#	Form of Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)
3.4*	Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)
4.1*	Specimen stock certificate evidencing the shares of common stock
4.2#	Investor Rights Agreement dated as of December 20, 2012
4.3*	Form of Representative's Warrant Agreement
5.1*	Opinion of Gunderson Dettmer, LLP
10.1*	Form of Indemnity Agreement for Directors and Officers
10.2+#	Offer Letter, effective as of August 1, 2013, between the Registrant and Todd C. Brady, M.D., Ph.D.
10.3+#	Offer Letter, effective as of July 15, 2013, between the Registrant and Scott L. Young
10.4+*	Offer Letter, effective November , 2013 between the Registrant and Todd C. Brady, M.D., Ph.D.
10.5+*	Offer Letter, effective November 27, 2013, between the Registrant and Scott L. Young
10.6+#	2004 Employee, Director and Consultant Stock Plan, as amended, and form of option agreement thereunder
10.7+#	2010 Employee, Director and Consultant Equity Incentive Plan, as amended, and form of option agreement thereunder
10.8*+	2013 Equity Incentive Plan and form of option agreement thereunder
10.9*+	Independent Director Compensation Policy
10.10†	License and Supply Agreement dated as of February 19, 2010 between the Registrant and CyDex Pharmaceuticals, Inc.
10.11#	Loan and Security Agreement, dated as of April 12, 2012, between Square 1 Bank and the Registrant
10.12#	Amendment No. 1 to Loan and Security Agreement, date as of November 20, 2013 between Square 1 Bank and the Registrant
10.13#	Amended and Restated Intellectual Property Security Agreement dated as of November 20, 2013 between Square 1 Bank and the Registrant
23.1*	Consent of BDO USA, LLP, independent registered public accounting firm
23.2*	Consent of Gunderson Dettmer LLP (included in Exhibit 5.1)
24.1#	Power of Attorney (included on signature page)

* To be filed by amendment.

+ Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. Omitted portions have been submitted separately to the Securities and Exchange Commission.

Previously submitted.

(b) Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act, and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes to provide the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

3. For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

4. In a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

   (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

   (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

   (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

   (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on this day of , 2013.

ALDEXA THERAPEUTICS, INC.

By: _____
Todd Brady, M.D., Ph.D.
President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Todd C Brady, M.D., Ph.D., and Scott L. Young, and each of them singly (with full power to each of them to act alone), and each of them, as his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments) and any registration statement related thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
Todd C. Brady, M.D., Ph.D.	Chief Executive Officer and Director (principal executive officer and principal financial and accounting officer)	, 2013
C. Boyd Clarke	Chairman of the Board of Directors	, 2013
Ben Bronstein, M.D.	Director	, 2013
Martin J. Joyce	Director	, 2013
Gary Phillips, M.D.	Director	, 2013
Jesse Treu, Ph.D.	Director	, 2013
Neal Walker, D.O.	Director	, 2013

EXHIBIT INDEX

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10.13#	Amended and Restated Intellectual Property Security Agreement dated as of November 20, 2013 between Square 1 Bank and the Registrant
23.1*	Consent of BDO USA, LLP, independent registered public accounting firm
23.2*	Consent of Gunderson Dettmer LLP (included in Exhibit 5.1)
24.1#	Power of Attorney (included on signature page)

* To be filed by amendment.

+ Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. Omitted portions have been submitted separately to the Securities and Exchange Commission.

Previously submitted.

CONFIDENTIAL TREATMENT REQUESTED

LICENSE AND SUPPLY AGREEMENT

THIS LICENSE AND SUPPLY AGREEMENT (this "**Agreement**") is made this 19th day of February 2010 (the "**Effective Date**") between:

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

Neuron Systems, Inc, a Delaware corporation with offices at 15 New England Executive Park, Burlington MA 01803 ("**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®, a patented drug formulation system designed to enhance the solubility and stability of drugs;

WHEREAS, Company desires to obtain a license to use such patented drug formulation system 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, 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:

1. DEFINITIONS.

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

1.1 "**Affiliate**" means, with respect to any party, any entity controlling, controlled by, or under common control with such party, during and for such time as such control exists. For these purposes, "control" shall refer to the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of the relevant entity.

1.2 "**Captisol**" means Captisol®, also known scientifically as ****.

1.3 "**Captisol Data Package**" means ****.

****

1.4 "**Captisol Improvement**" means any technology or improvement specific to Captisol, whether or not patentable, that is developed by Company or its Affiliates or Sublicensees, solely or jointly with a third party.

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

1.6 "**Clinical Grade Captisol**" means Captisol which (a) has been manufactured under conditions of current good manufacturing practices for bulk excipients as set forth in U.S. Pharmacopoeia <1078> as of the Effective Date or any successor thereto, (b) is intended for use in humans, (c) is intended for clinical trials for the Licensed Product and (d) meets the Specifications.

1.7 "**Commercial Grade Captisol**" means Captisol which (a) has been manufactured under conditions of current good manufacturing practices for bulk excipients as set forth in U.S. Pharmacopoeia <1078> as of the Effective Date or any successor thereto, (b) is intended for use in humans, (c) is intended for commercial sale of the Licensed Product and (d) meets the Specifications.

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

1.9 "**Compound**" means that certain pharmaceutical compound known as **NS-2** with the chemical name ****, owned by or licensed to Company and developed and manufactured by or on behalf of Company.

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

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

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

1.13 "**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.

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

1.15 "**Field**" means any ocular treatment for ****.

1.16 "**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.

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

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

1.19 "**Licensed Patents**" means all patents and patent applications in the Territory which cover Captisol and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. Set forth in ***Exhibit A*** attached hereto is a list of the Licensed Patents as of the Effective Date. Such ***Exhibit A*** may be updated by CyDex from time to time during the Term.

1.20 "**Licensed Product**" means the Compound combined with or formulated using Captisol covered by the Licensed Patents in all dosage forms/formulations for ultimate use in humans. ****

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

1.22 "**Marketing Approval**" means final approval of an NDA by the FDA, 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.

1.23 "**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.

1.24 "**Net Sales**" means gross amounts invoiced by Company, its Affiliates and Sublicensees for sales of the Licensed Product, less the following: (a) normal and customary trade, quantity and/or cash discounts, allowances and rebates actually allowed or given; returns and credits actually allowed for rejections, defects or recalls of Licensed Product, outdated or returned Licensed Product, or because of rebates or retroactive price reductions; freight, postage, shipping insurance and other transportation expenses (if separately identified on the invoice); and (d) sales, value-added, excise or use taxes, tariffs, duties and customs fees and other taxes imposed with respect to specific sales.

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

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

1.27 **** has the meaning specified in Section 8.5.

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

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

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

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

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

1.33 "**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.

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

1.35 "**Sublicensees**" has the meaning specified in Section 2.3.

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

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

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

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

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

2. GRANT OF RIGHTS.

2.1 License Grants from CyDex to Company.

(a) Licensed Patents. Subject to the terms and conditions of this Agreement, including but not limited to payment of the amounts set forth in Section 4.1 below, CyDex hereby grants to Company, an exclusive, nontransferable (except with respect to the assignment provision in Section 14.15) license in the Field during the Term under the Licensed Patents, solely to make, use, sell, offer for sale and import the Licensed Product in the Territory. Company may not make, use, sell, offer for sale, or import the Licensed Product for any other purposes. Company may not sublicense the Licensed Patents, except as expressly set forth in Sections 2.3 and 2.4 below.

(b) Captisol Data Package. Subject to the terms and conditions of this Agreement, including but not limited to payment of the amounts set forth in Section 4.1 below, CyDex hereby grants to Company a non-exclusive, nontransferable (except with respect to the assignment provision in Section 14.15) license during the Term under CyDex's right in and to the Captisol Data Package, solely to make, use, sell, offer for sale and import the Licensed Product in the Territory in the Field. Company may not sublicense its rights to the Captisol Data Package, except as expressly set forth in Sections 2.3 and 2.4 below.

(c) Scope of Licenses. Without limiting the generality of the foregoing, CyDex grants no rights to Company to manufacture, import, sell or offer for sale bulk Captisol. Licensee acknowledges that not all rights of CyDex related to Captisol are included within the rights licensed hereunder, given that CyDex shall supply Company's requirements of Captisol for the Licensed Product. Company shall not attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol. ****

(d) Ownership of Captisol Improvements. All Captisol Improvements shall be owned by CyDex. Company shall provide notice to CyDex in reasonable detail of all Company's Captisol Improvements. CyDex shall have the sole right at its cost to file patent applications claiming Captisol Improvements, *provided* that all such patents shall be exclusively licensed to Company for use in the Field and included within the Licensed Patents licensed pursuant to Section 2.1(a) hereof. For clarity, CyDex agrees that it shall not after the Effective Date grant to a third party any new licenses in the Field, with respect to any Captisol Improvements created solely by Company. ****

2.2 Ownership of Licensed Product Improvements. Any technology or improvement related to the Licensed Product, whether or not patentable, that is developed by Company or its Affiliates or Sublicensees during the Term, in each case related to the Licensed Products, and which is not a Captisol Improvement, shall be owned by Company. Company shall have the sole right at its cost to file patent applications claiming such technology or improvements.

2.3 Sublicensing. Company shall have the right to grant sublicenses to its Affiliates and licensees of the Licensed Product (collectively "**Sublicensees**") under the licenses granted to Company pursuant to Section 2.1; *provided* that Company warrants and shall procure, as a condition precedent thereto, that each such Sublicensee shall first be advised of the restrictions set forth in this Agreement with respect to the transfer of the rights sublicensed to such Sublicensee and such Sublicensee shall enter into an agreement **** 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.

2.4 Contracting. Company 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 reputable FDA-inspected third party manufacturers upon notification to CyDex in writing of Company's intent to do so (such notice to include the identity and location of the

proposed third party manufacturers). To the extent necessary to engage a third party manufacturer for the Licensed Product, Company 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 Company shall procure, as a condition precedent thereto, that (a) any such third party manufacturer shall first be advised of the restrictions set forth in this Agreement with respect to the transfer of the rights licensed to Company and its Sublicensees hereunder and (b) any such third party manufacturer shall enter into an agreement **** 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.

3. MANUFACTURE AND SUPPLY OF CAPTISOL.

3.1 Purchase of Captisol. **** CyDex agrees that CyDex shall produce (or have produced for it) and sell to Company **** Company's and its Affiliates' and Sublicensees' requirements for Captisol in the formulation of Licensed Product, during the Term and subject to the provisions of this Agreement. 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 properly 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.

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 Commercial Grade Captisol for each of the following ****. Such long-term forecast shall thereafter be updated by Company at least once every ****

(b) Binding Detailed Forecast. At least **** calendar quarters prior to the first order of Commercial Grade Captisol, Company shall deliver to CyDex a detailed rolling forecast setting forth Company's requirements and anticipated delivery schedules for Commercial Grade Captisol for each calendar quarter during the succeeding **** period (the "**Detailed Forecast**"). For purposes of this Agreement, a calendar quarter means the consecutive three (3) month period ending March 31, June 30, September 30, and December 31, respectively. The parties acknowledge and agree that the first calendar quarter covered in the Detailed Forecast may be for a period less than the full three (3) month period but that each

subsequent calendar quarter shall be for a full three (3) month period. The Detailed Forecast shall thereafter be updated by Company quarterly on a rolling basis, no later than the first day of each calendar quarter, so that each calendar quarter CyDex shall have been provided with a rolling Detailed Forecast for each calendar quarter during the **** period commencing on the first day of the next calendar quarter following the date on which such Detailed Forecast is submitted. The Detailed Forecast shall be **** covered by such updated Detailed Forecast ("**Q1**", "**Q2**", "**Q3**", respectively, and where the fourth calendar quarter shall be "**Q4**"). 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 **** period.

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

(i) for the Q1 covered by such updated Detailed Forecast, **** may be made to the forecast provided for the Q2 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

(ii) for the Q2 covered by such updated Detailed Forecast, **** may be made to the forecast provided for the Q3 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(iii) for the Q3 covered by such updated Detailed Forecast, **** may be made to the forecast provided for the Q4 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

In each case CyDex's consent may be ****

(d) Purchase Orders. Together with each Detailed Forecast provided under Section 3.2(b), Company shall place a firm purchase order with CyDex in a form mutually agreed upon by the parties, for Company's order of Commercial Grade Captisol for delivery consistent with the Detailed Forecast. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (i.e., Commercial Grade Captisol, Clinical Grade Captisol or Research Grade Captisol); (ii) quantities; (iii) delivery dates; and (iv) reasonable shipping instructions. CyDex shall **** comply with Company's requested delivery dates; *provided*, *however*, that the purchase order is received by CyDex at least **** prior to the stipulated delivery date. No purchase order shall be binding upon CyDex until accepted by CyDex in writing; provided that CyDex (x) shall accept in writing within **** after CyDex's receipt of each purchase order for Clinical Grade Captisol or Research Grade Captisol, (y) shall accept in writing within **** after CyDex's receipt of each purchase order for Commercial Grade Captisol from Company with

respect to the quantities of Captisol ordered that do not exceed the Purchase Volume Limitations, and (z) shall notify Company of CyDex's ability to fill any quantities of such purchase order for Commercial Grade Captisol that are in excess of the Purchase Volume Limitations (but under the Volume Threshold) within **** after CyDex's receipt of such purchase order. CyDex shall not be obligated to accept such orders to the extent that the quantities of Commercial Grade Captisol ordered exceed the Purchase Volume Limitations, but CyDex shall **** fill such orders for such excess quantities (provided that such quantities are less than the Volume Threshold) from available supplies. If CyDex**** is unable to supply such quantities that exceed the Purchase Volume Limitations to Company, ****. 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, EXW (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. **** Quantities actually delivered to Company or Company's designee pursuant to an accepted purchase order **** and still be deemed to be in compliance with such purchase order; provided, however, ****. CyDex will ****.

3.4 Modified Specifications.

(a) General. **** In such event, CyDex shall give company at least **** notice of such change. Company shall cooperate with CyDex to have such change approved by all regulatory agencies having jurisdiction. Company shall have the right to request changes to the Specifications from time to time during the Term. CyDex shall ****. 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. CyDex shall promptly advise Company as to any lead-time changes or other terms that may result from a change to the Specifications, including but not limited to price adjustments necessary to enable CyDex to recover costs it incurred for materials already

purchased by CyDex expressly for Company, its Affiliates or Sublicensees and rendered unusable by Company, its Affiliates or Sublicensees due to a change in Specifications necessary to comply with government regulatory requirements. If a regulatory agency requires a change to the Specifications where such change is specific to Captisol as implemented in the Licensed Product, then **** shall be responsible for the costs incurred to generate such unique, modified Specifications.

(b) Material Change. In the event a change made pursuant to Section 3.4(a) results in Company not being able to use **** the new Captisol formulation (a "Material Change"), then the provisions of Section 3.7(c) shall apply.

3.5 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. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for each lot of Captisol therein.

(b) Acceptance Testing.

(1) ** Batch Selection Prior to Delivery**. Company has developed an assay (the "Assay") to detect and quantify a certain impurity, ****, in Captisol. Company desires to receive quantities of Captisol that, while meeting CyDex's Specifications for Captisol, have a maximum of **** for **** (the "****"). As requested from time to time by Company, CyDex shall reasonably cooperate with Company by providing documented samples from available batches of Captisol so that Company, prior to delivery of Captisol hereunder, may at Company's sole cost use the Assay to evaluate the **** content of such batches. For clarity, such evaluation by Company shall (i) be at ****, (ii) be under the **** of Company, (iii) not result in the Specifications for Captisol being modified with respect to **** or the ****, (iv) **** the warranty or other obligations of CyDex hereunder, and (v) not require **** to ****. Company shall promptly provide the results of such evaluation to CyDex in writing, including a list of such batches that conform to the **** and a list of such batches that do not conform to the ****. CyDex shall **** only deliver Captisol from such batches documented by CyDex as being the source of the samples identified by Company as conforming to the ****. CyDex shall not be liable to Company for any delay in delivering Captisol hereunder if such delay is a result of Company not timely reporting the results of such evaluation or a shortage of batches that conform the ****. **** shall have sole responsibility for ensuring that identified batches of Captisol conforms to the ****.

(2) General Acceptance Testing After Delivery. Company shall have a period of **** from the date of receipt to test or cause to be tested Captisol supplied under this Agreement. Company or its designee shall have the right to reject any shipment of Captisol that does not conform in all material respects 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 **** period describing the reasons for the rejection in reasonable detail. Once a delivery of Captisol is accepted or deemed accepted hereunder, Company shall have **** against CyDex in the event Captisol is subsequently deemed unsuitable for use for any reason****

(c) Confirmation. After its receipt of a notice of rejection from Company pursuant to Section 3.5(b) above, CyDex shall notify Company as soon as reasonably practical whether it accepts Company's basis for rejection and Company shall cooperate with CyDex in determining 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 ****, such notification to not be unreasonably withheld. 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. If Company pays in full for a shipment of Captisol and subsequently properly rejects such shipment in accordance with this Section 3.5, Company shall upon confirmation that such shipment failed to meet the Specifications in all material respects, be entitled, , either: (i) to a refund or credit equal to the full purchase price paid with respect to such rejected shipment; or (ii) to require CyDex to replace such rejected shipment within **** at no additional cost to Company **** Upon confirmation that such shipment failed to meet the **** in all material respects, Company shall be entitled to return all un-opened Captisol containers with respect to such rejected shipment ****

****.

(f) Exceptions. Company's rights of rejection, return, refund and replacement set forth in this Section 3.5 shall not apply to any Captisol that is non-conforming due to damage (i) caused by 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) that occurs 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.

3.6 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 **** . If such inspection is of the facilities of a Third-Party Manufacturer, Company shall ****. 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.

3.7 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; (ii) shall take all reasonable steps necessary to minimize supply delays and (iii) shall notify Company of its plan to alleviate supply delays.

(c) Shortage of Supply and Back-Up Manufacturing Rights. Each party hereby acknowledges that a material failure in the CAPTISOL supply chain may adversely affect the supply of the Licensed Product. If (1) CyDex fails to timely supply to Company at least **** of the quantities of CAPTISOL properly forecasted and ordered by Company (and provided such order was within the Purchase Volume Limitations) that conform to the Specifications **** or (2) CyDex is unable to supply or to timely supply to Company the quantity of CAPTISOL that CyDex is required to deliver to Company pursuant to accepted purchase orders due to an event of *Force Majeure* that lasts for more than **** (each, a "**Failure to Supply**") or in the event of a Material Change, then the following provisions shall be applicable:

(i) Alternate Facility. At Company's written request, CyDex shall negotiate with its Third-Party Manufacturer the terms under which the Third-Party Manufacturer would be willing to validate and qualify a backup manufacturing facility for the manufacture of CAPTISOL.

(ii) ** Inventory**. Upon CyDex's receipt of Company's written request and a purchase order covering a period of ****, both of which should be provided by Company within **** after Company's written notice, CyDex will segregate in its inventories of Captisol manufactured prior to the Material Change and at the unchanged Specifications, the amount of Captisol ordered in such purchase order provided that the amount will not exceed **** the aggregate quantity of Captisol specified in the last Long-Term forecast provided by Company to CyDex. For clarity, the provision under this Section 3.7(c)(ii) is only provided for a Material Change event.

(iii) Alternate Supplier. At Company's written request, CyDex shall negotiate with its Third-Party Manufacturer the terms under which the Third-Party Manufacturer would be willing to qualify one or more alternate suppliers for the manufacture of CAPTISOL, including without limitation, the terms of such Third-Party Manufacturer's reasonable cooperation with CyDex to qualify such alternate supplier.

(iv) Transfer of Manufacturing Technology. Company may, by providing written notice of the occurrence of such Failure to Supply or Material Change, elect to assume manufacturing of CAPTISOL under its Manufacturing License (as defined below). In the event Company elects to use another supplier to manufacture and supply CAPTISOL pursuant to this Section 3.7(c), CyDex, within **** of receipt of Company's written notice, or during such longer period as may be reasonably necessary, shall provide Company with the documentation, know-how and technical information that is necessary to make and have made CAPTISOL. ****

****. To the extent practicable, CyDex shall continue to supply Company with its needs of CAPTISOL under the terms of this Agreement until Company is capable of doing so.

(d) Manufacturing License. CyDex hereby grants to Company a non-exclusive, non-transferable license (without the right to sublicense) under all intellectual property rights of CyDex that are needed to manufacture CAPTISOL in the same manner as manufactured by the Third-Party Manufacturers solely to make, or to have made, CAPTISOL for the purpose of manufacturing Company's requirements of CAPTISOL for use in the manufacture of the Licensed Product in the Territory ("**Manufacturing License**") for the remainder of the Term; provided that such Manufacturing License shall not be exercised until the occurrence of a Failure to Supply. For clarity, the Manufacturing License shall not include the right to make CAPTISOL for any other product or for any third party and Company's exercise of the Manufacturing License and back-up manufacturing right pursuant to Section 3.7(c) hereof shall not be deemed a violation of this Agreement and thereafter Company shall not be required to purchase any of its requirements of CAPTISOL under either this Agreement.

4. COMPENSATION.

4.1 Payments and Royalties for Licenses.

(a) One-Time Fee. Company shall pay to CyDex a non-refundable, one-time fee of ******** in partial consideration of the rights granted Company under this Agreement, which amount shall be due and payable in full upon the Effective Date.

(b) Milestone Payments. Within **** following the occurrence of each of the milestone events listed below with respect to each Licensed Product, Company shall provide written notice to CyDex of the achievement of such milestone event, and within **** of the occurrence of each of the milestone events, pay to CyDex the applicable non-refundable milestone fee listed next to each such event in further consideration of the rights granted Company hereunder. The milestone payments are as follows:

MILESTONE	MILESTONE PAYMENT
****	****
****	****
****	****
****	****
****	****
****	****

(c) Royalties.

(i) In addition to amounts payable pursuant to Sections 4.1(a) and 4.1(b) above, Company shall make royalty payments to CyDex during the Term on a calendar

quarterly basis, in an amount equal to ******** of the applicable Net Sales during such quarter arising from the sale of the Licensed Product in the Territory, commencing on the first Commercial Launch Date of the Licensed Product in the Field in the Territory and continue on a country by country basis. Such royalties accrued and payable by Company to CyDex shall be capped at **** on a calendar annual basis. All royalties payable to CyDex pursuant to this Section 4.1(c)(i) shall be due and payable within **** after the conclusion of each calendar quarter.

(ii) Following the expiration of the last to expire Licensed Patent, on a country by country basis, then Company shall have the right to reduce by **** the royalty payments owed pursuant to Section 4.1(c)(i) All royalties payable to CyDex pursuant to this Section 4.1(c)(ii) shall be due and payable within **** after the conclusion of each calendar quarter. Company's obligation to pay royalties pursuant to this Section 4.1(c)(ii) shall continue until the seventh (7th) anniversary of the expiration date of the last to expire Licensed Patent, on a country by country basis provided the Licensed Product is covered by one or more Company patents.

(iii) In establishing the royalty structure hereunder, the parties recognize, and Company acknowledges, the substantial value of the various obligations being undertaken by CyDex under this Agreement, in addition to the grant of the licenses under the Licensed Patents and Captisol Data Package, to enable the rapid and effective market introduction of the Licensed Product in the Territory. The parties have agreed to the payment structure set forth herein as a convenient and fair mechanism to compensate CyDex for these obligations.

4.2 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 on ***Exhibit C*** on each **** during the Term, by **** advance written notice to Company, by a percentage equal to **** The minimum order for Commercial Grade Captisol shall be in **** increments. Notwithstanding the foregoing, if Company fails to order for any Q1 a quantity of Commercial Grade Captisol to be delivered during such Q1 that is equal to or greater than the quantity of Commercial Grade Captisol Company is obligated to purchase pursuant to the applicable Detailed Forecast (the difference between the quantity of Commercial Grade Captisol Company is obligated to purchase in Q1 pursuant to the applicable Detailed Forecast and the amount of Commercial Grade Captisol that Company actually orders in Q1, 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 thereof.

4.3 Currency. All amounts due hereunder are stated in, and shall be paid in, U.S. dollars. Net Sales based on foreign revenue will be converted to U.S. dollars at the rate of exchange published in Reuters Daily Rate Report or The Wall Street Journal, Eastern U.S. Edition on the last day of each calendar quarter. Company 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. All amounts due hereunder exclude all applicable sales, use, and other taxes, and **** will be responsible for payment of ****. **** shall indemnify and hold **** harmless from any and all such ****.

4.5 Late Payments. Unpaid balances shall accrue interest, from due date until aid, at a rate equal to the lesser of (i) ****or (ii) ****. If any amount due hereunder and not subject to a reasonable, good-faith dispute by Company remains outstanding for more than **** after its due date, CyDex may, in addition to any other rights or remedies it may have, ****.

5. RECORDS; REPORTS; AUDIT.

5.1 Records. During the Term and for a period of **** years thereafter, Company shall, and shall require its Affiliates and Sublicensees to, maintain complete and accurate records relating to (a) **** and (b) Net Sales of Licensed Product.

5.2 Reports.

(a) Quarterly Reports. Within **** following the conclusion of each calendar quarter during the Term, Company shall upon request provide CyDex with written reports with respect to such calendar quarter that (i) describe in reasonable detail Company's **** (ii) set forth in reasonable detail complete and accurate records of Company's, its Affiliates' and Sublicensees' Net Sales of the Licensed Product in the Territory during such calendar quarter.

(b) Annual Reports. Annually, by **** of each calendar year during the Term, Company shall upon request provide CyDex with written reports that: (i) describe in reasonable detail Company's **** during such calendar year; (ii) summarize in reasonable detail **** during such calendar year; (iii) detail Company's ****; (iv) after relevant Marketing Approvals, provide CyDex with ****; and (v) set forth such other information regarding Captisol as mutually agreed upon by the parties.

5.3 Audit. During the Term and for a period of **** thereafter, CyDex shall have the right, no more frequently than **** and only during normal business hours and upon reasonable notice, to inspect and audit **** records relevant to (a) **** and (b) Net Sales. The costs of such audits shall be borne solely by CyDex; *provided*, *however*, that in the event such an audit reveals either a failure by Company to pay any **** or an underpayment by Company of royalties owed hereunder, Company shall immediately (i) pay CyDex all amounts by which Company has underpaid CyDex as revealed by the audit, plus interest accrued thereon (from the applicable original due date) at the rate set forth in Section 4.5 above and (ii) reimburse CyDex for the costs of such audit if such underpayment is more than **** of the total due for the relevant period. All information concerning royalty payments and reports, and any information learned in the course of any audit or inspection under this Section 5.3, shall be deemed to be Confidential Information of Company, subject to the terms and provisions of Section 8 below****.

6. DEVELOPMENT AND COMMERCIALIZATION BY COMPANY.

6.1 Diligence. Company agrees that, during the Term, it will (i) use, and shall require its Affiliates and Sublicensees to use, ****, and (ii) comply with the requirements set forth in ***Exhibit D*** hereto. For clarity, in the event that Company fails to meet such requirements, ****.

6.2 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.

6.3 In Vivo Studies. If Company wishes to conduct any in vivo study (preclinical or clinical, in animals or in humans, each a "**Study**") of the Licensed Product utilizing Captisol, then Company shall notify CyDex of any such Study and of the protocol therefore in writing at least **** prior to commencing such Study for pre-clinical studies, and at least **** prior to commencing such Study for clinical studies, and the following provisions shall apply:

(a) Dosing. Company shall not exceed the maximum allowable dosing levels of Captisol specified in ***Exhibit E*** hereto without the written consent of CyDex.

(b) Review of Protocol. Company shall provide information regarding each protocol pertaining solely to the use and administration of Captisol for each Study and agrees to allow CyDex to review and comment upon the aspects of such protocol which pertain solely to the use and administration of Captisol. Company shall **** any input that CyDex provides regarding such protocol to the extent it pertains solely to the use and administration of Captisol.

(c) Evaluation. If CyDex reasonably determines that such study would materially adversely affect a product utilizing Captisol, CyDex shall notify Company within the above-specified review periods, and the parties shall discuss and attempt to resolve the matter in good faith. If the parties cannot resolve such matter within **** days after CyDex notifies Company of such determination, then the dispute shall be presented to the Chief Executive Officer of each party, or his or her respective designee, for resolution. If the parties' Chief Executive Officers, or their respective designees, cannot resolve the dispute within **** of being requested by a party to resolve such dispute, either party may initiate a short-form arbitration proceeding pursuant to Section 14.4(b) below.

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

(e) Adverse Events. Company agrees to immediately inform CyDex if any adverse effects are observed and ascribed to Captisol in any Study in accordance with Section 7.3 hereof. ****.

(f) **** Within **** after the completion of the relevant Study, ****

(g) Review of Regulatory Filings and Publications. At least **** a submission of any proposed written publication material or regulatory submission (which shall be subject to the restrictions of Section 8 hereof), Company shall provide to CyDex for CyDex's review and comment a copy of any proposed written publication, material or regulatory submission reporting results of a Study where such publication material containing Captisol data alone (and not in conjunction with the Licensed Product) or refers solely to the use and administration of Captisol or to ****. Company shall give due consideration and reasonably incorporate any input that CyDex provides regarding Captisol or ****.

6.4 ****

6.5 ****

7. 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, 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) sixty (60) days 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 attempt to resolve the matter in good faith. If the parties cannot resolve such matter within **** after CyDex notifies Company of such a determination, then the dispute shall be presented to the Chief Executive Officer of each party, or his or her respective designee, for resolution. If the parties' Chief Executive Officers, or their respective designees, cannot resolve the dispute within **** of being requested by a party to resolve such dispute, either party may initiate a short-form arbitration proceeding pursuant to Section 14.4(b) below. ****

****.

7.2 Material Safety. CyDex shall provide Company, 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, 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, (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 shall provide CyDex with summaries of all reports of any such adverse event which is serious (any such adverse event involving Captisol **** 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 has reason to believe are associated with Captisol within **** days 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. **** Reports from Company shall be delivered to the attention of Vice President, Chief Scientific Officer, CyDex, with a copy to Chief Executive Officer, CyDex, at the address set forth in Section 14.7. The parties shall mutually cooperate with regard to investigation of any such serious adverse event, whether experienced by Company, CyDex or any other Affiliate, Sublicensee, co-marketer or distributor of CyDex or Company.

7.4 Product Recalls. If any Captisol should be alleged or proven not to meet the Specifications, Company shall notify CyDex immediately, and both parties shall cooperate fully regarding the investigation and disposition of any such matter. **** Company shall maintain records of all sales of Licensed Product and customers sufficient to adequately administer any such recall, for a period of **** after expiration or termination of this Agreement.

8. 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 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.

8.2 Obligation. CyDex and Company 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. Company may also disclose (i) the financial terms of this Agreement to third parties which are potential Sublicensees, and (ii) other Confidential Information of CyDex to third parties which are actual Sublicensees, *provided* that Company shall first obtain the written agreement of each such third party **** to comply with the obligations of Licensee under this Section 8.2 **** and such disclosure shall be limited to the maximum extent possible. Unless expressly permitted by the terms of this Section 8.2, neither party shall disclose Confidential Information of the other to any third party without the other's prior consent, and any such permitted 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 **** of the request, and in any event, promptly following the expiration or termination of this Agreement.

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:

(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 makes 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.

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

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, or, with respect to Company, because of any act by its Affiliates or Sublicensees; 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 Limited Warranty. CyDex warrants solely to Company 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; and (ii) shall have been manufactured under conditions of current good manufacturing practices for bulk excipients as set forth in U.S. Pharmacopoeia <1078> and the process described in the DMF. ****

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. CYDEX'S WARRANTIES UNDER THIS AGREEMENT ARE SOLELY FOR THE BENEFIT OF COMPANY AND MAY BE ASSERTED ONLY BY COMPANY AND NOT BY ANY AFFILIATE, SUBLICENSEE OR

ANY CUSTOMER OF COMPANY, ITS AFFILIATES OR SUBLICENSEES. COMPANY, ITS AFFILIATES AND SUBLICENSEES SHALL BE SOLELY RESPONSIBLE FOR ALL REPRESENTATIONS AND WARRANTIES THAT COMPANY, ITS AFFILIATES OR SUBLICENSEES MAKE TO ANY CUSTOMER OF COMPANY, ITS AFFILIATES OR SUBLICENSEES.

10. INDEMNIFICATION.

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 ****.

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: ****.

10.3 Expenses. ****

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.

**** 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 LICENSED PATENTS AND CAPTISOL DATA PACKAGE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF **** WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. **** TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED ****. 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.

12. MANAGEMENT OF LICENSED PATENTS.

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

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

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 until the expiration of Company's obligation to pay royalties under Section 4.1(c), unless terminated earlier as set forth herein.

13.2 Termination by CyDex. If Company should violate or fail to perform any 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 thirty (30) days (or ten (10) days with respect to any payment obligation) of the date of such notice 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 effective date of such notice. **** 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 ninety (90) days prior written notice or at least forty-five (45) days prior written notice in the event of a material breach.

13.4 Effect of Termination. Following the termination or expiration of this Agreement, all rights granted to Company herein shall immediately terminate and each party shall promptly return all relevant records and materials in its possession or control containing the other party's Confidential Information with respect to which the former party does not retain rights hereunder; *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 (a) royalties for all Licensed Product sold by Company, its Affiliates or Sublicensees prior to the effective date of such expiration or termination, or (b) sums due in respect of Captisol shipped prior to termination or expiration of this Agreement. Unless terminated for material breach by Company, Sections 2.2 (Grant of License from Company to CyDex), 3.5 (Quality Control; Acceptance and Rejection), 4.1 (Payments and Royalties for Licenses), 4.3 (Currency), 4.4 (Taxes), 4.5 (Late Payments), 5 (Records; Reports; Audits), 6.3(f) (Reporting and Study Data), 6.5 (Access to Company's Data), 7.3 (Adverse Event Reporting), 7.4 (Product Recalls), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification), 11 (Limitation of Liability), 13.4 (Effect of Termination), 13.5 (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. Company agrees that use of the Licensed 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 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 ****. The arbitration shall be conducted by an arbitrator 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 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 14.4(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. ****

(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 **** 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 ****. ****. 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 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

If to Company, to.

Neuron Systems
15 New England Executive Park
Burlington, MA 01803 Attention: President
Fax: (781) 270-0630

If sent by facsimile transmission, the date of transmission shall be deemed to be the date on which such notice, request or communication was given. If sent by overnight courier, the next business day 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 third 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. **** hereby grants a non-exclusive, nontransferable license to use its name, logo and other trademarks in connection with marketing and other materials for customers, investors and potential customers and investors, including but not limited to use in connection with materials filed with the SEC or other regulatory agencies. Except as otherwise provided herein, **** 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 as may be required by applicable law or regulation.

14.9 Public Announcements. 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, which approval shall not be unreasonably withheld. Notwithstanding the above, once the content and timing of a public announcement of the fact that the parties have entered into this Agreement has been agreed to between the parties and such announcement has been made, **** shall be free to disclose to third parties the fact that it has entered into the Agreement with **** (including a description of the field of use of the Licensed Product, but without disclosing the economic terms thereof), as well as any other information contained in said public announcement. 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.

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

14.11 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.

14.12 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.

14.13 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.

14.14 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.

14.15 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, a 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 pertaining to the subject matter of this Agreement, sale of stock or otherwise, without the other Party's consent. Except in the case of a merger, sale of all or substantially all of its assets pertaining to the subject matter of this Agreement, as a condition to any other 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 14.15 shall be void.

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: _____

Name: _____

Title: _____

NEURON SYSTEM, INC

By: _____

Name: _____

Title: _____

EXHIBIT A

****

****	****	****	****	****	****
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****CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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****CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

EXHIBIT B

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EXHIBIT C

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CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT D

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****CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

**** **EXHIBIT E**

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