Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1 REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

SAGE THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

2834 (Primary Standard Industrial Classification Code Number)

27-4486580 (I.R.S. Employer Identification No.)

215 First Street Cambridge, Massachusetts 02142 (617) 299-8380

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

Jeffrey M. Jonas, M.D. President and Chief Executive Officer Sage Therapeutics, Inc. 215 First Street Cambridge, Massachusetts 02142 (617) 299-8380

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

Copies to:

Mitchell S. Bloom, Esq. Michael H. Bison, Esq. Goodwin Procter LLP **Exchange Place** Boston, Massachusetts 02109 (617) 570-1000

Non-Accelerated Filer

Jeffrey M. Jonas, M.D. President and Chief Executive Officer Sage Therapeutics, Inc. 215 First Street Cambridge, Massachusetts 02142 (617) 299-8380

Patrick O'Brien, Esq. Ropes & Gray LLF Prudential Tower 800 Boylston Street Boston, Massachusetts 02199-3600 (617) 951-7000

,	Approximate d	late o	f commencement of	of proposed	sale to p	oublic: A	As soon as	s practicable	e after this	Registration	Statement becom	es effective.

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: \Box 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: $\hfill \square$ 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: \Box

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.

Large Accelerated Filer

Accelerated Filer П Smaller Reporting Company

Amount of

Proposed Maximum

Aggregate

CALCULATION OF REGISTRATION FEE

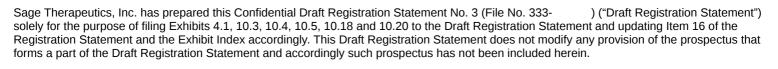
Securities to be Registered Offering Price(1) Registration Fee(2) Common Stock, par value \$0.0001 per share Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. Includes the offering price of shares that the underwriters have (1)

- the option to purchase to cover over-allotments, if any
- (2) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.

Title of Each Class 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 said Section 8(a), may determine.

Explanatory Note



PART II

Information Not Required in Prospectus

Item 13. Other expenses of issuance and distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by Sage Therapeutics, Inc. (the "Company" or the "Registrant") in connection with the sale of the common stock being registered. All the amounts shown are estimates except the SEC registration fee and the FINRA filing fee.

	Amo	unt
SEC registration fee	\$	*
FINRA filing fee		*
NASDAQ initial listing fee		*
Blue sky qualification fees and expenses		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Transfer agent and registrar fees		*
Miscellaneous		*
Total	\$	*

^{*} To be filed by amendment.

Item 14. Indemnification of directors and officers

Section 145 of the Delaware General Corporation Law permits a corporation to include in its charter documents, and in agreements between the corporation and its directors and officers, provisions expanding the scope of indemnification beyond that specifically provided by the current law.

Section 145(a) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, 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.

Section 145(b) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit 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, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable

to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the Delaware General Corporation Law provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the Delaware General Corporation Law.

The Company's amended and restated certificate of incorporation, which will become effective upon completion of the offering, provides for the indemnification of directors to the fullest extent permissible under Delaware law.

The Company's amended and restated by-laws, which will become effective upon completion of the offering, provide for the indemnification of officers, directors and third parties acting on the Company's behalf if such persons act in good faith and in a manner reasonably believed to be in and not opposed to the Company's best interest, and, with respect to any criminal action or proceeding, such indemnified party had no reason to believe his or her conduct was unlawful.

The Company is entering into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provisions provided for in its charter documents, and the Company intends to enter into indemnification agreements with any new directors and executive officers in the future. These agreements will provide that we will indemnify each of our directors and executive officers, and such entities to the fullest extent permitted by law.

The underwriting agreement (to be filed as Exhibit 1.1 hereto) will provide for indemnification by the underwriters of the Company, and its executive officers and directors, and indemnification of the underwriters by the Company for certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, in connection with matters specifically provided in writing by the underwriters for inclusion in the registration statement.

The Company intends to purchase and maintain insurance on behalf of any person who is or was a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in that capacity, subject to certain exclusions and limits of the amount of coverage.

Item 15. Recent sales of unregistered securities

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

Issuances of capital stock

On September 30, 2011, we issued 6,000,000 shares of our Series A redeemable convertible preferred stock to one investor for an aggregate consideration of \$6,000,000. On April 9, 2012, we issued 4,000,000 shares of our Series A redeemable convertible preferred stock to one investor for \$4,000,000. On November 9, 2012, we issued 5,000,000 shares of our Series A redeemable convertible preferred stock to one investor for \$5,000,000. On March 18, 2013, we issued 5,000,000 shares of our Series A redeemable convertible preferred stock to one investor for \$5,000,000. On

July 1, 2013, we issued 5,000,000 shares of our Series A redeemable convertible preferred stock to one investor for \$5,000,000. On September 12, 2013, we issued 12,500,000 shares of our Series A redeemable convertible preferred stock to two investors for \$12,500,000. On October 18, 2013, we issued 250,000 shares of our Series A redeemable convertible preferred stock to one investor for \$250,000.

On December 13, 2013, we issued 150,000 shares of our common stock in connection with entering into a license agreement.

On January 7, 2014, we issued 6,666,666 shares of our Series B redeemable convertible preferred stock to two investors for aggregate consideration of \$10,000,000. On February 12, 2014, we issued an aggregate of 3,333,333 shares of our Series B redeemable convertible preferred stock to two investors for \$5,000,000.

On January 24, 2014, we issued 25,000 shares of our common stock to a nonemployee advisor upon attainment of certain clinical milestones.

On March 11, 2014, we issued 8,973,905 shares of our Series C redeemable convertible preferred stock to 13 investors for aggregate consideration of \$38,000,000.

On March 26, 2014, we issued 25,000 shares of our common stock to a nonemployee advisor upon attainment of certain clinical milestones.

No underwriters were used in the foregoing transactions. All sales of securities described above were made in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act (and/or Regulation D promulgated thereunder) for transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

Grants of stock options and restricted stock

Since January 1, 2011, we have granted stock options to purchase an aggregate of 5,923,500 shares of our common stock, with exercise prices ranging from \$0.0001 to \$2.83 per share, to employees, directors and consultants pursuant to our stock option plan. Since January 1, 2011, we have granted an aggregate of 4,752,500 shares of restricted stock. The issuances of these securities were exempt either pursuant to Rule 701, as a transaction pursuant to a compensatory benefit plan, or pursuant to Section 4(2), as a transaction by an issuer not involving a public offering.

Item 16. Exhibits and financial statement schedules

(a) Exhibits.

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial statement schedules.

None.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities 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 Securities Act of 1933 and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on the day of , 2014.

SAGE THERAPEUT	ICS	. INC.
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Ву:		
	Jeffrey M. Jonas, M.D.	
	President and Chief Executive Officer	

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Jeffrey M. Jonas and Kimi Iguchi and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney in fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Registration Statement, including any and all post effective amendments and amendments thereto, and any registration statement relating to the same offering as this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys in fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys in fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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 indicated below on the day of , 2014.

Signature	Title	Date
Jeffrey M. Jonas, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2014
Kimi Iguchi	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2014
Robert T. Nelsen	Director	, 2014
Steven Paul, M.D.	Director	, 2014
Kevin P. Starr	Director	, 2014
Howard Pien	Director	, 2014

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
3.1**	Third Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
3.2**	Form of Fifth Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon completion of the offering
3.3**	By-laws of the Registrant and the amendments thereto, as currently in effect
3.4**	Form of Amended and Restated By-laws of the Registrant, to be in effect upon completion of the offering
4.1	Specimen Common Stock Certificate
4.2**	Second Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders dated March 11, 2014
5.1*	Opinion of Goodwin Procter LLP
10.1**	2011 Stock Option Plan and forms of award agreements thereunder
10.2*#	2014 Stock Option and Incentive Plan and forms of award agreements thereunder
10.3†	Exclusive License Agreement by and between the Registrant and Washington University, dated November 11, 2013
10.4†	Commercial License Agreement by and between the Registrant and CyDex Pharmaceuticals, Inc., dated August 21, 2013, as amended April 30, 2014
10.5†	Non-Exclusive License Agreement by and between the Registrant and the Regents of University of California, dated October 23, 2013, as amended May 14, 2014
10.6**	Lease Agreement, by and between the Registrant and ARE-MA Region No. 38, LLC, dated December 11, 2011, as amended by First Amendment to Lease, by and between ARE-MA Region No. 38, LLC, dated October 26, 2012, and Second Amendment to Lease, by and between ARE-MA Region No. 38, LLC, dated May 9, 2013
10.7**	Offer letter by and between the Registrant and Jeffrey M. Jonas, dated July 18, 2013
10.8**	Offer letter by and between the Registrant and Albert J. Robichaud, dated September 25, 2011
10.9**	Offer letter by and between the Registrant and Stephen J. Kanes, dated May 21, 2013
10.10**	Offer letter by and between the Registrant and Kimi Iguchi, dated February 7, 2013
10.11**	Non-Solicitation, Confidentiality and Assignment Agreement by and between the Registrant and Jeffrey M. Jonas, dated August 19, 2013
10.12**	Non-Solicitation, Confidentiality and Assignment Agreement by and between the Registrant and Albert J. Robichaud, dated November 7, 2011
10.13**	Non-Solicitation, Confidentiality and Assignment Agreement by and between the Registrant and Stephen J. Kanes, dated July 17, 2013
10.14**	Non-Solicitation, Confidentiality and Assignment Agreement by and between the Registrant and Kimi Iguchi, dated March 8, 2013
10.15#**	Senior Executive Cash Incentive Bonus Plan
10.16**	Form of Indemnification Agreement to be entered into between the Registrant and its directors

Exhibit No.	Description
10.17**	Form of Indemnification Agreement to be entered into between the Registrant and its officers
10.18†	Supply Agreement by and between the Registrant and CyDex Pharmaceuticals, Inc., dated December 13, 2012, as amended August 21, 2013 and April 30, 2014
10.19*#	2014 Employee Stock Purchase Plan
10.20	Offer Letter by and between the Registrant and Thomas D. Anderson, dated April 15, 2014
21.1*	Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

 ^{*} To be filed by amendment.
 ** Previously filed.
 † Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.
 # Represents management compensation plan.

Certificate Number ZQ00000000	COMMON STOCK PAR VALUE \$0,0001	O SAGE THERAPEUTICS		
		SAGE THERAPEUTICS, INC. INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE		603333
	THIS CERTIFIES THAT	The American Conference — A American Conference — In American Conference — A American Conference — A American Conference — In American Conference — A American Conference — In American — In A	CUSIP XXXXXX XX	
1	is the owner of	ZERO HUNDRED THOUSAND ZERO HUNDRED AND ZERO LLY-PAID AND NON-ASSESSABLE SHARES OF COMMON ST	OCK OF	
	person or by duly authori, the shares represented h Incorporation, as amende Company and with the Tr	(hereinafter called the "Company"), transferable on the zed attorney, upon surrender of this Certificate properly encepty, are issued and shall be held subject to all of the product, and the By-Laws, as amended, of the Company (copies ansfer Agent), to all of which each holder, by acceptance hess countersigned and registered by the Transfer Agent and	dorsed. This Certificate and visions of the Articles of of which are on file with the sereof, assents. This	
	Chief Executive Officer Chief Financial Officer Chief Financial Officer	COMPUTE	DO-MMM-YYYY SIGNED AND REGISTERED: RSHARE TRUST COMPANY, N.A. R AGENT AND REGISTRAR. AUTHORIZED SIGNATURE	

SAGE THERAPEUTICS, INC.

_				
TEN COM	- as tenants in common	UNIF GIFT MIN ACT	- Custodia	n
			(Cust)	(Minot)
TEN ENT	 as tenants by the entireties 		under Uniform Gifts to Minors Act	
JT TEN	-as joint tenants with right of survivorship and not as tenants in common	UNIF TRF MIN ACT	(Cust)	in (until age

THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH SHARIEHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATINE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OF THE COMPANY AND THE QUALLIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE VARIATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH HAVE FIXED BY THE ARTICLES OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE AUTHORITY OF THE BOARD OF DIRECTORS TO DETERMINE VARIATIONS FOR RUTURES SERIES. SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE OWNER OF A LOST OR DESTROYED STOCK CERTIFICATE, OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY A BOND TO INDEMNIFY IT AND ITS TRANSFER AGENTS AND REGISTRANS AGAINST MY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE.

ON ACCOUNT OF THE ALLEGED	LOSS OR DESTRUCTION OF ANY SUCH CERTIF	
For value received,	hereby sell, assign and transfer	REASE INSERTS OGAL SECURITY OR OTHER DENTE WAS NAMER OF ASSOM
R. SAUS PRINT OR TURNING ITS NAME A NO ACCOR	DIS, NCLI (IPS) POSTAL JP (IDS), OF ASSESSE)	
	by the within Certificate, and do hereby irrevo cably	Shar
	ooks of the within-named Company with full power	Afform
Dated:		Signature(s) Guaranteed: Medallon Quaranteed Stamp The grownungs; brass of discussionment of An Elicial Guarantee Stamp Sedimen, Sings and Line Associates and Ovel Deed; bits EMECORDE IN AN APPROVED SOURCES COMMENTER MODIL OF PROCESSE, PROSENT DISC. DISC. EL CIA-6: 1. The Comment of Comments
Igrature:		
Signature:		
as written upon	this assignment must correspond with the name in the face of the certificate, in every particular, in or enlargement, or any change whatever.	

SECURITY INSTRUCTIONS

THIS IS WATERWARKED PAPER, DO NOT ACCEPT WITHOUT NOTING WATERWARK, HOLD TO U.GHT TO VERIFY WATERWARK.



The IRIS requires that we regard the cost basis of contribin shares acquired affire, Jenney 1, 2075. If your shares were covered by the legislation and you have add or harefurest to shares and requested a specific cost basis calculation method, we have processed as requested. If you did not apacify a cost basis calculation method, we have defaulted to the Battin, find cut IFI or method. Pleases with our whole or consult your loss activities me and activitional information allocation cost basis.

activity in your account for the time periods specified by statlaw, your property could become subject to state unclaimed property laws and transferred to the appropriate state.

EXCLUSIVE LICENSE AGREEMENT

PREAMBLE

This Agreement is made and entered into, effective as of November 11, 2013 ("**Effective Date**"), by and between: Washington University, a corporation established by special act of the Missouri General Assembly approved February 22, 1853 and acts amendatory thereto, having its principal offices at One Brookings Drive, St. Louis, Missouri 63130 (hereinafter referred to as "**WU**"); and SAGE Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware having its principal offices at 215 First Street, 2nd Floor, Cambridge, MA 02142 (hereinafter referred to as "**Licensee**") and the following correspondence addresses;

Attn: Legal 215 First Street, 2nd Floor Cambridge, MA 02142 Email: jeff@sagcrx.com Attn: Accounting 215 First Street, 2nd Floor Cambridge, MA 02142 Email: ap@sagerx.com

Attn: Technical 215 First Street, 2nd Floor Cambridge, MA 02142 Email: Al@sagerx.com

<u>License Issue Fee</u>: Licensee shall pay a sum of [...***...] dollars (\$[...***...]), within fifteen (15) days after the Effective Date. Such License Issue Fee shall be non-refundable and shall not be credited against any other payments that may be due hereunder.

<u>License Maintenance Fee</u>: Licensee agrees to pay a sum of [...***...] dollars (\$[...***...]) by the first anniversary of the Effective Date and by each subsequent anniversary thereafter, until and including the year in which the first Phase II clinical study for a Licensed Product is initiated. All License Maintenance Fees shall be non-refundable and shall not be credited against any other payments that may be due hereunder.

<u>Financial Milestone Payments</u>: Licensee agrees to pay WU milestone payments in the amounts set forth below for milestones achieved by Licensee, its Affiliates or Sublicensees, within thirty (30) days after the date on which the applicable milestone event is met; provided, that each milestone payment shall be payable not more than once with respect to each Licensed Product.

Payment (U.S. Dollars)	Milestone Event for Each Licensed Product
a. \$[***]	[***]
b. \$[***]	[***]
c. \$[***]	[***]
d. \$[***]	[***]
e. \$[***]	[***]

Non-Financial Diligence Milestones:

Milestone Event	Timeline
a. [***]	within [***] years after the Effective Date
b. [***]	within [***] years after the Effective Date
C. [***]	within [***] years after the Effective Date
d. [***]	within [***] years after the Effective Date
e. [***]	within [***] years after the Effective Date

Each of the Non-Financial Diligence Milestones above needs to be achieved only once during the Term.

Milestone Extensions: Licensee may elect to extend each of the non-financial diligence milestones indicated above only once by an extension period of [... ***...] months by making a [...***...] dollar (\$[...***...]) payment (the "Milestone Extension Fee") for each such [...***...] month extension provided that Licensee may exercise no more than three separate extensions (i.e., non-financial diligence milestone (e) above may not be extended beyond 14 years after the Effective Date as a result of Licensee's exercise of such extension right). If a specific milestone is extended, then the subsequent milestones are extended automatically by [...***...] months without requiring an additional payment. In addition, the non-financial diligence milestones indicated above shall each extend by a period of [...***...] months to reflect any delay in the achievement of the applicable milestone attributable to External Factors.

Royalty Rate by Licensee or Sublicensee:

a. [***]	[***] % of Net Sales for Licensed Products covered under Patent Rights, provided, however, that the Patent Royalty Rate shall be [***]% of Net Sales for any Special Licensed Product, as set forth in Section 5.3.
b. [***]	[***]% of Net Sales for Licensed Products covered under Technical Information and/or embodying Tangible Research Property, but not covered under Patent Rights, as set forth in Section 5.3.

<u>Sublicensing Revenue</u>: [...***...]% of Sublicensing Revenue amounts actually received by Licensee from Sublicensees hereunder at any time during the first three years after the Effective Date, after which it will be [...***...]% if received at any time during the next two years after the Effective Date, after which it will be [...***...]% if received at any time during the next five years after the Effective Date, and [...***...]% if received thereafter during the Term.

a. [***]	[***]%
b. [***]	[***]%
C. [***]	[***]%
d. [***]	[***]%

<u>Equity</u>: Licensee shall issue [...***...] common shares (as per capitalization table, refer to <u>Exhibit D</u>) to WU within [...***...] days after the Effective Date pursuant to an equity issuance agreement executed concurrently with this Agreement.

Licensee is solely responsible for all past, present and future patent expenses for Patent Rights incurred by WU during the Term, as set forth in Section 9.2. Licensee shall pay past patent expenses no later than [...***...] days from the Effective Date of the Agreement.

Field: Therapeutic, diagnostic, prophylactic indications in humans and animals,

Territory: Worldwide, except as set forth in Section 1.32.

<u>Term</u>: The term of this Agreement shall commence on the Effective Date and continue on a Licensed Product-by-Licensed Product and country-by-country basis until the later of: (a) the last day that at least one Valid Claim exists that covers such Licensed Product in such country; or (b) the tenth anniversary of the day of the First Commercial Sale of such Licensed Product in such country.

RECITALS

- A. WU possesses certain Patent Rights (as defined below), Technical Information (as defined below), and Tangible Research Property (as defined below).
- B. Licensee has developed a plan to develop, manufacture, promote, import, sell and/or market products based on the Patent Rights, the Technical Information, and/or the Tangible Research Property, which plan is attached hereto as Exhibit A (the "**Development Plan**").
- C. Licensee desires to obtain from WU certain licenses to the Tangible Research Property, Technical Information, and Patent Rights and WU desires to grant such licenses to Licensee.

TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the premises, covenants and agreements set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Definitions.

As used in this Agreement, the following terms have the meaning ascribed to them below:

- 1.1 "Agreement" is defined in the Preamble above.
- **1.2** "Affiliate" means an entity that controls or is controlled by or is under common control with a party to this Agreement. For purposes of this definition, "control" means the direct or indirect ownership of more than 50% of the outstanding voting securities of a corporation, the direct or indirect ownership by a person or entity of more than 50% of the outstanding voting shares of another entity, the right to receive more than 50% of the earnings of a person, corporation or other entity, or the right to control the business decisions of a person, corporation or other entity.
 - **1.3** "Calendar Half" means each six-month period of a calendar year, or portion thereof, beginning on January 1 or July 1.
 - **1.4** "Claims" is defined in Section 11.1 below.
- **1.5** "Commercially Reasonable Efforts" means, with respect to the efforts to be expended with respect to a specified objective, those reasonable, diligent, good faith efforts to accomplish such objective as a similarly situated biotechnology company would normally use to accomplish a similar objective.
 - **1.6 "Confidential Information"** is defined in <u>Section 7.1</u> below.
 - **1.7** "**Development Plan**" is defined in Recital C above.
 - **1.8** "Effective Date" is defined in the Preamble above.
 - **1.9** "Election Notice" is defined in Section 9.3 below.
- **1.10** "External Factor" means the occurrence of one or more of the following with respect to a Licensed Product; *provided* that such occurrence was not caused by any negligence, misconduct, violation of applicable laws, or failure to act by Licensee: (a) any change imposed by a regulatory agency which is new or unanticipated and requires Licensee's compliance; (b) the primary endpoint in any clinical study is not achieved; (c) adverse changes occur in applicable laws relating to the development or marketing of the Licensed Product; or (d) an event of force majeure occurs as set forth in Section 15.12.
 - **1.11 "Fees"** is defined in <u>Section 11.1</u> below.
 - **1.12** "Field" is defined in the Preamble above.
- **1.13** "**First Commercial Sale**" means the earliest date on which Licensee, its Affiliates or Sublicensees transfers a Licensed Product for compensation (including equivalent cash value for trades or other non-cash payments).

- **1.14** "License Issue Fee" is defined in the Preamble above.
- 1.15 "Licensed Product" means any product made, made for, used, sold, offered for sale, or imported by Licensee and/or any of its Affiliates and/or Sublicensees that: (a) in the absence of this Agreement would infringe at least one pending or issued Valid Claim (if such pending Valid Claim were issued in its then current form); (b) uses a process covered by a pending or an issued Valid Claim (if such pending Valid Claim were issued in its then current form); (c) embodies, or was made using a method or process that used, in whole or in part, or was otherwise derived from, Technical Information and/or Tangible Research Property that, when used by Licensee, its Affiliates and/or Sublicensees, was not publicly available for use by Third Parties; and/or (d) in the absence of this Agreement, would infringe at least one pending or issued Valid Claim (if such pending Valid Claim were issued in its then current form) of a Special Patent Right, regardless of whether Licensee is determined to have certain ownership rights in such Special Patent Right pursuant to Section 9.5. For the avoidance of doubt, for the purpose of this Section 1.15(d), the term "infringe" will assume that WU is the sole owner of such Special Patent Right, even if Licensee is determined to have certain ownership rights in such Special Patent Right pursuant to Section 9.5.
 - **1.16** "Licensee" is defined in the Preamble above.
 - **1.17** "Licensee Indemnitee" is defined in <u>Section 11.1</u> below.
 - **1.18** "Losses" is defined in Section 11.1 below.
 - **1.19** "Milestone Extension Fee" is defined in the Preamble above.
- **1.20** "Net Sales" means the gross value, compensation, and payments, whether in cash or in kind, received by Licensee, its Affiliates or Sublicensees for Sales of Licensed Products, less all Permissible Deductions.
- **1.21 "Patent Rights"** means, subject to Section 9.3 below, (a) the patents and patent applications listed in Exhibit B, (b) any other patents or patent applications owned by WU that are filed on invention disclosures which are made as of the Effective Date and listed in Exhibit B, and (c) all foreign counterparts, continuations, continuations-in-part (excluding any claim to new subject matter therein not included in clause (a) or (b)), divisions, patents, extensions, reexaminations and reissues of any of the foregoing that trace their earliest priority filing date to any of the items set forth in clauses (a) or (b).
- **1.22** "**Permissible Deductions**" means, and shall be limited to, any (a) trade, quantity and cash discounts on Licensed Products actually provided to Third Parties in connection with arm's-length transactions, (b) credits, allowances or refunds, not to exceed the original invoice amount, for actual claims, damaged goods, rejections or returns of Licensed Products, (c) excise, sale, use, or custom duties, value added or other taxes, other than income taxes, paid by Licensee, its Affiliates or Sublicensees due to the Sale of Licensed Products, (d) government mandated rebates, including but not limited to Medicaid rebates paid by Licensee, its Affiliates or Sublicensees to Medicaid authorities, and (e) a lump sum deduction not to exceed one and a half percent (1.5%) of Net Sales in lieu of any other deductions from gross Sales receipts that are not accounted for in clauses (a) through (d) of this paragraph.

- **1.23** "Sale" means any transaction in which a Licensed Product is exchanged or transferred for any value, payment or compensation of any type or kind. A Sale of a Licensed Product will be deemed to have been made when such Licensed Product is paid for and the purchase price is collected by Licensee or its Affiliate or Sublicensee. Notwithstanding the foregoing, Sales of any kind shall not include and shall expressly exclude transfers by Licensee: (a) to a Sublicensee or Affiliate for distribution or their own internal testing of samples of any Licensed Product; *provided* that such testing is not conducted for or on behalf of any end user; and *further provided* that Licensee receives no payment for such Licensed Product in excess of the fully burdened (i.e., direct and indirect) costs of producing and transporting such materials; and (b) for its and its Affiliates' and Sublicensees' own non-commercial laboratory research and development purposes, manufacturing, marketing/promotional purposes, beta testing and/or clinical testing, provided that the foregoing is not performed for or on behalf of any end user and further provided that Licensee receives no payment for such Licensed Product in excess of the fully burdened (*i.e.*, direct and indirect) costs of producing and transporting such materials and/or providing such Licensed Product.
- **1.24** "Special Licensed Product" means a Licensed Product that (a) contains the molecule identified on Exhibit E and (b) is covered by one or more Valid Claim(s) of the Special Patent Rights in the country of Sale or country of manufacture. For clarity, any Licensed Product that does not contain the molecule identified on Exhibit E shall not be deemed a Special Licensed Product, even if such Licensed Product is covered by a Valid Claim of the Special Patent Rights in the country of Sale or country of manufacture.
- **1.25** "Special Patent Rights" means the Patent Right [...***...] identified as such on Exhibit B, and all foreign counterparts, continuations, continuations-in-part (excluding any claim to new subject matter therein unless included in clauses (a) or (b) of Section 1.21), divisions, patents, extensions, reexaminations and reissues of such Patent Right that trace their earliest priority filing date to such Patent Right.
- **1.26** "Sublicensee" means a Third Party that has received a sublicense under the license rights granted to Licensee in <u>Article 2</u> of this Agreement (the written agreement containing such sublicense, a "Sublicense"). This term includes any sublicensee of a Sublicensee as permitted pursuant to <u>Section 2.9.1</u>.
- 1.27 "Sublicensing Revenue" means all value, payment or compensation of any type or kind, other than earned royalties on Net Sales, received by Licensee from or through its Sublicensees to the extent such amounts are allocable to the licensing, cross-licensing or other authorized use of any license or right granted herein by WU and granted by Licensee to the applicable Sublicensee. Sublicensing Revenue shall include, without limitation, all fees, milestone payments, cash equivalents, equities, securities, equipment, property, rights or anything else of value received by Licensee as sublicensing consideration from or for the benefit of any Sublicensee, but shall exclude any amount received from any Sublicensee as (a) support of Licensee's or its Affiliates' research, development or clinical programs mandated under the Sublicense and directly relating to the Licensed Products as evidenced by detailed research and budget proposals provided to WU prior to Licensee's receipt of such funding, or (b) the portion of the purchase price for Licensee's and/or its Affiliates' debt or equity securities that reflects the then current market price of such securities or, if such securities are not publicly traded, the then

current market value of such securities. For clarity, payment of milestone payments is in addition to the payment of Sublicensing Revenue and WU shall have the right to audit Licensee with respect to any such sublicensing transaction in accordance with Section 6.4. In the event that Licensee intends to enter into an agreement to sublicense the rights (regardless of whether WU's rights and Licensee's rights are licensed under the same or separate agreements) granted herein by WU along with other intellectual property that is not owned by WU, Licensee shall promptly deliver to WU a written report setting forth the proportion of any consideration payable to Licensee under such agreement that shall be allocable to the rights granted by WU under this Agreement. If WU disagrees with the apportionment made by Licensee in such report, WU shall so notify Licensee within [...***...] days after receipt of Licensee's report and the parties shall meet to discuss and resolve such disagreement in good faith. If no amicable settlement is reached within [...***...] days from the start of such discussions, the matter shall be finally settled by arbitration administered by the American Arbitration Association under its Commercial Arbitration Rules, the arbitration shall take place in St. Louis, Missouri, and the arbitral decision may be enforced in any court.

- **1.28** "Tangible Research Property" means, subject to Section 9.3 below, any and all tangible research tools and other tangible personal property that WU may provide to Licensee and that Licensee may accept. Licensee, its Affiliates and Sublicensees shall have no restrictions or obligations with respect to any item of Tangible Research Property from and after the date on which it became publicly available for use by Third Parties, provided that it did not become publicly available through Licensee's breach of its obligations under Sections 2.7 and 7 below.
- **1.29** "**Technical Information**" means, subject to Section 9.3 below, all ideas, trade secrets, research and development information, unpatented inventions, know-how, data, methods, procedures, processes and technical data and information (but excluding Tangible Research Property) owned by WU and disclosed in writing as per Section 7.1 to Licensee by WU, resulting from research performed by or under the direction of Dr. Douglas F. Covey relating to neuroactive steroids and/or steroids that modulate GABA(A) receptors, in each instance that contribute to the practice of the inventions in the Patent Rights. Technical Information excludes claims to inventions included in Patent Rights but, for clarity, may include other information disclosed but not claimed in patent applications. Licensee, its Affiliates and Sublicensees shall have no restrictions or obligations with respect to any item of Technical Information from and after the date on which it became publicly available for use by Third Parties, provided that it did not become publicly available through Licensee's breach of its obligations under Section 7 below.
 - **1.30** "Term" is defined in the Preamble above.
 - **1.31 "Termination Fee"** is defined in <u>Section 13.2</u> below.
- **1.32** "**Territory**" is worldwide, except that it shall exclude those countries to which export of technology or goods is prohibited at the applicable time by applicable U.S. export control laws or regulations.
 - 1.33 "Third Party" means any person or entity other than WU, Licensee, or any of their respective Affiliates.

- **1.34** "Valid Claim" means a claim (a) of a pending patent application within the Patent Rights that has been pending for no longer than seven (7) years after its earliest priority date, or (b) of an issued and unexpired patent within the Patent Rights that has not been (i) held invalid or unenforceable by a court or other governmental agency of competent jurisdiction in a decision or order that is not subject to appeal, (ii) canceled, or (iii) abandoned in accordance with, or as permitted by, the terms of this Agreement or by mutual written agreement of WU and Licensee.
 - 1.35 "WU" is defined in the Preamble above.
 - **1.36** "WU Indemnitee" is defined in Section 11.1 below.

2. License Grants and Restrictions.

- **2.1** <u>Patent Rights</u>. Subject to the terms and conditions of this Agreement, WU hereby grants to Licensee, and Licensee hereby accepts, a non-transferable (except pursuant to <u>Section 15.6</u>), exclusive (subject to <u>Section 2.4</u> below) and royalty-bearing license under the Patent Rights, for the Term, to make, have made, sell, offer for sale, use, and import Licensed Products, solely in the Territory and in the Field. For the avoidance of doubt, Licensee acknowledges and agrees that no license is granted or implied under the Patent Rights outside the Field or the Territory.
- **2.2** <u>Technical Information</u>. Subject to the terms and conditions of this Agreement, WU hereby grants to Licensee, and Licensee hereby accepts, a nontransferable (except pursuant to <u>Section 15.6</u>), nonexclusive and royalty-bearing license for the Term to use the Technical Information solely for the purpose of making, having made, selling, offering for sale, using, and importing Licensed Products, solely in the Territory and in the Field. For the avoidance of doubt, Licensee acknowledges and agrees that no license is granted or implied under the Technical Information outside the Field or the Territory.
- **2.3** Tangible Research Property. Subject to the terms and conditions of this Agreement, WU hereby grants to Licensee, and Licensee hereby accepts, a non-transferable (except pursuant to Section 15.6), nonexclusive and royalty-bearing license, for the Term, to use the Tangible Research Property solely for the purpose of making, having made, selling, offering for sale, using, and importing Licensed Products, solely in the Territory and in the Field. For the avoidance of doubt, Licensee acknowledges and agrees that no license is granted or implied to use the Tangible Research Property for any other purpose.
- **2.4** <u>Limitations on Patent Rights License</u>. WU retains its right to use the Patent Rights to make, have made, use, and import Licensed Products in the Territory and in the Field for research and educational purposes including collaboration with other nonprofit entities, which shall expressly exclude any commercial purposes.
- **2.5** <u>Clarifications</u>. For the avoidance of doubt, the license "to have made" granted in <u>Section 2.1</u> above means that the Licensee, its Affiliates and Sublicensees may contract with one or more Third Parties to make Licensed Products for Licensee, its Affiliates and Sublicensees for Sale or offer for Sale by Licensee, its Affiliates and Sublicensees within the scope of their sales operations or for research and development purposes. In any such event, Licensee, its Affiliates

and Sublicensees shall require all such Third Parties to be bound to a written confidentiality agreement that contains non-use and nondisclosure obligations that are at least as restrictive as those that are contained in Article 7 below before any WU Confidential Information is disclosed to such Third Parties.

- 2.6 Government Rights. In accordance with Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. §§ 200-212, the United States government retains certain rights to inventions arising from federally supported research or development. Under these laws and implementing regulations, the government may impose requirements on such inventions. Licensed Products embodying inventions subject to these laws and regulations sold in the United States must be substantially manufactured in the United States. The license rights granted in this Agreement arc expressly made subject to these laws and regulations as amended from time to time. Licensee shall be required to abide by all such laws and regulations.
- 2.7 Reservation of Rights and Restrictions. Nothing in this Agreement provides Licensee with any ownership rights of any kind in the Patent Rights, the Technical Information and/or any intellectual property rights in the Tangible Research Property. All ownership rights in the Patent Rights (other than any Special Patent Rights that may be jointly owned by Licensee), the Technical Information and intellectual property rights in the Tangible Research Property shall remain the sole and exclusive property of WU. The risk of loss of all Tangible Research Property shall pass to Licensee upon delivery. For the avoidance of doubt, Licensee's rights in any Tangible Research Property extend only to the specific Tangible Research Property delivered by WU to Licensee. Accordingly, Licensee shall have no right to any tangible research property retained by WU, including, without limitation, any original tangible research property that may be retained by WU and on which the Tangible Research Property delivered to Licensee may be based. No license or right is granted by WU, by implication or otherwise, to any patent other than the Patent Rights. Other than the licenses expressly granted in Sections 2.1, 2.2 and 2.3 above, all of WU's rights in and to the Patent Rights, the Tangible Research Property and any Technical Information are hereby reserved by WU. Licensee agrees not to practice or use the Patent Rights, the Tangible Research Property and/or the Technical Information or do any act in respect thereof outside the scope of the licenses expressly granted above, including, without limitation, providing any Tangible Research Property to any Third Party other than a Sublicensee. Licensee further agrees that it will not do any act or thing which would in any way contest WU's ownership in, or otherwise derogate from the ownership by WU, of any rights in the Patent Rights, the Tangible Research Property and/or Technical Information. In furtherance of the foregoing but without limiting the generality thereof, Licensee agrees not to register or attempt to register in the Territory or elsewhere any rights in the Patent Rights, the Tangible Research Property and/or Technical Information or to assist any Third Party to do so. Notwithstanding anything to the contrary in the foregoing, (a) Licensee shall have the right, subject to payment of royalties as set forth in Section 5.3(a)(ii), to prepare, file and prosecute any patent application and maintain any patent claiming inventions derived solely by or on behalf of Licensee from Technical Information and/or Tangible Research Property, and, as between Licensee and WU, Licensee shall be the sole owner of any such patent application or patent, and (b) the limitations on Licensee set forth in this Section 2.7, and Sections 8.2, 13.3(a), 13.5(a)-(d) and last sentence of Section 13.5 with respect to Patent Rights shall not apply to any Special Patent Right determined to be jointly owned by WU and Licensee.

2.8 <u>Markings</u>. Licensee shall ensure that appropriate markings, such as "Patent Pending" or the Patent Rights patent numbers or application serial numbers, appear, to the extent required by each country's patent laws, on all Licensed Products (or their packaging, as appropriate) sold by or on behalf of Licensee.

2.9 Sublicensing.

- **2.9.1 General**. Subject to the further provisions of this Section 2.9. Licensee may grant sublicenses of the licenses granted to Licensee in Sections 2.1, 2.2 and 2.3 above to Affiliates, or to Third Parties by entering into a written agreement with any such Third Party. Each Sublicensee may grant a further sublicense under the sublicense granted by Licensee; provided, however, that no such further Sublicensee shall have the right to grant any further sublicense.
- **2.9.2 Requirements of each Sublicense Agreement.** Licensee agrees that it will require all Sublicensees to comply with the terms and conditions set forth in this Agreement and applicable to Licensee. In furtherance of the foregoing but without limiting the generality thereof, each Sublicense shall, for the express benefit of WU, bind the Sublicensee to terms and conditions no less favorable to WU than those between WU and Licensee contained in this Agreement. To the extent that any term, condition, or limitation of any Sublicense is inconsistent with the terms, conditions and limitations contained in this Agreement, such term, condition, and/or limitation shall be null and void against WU, Without in any way narrowing or limiting the scope of the foregoing provisions of this Section 2.9.2, all Sublicenses shall contain the terms and conditions set forth in Exhibit C hereto. Within thirty (30) days after the effective date of any Sublicense, Licensee shall provide WU a complete copy of the Sublicense including, without limitation, any and all exhibits and/or attachments thereto; provided, that Licensee may redact any non-financial terms not reasonably relevant to obligations owed to WU hereunder provided that there is no dispute between the parties. If the Sublicense is written in a language other than English, the copy of the Sublicense shall be accompanied by a complete translation written in English. Upon delivery of such translation to WU, Licensee shall be deemed to represent and warrant to WU that such translation is a true and accurate translation of the Sublicense.
- **2.9.3** <u>Survival of Sublicenses</u>. At Licensee's written request, any Sublicense granted by Licensee under this Agreement will remain in effect in the event that this Agreement is terminated prior to expiration. Any such Sublicensee will automatically become a direct licensee of WU under the rights originally sublicensed to it by Licensee provided the Sublicensee did not cause the termination of this Agreement and the Sublicensee agrees to comply with the terms of this Agreement and to fulfill all the responsibilities of Licensee hereunder. Each such Sublicensee shall be an intended third party beneficiary of this <u>Section 2.9.3</u>. In the event that this Agreement is terminated, all amounts subsequently due to Licensee with respect to any such Sublicense granted under the licenses granted under this Agreement shall become paid directly to WU following the date of termination.
- **2.9.4** <u>Primary Liability</u>. Licensee will be primarily liable to WU for all of Licensee's obligations contained in this Agreement. Any act, error or omission of a Sublicensee that would be a breach of this Agreement if imputed to Licensee, will be deemed to be a breach of this Agreement by Licensee if Licensee has neither cured such breach nor terminated the applicable Sublicense within sixty (60) days after Licensee's receipt of such notice.

3. Development Plan.

- **3.1** <u>Development Plan</u>. Licensee represents and warrants as of the Effective Date that (a) the Development Plan (refer <u>Exhibit A</u>) contains Licensee's good faith, bona fide plans for developing Licensed Products for commercialization, and (b) Licensee has or plans to obtain the knowledge, expertise, experience and resources to fully carry out such plans.
- 3.2 <u>Progress Reports</u>. Licensee will deliver to WU written reports on Licensee's progress against the Development Plan no later than January 31 and July 31 of the first two calendar years following the calendar year in which the Effective Date falls, and no later than January 31 of each calendar year thereafter. Each such report will summarize Licensee's progress against the Development Plan in reasonable detail including, without limitation, the progress achieved and any problems encountered in the development, prototyping, evaluation, testing, manufacture, Sale, and/or marketing of, as applicable, each Licensed Product. Upon reasonable request by WU from time-to-time, Licensee will meet with WU to consult with WU about Licensee's then-current progress against the Development Plan.
- **3.3** <u>Changes to Development Plan</u>. Licensee may not amend, change or otherwise modify the Development Plan without providing a written update thereof to WU. WU will be provided a reasonable opportunity to review and comment on any such amendment or modification of the Development Plan, and Licensee shall give due consideration to all comments provided by WU.

4. Diligence.

- **4.1** Licensee agrees to, throughout the Term, use Commercially Reasonable Efforts, itself or through its Affiliates, Sublicensees or contractors, to develop Licensed Products, and to manufacture, promote and sell Licensed Products throughout the Territory and in the Field, which efforts may be satisfied with respect to development (but not commercialization) through achievement of the financial and non-financial milestones set forth in the Preamble after any applicable adjustment.
- **4.2** Should WU conclude in its reasonable judgment that Licensee fails to meet the diligence requirements set out in Section 4.1 above, WU may notify Licensee of its conclusions and the basis therefor. The parties shall then undertake to resolve WU's concerns through good faith negotiations for a period of 90 days. Should such negotiations fail to result in a plan reasonably acceptable to WU for achieving a level of diligence consistent with its obligations under Section 4.1 above, then WU may require Licensee to pay the Milestone Extension Fee set forth in the Preamble (if the alleged diligence failure relates to a milestone set forth in the Preamble) and, if Licensee fails to do so, or if the alleged diligence failure does not relate to a milestone set forth in the Preamble, WU may exercise its right to terminate this Agreement as provided in Article 13 below.

5. Fees, Payments and Royalties.

- 5.1 License Issue Fee. Licensee agrees to pay the License Issue Fee to WU as set forth in the Preamble.
- **5.2** <u>License Maintenance Fee</u>. Licensee agrees to pay the License Maintenance Fee to WU as set forth in the Preamble.

5.3 Royalties.

- (a) Subject to Section 5.3(b) below, Licensee agrees to pay WU an earned royalty equal to (i) the [...***...]% Patent Royalty Rate of Net Sales (including, for clarity, Net Sales by Sublicensees) of Licensed Products if there is a Valid Claim of the Patent Rights covering the Licensed Product in the country of Sale or country of manufacture; provided, however, that the earned royalty shall be equal to the [...***...]% Patent Royalty Rate of Net Sales (including, for clarity, Net Sales by Sublicensees) of Special Licensed Product, or (ii) the [...***...]% Non-Patent Royalty Rate of Net Sales (including, for clarity, Net Sales by Sublicensees) of Licensed Products if there is no Valid Claim of the Patent Rights covering the Licensed Product in the country of Sale or country of manufacture. Such earned royalties shall be paid by Licensee within [...***...] days after the end of each Calendar Half in which the Sale of the Licensed Products to which such earned royalties occurs.
- (b) If rights under any intellectual property owned by any Third Party are needed to practice, use, make, sell, offer to sell or import any Licensed Product, then royalties payable to WU with respect to such Licensed Product under Section 5.3(a)(1) may be reduced by Licensee dollar for dollar in an amount up to [...***...] percent ([...***...]%) of any royalty payable by Licensee to any such Third Party for such right. However, in no event shall any such royalty be reduced below [...***...]% (as a result of any such deductions) if the original royalty under Section 5.3(a)(i) is [...***...]%, or below [...***...]% if the original royalty under Section 5.3(a)(i) is [...***...]%. The royalty reductions in this Section 5.3(b) shall only be applicable for Third Party licenses needed to provide freedom to operate under the Patent Rights and do not apply to other licenses or permissions that Licensee may obtain to develop, produce or market a finished Licensed Product, including Third Party formulation technology.
- **5.4** <u>Milestone Payments</u>. Licensee agrees to pay WU milestone payments in the amounts set forth in the Preamble, within [...***...] days after the date that the applicable milestone is achieved.
- 5.5 <u>Clarifications</u>. For the avoidance of doubt, no multiple royalty will be required to be paid on a single unit of Licensed Product or because a Licensed Product or its manufacture, use, Sale or importation is covered by more than one Valid Claim. However, WU will be entitled to the highest applicable royalty rate. No royalty shall be payable on Sales of any Licensed Product unless such Licensed Product is either covered by a Valid Claim in the country of Sale or country of manufacture, or embodies, or was made using a method or process included in, Technical Information and/or Tangible Research Property that, when used by Licensee or Sublicensee, as applicable, was not generally available for use by Third Parties. In order to ensure that WU obtains the full amount of royalty payments contemplated in this Agreement, if

any Licensed Product is sold or transferred internally within Licensee, its Affiliates or any Sublicensee or other Third Party with whom Licensee or any of its Affiliates has any agreement or arrangement regarding consideration (including but not limited to an option to purchase stock, stock ownership, division of profits, or special rebates or allowances), the amount of the Sale shall be deemed to be the greater of (a) the price at which the Licensed Product is resold to the end user or (b) the fair market value of the Licensed Product.

5.6 <u>Sublicensing Revenue Obligations</u>. Licensee shall pay to WU the applicable percentage of Sublicensing Revenue identified in the Preamble above within [...***...] days after the end of the Calendar Half in which Licensee receives the Sublicensing Revenue.

6. Place and Method of Payment; Reports and Records; Audit; Interest.

- **6.1** <u>Method of Payment</u>. All dollar (\$) amounts referred to in this Agreement are expressed in United States dollars. All payments to WU shall be made in United States dollars by check or electronic transfer payable to "Washington University." Any Sales revenues for Licensed Products in currency other than United States dollars shall be converted to United States dollars at the conversion rate for the foreign currency as published in the Eastern edition of The Wall Street Journal as of the last business day in the United States of the applicable Calendar Half.
 - **6.2 Place of Payment.** Checks shall reference WU Contract Number [...***...] and shall be sent to:

Accounting Department Office of Technology Management Washington University in St. Louis 660 South Euclid Avenue, CB 8013 St. Louis, MO 63110

All payments shall include the WU Contract Number to ensure accurate crediting to Licensee's account. Electronic transfers shall be made to a bank account designated in writing by WU.

- **6.3** Reports. Within forty-five (45) days after the end of each Calendar Half in which a Licensed Product is Sold, Licensee shall deliver to WU, a written report setting forth the calculation of all amounts due to Licensee under Sections 5.3 and 5.6 above for such Calendar Half. For Licensed Products, each such report shall show, at a minimum, (a) the number of Licensed Products Sold and amount of Sales by country during such Calendar Half, (b) the gross receipts for Sales of Licensed Products dining such Calendar Half including total amounts invoiced and received, (c) any Permissible Deductions giving totals by each type for such Calendar Half, (d) Net Sales of Licensed Products by country for such Calendar Half, and (e) royalties, fees and payments due to WU for such Calendar Half, giving totals for each category.
- **6.4** <u>Books and Records</u>. Licensee shall maintain complete and accurate books of account and records that would enable an independent auditor to verify the amounts paid as royalties, fees and payments under this Agreement. The books and records must be maintained for six (6) years following the Calendar Half after submission of the reports required by this

Agreement. Upon reasonable notice by WU, Licensee must give WU (or auditors or inspectors appointed by and representing WU) access to all books and records relating to Sales of Licensed Products by Licensee to conduct, at WU's expense, an audit or review of those books and records. This access must be available at least once every twelve (12) months, during regular business hours, during the Term and for three (3) years following the termination or expiration of this Agreement. If any such audit or review determines that Licensee has underpaid royalties by 5% or more for any Calendar Half, Licensee shall (a) reimburse WU for the costs and expenses of the accountants and auditors in connection with the review and audit, and (b) immediately pay WU the amount of such underpayment along with interest on the past due amount as provided in Section 6.5 below.

6.5 <u>Interest and Collection</u>. Any amounts not paid by Licensee to WU when due shall accrue interest, from the date [...***...] days after the balance is due, at an annual interest rate of [...***...]% above the prime rate published in the Eastern edition of *The Wall Street Journal* during the period of arrearage (or the maximum allowed by law, if less than the amount specified herein). In addition, Licensee will reimburse WU for all reasonable costs and expenses incurred (including reasonable attorneys' fees) in collecting any overdue amounts.

6.6 Foreign Taxes. Payments shall be paid to WU free and clear of all foreign taxes. If laws, rules or regulations require withholding of income taxes or other rates imposed upon payments set forth in this Agreement, Licensee shall make such withholding payments as required without subtracting such withholding payments from such payments to WU. Licensee shall submit appropriate proof of payment of the withholding rates to WU within a reasonable period of time. Licensee shall use efforts consistent with its usual business practices to minimize the extent of any withholding taxes imposed under the provisions of the current or any future double taxation treaties or agreement between foreign countries, and the parties shall cooperate with each other with respect thereto, with the appropriate party under the circumstances providing the documentation required under such treaty or agreement to claim benefits thereunder. Any refund, rebate or abatement of any tax in respect of which a withholding payment under this Section 6.6 has been made by Licensee shall be solely for the account of Licensee.

7. Confidentiality.

7.1 <u>Definition of Confidential Information</u>. The parties acknowledge that, prior to and during the Term, the parties may disclose to one another scientific, technical, trade secret, business, or other information which is treated by the disclosing party as confidential or proprietary, including but not limited to unpublished Patent Rights patent applications, Technical Information, Tangible Research Property, Development Plans, progress reports, and royalty reports (all such information is hereinafter referred to collectively as "Confidential Information"). Both parties agree that in order to ensure that each party understands which information is deemed to be confidential, all Confidential Information will be in written form and clearly marked as "Confidential Information is initially disclosed in oral or some other non-written form, it will be confirmed and summarized in writing and clearly marked as "Confidential" within thirty (30) days after disclosure. The receiving party shall hold the disclosing party's Confidential Information in confidence and shall treat such information in the same manner as it treats its own confidential information but not less than with a reasonable

degree of care. In recognition that WU is a non-commercial, academic institution, Licensee agrees to limit to the extent possible the delivery of Licensee Confidential Information to WU. Each party retains the right to refuse to accept any Confidential Information from the other party which it does not consider to be essential to this Agreement or which it believes to be improperly designated, for any reason, but such refusal shall not eliminate the obligation of the individual making such a determination from treating such information as confidential hereunder where such information has been read by such individual. The Confidential Information provided to the receiving party will remain the property of the disclosing party, and will be disclosed only to those persons necessary for the performance of this Agreement.

- **7.2** Exclusions. Confidential Information does not include information that (a) was known to the receiving party prior to receipt from the disclosing party as evidenced by the receiving party's records; (b) is or becomes publicly available through no act by or on behalf of the receiving party; (c) is lawfully received by the receiving party from a Third Party without any restrictions, and/or (d) comprises identical subject matter to that which had been originally and independently developed by the receiving party personnel without knowledge or use of any Confidential Information as evidenced by the receiving party's records.
- **7.3 General Obligations**. Subject to Section 2.5 above and to Sections 7.5 and 7.6 below, the receiving party agrees that during the Term and forever thereafter it will (a) refrain from disclosing any of the other party's Confidential Information to Third Parties, (b) disclose the other party's Confidential Information to only those employees of the receiving party necessary for the receiving party to use the Confidential Information in accordance with this Agreement and who are subject to restrictions on use and disclosure at least as restrictive as those set forth in this Agreement, (c) keep confidential the other party's Confidential Information, and (d) except for use in accordance with the rights and licenses which are expressly granted in this Agreement, refrain from using the other party's Confidential Information,
- **7.4 No License**. By disclosing the Confidential Information to the other party, the disclosing party does not grant any express or implied rights to the other party under any patents, copyrights, trademarks, or trade secrets other than the licenses expressly granted herein. Each party reserves, without prejudice, the ability to protect its rights under any such patents, copyrights, trademarks, or trade secrets.
- **7.5** <u>Judicial Procedures</u>. The receiving party may, to the extent necessary, disclose the disclosing party's Confidential Information in accordance with a judicial or other governmental rule, regulation or order; *provided* that the receiving party either (a) gives the disclosing party reasonable notice prior to such disclosure to allow the disclosing party a reasonable opportunity to seek a protective order or equivalent, or (b) obtains written assurance from the applicable judicial or governmental entity that it will afford such Confidential Information the highest level of protection afforded under applicable law or regulation.
- **7.6** <u>Permitted Disclosures</u>. Licensee may, to the extent necessary, use and disclose the WU Confidential Information (a) to secure governmental approval to clinically test or market a Licensed Product, (b) if applicable, to secure patent protection for an invention within the Patent Rights or pursuant to <u>Section 2.7</u>, or (c) to actual or potential Sublicensees or contractors

performing development and/or commercialization services with respect to Licensed Products, provided such potential Sublicensees or contractors first agree in writing to be bound by terms that are at least as restrictive as the terms set forth in this Agreement. Licensee will, in any such event, take all reasonably available steps to maintain the confidentiality of the disclosed Confidential Information and to guard against any further disclosure.

8. Representations and Warranties.

- **8.1** <u>Authority.</u> Each of WU and Licensee represents and warrants to the other of them that (a) this Agreement has been duly executed and delivered and constitutes a valid and binding agreement enforceable against such party in accordance with its terms, (b) no authorization or approval from any Third Party is required in connection with such party's execution, delivery, or performance of this Agreement, and (c) the execution, delivery, and performance of this Agreement does not violate the laws of any jurisdiction or the terms or conditions of any other agreement to which it is a party or by which it is otherwise bound.
- **8.2** Compliance with Laws. Licensee represents and warrants that it will (a) use the Patent Rights, Tangible Research Property and Technical Information only to exploit the license rights granted in Sections 2.1, 2.2 and 2.3 in accordance with the provisions of this Agreement and with such laws, rules, regulations, government permissions and standards as may be applicable thereto in the Territory and in the Field, and (b) otherwise comply with all laws, rules, regulations, government permissions and standards as may be applicable to Licensee in the Territory with respect to the performance by Licensee of its obligations hereunder.
- **8.3** <u>Reports</u>. Licensee warrants that all reports provided by Licensee hereunder are true and correct and are certified true and correct by Licensee upon delivery to WU.
- **8.4** Additional Warranties of Licensee. Licensee represents and warrants that (a) it has obtained the insurance coverage required by Article 12 below, and (b) there is, to the best of its knowledge, no pending litigation and no threatened claims against it that could impair its ability or capacity to perform and fulfill its duties and obligations under this Agreement.
- **8.5** Additional Warranties of WU. WU represents and warrants that (a) it has in place an intellectual property policy that provides for its ownership (subject to any rights retained by the U.S. government by operation of law) of the Patent Rights, Technical Information and Tangible Research Property; (b) as of the Effective Date, it has received no notice of any Third Party claims challenging WU's ownership or control, and to the best of its knowledge, it is the sole owner, of the Patent Rights, Technical Information and Tangible Research Property, and has the authority to grant the licenses set forth herein; (c) it has obtained assignments from all WU inventors named in patent applications within the Patent Rights assigning to WU all their right, title and interest in and to the Patent Rights and to the best of WU's knowledge, no person or entity has infringed the Patent Rights or misappropriated the Technical Information and/or Tangible Research Property; and (d) it has not granted or conveyed to any other person or entity any right or option to the Patent Rights that would conflict with the rights granted to Licensee hereunder.

9. Application, Prosecution and Maintenance of Patent Rights.

9.1 Patent Applications.

- 9.1.1 Patent Rights. WU has the first right to control the preparation, filing, prosecution, issue and maintenance of Patent Rights patents and applications. Subject to compliance by Licensee of the terms and conditions of this Agreement (including, without limitation, Section 9.2 below), WU will (a) prosecute and maintain the applications and patents within the Patent Rights and (b) prepare, file and prosecute additional applications within the Patent Rights as Licensee may reasonably request, in WU's name and, if applicable, Licensee's name, at Licensee's sole cost and expense. WU will select qualified outside patent counsel and corresponding foreign associates reasonably acceptable to Licensee to prepare, file, prosecute and maintain U.S. patents/applications and foreign counterparts within the Patent Rights. WU will consult with Licensee regarding the prosecution of Patent Rights patent applications, including, without limitation, providing Licensee a reasonable opportunity to review and comment on proposed submissions to any patent office before the submission is filed, and giving due consideration to all comments provided by Licensee. WU will keep Licensee reasonably informed of the status of Patent Rights patents and applications by timely giving Licensee copies of significant communications relating to such Patent Rights that are received from any patent office or outside patent counsel of record or foreign associate. Should WU decide to abandon any Patent Rights patents and applications, WU shall notify Licensee of such intent at least thirty (30) days prior to any deadline at which such abandonment becomes irrevocable and Licensee may, at its own expense, prosecute and maintain said patent application. Should Licensee assume such prosecution and maintenance, WU agrees to reasonably cooperate with Licensee at Licensee's request to whatever extent is reasonably necessary, to procure patent protection for Patent Rights, including fully agreeing to execute any and all documents to provide Licensee the ful
- **9.2** <u>Costs and Expenses</u>. Subject to <u>Section 9.3</u> below, Licensee agrees to reimburse WU for all reasonable costs and expenses incurred by WU in connection with the preparation, filing, prosecution, issue and/or maintenance of patents and applications within the Patent Rights both prior to the Effective Date and at any time thereafter during the Term. Licensee agrees to pay WU the amount of any such reimbursement within forty-five (45) days after receipt by Licensee of documentation for any such costs and expenses, which WU may provide to Licensee from time-to-time.
- **9.3** Failure to Reimburse. Licensee may elect not to reimburse WU for amounts due under Section 9.2 in respect to one or more Patent Rights patent and/or applications only by giving WU notice of such election at least ninety (90) days before the date on which the applicable cost or expense is to be incurred by WU (each an "Election Notice"). For purposes of this Section 9.3, a cost or expense shall be deemed to be incurred by WU on the earlier of (a) the date WU actually pays the cost or expense, or (b) the date WU becomes obligated to pay the cost or expense (which, for example, shall be the date WU engages a third party to perform the service which gives rise to a commitment to pay any such cost or expense). Any such Election Notice shall specify the Patent Rights patents and/or applications to which such Election Notice relates ("Excluded Patent Rights"). In the event any Election Notice is given by Licensee, (x) the term "Patent Rights" shall be modified to exclude such Excluded Patent Rights, (y) the

term "**Technical Information**" shall be modified to exclude any research and development information, unpatented inventions, know-how, data, methods, and technical data and information that relate solely to the Excluded Patent Rights ("**Excluded Technical Information**"), and (z) the term "**Tangible Research Property**" shall be modified to exclude any and all tangible research tools and other tangible personal property that WU may have provided to Licensee that relate solely to the Excluded Patent Rights ("**Excluded Tangible Research Property**"), in each instance as of the date the Election Notice is given. Accordingly, and for the avoidance of doubt, as of the date the Election Notice is given, the license to the Excluded Patent Rights, Excluded Technical Information and the Excluded Tangible Research Property granted to Licensee under <u>Sections 2.1</u>, <u>2.2</u> and <u>2.3</u> above shall terminate, and WU shall be free, without any further obligation to Licensee whatsoever, to abandon the applications or patents subject to the Election Notice, or to continue prosecution or maintenance, for WU's sole use and benefit, including a license to unrelated Third Parties, at WU's option and sole cost and expense. Licensee agrees to deliver to WU, along with any Election Notice, all Excluded Technical Information and Excluded Tangible Research Property to which such Election Notice relates. For the avoidance of doubt, WU will not refund any amounts paid under <u>Section 9.2</u> to WU prior to WU's receipt of an Election Notice.

9.4 Community of Interest. The parties desire to avail themselves to the maximum extent possible of all applicable legal privileges. The parties intend that information regarding the preparation, filing, prosecution and maintenance of the applications and patents within the Patent Rights ("Shared Information") that would otherwise be subject to one or more legal privileges or protections is and shall be subject to those same privileges and protections despite the fact that it has been developed by or exchanged between or among them and/or their joint or independent counsel. The parties further intend that Shared Information is and shall be subject to the joint defense doctrine and common interest/community of interest doctrine. The parties acknowledge that the legal privileges and protections pertaining to Shared Information are held jointly by both parties, and that no individual party is authorized to waive any such privilege or protection. Further, this Agreement shall not affect the ethical, fiduciary or other obligations inherent in those attorney-client relationships other than to extend the cloak of confidentiality and privilege to the Shared Information as provided herein. Each party agrees that Shared Information obtained from the other party or developed jointly shall be used only for the preparation and prosecution of the Patent Rights and for no other purpose. Each party agrees to keep Shared Information confidential in accordance with Article 7.

9.5 <u>Inventorship Determination</u>. WU's and Licensee's legal counsel will determine whether Licensee is an inventor of the invention claimed in the Special Patent Right application. Such determination will commence upon the Effective Date and last no longer than thirty (30) days. Such inventorship determination shall have no bearing on the royalty rate to be paid with respect to the Special Licensed Product and the royalty rate will be [...***...]% pursuant to <u>Section 5.3(a)(i)</u>.

10. Infringement, Enforcement, and Defense.

10.1 Notice of Infringement. Throughout the Term, each of WU and Licensee agree to give the other prompt notice of (a) any known or suspected infringement of the Patent Rights or unauthorized use or disclosure of the Technical Information and/or Tangible Research Property in the Territory, and (b) any claim that a Licensed Product infringes the intellectual property rights of a Third Party.

10.2 Patent Rights.

- **10.2.1** Enforcement. Licensee, at its sole expense, will have the initial right to attempt to stop promptly any infringement of the Patent Rights in the Territory. Licensee may initiate and prosecute actions in its own name or, if required by law, in WU's name against Third Parties for infringement of the Patent Rights in the Territory through outside counsel of Licensee's choice who are reasonably acceptable to WU. Licensee shall consult with WU prior to and in conjunction with all significant issues, shall keep WU informed of all proceedings, and shall provide copies to WU of all pleadings, legal analyses, and other papers related to such actions. WU will provide reasonable assistance to Licensee, at Licensee's cost, in prosecuting, resolving and/or settling any such actions, including but not limited to joining as a party if necessary or desirable. If Licensee fails or declines to take any action under this Section 10.2.1 within a reasonable time after learning of the infringement of the Patent Rights, WU shall have the right (but not the obligation) to take appropriate actions including, without limitation, filing a lawsuit, at WU's cost. Licensee will provide reasonable assistance to WU, at WU's cost, in prosecuting, resolving and/or settling any such actions.
- **10.2.2** Restrictions on Settlement. Notwithstanding anything in this Agreement to the contrary, neither party may, without the advanced written consent of the other party, not to be unreasonably withheld, conditioned or delayed, settle, compromise, or otherwise enter into any form of settlement (or other similar agreement) regarding any claim of action brought under Section 10.2.1 above that either (a) admits liability on the part of the other party, (b) otherwise negatively affects the rights of the other party or imposes any liability, restrictions or obligation upon the other party, (c) requires any financial payment by the other party, (d) concedes or otherwise portions the Territory, and/or (e) grants rights or concessions to a Third Party to the Patent Rights or any Licensed Products.
- **10.2.3** <u>Proceeds</u>. If Licensee obtains any value, payment or compensation of any type or kind as a result of any claim brought pursuant to <u>Section 10.2.1</u> above, Licensee shall pay to WU a percentage of any such proceeds (after recouping reasonable and necessary attorney's fees and expenses incurred in connection with such claim) equal to the applicable Patent Royalty Rate.
- **10.3** <u>Technical Information</u>. WU shall have the exclusive right (but not the obligation) to institute legal action against any Third Party arising out of such Third Party's actual or threatened misappropriation of the Technical Information, and WU shall retain any and all proceeds from any such actions. Licensee shall have no right to make any demands or claims, bring suit, effect any settlements or take any other action with respect to any such misappropriation without the prior written consent of WU.

11. Indemnification.

11.1 Notwithstanding anything else in this Agreement, Licensee agrees to indemnify, reimburse and hold harmless WU, WU personnel, WU's Affiliates, and each of their respective trustees, faculty, staff, employees, students, directors, officers, agents, successors and assigns (altogether the "WU Indemnitees") from, for and against any and all judgments, settlements, losses, expenses, damages and/or liabilities (the "Losses") and any and all court costs, reasonable attorneys' fees, and expert witness fees and expenses ("Fees") that a WU Indemnitee may incur from any and all allegations, claims, suits, actions or proceedings brought by a Third Party (the "Claims") to the extent arising out of, relating to, or incidental to Licensee's breach of this Agreement or its use, commercialization, or other exploitation of Patent Rights, Technical Information or Tangible Research Property, whether by or through Licensee, Licensee's Affiliates, Sublicensees, or contractors, and including all Claims for infringement, injury to business, personal injury and product liability, but excluding Losses to the extent they are adjudicated by a Court of competent jurisdiction to be caused by the gross negligence or willful misconduct of a WU Indemnitee. WU agrees to indemnify, reimburse and hold harmless Licensee, Licensee personnel, Licensee's Affiliates, Sublicensees, and its and their staff, employees, directors, officers, agents, successors and assigns (together the "Licensee Indemnitees") from, for and against any and all Losses and Fees that a Licensee Indemnitee may incur from any and all Claims to the extent arising out of, relating to, or incidental to (a) WU's activities pursuant to this Agreement, including, without limitation, WU's use, storage or handling of Licensee property at WU, or (b) WU's breach of this Agreement or (c) use, commercialization, or other exploitation, of Technical Information or Tangible Research Property, whether by WU or any of its licensees, except Licensee, or (d) use of its retained rights in Paten

11.2 Obligations set forth in this Article 11 shall survive termination of this Agreement, shall continue even after assignment of rights and responsibilities, and shall not be limited by any provision of this Agreement outside this section. A party seeking indemnification under this Agreement shall: (a) give the indemnifying party prompt written notice of the Claim; (b) cooperate with the indemnifying party, at the indemnifying party's expense, in connection with the defense and settlement of the Claim; and (c) not settle or compromise the Claim without the written consent of the indemnifying party, which shall not be unreasonably withheld, conditioned or delayed. An indemnifying party may satisfy its duty to indemnify for Fees by accepting an irrevocable duty to defend the Claim on behalf of the WU Indemnitees or Licensee Indemnitees, as applicable, without a reservation of rights, at which time the indemnifying party shall be entitled to conduct and direct the defense of the applicable indemnitees against such Claim using attorneys of its own selection; for all other Claims, the applicable indemnitee shall be entitled to conduct and direct its own defense and that of other indemnitees using attorneys of its own selection with Fees subject to the indemnifying party's ongoing obligation to indemnify for Fees.

12. Insurance.

Throughout the Term and for a period of [...***...] years thereafter, Licensee shall obtain and maintain comprehensive general liability insurance in the following minimum annual limits: \$[...***...] per occurrence and \$[...***...] in the aggregate; and

From the date at least one day prior to the first clinical study of a Licensed Product throughout the Term and for a period of [...***...] years thereafter, Licensee shall obtain and maintain comprehensive product liability insurance in the following minimum annual limits: \$[...***...] per occurrence and \$[...***...] in the aggregate.

Each of the above insurance policies shall be with carrier(s) having at least A.M. Best ratings/class sizes of A/VII and shall name WU as an additional insured. Licensee will provide WU with a certificate of insurance within thirty (30) days after the Effective Date and annually thereafter. The certificates must provide that Licensee's insurer will notify WU in writing at least thirty (30) days prior to cancellation or material change in coverage. The specified minimum insurance coverage and limits do not constitute a limitation on Licensee's liability or obligation to indemnify or defend under this Agreement.

13. Term and Termination.

- **13.1 Term.** The Term is defined in the Preamble and is subject to earlier termination as provided herein.
- **13.2** <u>Termination By Licensee</u>. Licensee may terminate this Agreement without cause by giving at least ninety (90) days' notice thereof to WU. Licensee shall pay WU all amounts due and owing to WU under this Agreement as of the date of termination, including the above mentioned ninety (90) day notice period, within ten (10) days after receipt of an invoice from WU for such amounts, as a termination fee ("**Termination Fee**").
- **13.3** Termination by WU. WU may terminate this Agreement by giving notice thereof to Licensee upon the occurrence of any one or more of the following events (in which event this Agreement shall terminate on the date such notice is given): (a) Licensee exercises any rights with respect to the Patent Rights, Tangible Research Property, and/or the Technical Information outside the scope of the licenses granted to Licensee in Article 2 above and does not cease such exercise within thirty (30) days after the day that WU gives Licensee notice demanding that such exercise cease, and/or (b) (i) a bankruptcy proceeding is filed by Licensee or a bankruptcy proceeding is filed against Licensee and is not dismissed within sixty (60) days, or (ii) Licensee suffers the appointment of a receiver, receiver and manager, or administrative receiver of the whole or any substantial portion of its assets or business, or (iii) a resolution is passed for its dissolution (other than for the purpose of amalgamation or reconstruction).
- **13.4** Breach and Failure to Cure. WU may terminate this Agreement by giving notice thereof to Licensee in the event Licensee commits a material breach of any provision of this Agreement and fails to cure such breach within sixty (60) days after the day that WU gives Licensee notice of such breach. Such termination shall be effective on the date such notice of termination is given. Licensee may terminate this Agreement by giving notice thereof to WU in the event WU commits a material breach of any provision of this Agreement and fails to cure such breach within sixty (60) days after the day that Licensee gives notice to WU of such breach, and such termination shall be effective on the date such notice of termination is given.
- **13.5** <u>Duties Upon Expiration or Earlier Termination</u>. For the avoidance of doubt, on the date of expiration or earlier termination of this Agreement, all license rights granted to Licensee under Article 2 above shall terminate; *provided*, *however*, that upon expiration of this Agreement, the licenses granted in <u>Sections 2.2</u> and <u>2.3</u> shall survive and become irrevocable,

perpetual, royalty-free and fully paid up. Licensee agrees to, promptly upon earlier termination (but not expiration) of this Agreement, deliver to WU all originals, copies, reproductions and summaries of all Tangible Research Property, Technical Information and WU's Confidential Information, and WU likewise agrees to deliver to Licensee all originals, copies, reproductions and summaries of all Licensee's Confidential Information promptly upon earlier termination of this Agreement, in each instance in the format in which it exists at the time of earlier termination of this Agreement, or in another mutually agreed format. Within ten (10) days after earlier termination (but not expiration) of this Agreement for any reason whatsoever, Licensee agrees to deliver a written report to WU of all Licensed Products in inventory. If this Agreement terminates before the expiration of the last-to-expire of the Patent Rights, then, upon the termination of this Agreement, Licensee agrees (a) to immediately discontinue the exportation of Licensed Products arising from the use of Patent Rights, Technical Information or Tangible Research Property that were made in the Territory, (b) to immediately discontinue the manufacture, Sale and distribution of the Licensed Products arising from the use of Patent Rights, Technical Information or Tangible Research Property in the Territory, (c) to immediately destroy all Licensed Products arising from the use of Patent Rights, Technical information or Tangible Research Property in inventory, and (d) not to manufacture, sell and/or distribute Licensed Products in the Territory until the expiration of the Term. Further, upon such termination, Licensee shall cease all use of the Patent Rights, Technical Information or Tangible Research Property.

13.6 Effect of Expiration or Earlier Termination. For the avoidance of doubt, the expiration or earlier termination of this Agreement shall not relieve Licensee of its obligation to account for and make payment to WU of any amount due hereunder that accrued during the Term, including, without limitation, any royalties and amounts under Sections 9.2 and 13.2 above.

14. Disclaimer and Limitation of Liability.

NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, EVERYTHING PROVIDED BY WU UNDER THIS AGREEMENT IS UNDERSTOOD TO BE EXPERIMENTAL IN NATURE, MAY HAVE HAZARDOUS PROPERTIES, AND, EXCEPT AS SET FORTH IN SECTION 8, IS PROVIDED WITHOUT ANY WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF ANY THIRD-PARTY PATENT, TRADEMARK, COPYRIGHT OR ANY OTHER THIRD-PARTY RIGHT. WU MAKES NO WARRANTIES REGARDING THE QUALITY, ACCURACY, COMMERCIAL VIABILITY OR ANY OTHER ASPECT OF ITS PERFORMANCE PURSUANT TO THIS AGREEMENT OR REGARDING THE PERFORMANCE, VALIDITY, SAFETY, EFFICACY OR COMMERCIAL VIABILITY OF ANYTHING PROVIDED BY WU UNDER THIS AGREEMENT. LICENSEE DOES NOT WARRANT THAT ANY LICENSED PRODUCT WILL BE SUCCESSFULLY DEVELOPED, APPROVED OR COMMERCIALIZED OR THAT ANY SALE OR LEVEL OF SALES WILL BE ACHIEVED PROVIDED THAT THE FOREGOING DISCLAIMER SHALL NOT RELIEVE OR WAIVE LICENSEE'S DILIGENCE OBLIGATIONS UNDER THIS AGREEMENT. EXCEPT FOR THEIR RESPECTIVE INDEMNITY OBLIGATIONS, IN NO EVENT SHALL WU OR LICENSEE BE LIABLE FOR ANY INDIRECT, SPECIAL OR

CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS AGREEMENT, WHETHER IN BREACH OF CONTRACT, TORT OR OTHERWISE, EVEN IF THE PARTY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT FOR THEIR RESPECTIVE INDEMNITY OBLIGATIONS, EACH OF WU'S AND LICENSEE'S AGGREGATE LIABILITY TO THE OTHER UNDER THIS AGREEMENT SHALL NOT EXCEED THE PAYMENTS MADE OR PAYMENTS DUE UNDER THIS AGREEMENT, RESPECTIVELY.

15. General Provisions.

- 15.1 <u>Import/Export Controls</u>. In performing their respective obligations under the Agreement, the parties will comply with United States export control and asset control laws, regulations, and orders, as they may be amended from time to time, applicable to the export or re-export of goods or services, including software, processes, or technical data. Such regulations include without limitation the Export Administration Regulations ("EAR"), International Traffic in Arms Regulations ("ITAR"), and regulations and orders administered by the Treasury Department's Office of Foreign Assets Control (collectively, "Export Control Laws"). WU is not transferring any information or material outside of the United States under this Agreement and is providing no representation regarding the export control status or classification of any information or materials provided hereunder.
- **15.2** Entire Agreement; Amendment. This Agreement embodies the entire understanding of the parties and supersedes all other past and present communications and agreements relating to the subject matter. No amendment or modification of this Agreement shall be valid unless made in writing and signed by authorized representatives of both parties.
- **15.3** Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, other than its rules or procedures involving conflicts of laws.
- **15.4** <u>Survival</u>. Each provision of this Agreement that would by its nature or terms survive, shall survive any termination or expiration of this Agreement, regardless of the cause. Such provisions include, without limitation, <u>Sections 1, 2.7(b)</u>, <u>2.9.3</u>, <u>7, 8.2</u>, <u>8.3</u>, <u>9.4</u>, <u>11</u>, <u>12</u>, <u>13.2</u>, <u>13.5</u>, <u>13.6</u>, <u>14</u>, <u>15.3</u>, <u>15.4</u>, <u>15.11</u>, <u>15.13</u> and <u>15.14</u>.
- **15.5** <u>Notices</u>. Notices delivered pursuant to this Agreement shall be to the following contacts or other addresses provided in accordance with this <u>Section 15.5</u> and are effective on the next business day if sent by a nationally recognized commercial carrier's overnight delivery service, or when received if sent otherwise:

Office of Technology Management Attention: Director Washington University in St. Louis 660 South Euclid Avenue, CB 8013 St. Louis, MO 63110

SAGE Therapeutics, Inc. Attention: CEO 215 First Street, 2nd Floor Cambridge, MA 02142

- **15.6** Assignment. This Agreement is binding upon and inures to the benefit of the parties and their successors, but this Agreement may not be assigned by either party without the prior written consent of the other party; provided, however, that Licensee may assign this entire Agreement, without WU's consent, to an Affiliate or to a Third Party that acquires all or substantially all of Licensee's business or assets to which this Agreement relates through merger, sale, acquisition or otherwise; provided, further, that the successor agrees in writing to assume all the obligations and liabilities of Licensee to WU hereunder.
- **15.7** Construction. The recitals and Preamble to this Agreement are hereby incorporated as an integral part of this Agreement as if restated herein in full. Headings are included for convenience and reference only and are not incorporated as an integral part of this Agreement. This Agreement may be executed in any number of counterparts each of which shall be deemed an original and as executed shall constitute one agreement, binding on both parties, even though both parties do not sign the same counterpart.
- **15.8** Relationship of the Parties. Each party is an independent contractor and not a partner or agent of the other party. This Agreement will not be interpreted or construed as creating or evidencing any partnership or agency between the parties or as imposing any partnership or agency obligation or liability upon either party. Further, neither party is authorized to, and will not, enter into or incur any agreement, contract, commitment, obligation or liability in the name of or otherwise on behalf of the other party.
- **15.9** Severability. If any provision in this Agreement is held invalid, illegal, or unenforceable in any respect, such holding shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if it had never contained the invalid, illegal, or unenforceable provisions.
- **15.10** Remedies. The failure of either party to insist upon or enforce strict performance by the other party of any provision of this Agreement, or to exercise any right or remedy under this Agreement will not be interpreted or construed as a waiver or relinquishment of that party's right to assert or rely upon any such provision, right or remedy in that or any other instance; rather, the same will be and remain in full force and effect. All rights and remedies under this Agreement are cumulative of every other such right or remedy and may be exercised concurrently or separately from time-to-time.
- **15.11** <u>Use of Names</u>. Neither party may use the trademarks or name of the other party or its employees for any commercial, advertisement, or promotional purposes without the prior written consent of the other with WU acting through an authorized corporate officer. If either party is required by law, governmental regulation, or its own authorship or conflict of interest policies to disclose its relationship with the other party, including, but not limited to, in SEC filings, scientific publications or grant submissions, it shall provide the other party with a copy of the disclosure.

- **15.12** <u>Force Majeure</u>. Neither WU nor Licensee will be liable for failure of or delay in performing obligations set forth in this Agreement, and neither will be deemed in breach of its obligations, other than for payments, if such failure or delay is due to natural disasters or other causes reasonably beyond the control of a party and reasonable notice of the delay is provided to the other party.
- **15.13** <u>WU Personnel</u>. Licensee and WU agree that for all WU faculty or staff members who serve Licensee in the capacity of consultant, officer, employee, board member, advisor, or otherwise through a personal relationship with Licensee (a "**Consultant**") (a) such Consultant shall serve the Licensee in his or her individual capacity, as an independent contractor, and not as an agent, employee or representative of WU; (b) WU exercises no authority or control over such Consultant while acting in such capacity; (c) WU receives no benefit from such activity; (d) neither Licensee nor the Consultant may use WU resources in the course of such service and, as long as WU resources are not used, WU shall not own any result of Consultant's work; (e) WU makes no representations or warranties regarding such service and otherwise assumes no liability or obligation in connection with any such work or service undertaken by such Consultant; and (f) any breach, error, or omission by a Consultant acting in the capacity set forth in this paragraph shall not be imputed or otherwise attributed to WU, and shall not constitute a breach of this Agreement by WU.
- **15.14** <u>Further Acts</u>. Each party shall, at the reasonable request of the other, execute and deliver to the other such instruments and/or documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.
- **15.15** <u>Impact on Tax-Exempt Status</u>. WU advises (a) that it is exempt from federal income tax under Section 501(c) (3) of the Internal Revenue Code, (b) that maintenance of such exempt status is of critical importance to WU and to its members, and (c) that WU has entered into this Agreement with the expectation that there will be no adverse impact on its tax exempt status. As such, and if it becomes necessary, the parties agree to amend, modify or reform this Agreement as necessary (i) in order to ensure that there is no material adverse impact on WU's tax exempt status, and (ii) in a manner that preserves the economic terms of the Agreement as such are set forth in this Agreement.

[Signature page follows]

The signatures of the undersigned indicate that they have read, understand and agree with the terms of this Agreement and have the authority to execute this Agreement on behalf of their represented party and to bind their party to all the terms of this Agreement.

Signature: /s/ Evan Kharasch

Date: November 12, 2013

By: Evan Kharasch

Title: Vice Chancellor for Research

SAGE THERAPEUTICS, INC.

Signature: /s/ Jeff Jonas

Date: November 20, 2013

By: Jeff Jonas

Title: President and CEO

Read and Understood

/s/ Douglas Covey

Dr. Douglas Covey WU Principal Investigator

Date: November 14, 2013

Exhibit A

[...***...]

Exhibit B

Certain Patent Rights

[...***...]

Exhibit C

Sublicense Agreement Provisions

Sublicensee agrees to indemnify and hold harmless WU Indemnitees to the same extent and under terms no less favorable to WU Indemnitees as Licensee's obligations under Article 11 of this Agreement.

Sublicensee agrees to maintain insurance for WU's benefit to the same extent and under terms no less favorable to WU as Licensee's obligations under Article 12 of this Agreement.

Sublicensee agrees to maintain books and records and allow audits for WU's benefit to the same extent and under terms no less favorable to WU as Licensee's obligations under this Agreement.

If a bankruptcy proceeding is filed by Licensee or a bankruptcy proceeding is filed against Licensee and is not dismissed within sixty (60) days or Licensee suffers the appointment of a receiver, receiver and manager, or administrative receiver of the whole or any substantial portion of its assets or business, and this Agreement and the Sublicense both remain in effect, amounts then or thereafter due to Licensee under the Sublicense that arc payable by Licensee to WU under the Agreement will, upon notice from WU to any Sublicensee, become directly due and owing to WU for the account of Licensee. WU will remit to Licensee any amounts received that exceed the sum actually owed by Licensee to WU under this Agreement in connection with the Sublicense.

Washington University is a third party beneficiary of the Sublicense. Accordingly, Washington University may enforce the Sublicense against Sublicensee to the same extent as Licensee.

Exhibit D

Capitalization Table

[...***...]

Exhibit E

Special Licensed Product Molecule

[...***...]

COMMERCIAL LICENSE AGREEMENT

This COMMERCIAL LICENSE AGREEMENT (this "Agreement") is made this 21st day of August, 2013 (the "Effective Date") between:

CYDEX PHARMACEUTICALS, INC., a Delaware corporation with offices at 11119 North Torrey Pines Road, Suite 200, La Jolla, California 92037 ("CyDex"); and

SAGE THERAPEUTICS INC., a Delaware corporation with offices at 29 Newbury Street, Suite 301, Boston, Massachusetts 02116 ("Sage").

RECITALS

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

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

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

WHEREAS, Sage desires to obtain a license to use Captisol together with the Compound for the development and commercialization of the Licensed Product (defined below) and the conduct of the Probe Studies and CyDex is willing to grant such license to Sage under the terms and conditions set forth herein;

WHEREAS, CyDex and Sage entered into a Commercial License Agreement with an effective Date of December 13, 2012 (the "**Old Agreement**" and such effective date, the "**Old Agreement Effective Date**"), which the parties are terminating as of the Effective Date; AND

WHEREAS, on or about December 13, 2012, CyDex and Sage entered into a Supply Agreement, specifying the terms under which CyDex would sell Captisol to Sage or its Contract Manufacturers (defined below), and Sage would obtain supplies of Captisol from CyDex, for use in development of and in the Licensed Product (the "Supply Agreement").

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

1. DEFINITIONS.

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

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

"Bankruptcy Code" means title 11 of the United States Code.

"Captisol" means Captisol, also known scientifically as sulfobutylether b(beta) cyclodextrin, sodium salt, and any modified or improved form of Captisol®, including without limitation, any improved or modified form of sulfobutylether b(beta) cyclodextrin that is marketed with the use of the Captisol® trademark or a variation thereof.

"Captisol Data Package" means (a) all toxicology/safety and other relevant scientific data owned, licensed or developed by CyDex and its Affiliates relating to Captisol; and (b) all toxicology/safety and other relevant scientific data owned, licensed or developed by the licensees or sublicensees of CyDex or its Affiliates or other third parties (to the extent permitted in the applicable license or other agreements between CyDex and/or its Affiliates and such licensees, sublicensees or other third parties), in each case relating to Captisol alone (and not in conjunction with a product formulation).

"Captisol Improvement" means any modification or improvement of Captisol alone, whether or not patentable, that is developed by Sage or its Affiliates, solely or jointly with a third party. For clarity, Captisol Improvements shall not include technology or improvements which are related to the Compound and/or other non-Captisol components of the Licensed Product.

"Captisol Patents" means all patents and patent applications in the Territory which pertain to Captisol, other than the Licensed Product Patents, and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. For avoidance of doubt, all intellectual property pertaining to the Licensed Product or the Probe Study Product generated by Sage or its Affiliates or their Sublicensees during the Term of this Agreement or during the term of the Old Agreement shall be solely owned by Sage and shall not be part of the Captisol Patents. The Captisol Patents include the patents and patent applications set forth on Exhibit A may be updated by CyDex from time to time during the Term.

"Claim" has the meaning specified in Section 1.0.1.

"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, and (c) is intended for clinical trials for the Product.

"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, and (c) is intended for commercial sale of the Product.

"Commercial Launch Date" means the first commercial sale by Sage, its Affiliates or Sublicensees of the Licensed Product to a Third Party. For avoidance of doubt, any transfer of the Licensed Product to a Third Party for preclinical, clinical or regulatory purposes shall not be deemed as commercial launch.

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

"Compound" means that certain neuroactive steroid known as Allopregnanolone.

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

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

"Cover" (including variations thereof such as "Covered," "Coverage," or "Covering") means that the manufacture, use, importation or sale of the applicable Licensed Product or Probe Study Product would infringe a Valid Claim of a specified patent in the absence of a grant of rights under such patent. The determination of whether an item or process is Covered by a Valid Claim shall be made on a country-by-country basis.

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

"**DMF**" means a Drug Master File for Captisol, as filed as of the Effective Date, or as hereafter updated from time to time during the Term, by CyDex with the FDA.

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

"Field" means as applicable, either or both of the Epilepticus Field and the TBI Field, where the "Epilepticus Field" means the field of therapeutic use against status epilepticus in humans and "TBI Field" means the treatment of traumatic brain injury in humans.

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

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

"License Agreement" means the License Agreement dated October 13, 2011 between CyDex and Sage.

"Licensed Patents" means, collectively, the Captisol Patents and the Licensed Product Patents.

"Licensed Product" means a pharmaceutical composition in and for the Field comprising the Compound combined with or formulated using Captisol that is Covered by the Licensed Patents or that is developed with the assistance of or incorporates any component of the Captisol Data Package. For clarity, the Licensed Product shall not include any product the composition of which includes the Compound and any other active pharmaceutical ingredient.

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

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

"Marketing Approval" means final approval of an NDA by the FDA for the United States, or final approval of a comparable document filed with an equivalent health regulatory authority in any other country or in the European Union (using the centralized process or mutual recognition).

"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.

"Net Sales" means, with respect to a particular time period, the total gross amounts invoiced by Sage and its Affiliates and their Sublicensees for sales of the Licensed Product made during such time period to unaffiliated Third Parties, less the following deductions to the extent actually allowed or incurred with respect to such sales:

- (a) reasonable and customary discounts (other than discounts which have already diminished the gross amount invoiced), including cash, trade and quantity discounts, fees for service, patient assistance discounts, administrative fees, and rebates granted to trade customers, government, and distributors; *provided* that such discounts shall be subject to audit pursuant to Section 5.3 below;
 - (b) credits or allowances granted for damaged, outdated, spoiled, returned or rejected products, including, without limitation, in connection with recalls;
 - (c) freight, postage, insurance and transportation charges (if separately identified on the invoice); and
- (d) sales, use, value-added or excise taxes, tariffs, customs fees, duties or other governmental charges (other than income taxes) levied on, absorbed or otherwise imposed on sales of the Licensed Product (if separately identified on the invoice), as adjusted by any refunds.

Notwithstanding the foregoing, amounts invoiced by Sage and its Affiliates for the sale of the Licensed Product among Sage or its Affiliates for resale shall not he included in the computation of Net Sales. For purposes of determining Net Sales, a "sale" shall not include reasonable transfers or dispositions as samples for promotional purposes, or transfers or dispositions at no cost for preclinical, clinical or regulatory purposes.

"Non-breaching Party" has the meaning specified in Section 13.2.

"Notified Party" has the meaning specified in Section 13.2.

"Pfizer" has the meaning specified in Section 8.5.

"Pre-Existing Agreement" has the meaning ascribed to it in Sections 1.1 and 13 of the License Agreement.

"**Probe Condition**" mean any of the following: (a) [...***...], (b) [...***...], (c) [...***...], (d) [...***...], (e) [...***...], or (f) [...***...].

"Probe Study" means [...***...].

"Probe Study Product" means [...***...].

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

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

"Sage Know-How" means information or data owned, licensed or generated by Sage and its Affiliates, before and during the Term of this Agreement or the term of the Old Agreement. For clarity, Sage Know-How shall not include information within the Captisol Data Package; nor does Sage Know-How include any other information or data to which CyDex has obtained rights before the term of the Old Agreement, to the extent of such rights.

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

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

"Study" has the meaning specified in Section 6.3.

"Sublicensees" has the meaning specified in Section 2.3.

"**Term**" has the meaning specified in <u>Section 13.1</u>.

"Territory" means the entire world.

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

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

2. GRANT OF RIGHTS.

2.1 License Grants from CyDex to Sage.

(a) Field Licenses.

- (i) **Licensed Patents**. Subject to the terms and conditions of this Agreement, CyDex hereby grants to Sage an exclusive, nontransferable (except as provided in <u>Section 14.14</u>) license during the Term under the Licensed Patents, solely to research, develop, make, have made, import, use, offer for sale and sell the Licensed Product in the Territory in and for the Field. Notwithstanding the foregoing, to the extent that any Licensed Patents are licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to Sage in the foregoing sentence shall be exclusive as to CyDex but non-exclusive as to such Third Party and other persons whose rights derive from such Third Party. Sage may not sublicense the Licensed Patents, except as expressly set forth in <u>Section 2.3</u> and <u>Section 2.4</u> below.
- (ii) **Know-How License**. Subject to the terms and conditions of this Agreement, CyDex hereby grants to Sage an exclusive, nontransferable (except with respect to the assignment provision in <u>Section 14.14</u>) license during the Term under CyDex's rights in and to the Captisol Data Package, solely to research, develop, make, have made, import, use, offer for sale and sell the Licensed Product in the Territory in and for the Field. Notwithstanding the foregoing, to the extent that any contents of the Captisol Data Package are licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to Sage in the foregoing sentence shall be exclusive as to CyDex but non-exclusive as to such Third Party and other persons whose rights derive from such Third Party. Sage may not sublicense its rights to the Captisol Data Package, except as expressly set forth in <u>Section 2.3</u> and <u>Section 2.4</u> below.

(b) Probe Study Licenses.

(i) **Licensed Patents**. Subject to the terms and conditions of this Agreement, CyDex hereby grants to Sage a non-exclusive, nontransferable (except as provided in <u>Section 14.14</u>) license during the Term under the Licensed Patents, solely to research, develop, make, have made, import and use the Probe Study Product in the Territory in and for the Probe Studies. Sage may not sublicense the Licensed Patents, except as expressly set forth in <u>Section 2.3</u> and <u>Section 2.4</u> below.

- (ii) **Know-How License**. Subject to the terms and conditions of this Agreement, CyDex hereby grants to Sage a non-exclusive, nontransferable (except with respect to the assignment provision in <u>Section 14.14</u>) license during the Term under CyDex's rights in and to the Captisol Data Package, solely to research, develop, make, have made, import and use the Probe Study Product in the Territory in and for the Probe Studies. Sage may not sublicense its rights to the Captisol Data Package, except as expressly set forth in <u>Section 2.3</u> and <u>Section 2.4</u> below.
- (iii) **Development and Commercialization License.** Sage shall notify CyDex if Sage wishes subsequent to a Probe Study to further develop a Probe Study Product for any Probe Condition for potential commercialization, in which event the parties shall negotiate in good faith a license agreement with commercially reasonable terms for a license of appropriate scope.
- (c) Scope of Licenses. CyDex grants no licenses or rights to use other than as expressly set forth herein. Unless otherwise provided in this Agreement, CyDex grants no rights to Sage to manufacture, import, sell or offer for sale bulk Captisol. Sage acknowledges that not all rights of CyDex related to the manufacture of Captisol are included within the rights licensed hereunder, given that CyDex shall supply Sage's requirements of Captisol for the Licensed Product. Sage shall not attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol except as and to the extent reasonably required to determine an optimal formulation of the Licensed Product or Probe Study Product, and such structure and composition (as and if so determined) shall be considered Confidential Information of CyDex. Sage acknowledges and agrees that (i) CyDex shall not be required to obtain or maintain patent rights for the Licensed Patents, (ii) except as expressly provided herein, CyDex shall not be restricted in making sales of Captisol or licensing rights to other parties, and (iii) CyDex does not warrant or indemnify Licensee or its Affiliates and Sublicensees against the Licensed Product infringing third party rights.
- (d) **Non-Suit**. During the term of this Agreement, neither CyDex nor any of its Affiliates shall sue or threaten to sue, or take any similar action against, or aid, abet or enable any third party to sue, threaten to sue or take any similar action against. Sage, or any Sublicensees, or any of their respective Affiliates, or any customers or end-users of any Licensed Products, or any users of any Probe Study Product, claiming that the manufacture, use, sale, offer for sale or importation of any Licensed Product, or the manufacture, use or importation of any Probe Study Product, infringes any patents or patent applications owned, licensed, sublicensed or otherwise controlled by, now or in the future, CyDex or any of its Affiliates.
- (e) **Negative Covenant**. During the term of this Agreement, CyDex and its Affiliates shall not grant any rights to any Third Party that conflict with the exclusive rights granted herein to Sage or that conflict with or otherwise impair Sage's ability to conduct the activities described herein; *provided*, that, if CyDex negotiates toward and/or enters into a further agreement with a party to a Pre-Existing Agreement as expressly contemplated by such Pre-Existing Agreement (for example, upon the exercise by such party of an option granted in a Pre-Existing Agreement), such negotiation and/or agreement shall not be deemed to impermissibly conflict with the exclusive rights granted herein to Sage or to impermissibly conflict with or otherwise impair Sage's ability to conduct the activities described herein and such further

agreement shall, from and after the date of execution and delivery, constitute a "Pre-Existing Agreement" for purposes of the definition of "Probe Condition" herein; *provided further* that CyDex shall provide notice to Sage of the terms and conditions included in any such further agreement prior to executing same, Without limiting the generality of the foregoing, in the event that CyDex or any of its Affiliates become aware that a Third Party is (other than as permitted by a Pre-Existing Agreement) conducting research, development or commercial activities using the Compound with Captisol, then CyDex shall take all reasonable measures to cease the supply of Captisol to such Third Party and to any other Third Party that is determined to be supplying Captisol to such Third Party. Sage hereby acknowledges that CyDex's performance of its obligations under any Pre-Existing Agreement, and the exercise by a Third Party of its rights under any Pre-Existing Agreement, are hereby deemed not to be a breach by CyDex or any of its Affiliates of this Section 2.1(e).

- (f) **Bankruptcy Code**. All rights and licenses granted under or pursuant to this Agreement by CyDex to Sage are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The parties agree that Sage, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.
- 2.2 **Grant of License from Sage to CyDex**. Sage hereby grants to CyDex a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to gran' sublicenses (through multiple tiers of sublicensees), under Sage's and its Affiliates' rights in and to Captisol Improvements to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol, any Captisol Improvement and products formulated with Captisol or any Captisol Improvement (in each case, other than the Compound, the Licensed Product and any other compound that is a "Compound" under any other Commercial License Agreement entered into by and between Sage and CyDex and any other product that is a "Licensed Product" under any other Commercial License Agreement entered into by and between Sage and CyDex). If during the Term any of (a) Sage, (b) Affiliates to whom Sage has provided rights under the licenses granted to Sage by CyDex pursuant to Section 2.1, or (c) Sublicenses pursuant to the practice of their respective sublicenses from Sage under Section 2.3, tile any patent application claiming Captisol anywhere in the world, CyDex shall be deemed automatically to have a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under the claims relating specifically to Captisol to make, have made, use, market, distribute, import, sell, and offer for sale Captisol and all products formulated with Captisol (in each case, other than the Compound, the Licensed Product and any other compound that is a "Compound" under any other Commercial License Agreement entered into by and between Sage and CyDex and any other product that is a "Licensed Product" under any other Commercial License Agreement entered into by and between Sage and CyDex and any other product that is a "Licensed Product" under any other Commercial License Agreement entered into by and between Sage and CyDex). Sage shall provide prompt notice of any Captisol

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

- 2.3 **Sublicensing**. Sage shall have the right to grant sublicenses to any Third Party (collectively "**Sublicensees**") under the licenses granted to Sage pursuant to Section 2.1; provided that Sage 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 (in a form reasonably satisfactory to CyDex, with CyDex named as an intended third-party beneficiary) with Sage 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 this Section 2.3 and Section 2.4. Sage shall not have the right to grant sublicenses to any third party under the licenses granted pursuant to Section 2.1. Sage shall ensure that all of its Sublicensees will comply with the terms and conditions of this Agreement and shall remain fully responsible for the compliance by such Sublicensees with the terms and conditions of this Agreement as if such Sublicensees were Sage hereunder.
- 2.4 Contracting. Sage may manufacture the Licensed Product or the Probe Study Product (but not the bulk Captisol) or contract the manufacture of the Licensed Product or the Probe Study Product (but not the manufacture of bulk Captisol) with reputable FDA-inspected third party manufacturers (each a "Contract Manufacturer") upon notification to CyDex in writing of Sage's intent to do so (such notice to include the identity and location of the proposed Contract Manufacturers). To the extent necessary to engage a Contract Manufacturer tor the Licensed Product or the Probe Study Product, Sage shall be permitted under this Agreement to grant any such Contract Manufacturer a sublicense under the licenses granted to Sage pursuant to Section 2.1 solely for such purposes; provided that Sage warrants and shall procure, as a condition precedent thereto, that (a) any such Contract Manufacturer shall first be advised of the restrictions set forth in this Agreement with respect to the transfer of the rights licensed to Sage mid its Sublicensees hereunder and (b) any such Contract Manufacturer shall enter into an agreement (in a form reasonably satisfactory to CyDex, with CyDex named as an intended third-party beneficiary) with Sage pursuant to which such Contract Manufacturer shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this Agreement. Sage shall ensure that all of its Contract Manufacturers will comply with the terms and conditions of this Agreement as if such Contract Manufacturers were Sage hereunder.
- 2.5 **Technology Transfer**. CyDex shall, for a period of one year after the Old Agreement Effective Date, make its personnel available to Sage and its Contract Manufacturers to respond to informational inquiries and provide technical assistance related to the Captisol Data Package. Sage shall compensate CyDex at the rate of \$150 per hour for the time of CyDex personnel incurred to provide such services. Such technology transfer shall not include information related to the manufacture of bulk Captisol.

2.6 **Negative Covenant by CyDex**. During the Term of this Agreement, CyDex and its Affiliates shall not develop or commercialize any pharmaceutical composition comprising the Compound in and for the Field, and shall not in any way assist any Third Party in developing or commercializing any pharmaceutical composition comprising the Compound (including without limitation by granting any license or similar rights under intellectual property) in and for the Field.

3. MANUFACTURE AND SUPPLY OF CAPTISOL.

The provisions of the Supply Agreement and any related quality agreement shall govern the manufacture and supply of Captisol for use in the formulation of the Licensed Product or Probe Study Product, and nothing in the Supply Agreement (including <u>Section 2.2</u> thereof) shall limit Sage's right to use Probe Study Product in accordance with the terms of this Agreement.

4. COMPENSATION.

- 4.1 Payments and Royalties for Licenses.
 - (a) One-Time Fees.
- (i) Upon the exercise of its option under the License Agreement to enter into the Old Agreement and the Supply Agreement, Sage has paid to CyDex a nonrefundable, one-time option exercise fee. Receipt of such fee is hereby acknowledged.
- (ii) In consideration of CyDex entering into this Agreement, Sage agrees to pay to CyDex \$[...***...] by wire transfer on the Effective Date.
- (b) **Milestone Payments.** Within ten (10) days following the occurrence of each of the milestone events listed below with respect to the Licensed Product, Sage shall provide written notice to CyDex of the achievement of such milestone event, and within twenty (20) days of the occurrence of each of the milestone events, pay to CyDex the applicable nonrefundable milestone fee listed next to each such event in further consideration of the rights granted Sage hereunder. The milestone payments (each payable only one time per Field regardless of the number of times achieved by the Licensed Product for the applicable Field; for the avoidance of doubt, if the same Licensed Product achieves one or more given milestones for both the Epilepticus Field and the TBI Field, then the milestone payment for that event must be paid twice) are as follows. If any such milestone is achieved before all prior sequential milestones have been actually achieved, then any and all prior sequential milestones which were not previously actually achieved shall be deemed to have thereby been achieved, and the milestone payments for such deemed-achieved milestones shall also be payable within such twenty (20) days.

	MILESTONE	MILESTONE PAYMENT
(i)	[***]	\$[***]
(ii)	[***]	\$[***]
(in)	[***]	\$[***]
(iv)	[***]	\$[***]

(c) **Royalties**. In addition to amounts payable pursuant to <u>Sections 4.1(a)</u> and <u>4.1(b)</u> above, Sage shall make royalty payments to CyDex on a calendar quarterly basis, in amounts equal to [...***...]% times the Net Sales during such quarter arising from the sale of Licensed Products in the Territory in the Field during the Term. All royalties payable to CyDex pursuant to this <u>Section 4.1(c)</u> shall be due and payable within 60 days after the conclusion of each calendar quarter.

All royalties payable to CyDex pursuant to this <u>Section 4.1(c)</u> shall be due and payable within 60 days after the conclusion of each calendar quarter. For avoidance of doubt, Net Sales under any other agreements entered into pursuant between the parties shall not be accumulated with Net Sales under this Commercial License Agreement for any purposes under this Agreement.

Following the expiration of the last to expire Valid Claim within the Licensed Patents Covering the manufacture, use, sale or importation of a Licensed Product in or into a given country of the Territory, Sage shall have the right to reduce by [...***...]% the royalty payments which would otherwise thereafter be owed pursuant to the first paragraph of this Section 4.1(c) with respect to Net Sales arising from the sale of Licensed Product in such country.

For avoidance of doubt, the parties confirm that if different royalty rates could apply to Net Sales of a particular unit of Licensed Product (*e.g.*, manufactured in Country A but sold in Country B, and different royalty rates are then applicable to Country A than to Country B), the higher of the royalty rates shall apply to such unit of Licensed Product.

In establishing the royalty structure hereunder, the parties recognize, and Sage 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 Captisol Data Package as well as under the Licensed Patents, to enable the rapid and effective market introduction of the Licensed Product. The parties have agreed to the payment structure set forth herein as a convenient and fair mechanism to compensate CyDex for these obligations.

- (d) **Probe Study Milestone Payment.** Within ten (10) days following a new IND submission for a Probe Study or the first submission of an amendment to an existing/open 1ND for a Probe Study, Sage shall provide written notice to CyDex of the achievement of such milestone event, and within twenty (20) days after the occurrence of such milestone event, pay to CyDex \$[...***...]. Such milestone payment shall be payable only one time; *provided* that it is not achieved more than five (5) times by a Probe Study Product; and *provided* that no more than five (5) Probe Studies are performed.
- 4.2 **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 *The Wall Street Journal*, Eastern U.S. Edition on the last day of each calendar quarter (or the last previous publication date if such day is not a publication date). Sage shall provide CyDex, together with each royalty payment owed pursuant to <u>Section 4.1(c)</u> above, a schedule detailing the calculation of Net Sales resulting from the conversion of foreign revenue to U.S. dollars as set forth herein.

4.3 **Taxes.** All amounts due hereunder exclude all applicable sales, use, and other taxes, and Sage will be responsible for payment of all such taxes (other than taxes based on CyDex's income), fees, duties, and charges, and any related penalties and interest, arising from the payment of amounts due under this Agreement or the sublicense or license, as the case may be, under the Licensed Patents and Captisol Data Package under this Agreement. The parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Sage to CyDex under this Agreement. To the extent Sage is required to withhold taxes on any payment to CyDex, Sage shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CyDex may reasonably request, to establish that such taxes have been paid. CyDex shall provide Sage any tax forms that may be reasonably necessary in order for Sage to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, CyDex shall use reasonable efforts to provide any such tax forms to Sage at least 30 days before the due date for any payment for which CyDex desires that Sage apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or value added tax.

4.4 **Late Payments.** Payments that are not made when due hereunder shall accrue interest, from due date until paid, at a rate equal to the prime rate, as reported in The Wall Street Journal, Eastern U.S. Edition, on the date such payment is due (or the last previous publication date if such day is not a publication date), plus an additional 200 basis points.

5. RECORDS; REPORTS; AUDIT.

5.1 **Records.** During the Term and for a period of three years thereafter, Sage shall, and shall require its Affiliates and Sublicensees to, maintain accurate records relating to clinical study subject enrollment for Studies of the Licensed Product and Net Sales of the Licensed Product.

5.2 **Reports**

(a) **Quarterly Reports.** Within 30 calendar days following the conclusion of each calendar quarter during the Term, Sage shall provide CyDex with written reports with respect to such calendar quarter (with a monthly breakdown) that describe in reasonable detail Sage's progress made toward achievement of the milestones specified in Section 4.1(h) above during such calendar quarter, including without limitation Sage's then-current best estimate for the dates to achieve such milestones and the number of human subjects enrolled during such calendar quarter in a clinical study conducted by or on behalf of Sage, its Affiliates and Sublicensees to support Marketing Approval for the Licensed Product and that received Licensed Product during such calendar quarter. Within 60 calendar days following the conclusion of each calendar quarter during the Term, Sage shall provide CyDex with a written report with respect to such calendar quarter (with a monthly breakdown) that sets forth in reasonable detail complete and accurate records of Sage's, its Affiliates' and Sublicensees' Net Sales of the Licensed Product during such calendar quarter.

- (b) **Annual Reports.** Annually, by February 1st of each calendar year during the Term, Sage shall provide CyDex with written reports that: (i) update CyDex regarding development and commercial activities with respect to the Licensed Product, (ii) describe in reasonable detail Sage's progress made toward achievement of the milestones specified in Section 4.1(b) above during the preceding calendar year; (iii) summarize in reasonable detail Sage's communications and meetings involving the FDA related to Captisol as used in the Licensed Product during the preceding calendar year; (iv) detail Sage's anticipated preclinical and clinical use of Captisol in the Licensed Product for the then-current calendar year; (v) provide CyDex with Sage's non-binding, reasonable, estimated rolling projection for sales of the Licensed Product, in terms of volume quantities and Net Sales values, for the then-current and the next two succeeding calendar years; and (vi) set forth such other information regarding Captisol as mutually agreed upon by the parties.
- 5.3 **Audit.** Upon reasonable prior notice, such <u>Section 5.1</u> records shall be available during regular business hours for examination and audit at the expense of CyDex, and not more often than once each calendar year, by an independent certified public accountant selected by CyDex and reasonably acceptable to Sage, for the sole purpose of verifying the accuracy of the financial reports furnished by Sage pursuant to this Agreement. Any amounts shown to be owed but unpaid shall be paid within 30 days from the accountant's report from the original due date, plus interest accrued thereon (from the applicable original due date) at the rate set forth in <u>Section 4.4</u> above. Any amounts shown to have been overpaid shall be refunded within 30 days CyDex shall bear the full cost of such audit unless such audit discloses failure by Sage to pay any applicable milestone payment due or an underpayment by Sage of more than 5% of the amount due or any other material inaccuracies in a Sage report, in which case Sage shall bear the full cost of such audit, plus (as in all eases of underpayment) the underpayment amount and interest at the rate set forth in <u>Section 4.4</u> above. All information learned in the course of any audit or inspection under this <u>Section 5.3</u> shall be deemed to be Confidential Information of Sage, subject to the terms and provisions of <u>Section 8</u> below, except to the extent necessary for CyDex to enforce its rights under this Agreement.

6. DEVELOPMENT AND COMMERCIALIZATION BY SAGE.

6.1 **Diligence.** Sage shall (i) use at least Commercially Reasonable Efforts, and shall further require its Affiliates and Sublicensees to use at least Commercially Reasonable Efforts, to develop the Licensed Product, to seek Regulatory Approval of the Licensed Product in all countries and regions where it is commercially reasonable to so seek, and to commercialize the Licensed Product in each respective country and region following Regulatory Approval of the Licensed Product in such respective country/region, and (ii) comply with the requirements set forth in Exhibit D hereto due to unanticipated events or changed circumstances that are beyond the reasonable control of Sage, including, for example, delays caused by changes to the development plan that are required in the exercise of sound scientific or commercial judgment due to new information regarding the development of product candidates or changes to the applicable regulatory requirements, then the Parties shall meet and make reasonable extensions to the

deadlines provided on Exhibit D. For clarity, Sage may meet the requirements of this Section 6.1 through its activities with respect to the Licensed Product in just one of the Fields. In the event that Sage fails to meet the requirements of this Section 6.1, CyDex shall have the right to terminate this Agreement pursuant to Section 13.2 hereof

- 6.2 **Costs and Expenses.** Other than those specified in this Agreement, Sage shall be solely responsible for all costs and expenses related to its development and commercialization of the Licensed Product and its development of the Probe Study Product, including without limitation, all Sage's costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Product or the Probe Study Product.
- 6.3 **In Vivo Studies.** If Sage wishes to conduct any in vivo study ([...***...], each a "Study") [...***...], then Sage shall notify CyDex of any such Study and of the protocol therefor in writing at least [...***...] days before commencing such Study, and the following provisions shall apply:
 - (a) **Dosing**. Sage shall not exceed the dosing matrix levels of Captisol indicated by Exhibit E hereto without the written consent of CyDex.
- (b) **Review of Protocol.** [...***...]. Sage shall give due consideration and reasonably incorporate any input that CyDex provides regarding such protocol to the extent it pertains solely to the use and administration of Captisol. The contents of each such protocol shall be deemed to be Confidential Information of Sage, subject to the terms and provisions of Section 8 below.
- (c) **Compliance with Laws.** Sage represents and warrants that each Study will be performed in accordance with all applicable laws, regulations and requirements. Sage 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.
- (d) **Adverse Events.** Sage agrees to immediately inform CyDex if any adverse effects are observed and ascribed to Captisol in any Study in accordance with <u>Section 7.3</u> hereof if applicable and in a reasonable and prompt manner if <u>Section 7.3</u> hereof is not applicable. To accurately track adverse events and preserve the validity of each Study, [...***...].
- (e) **Reporting and Study Data.** Sage agrees to provide CyDex with copies of the final and full reports of all Studies conducted under this <u>Section 6.3</u>, promptly upon completion thereof, and Sage hereby grants to CyDex a non-exclusive, royalty-free license (with the right to sublicense) to use and disclose such data as required by applicable law to [...***...].
- (f) **Review of Regulatory Filings and Publications.** At least 14 days before a submission of any proposed written publication material or regulatory submission (which shall be subject to the restrictions of <u>Section 8</u> hereof). Sage 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 refers to [...***...]. Sage shall give due consideration and reasonably incorporate any input that CyDex provides regarding [...***...].

- 6.4 **Right of Reference.** Sage shall have the right to reference the [...***...] in connection with obtaining Regulatory Approval for the Licensed Product.
- 6.5 **Access to Sage's Data.** [...***...], its Sublicensees or Affiliates as required by applicable laws relating to adverse event reporting and/or in connection with development and commercialization of Captisol or for fulfilling its obligations under this Agreement, all at no cost to CyDex. [...***...].

7. REGULATORY MATTERS.

- 7.1 **Captisol Information Submitted for Regulatory Review.** Except as otherwise set forth herein. Sage shall be solely responsible for all communications with regulatory agencies in connection with the Licensed Product or with respect to Sage's activities in connection with the Probe Study Product. Sage shall provide CyDex with copies of the portions of all regulatory submissions containing Captisol data alone (and not in conjunction with any product formulation) 60 days before submission and shall allow CyDex to review and comment upon said submissions. The contents of each such submission shall be deemed to be Confidential Information of Sage, subject to the terms and provisions of Section 8 below. Sage shall promptly inform CyDex of meetings with the FDA (or other regulatory agencies in the Territory) regarding the Licensed Product. If Sage submits written responses to the FDA that include data on Captisol alone, CyDex shall be permitted to review such written materials before submission. If CyDex reasonably objects to the contents of such written responses relating to Captisol, the parties agree to cooperate in working toward a reasonable and mutually agreeable response, provided that Sage shall be entitled to in good faith and with full regard for CyDex's interests and concerns make the final determination as to the contents of any such materials.
- 7.2 **Material Safety.** CyDex shall provide Sage, in writing, from time to time, with (a) relevant material information currently known to it regarding handling precautions, toxicity and hazards with respect to Captisol, and (b) the then-current material safety data sheet for Captisol. CyDex warrants that all such information shall to CyDex's knowledge be complete and accurate. Notwithstanding the foregoing or anything in this Agreement to the contrary, with respect to any information that is provided in accordance with this Agreement by CyDex, Sage is solely responsible for (i) use of such documentation, including without limitation, use in any regulatory submission to the FDA or any other regulatory agency, (ii) document control and retention, and (iii) determining the suitability of any such documentation for use in any regulatory submission.
- 7.3 **Adverse Event Reporting.** Sage 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. Probe Study Product-related or Licensed Product-related, which occurs or worsens following administration of Captisol, Probe Study Product or Licensed Product. Sage shall provide CyDex with copies of

all reports of any such adverse event which is serious (any such adverse event involving Captisol, the Probe Study Product or the Licensed Product that results in death, is life-threatening, requires or prolongs inpatient hospitalization, results in disability, congenital anomaly or is medically important (*i.e.*, may require other medical or surgical intervention to prevent other serious criteria from occurring)) which Sage has reason to believe are associated with Captisol within 10 business days following (i) Sage's submission of any such report to any regulatory agency, or (ii) receipt from Sage's Sublicensee, co-marketer or distributor of any such report to any regulatory agency. Sage shall also advise CyDex regarding any proposed labeling or registration dossier changes affecting Captisol. Reports from Sage shall be delivered to the attention of Chief Scientific Officer, CyDex, with a copy to General Counsel, Ligand, 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 Sage, CyDex or any other Affiliate, Sublicensee, co-marketer or distributor of CyDex or Sage.

7.4 **Product Recalls.** If any Captisol should be alleged or proven not to meet the Specifications, Sage shall notify CyDex immediately, and both parties shall cooperate fully regarding the investigation and disposition of any such matter. In the event of a dispute arises between the parties as to whether or not Captisol purchased by Sage meets the Specifications, such dispute shall be immediately resolved by submitting it 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. If (i) Sage and CyDex agree in writing that it is appropriate to recall any Licensed Product, or (ii) the FDA requires the recall of any Licensed Product, and in either case, to the extent that such recall is due to issues relating to Captisol, then CyDex agrees, upon substantiation thereof, to bear a proportionate share (based on the extent to which the recall was caused by issues relating to Captisol) of the reasonable direct costs associated with said recall, including a proportionate share of the actual cost of conducting the recall in accordance with the recall guidelines of the applicable governmental authority, including without limitation, a proportionate share of the cost of the Licensed Product subject to the recall. Sage shall in all events be responsible for conducting any such recalls with respect to the Licensed Product and shall maintain records of all sales of Licensed Product and customers sufficient to adequately administer any such recall, for a period of five years after termination of this Agreement.

8. CONFIDENTIALITY.

8.1 **Definition.** Sage and CyDex each recognizes that, during the Term or the term of the Old Agreement, it may be (or was) 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 <u>Section 8</u>. Neither Sage 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, whether under this Agreement or the Old Agreement, and which is obviously Confidential Information, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally is declared to be confidential by the Disclosing Party

and confirmed in a writing delivered to the Receiving Party within 30 days of such disclosure, including but not limited to product specifications, data, know-how, formulations, product concepts, sample materials, business and technical information, financial data, batch records, trade secrets, processes, techniques, algorithms, programs, designs, drawings, and any other information related to a party's present or future products, sales, suppliers, customers, employees, investors or business. Without limiting the generality of the foregoing, CyDex's Confidential Information includes all materials provided as part of the Captisol Data Package, and Sage's Confidential Information includes Sage Patents and Sage Know-How.

- 8.2 **Obligation**. CyDex and Sage agree that they will disclose the other's Confidential Information to its (or its respective parent's) own officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Neither party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent, and any such disclosure to a Third Party shall be pursuant to the terms of a non-disclosure agreement no less restrictive than this Section 8. The party which disclosed Confidential Information of the other to any Third Party shall be responsible and liable for any disclosure or use by such Third Party (or its discloses) which would have violated this Agreement if committed by the party itself. Neither party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Unless otherwise specified in this Agreement and subject to terms and conditions in this Agreement, if so requested by the other party a party shall promptly return all relevant records and materials in its possession or control containing or embodying the other party's Confidential Information (including all copies and extracts of documents); provided, however, that each party may retain one archival copy (and such electronic copies that exist as part of the party's computer systems, network storage systems and electronic backup systems) of such records and materials solely to be able to monitor its obligations that survive under this
- 8.3 **Exceptions.** The use and non-disclosure obligations set forth in this Section 8 shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by appropriate documentation:
 - (i) at the rime 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 or its disclosees:
 - (iii) is independently developed by Receiving Party personnel with no reference or access to the Confidential Information; or
- (iv) is made available to the Receiving Party by an independent third party without obligation of confidentiality, 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 Securities and Exchange Commission, or in the course of litigation; *provided* that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) 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 temporary, preliminary and/or permanent injunctive relief in addition to any other remedy which it may have, without need to post any bond or security, in addition to any and all other legal and equitable rights and remedies available to the Disclosing Party.
- 8.5 **Third Party Information.** The parties acknowledge that the defined term "Confidential Information" shall include not only a disclosing party's own Confidential information but also Confidential Information of a Third Party which is in the possession of a disclosing party.

Sage acknowledges that CyDex's Confidential Information includes information developed by Pfizer that is confidential to both CyDex and Pfizer. In so far as Confidential Information of Pfizer is disclosed, Pfizer 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.

Sage agrees not to disclose to CyDex any Confidential Information of a Third Party which is in the possession of Sage, unless CyDex has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information. If CyDex refuses to provide such consent, then any obligation of Sage to provide such information to CyDex under this Agreement shall be deemed waived by CyDex.

8.6 **Public Announcements.** The parties will mutually agree on a press release to be issued upon execution of this Agreement or reasonably soon thereafter. Neither party shall make any subsequent public announcement concerning this Agreement or the terms hereof not previously made public without the prior written approval of the other party with regard to the form, content, and precise timing of such announcement, except as may be required to be made by either party in order to comply with applicable law, regulations, court orders, or tax, securities filings, financing arrangements, acquisitions, or sublicenses. Such consent shall not be unreasonably withheld or delayed by such other party. Before any such public announcement, the party wishing to make the announcement will submit a draft of the proposed announcement to the other party in sufficient time to enable such other party to consider and comment thereon.

9. REPRESENTATIONS AND WARRANTIES.

- 9.1 Mutual Representations and Warranties. Each party represents and warrants to the other (as of the Effective Date) 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 power and right to enter into this Agreement and to perform its obligations hereunder;
- (iii) this Agreement has been duly authorized, executed and delivered by such party and constitutes a legal, valid and binding obligation of such party enforceable against such party in accordance with its terms except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, receivership, moratorium, fraudulent transfer, or other similar laws affecting the rights and remedies of creditors generally and by general principles of equity;
- (iv) the execution, delivery and performance of this Agreement by such party do not conflict with any agreement, instrument or understanding, oral or written, to which such party is a party or by which such party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over such party;
- (v) all consents, approvals and authorizations from all governmental authorities or other third parties required to be obtained by such party in connection with the execution and delivery of this Agreement have been obtained:
- (vi) no person or entity has or will have, as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such party for any commission, fee or other compensation as a finder or broker because of any act by such party or its agents; and
- (vii) it has not entered into any agreement with any third party that is in conflict with the rights granted to the other party pursuant to this Agreement.
- 9.2 **CyDex Representation.** CyDex owns all right, title and interest in and to, or in-licenses with the right to sublicense, the Captisol Patents listed on Exhibit A attached hereto.
- 9.3 **Disclaimer.** THE WARRANTIES SET FORTH IN THIS <u>SECTION 9</u> AND IN THE SUPPLY AGREEMENT ARE PROVIDED IN LIEU OF, AND EACH PARTY HEREBY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT, CAPTISOL, THE LICENSED PATENTS OR THE CAPTISOL DATA PACKAGE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS.

10. INDEMNIFICATION.

- 10.1 **By CyDex**. CyDex shall defend, indemnify and hold Sage and its Affiliates and Sublicensees, and each of their respective directors, officers, agents and employees, harmless from and against any and all losses, judgments, damages, liabilities, settlements, penalties, fines, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively "**Losses**") incurred by Sage as a result of any claim, demand, action or other proceeding (each, a "**Claim**") by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Captisol by CyDex and its Affiliates (including without limitation, the sale of Captisol by CyDex to Sage under the Supply Agreement); (b) infringement of any person's intellectual property rights in Captisol *per se*; (c) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in Section 9.1, and (d) CyDex's negligence or misconduct.
- 10.2 **By Sage**. Sage shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers, agents and employees, harmless from and against any and all Losses incurred by CyDex as a result of any Claim by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of the Licensed Product by Sage, its Affiliates and Sublicensees, or the manufacture, use, handling, distribution or importation of the Probe Study Product by Sage, its Affiliates and Sublicensees; (b) any acts or omissions by Sage in connection with pre-clinical studies and clinical studies of actual or potential Licensed Products or Probe Study Products; (c) infringement of any person's intellectual property rights in connection with the subject matter of this Agreement (other than intellectual property rights in Captisol *per se*); (d) Sage's breach of this Agreement, including without limitation any of its representations and warranties set forth in Section 9.1 and (e) Sage's negligence or misconduct.
- 10.3 **Expenses**. As the parties intend complete indemnification, all costs and expenses of enforcing any provision of this <u>Section 10</u> shall also be reimbursed by the indemnifying Party.

10.4 Procedure.

(a) The person intending to claim indemnification under this Section 10 (an "Indemnified Party") shall promptly notify the other party (the "Indemnifying Party") of any Claim in respect of which the Indemnified Party intends to claim such indemnification, and a reasonable explanation of the basis for the Claim and the amount of alleged Losses to the extent of the facts then known by the Indemnified Party. (Notwithstanding the foregoing, no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency.) The Indemnifying Party shall assume the defense thereof whether or not such Claim is rightfully brought; provided, however, that if the Indemnifying Party assumes the defense, the Indemnified Party shall have the right to employ counsel separate from counsel employed by the Indemnifying Party in any such action and to participate in the defense thereof, but the fees and expenses of such counsel employed by the Indemnified Party shall be at the sole cost and expense of the Indemnified Party unless the Indemnifying Party consents to the retention of such

counsel or unless the named parties to any action or proceeding include both the Indemnifying Party and the Indemnified Party and a representation of both the Indemnifying Party and the Indemnified Party by the same counsel would be inappropriate due to the actual or potential differing interests between them. And *provided further* that, if the Indemnifying Party shall fail to assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.

- (b) The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (i) there is no finding or admission of any violation of law or any violation of the lights of any Person by an Indemnified Party, no requirement that the Indemnified Party admit fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.
- (c) Regardless of who controls the defense, the other party hereto shall reasonably cooperate m the defense as may be requested. Without limitation, the Indemnified Party, and its directors, officers, advisers, agents and employees, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

11. LIMITATION OF LIABILITY.

EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 10 ABOVE, EACH PARTY SPECIFICALLY DISCLAIMS 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 KFND 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 (PURSUANT TO OR IN CONNECTION WITH THE RIGHTS GRANTED UNDER THIS AGREEMENT) OF THE LICENSED PATENTS AND CAPTISOL DATA PACKAGE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN SECTION 10 ABOVE, IN NO EVENT SHALL EITHER PARTY'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT OR RESULTING FROM THE MANUFACTURE, HANDLING, MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCT OR PROBE STUDY PRODUCT OR USE OF THE LICENSED PATENTS AND CAPTISOL DATA PACKAGE PURSUANT TO OR IN CONNECTION

WITH THE RIGHTS GRANTED UNDER THIS AGREEMENT EXCEED THE GREATER OF (I) \$250,000 AND (II) THE TOTAL AMOUNTS ACTUALLY PAID UNDER THIS AGREEMENT BY SAGE TO CYDEX AS OF THE DATE SUCH CLAIM ARISES, PROVIDED, THAT THE FOREGOING LIMITATIONS SHALL NOT LIMIT CYDEX'S RIGHT TO TAKE ACTION TO ENFORCE THIS COMMERCIAL LICENSE AGREEMENT TO COLLECT AMOUNTS THAT ARE PROPERLY DUE AND OWING UNDER ARTICLE 4 HEREOF, NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN TWO YEARS AFTER SUCH PARTY HAS KNOWLEDGE OF THE LEGAL AND FACTUAL BASIS EOR SUCH CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER. FOR AVOIDANCE OF DOUBT, THE PARTIES' RESPECTIVE RIGHTS AND OBLIGATIONS WITH RESPECT TO ANY LIABILITY THAT MAY ACCRUE UNDER THE LICENSE AGREEMENT, ANY COMMERCIAL LICENSE AGREEMENT (OTHER THAN THIS AGREEMENT) OR ANY SUPPLY AGREEMENT OR IN CONNECTION WITH ACTIVITIES CONDUCTED PURSUANT TO OR CONTEMPI ATFD BY ANY SUCH AGREEMENTS SHALL BE DETERMINED PURSUANT TO THE TERMS OF THOSE AGREEMENTS AND NOT BY THE TERMS AND CONDITIONS SET FORTH IN THIS AGREEMENT.

12. MANAGEMENT OF LICENSED PATENTS.

12.1 Prosecution and Maintenance.

- (a) **CyDex Patents.** CyDex shall maintain, at its sole cost and expense and using reasonable discretion, the Captisol Patents. CyDex shall have the sole right to control the prosecution and maintenance of patent applications and the selection of countries where patent applications are tiled related to the Captisol Patents. CyDex agrees that, during the Term, it will use Commercially Reasonable Efforts to prosecute, obtain and maintain the Captisol Patents in the United States, China, Japan and the European Union. In the event that CyDex decides not to prosecute and maintain the Captisol Patents in a country or countries which is not a major market, CyDex shall provide not less than 30 days prior written notice of such decision, and Sage shall have the option to take over the prosecution and maintenance in such country or countries.
- (b) **Licensed Product Patents.** Sage shall have the right to maintain, at its sole cost and expense and using reasonable discretion, the Licensed Product Patents. Sage shall have the sole right to control the prosecution and maintenance of patent applications and the selection of countries where patent applications are filed related to the Licensed Product Patents, provided that CyDex shall be provided with the right and opportunity to give comments and recommendations as to the overall strategy regarding the filing, prosecution and maintenance of the Licensed Product Patents. In the event that Sage decides not to prosecute and maintain the Licensed Product Patents in a country or countries, Sage shall provide not less than 30 days prior written notice of such decision, and CyDex shall have the option to take over the prosecution and maintenance in such country or countries.

(c) **Sage Patents and Sage Know-How.** Sage shall be the sole and exclusive owner of Sage Patents and Sage Know-How. Sage, at its own cost and expense, shall be solely responsible for prosecuting and maintaining Sage Patents.

12.2 Infringement of Captisol Patents by Third Parties.

- (a) If Sage becomes aware that a third party may be infringing a Captisol Patent, it will promptly notify CyDex in writing, providing all information available to Sage regarding the potential infringement. CyDex shall take whatever, if any, action it deems appropriate, in its sole discretion, against the alleged infringer. If CyDex elects to take action, Sage shall, at CyDex's request and expense, cooperate and shall cause its employees and advisers to cooperate with CyDex in taking any such action, including but not limited to, cooperating with the prosecution of any infringement suit by CyDex related to a Captisol Patent. Sage shall not take any such action against the alleged infringer related to a Captisol Patent without the written consent of CyDex.
- (b) If Sage becomes aware that a third party may be infringing a Licensed Product Patent, it will promptly notify CyDex in writing, providing all information available to Sage regarding the potential infringement. Sage shall take whatever, if any, action it deems appropriate, in its sole discretion, against the alleged infringer if such infringement affects any of Sage's rights with respect to a Licensed Product. If Sage elects to take action, CyDex shall, at Sage's request and expense, cooperate and shall cause its employees and advisers to cooperate with Sage in taking any such action, including but not limited to, cooperating with the prosecution of any infringement suit by Sage related to a Licensed Product Patent. CyDex shall not take any such action against the alleged infringer related to a Licensed Product Patent without the written consent of Sage.

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 unless and until terminated as set forth herein. Upon the expiration or termination of the Term, this Agreement, and the rights, licenses and obligations granted hereunder, shall terminate, subject only to Section 13.5.

13.2 Termination for Breach.

(a) **Notice.** If either party believes that the other is in material breach of this Agreement, then the party holding such belief (the "Non-breaching **Party"**) may deliver notice of such breach to the other party (the "Notified Party"). The Notified Party shall have [...***...] days to cure such breach to the extent involving non-payment of amounts due hereunder, and [...***...] days to either cure such breach for all other material breaches, or, if cure of such breach other than non-payment cannot reasonably be effected within such [...***...] day period, to deliver to the Non-breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing but in no event in excess of an additional [...***...] day period. Following delivery of such a plan, the Notified Party shall diligently carry out the plan and cure the breach and the cues period shall be extended by the time period provided in such plan but in no event to exceed [...***...] days from the date of any initial breach notice delivered under this Section 13.2.

- (b) **Failure to Cure.** If the Notified Party fails to cure a material breach of this Agreement as provided for in <u>Section 13.2</u>, then the Nonbreaching Party may terminate this Agreement upon written notice to the Notified Party.
 - 13.3 Sage Right to Terminate. Sage shall have the right to terminate this Agreement, without cause, on 180 days' prior written notice to CyDex.
 - 13.4 **Termination of the Supply Agreement.** For clarity, this Agreement shall terminate if the Supply Agreement is terminated.
- 13.5 Survival. Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions before the termination of this Agreement shall survive the termination of this Agreement. And, such termination shall not relieve either party from obligations that are expressly indicated to survive termination of this Agreement, nor shall any termination of this Agreement relieve Sage of its obligation to pay CyDex royalties for all Licensed Product sold by Sage, its Affiliates or Sublicensees before the effective date of such termination. Sections 2.2 (Grant of License from Sage to CyDex), 4.1 (Payments and Royalties for Licenses) (to the extent owed but unpaid as of the date of termination of this Agreement), 4.2 (Currency), 4.3 (Taxes), 4.4 (Late Payments), 5 (Records; Reports; Audits), 6.5 (Access to Sage's Data), 7.3 (Adverse Event Reporting), 7.4 (Product Recalls), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification), 11 (Limitation of Liability), 13.5 (Survival), and 14 (General Provisions) shall survive termination of this Agreement.

14. GENERAL PROVISIONS.

- 14.1 **Non-Solicitation**. During the Evaluation Period (as defined in the License Agreement) and for a period of one year thereafter, neither party shall solicit 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 have the right to, and each party agrees not to purport to, incur any debts or make any commitments or contracts for the other,
- 14.3 **Compliance with Law**. Each of the parties shall comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing product quality and safety and patent, copyright and trade secret protection.

14.4 Arbitration.

- (a) **Procedure**. Except as otherwise expressly set forth in this Agreement, 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 Boston, Massachusetts. The arbitration shall be conducted by an arbitrator reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and Sage. If CyDex and Sage cannot agree on a single arbitrator within 30 days after a demand for arbitration has been made, CyDex shall appoint an arbitrator, Sage shall appoint an arbitrator, the two arbitrators shall appoint a third arbitrator, and the three arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within 45 days after service of the demand for arbitration, then the arbitrator appointed by the other party shall arbitrate any controversy in accordance with this Section 14.4(a). Except as to the selection of arbitrators, the arbitration proceedings shall be conducted promptly and in accordance with the rules of the American Arbitration Association then in effect. The expenses of any arbitration, including the reasonable attorney fees of the prevailing party, shall be borne by the party deemed to be at fault or on a pro-rata basis should the arbitration conclude in a finding of mutual fault.
- (b) **Confidentiality of Proceedings.** All arbitration proceedings hereunder shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each party's Confidential Information. Except as required by law, no party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrators) without prior written consent of the other party.
- (c) **Interim Equitable Relief.** Notwithstanding <u>Section 14.4(a)</u>, but subject to the limitations set forth in <u>Article 11</u>, each party shall not be precluded from seeking equitable relief (including but not limited to interim injunctive relief) in any court having jurisdiction to protect its interests.
- (d) **Binding Effect.** The provisions of this <u>Section 14.4</u> shall survive any 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 or national defense requirements,

or inability to obtain fuel, power, raw materials, labor or transportation facilities. If, due to any event offeree 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 and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

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 <u>Section 14.7</u>. Unless otherwise provided, all notices shall be sent:

If to CyDex, to:

CyDex Pharmaceuticals, Inc. 11119 North Torrey Pines Road, Suite 200 La Jolla, CA 92037 Attention: President Fax: (858) 550-7272

With a copy to:

General Counsel Ligand Pharmaceuticals Incorporated 11085 North Torrey Pines Road, Suite 200 La Jolla, CA 92037 Fax: (858)550-7272

If to Sage, to:

Sage Therapeutics, Inc. 29 Newbury Street, Suite 301 Boston, MA 02116 Attention: President

Fax: (617) 859-2891

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; Publicity**. No party shall use the name, trademark, trade name or logo of the other party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other party, except as may be required by law or the rules of NASDAQ. The parties agree that a party may disclose this Agreement's existence and terms, and material developments or material information generated under this Agreement, in (i) securities filings with the Securities and Exchange Commission (or equivalent foreign agency) to the extent required by law, or (ii) under conditions of confidentiality/nonuse in connection with investment and similar corporate transactions. Notwithstanding the above, once a public announcement has been made, either party shall be free to disclose to third parties any 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 before such announcement sufficiently in advance of the scheduled release of such announcement to afford such other party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure.
- 14.9 **Governing Law**. This Agreement shall be governed by and construed in accordance with the internal laws of the State of California (without giving effect to any conflicts of law principles that require the application of the law of a different state).
- 14.10 **Entire Agreement; Amendment**. The Commercial License Agreement and all Exhibits attached hereto contain the entire agreement of the parties relating to the subject matter hereof and thereof and supersede any and all prior or contemporaneous agreements, written or oral, between CyDex (and/or any of its Affiliates) and Sage (and/or any of its Affiliates) relating to the subject matter hereof and thereof, including, without limitation, the Old Agreement; provided, that (a) any confidentiality/nonuse provisions of any prior agreement (other than the Old Agreement) are not superseded and will remain in effect in addition to the confidentiality/nonuse provisions hereof, (b) the provisions stated to survive termination of the Old Agreement, as set forth in Section 13.5 therein, shall survive, other than Sections 6.3, 8 and 13.3, which are hereby terminated, and Section 4 therein shall survive only with respect to amounts owed but unpaid as of the Effective Date), and (c) the Supply Agreement is not superseded and will remain in effect. This Agreement cannot be amended except by way of an express writing signed by both parties.
- 14.11 **Binding Effect**. This Agreement shall be binding upon, and the rights and obligations hereof shall apply to, CyDex and Sage and any successor(s) and permitted assigns. The name of a party appearing herein shall be deemed to include the names of such party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement.
- 14.12 **Waiver**. The rights of either party under this Agreement may be exercised from time to time, singularly or in combination, and the exercise of one or more such rights shall not be deemed to be a waiver of any one or more of the others. No waiver of any breach of a term, provision or condition of this Agreement shall be deemed to have been made by either party unless such waiver is addressed in writing and signed by an authorized representative of that party. The failure of either party to insist upon the strict performance of any of the terms, provisions or conditions of this Agreement, or to exercise any option contained in this Agreement, shall not be construed as a waiver or relinquishment for the future of any such term, provision, condition or option or the waiver or relinquishment of any other term, provision, condition or option.

- 14.13 **Severability**. If any provision of this Agreement is determined by a final and binding court or arbitration judgment to be invalid, illegal or unenforceable to any extent, such provision shall not be not affected or impaired up to the limits of such invalidity, illegality or unenforceability; the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any way; and the parties agree to negotiate in good faith to replace such invalid, illegal and unenforceable provision (or portion of provision) with a valid, legal and enforceable provision that achieves, to the greatest lawful extent under this Agreement, the economic, business and other purposes of such invalid, illegal or unenforceable provision (or portion of provision). This Agreement shall not be invalidated by any future determination that any or all of the Licensed Patents have expired or been invalidated.
- 14.14 **Assignment**, Sage may not 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 CyDex, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, Sage may assign its rights and delegate its obligations under this Agreement to an Affiliate or to a third party successor, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise, without CyDex's prior written consent. As a condition to any permitted assignment hereunder, the assignor must guarantee the performance of any assignee to the terms and obligations of this Agreement. Any assignment by Sage not in accordance with this Section 14.14 shall be void. CyDex has the right to 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 any requirement for consent of Sage provided that CyDex also assigns all of its right, title and interest in all assets, including without limitation, intellectual property rights, pertaining to its Captisol business to the same third party contemporaneous with the assignment of this Agreement.
- 14.15 **Third Party Beneficiaries**. Except for the rights of Indemnified Parties pursuant to Section 10 hereof, and subject to <u>Section 8.5</u> hereof, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective successors or permitted assigns and it is not the intention of the parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CyDex under this Agreement shall only be pursued by Sage or such Indemnified Party, and not Sublicensees.
- 14.16 **Remedies Cumulative**. Except as provided in <u>Section 11</u>, any enumeration of a party's rights and remedies in this Agreement is not intended to be exclusive, and a party's rights and remedies are intended to be cumulative to the extent permitted by law and include any rights and remedies authorized in law or in equity.
- 14.17 **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.
- 14.18 **Interpretation**. The language used in this Agreement is die language chosen by the parties to express their mutual intent, and no provision of this Agreement will be interpreted for or against any party because that party or its attorney drafted the provision.

14.19 **Counterparts**. This Agreement may be executed in 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 Commercial License Agreement as of the Effective Date.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman

Name: Charles Berkman Title: VP and Secretary

SAGE THERAPEUTICS, INC.

By: /s/ Kimi Iguchi

Name: Kimi Iguchi

Title: CFO

August 21, 2013

EXHIBIT A: CAPTISOL PATENTS

[...***...]

[Exhibit continues on next page]

A-1

EXHIBIT B: LICENSED PRODUCT PATENTS

[...***...]

EXHIBIT C: SPECIFICATIONS

[...***...]

EXHIBIT D: SPECIFIED DILIGENCE REQUIREMENTS

Sage is required to achieve the following milestones by the following respective deadline dates for Licensed Product:

Milestone	Achievement Date Deadline
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

EXHIBIT E: DOSING

Dosing Matrix (Animals)

[...***...]

AMENDMENT TO COMMERCIAL LICENSE AGREEMENT

THIS AMENDMENT TO COMMERCIAL LICENSE AGREEMENT (this "Amendment") is made this 30th day of April, 2014 (the "Amendment Effective Date") between:

CYDEX PHARMACEUTICALS, INC., a Delaware corporation ("CyDex"); and

SAGE THERAPEUTICS INC., a Delaware corporation ("Sage").

RECITALS

WHEREAS, CyDex and Sage entered into a Commercial License Agreement (the "Agreement") as of August 21, 2013;

WHEREAS, CyDex and Sage wish to amend the Agreement in accordance with Section 14.10 thereof, including by deleting the payment of \$[...***...] upon the first submission of an IND, or an amendment to an IND, for a Probe Study (as defined in the Agreement prior to the Amendment Effective Date) and, instead, requiring such amount, along with an additional \$[...***...], to be paid in consideration of CyDex entering into this Amendment, as set forth below:

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

1. DEFINITIONS.

- **1.1 DEFINITIONS.** All terms used, but not defined, in this Amendment shall have the meaning set forth in the Agreement.
- **1.2 AMENDED DEFINITIONS.** The following definitions are hereby amended to read as follows:
- "Field" means the treatment, diagnosis or prevention of any disease or symptom in humans or animals, including the Epilepticus Field, the TBI Field and each Additional Subfield.

"Pfizer" means Pfizer Inc.

- "Probe Study" means the conduct of a human study (excluding any Phase III Study or Pivotal Study) of a Licensed Product in and for an Additional Subfield in fewer than fifty (50) subjects.
 - **1.3 Additional Definitions.** The following definitions are added to Section 1 of the Agreement:
- "Additional Subfield" means each disease or symptom in humans or animals that is not a Primary Subfield; for clarity, an Expansion to a particular Additional Subfield is not a separate Additional Subfield.

"Epilepticus Field" means the field of therapeutic use against status epilepticus in humans.

"Expansion" means, with respect to a particular Additional Subfield for which a clinical study was conducted, an NDA was filed or Marketing Approval was obtained, an additional clinical study, or receipt of NDA or Marketing Approval, of the Licensed Product in such Additional Subfield for a different subpatient population, line of therapy or new use as a monotherapy or in combination with another treatment or drug, other than the population, line of therapy or use for which the prior clinical study(ies) were conducted, NDA was filed or Marketing Approval was received.

"Phase II Study" means the conduct of a human study, as described in 21 C.F.R. §312.21(b) and its foreign equivalents, of a Licensed Product, but excluding any Probe Study.

"Phase III Study" means the conduct of a human study, as described in 21 C.F.R. §312.21(c) and its foreign equivalents, of a Licensed Product.

"Pivotal Study" means a controlled pivotal clinical study of a Licensed Product that is prospectively designed to demonstrate statistically whether such Licensed Product is effective and safe for use in a particular indication in a manner sufficient to obtain Marketing Approval to market such product in the United States, China, Japan or Germany (via the European Union (including the European Medicines Authority) or otherwise).

"Primary Subfield" means each of the following: the Epilepticus Field or the TBI Field.

"Subfield" means each Primary Subfield, on a Primary Subfield-by-Primary Subfield basis, and each Additional Subfield, on an Additional Subfield-by-Additional Subfield basis.

"TBI Field" means the treatment of traumatic brain injury in humans.

- **1.4 DELETED DEFINITIONS.** The definitions of "Probe Condition" and "Probe Study Product", and all references thereto, are hereby deleted from the Agreement.
- **2. PROBE STUDY LICENSE.** Section 2.1(b) of the Agreement is hereby amended to read:
 - (b) [Intentionally Omitted].
- **3. NEGATIVE COVENANT.** Section 2.1(e) of the Agreement is hereby amended to read:
- **(e) Negative Covenant.** During the term of this Agreement, CyDex and its Affiliates shall not grant any rights to any Third Party that conflict with the exclusive rights granted herein to Sage or that conflict with or otherwise impair Sage's ability to conduct the activities described herein. Without limiting the generality of the foregoing, in the event that CyDex or any of its Affiliates become aware that a Third Party is conducting research, development or commercial activities using the Compound with Captisol, then CyDex shall take all reasonable measures to cease the supply of Captisol to such Third Party and to any other Third Party that is determined to be supplying Captisol to such Third Party.

4. PAYMENTS.

- **4.1** Section 4.1(a)(ii) of the Agreement is hereby amended to read:
 - (ii) CyDex acknowledges receipt of the payment of \$[...***...] on the Effective Date.
- **4.2** In consideration of CyDex entering into this Amendment, Sage agrees to pay to CyDex \$[...***...] on the Amendment Effective Date.
- **4.3** Section 4.1(b) of the Agreement is hereby amended to read:

(b) Milestone Payments.

(i) Epilepticus Field and TBI Field. Within [...***...] days following the occurrence of each of the milestone events listed below with respect to the Licensed Product in either Primary Subfield, Sage shall provide written notice to CyDex of the achievement of such milestone event, and within [...***...] days 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 Sage hereunder. The milestone payments (each payable only one time per each of the Primary Subfields, regardless of the number of times achieved by the Licensed Product for such Primary Subfield; for the avoidance of doubt, if the same Licensed Product first achieves one or more given milestones for both the Epilepticus Field and the TBI Field, then the milestone payment for that event must be paid twice; and in no event shall the maximum payment under this Section 4.1(b)(i) exceed \$[...***...]) are as follows. If any such milestone is achieved in the relevant Primary Subfield before all prior sequential milestones have been actually achieved in such Primary Subfield, then any and all prior sequential milestones which were not previously actually achieved shall be deemed to have thereby been achieved with respect to such Primary Subfield, and the milestone payments for such deemed-achieved milestones shall also be payable with respect to such Primary Subfield within such [...***...] days.

	MILESTONE ACHIEVED IN THE RELEVANT PRIMARY SUBFIELD	MILESTONE PAYMENT
(i)	[***]	\$[***]
(ii)	$[^{***}]$	\$[***]
(iii)	[***]	\$[***]
(iv)	[***]	\$[***]

(ii) Additional Subfields. Within [...***...] days following the occurrence of each of the milestone events listed below with respect to the Licensed Product in an Additional Subfield, Sage shall provide written notice to CyDex of the achievement of such milestone event, and within [...***...] days 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 Sage hereunder. The milestone payments (each payable only one time per each of the first two (2) Additional Subfields, regardless of the number of times achieved by the Licensed Product for such Additional Subfield; for the

avoidance of doubt, if the same Licensed Product first achieves one or more given milestones for two Additional Subfields, then the milestone payment for that event must be paid twice; and in no event shall the maximum payment under this Section 4.1(b)(ii) exceed \$[...***...]) are as follows. Subject to the preceding sentence, if any such milestone is achieved in the relevant Additional Subfield before all prior sequential milestones have been actually achieved in such Additional Subfield, then any and all prior sequential milestones which were not previously actually achieved with respect to such Additional Subfield shall be deemed to have thereby been achieved, and the milestone payments for such deemed-achieved milestones shall also be payable with respect to such Additional Subfield within such [...***...] days.

		MILESTONE
	MILESTONE	PAYMENT
(i)	[***]	\$[***]
(ii)	[***]	\$[***]
(iii)	[***]	\$[***]
(iv)	[***]	\$[***]

- **4.4** Section 4.1(d) of the Agreement is hereby deleted in its entirety.
- **5. DILIGENCE.** The penultimate sentence of Section 6.1 of the Agreement is hereby amended to read:

For clarity, Sage may meet the requirements of this Section 6.1 through its activities with respect to the Licensed Product in just one of the Subfields.

- **6. REPRESENTATIONS AND WARRANTIES.** CyDex represents and warrants to Sage (as of the Amendment Effective Date) as follows:
- (i) Neither it nor any of its Affiliates has entered into any agreement with any third party (including any Pre-Existing Agreement) that is in conflict with the rights granted to Sage pursuant to this Agreement; and
- (ii) Neither CyDex nor any of its Affiliates has granted any Affiliate of CyDex or any Third Party any rights to develop or commercialize any pharmaceutical composition comprising the Compound combined with or formulated using Captisol.
- **7. INDEMNIFICATION**. Section 10.1(c) is hereby amended to read:
- (c) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Sections 9.1** and **9.2** of the Agreement or in Section 6 of the Amendment,
- **8. INTERPRETATION**. The following sentence is added to the end of Section 14.18 of the Agreement:

Except as the context otherwise requires, (a) the word "including" or correlatives thereof, means "including without limitation," and (b) the word "or" means "and/or."

- **9. ENTIRE AGREEMENT/AMENDMENTS.** Except as amended by this Amendment, the Agreement shall remain in full force and effect. After the Amendment Effective Date, every reference in the Agreement to the "Agreement" shall mean the Agreement as amended by this Amendment.
- **10. Counterparts**. This Amendment may be executed in 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 Amendment to Commercial License Agreement as of the Amendment Effective Date.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman
Name: Charles Berkman
Title: VP and Secretary

SAGE THERAPEUTICS, INC.

By: /s/ Jeffrey Jonas Name: Jeffrey Jonas

Title: CEO

Non-Exclusive License Agreement

between

The Regents of the University of California

and

Sage Therapeutics, Inc.

for

Allopregnanolone in the Treatment of Status Epilepticus and Post-Partum Depression

File No. [...***...]

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Non-Exclusive License Agreement for Allopregnanolone in the Treatment of Status Epilepticus and Post-Partum Depression

(File No. [...***...])

This non-exclusive license agreement ("Agreement") is effective this 23rd day of October 2013 ("Effective Date"), by and between The Regents of the University of California ("The Regents"), a California corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200, as represented by its Davis campus, having an address at UC Davis InnovationAccess, 1850 Research Park Drive, Suite 100, Davis, California 95618 and Sage Therapeutics, Inc. ("Licensee"), a Delaware corporation, having a principal place of business at 215 First Street, Cambridge, Massachusetts 02142. The Regents and Licensee will be referred to herein, on occasion, individually as "Party" or collectively as "Parties."

RECITALS

Whereas, the Material (defined below) was made at the University of California, Davis campus ("UC Davis") by Dr. Michael Rogawski ("Investigator");

Whereas, the development of the Material was sponsored in part by one or more agencies of the United States Government; accordingly, under Federal law, the Material is tangible research product owned by The Regents; also, any related invention rights are subject to the rights of the United States Government under 35 USC §§ 200-212 and implementing regulations; and The Regents is obligated to grant to the United States Government a non-exclusive, non-transferable, irrevocable, paid-up license to use the Material by or on behalf of the United States Government throughout the world;

Whereas, Licensee has requested from The Regents the Material as defined in Paragraph 1.1 below for the Research Use defined in Paragraph 1.6(ii) below, which Material was developed with the Department of Defense support under contract number W81XWH-09-1-0746 administered by the USA Med Research ACQ Activity;

Whereas, The Regents and Licensee have entered into a Letter Agreement (UC Agreement Control No. 2013-30-0469) effective March 12, 2013 ("Letter Agreement") for the purpose of granting Licensee an exclusive right to negotiate an exclusive license;

Whereas, The Regents and Licensee entered into an Investigational New Drug Application ("IND") Data Transfer Agreement (UC Agreement Control No. 2013-210514) effective April 1, 2013 ("IND Data Transfer Agreement") for the purpose of reference of data in Licensee's pre-IND interactions with the Food and Drug Administration ("FDA") in advance of a submission of Licensee's IND application for use of Allopregnanolone for the treatment of status epilepticus and pre-IND discussion pertaining to an IND application for such indication with the FDA;

Whereas, The Regents and Licensee entered into a Material Transfer Agreement (File No. 2013-816-M) effective July 9, 2013 ("MTA") for the purpose of The Regents to transfer a portion of the Material, Allopregnanolone (GMP grade chemical), to Licensee for developing a clinically relevant formulation for treatment of status epilepticus, such use limited to formulation/process development (prototype batch, material compatibility, filter study validation); engineering batch manufacture; and analytical support (re-release of API);

Whereas, The Regents and Licensee desire to have the Data (defined below) and Material (defined below) used by Licensee so that products resulting therefrom may be developed, commercialized and available for public use and benefit; and

Whereas, Licensee desires to acquire, and The Regents desires to grant, a license under Property Rights in accordance with the terms herein.

Now, therefore, the Parties agree as follows:

1. DEFINITIONS

- 1.1 "Material" means approximately [...***...] kilograms of Allopregnanolone (GMP grade chemical), approximately [...***...] grams of which was provided to Licensee prior to the Effective Date pursuant to the MTA.
- 1.2 "Modifications" mean substances created or made by or on behalf of the Licensee that either contain or incorporate the Material or were otherwise created through the use of the Material. For the purpose under this Agreement, pharmaceutical formulations of Material shall be considered Modifications. Notwithstanding the above, Licensee shall not chemically modify or alter the chemical structure of the Material.
- 1.3 "Data" means the confidential Investigational New Drug (IND) application package (IND Number 111,085) owned by The Regents and generated by the The Regents' Investigator for the use of Allopregnanolone for Traumatic Brain Injury and any updates to such IND.
- 1.4 "Derived Product" means a product containing Allopregnanolone produced by or on behalf of Licensee for Sale or Sold as a drug for status epilepticus and/or post-partum depression.
- 1.5 "Property Rights" means all personal proprietary rights of The Regents covering the tangible personal property in the Data and Material.
- 1.6 "Licensed Field of Use" means the (a) use of Data for Reference Use as defined below and (b) use of Material or Modifications for Research Use as defined below.
 - (i) "Reference Use" means use of Data by the Licensee, and by affiliates, contractors, consultants, agents and/or vendors on behalf of Licensee, for the sole purpose of reference or incorporation to the extent that such reference or incorporation identifies, labels it as an excerpt from Data and acknowledges UC Davis as the source of the Data in Licensee's IND application(s) with the FDA for use of Allopregnanolone for the treatment of status epilepticus and/or postpartum depression. [...***...].

- (ii) "Research Use" means use of Material or Modifications to develop a clinically relevant pharmaceutical formulation and use of such pharmaceutical formulation for FDA-approved human clinical trials for treatment of status epilepticus and/or post-partum depression. Research Use includes transfer of Material by Licensee to a third party who uses such Material to create a Modification on behalf of Licensee.
- 1.7 "Sale" means, for Derived Products, the act of selling, leasing or otherwise transferring, providing, or furnishing such product for any consideration.

 Correspondingly, "Sell" means to make or cause to be made a Sale, and "Sold" means to have made or caused to be made a Sale.
- 1.8 "Net Sales" means the gross invoice price charged by, and the value of any noncash consideration owed to, Licensee for Sales of Derived Products in the Licensed Territory, less the sum of the following actual and customary deductions where applicable: cash, trade or quantity discounts; sales, use, tariff, ^import/export duties or other excise taxes when included in gross sales, but not value-added taxes assessed or income taxes derived from such sales; transportation and related freight/shipping insurance charges; and allowances or credits to customers because of rejections or returns.
- 1.9 "Licensed Territory" means the United States of America and its territories and possessions, and any foreign countries where Property Rights exist.
- 1.10 "Research Use Results" means all technical information and data relating to the Licensed Field of Use.

2. GRANT; RESTRICTIONS

- 2.1 Subject to the limitations set forth in this Agreement, including without limitation the licenses granted to the United States Government referred to in the Recitals above and the rights reserved in Paragraphs 2.3 and 2.7 below, The Regents hereby grants to Licensee a non-exclusive license under Property Rights, in the Licensed Territory, to the extent such license rights may be lawfully granted, to (a) use Data for the Reference Use under the Licensed Field of Use in compliance with all applicable statutes and regulations, and (b) possess and use Material or Modifications solely for Research Use
- 2.2 (a) The rights granted to Licensee under Paragraph 2.1 above are limited for the purposes stated in this Agreement. Any other use of Data, Material or Modifications is expressly prohibited.
 - (b) Licensee agrees to use Material or Modifications in compliance with all applicable statutes and regulations, including, but not limited to, those related to research involving the use of humans, animals or recombinant DNA. The Material or Modifications will not be used by Licensee for commercial purposes or any other use other than the Research Use (provided that the use of Materials

- or Modifications to develop a clinically relevant pharmaceutical formulation, use of such pharmaceutical formulation for FDA-approved human clinical trials, for the purposes of eventual commercial sale of such pharmaceutical formulation, shall not be considered a use for commercial purposes).
- (c) Licensee shall not analyze the Material for chemical composition or physical structure or have or allow any component of the Material to be analyzed or make any use of any such analysis other than for quality testing purposes to meet FDA submission requirements. Licensee shall not make chemical modification or alter the chemical structure of the Material in any way except as pursuant to Paragraph 1.6.
- 2.3 The Regents reserves the right to do any one or more of the following:
 - (a) publish any technical data resulting from research performed by The Regents relating to the Data and Material;
 - (b) make and use the Data and Material and associated technology for educational and research purposes;
 - (c) practice Property Rights for educational and research purposes, including in order to make and use products;
 - (d) allow other educational and non-profit institutions to do any one or more of the activities of Subparagraphs 2.3 (a), (b), and (c) above, for educational and research purposes; and
 - (e) transfer or grant rights in the Data and Material as further described in Paragraph 2.7.
- 2.4 The Regents, through the Investigator, will endeavor to transfer to Licensee, the remaining amount (approximately [...***...] grams) of the Material within fourteen (14) days from the date this Agreement is executed by The Regents and Licensee shall pay all the storage, handling, associated shipping costs and incidental expenses, which shall be included in (and not separate from) the Material Fee (defined below). Licensee acknowledges that The Regents, through the Investigator, has transferred a portion of Material to Licensee in accordance with the terms and conditions of the MTA. The Material will be delivered to:

- 2.5 The Regents is not obligated to provide any replacements or any additional amounts of Material.
- 2.6 Except as otherwise permitted under this Agreement, Licensee will not Sell, donate, abandon, or otherwise transfer Data to any third party and will not Sell, donate, abandon, or otherwise transfer ownership of Material to any third party. Licensee acknowledges that The Regents retains ownership of Data and that ownership of Data is not transferred

to Licensee under this Agreement. However, ownership (title) of the Material will transfer to Licensee upon receipt by Licensee. For such Material that has title transferred to Licensee, such Material will otherwise remain as Material under this Agreement and all other terms of this Agreement will apply.

2.7 The Regents is free to transfer or grant rights in the Data to third parties for any purposes.

3. SUBLICENSES

.1 This Agreement specifically excludes the right of Licensee to issue sublicenses.

4. MATERIAL FEE

- 4.1 Licensee will pay to The Regents a sum of [...***...] Dollars (\$[...***...]) for the costs of storage, packaging, transport and incidental expenses for the Material ("Material Fee").
- 4.2 The Material Fee is due fifteen (15) days after receipt of an invoice therefor. The Material Fee is non-creditable, non-refundable and not an advance against royalties or other payments due under this Agreement.

5. ROYALTIES AND MILESTONES

- 5.1 Licensee will pay to The Regents earned royalties ("Earned Royalties") at the rate of [...***...] percent ([...***...]%) of the Net Sales in the Licensed Territory of each Derived Product for fifteen (15) years after first Sale of each such Derived Product.
- 5.2 Earned Royalties accruing to The Regents will be paid to The Regents semiannually within [...***...] days after the end of each [...***...] month period as follows: November 1 (for the [...***...] month period commencing March 1 of that year), and May 1 (for the [...***...] month period commencing September 1 of the prior calendar year).
- 5.3 All consideration due The Regents will be payable in United States dollars. When Derived Products are Sold for monies other than United States dollars, the Earned Royalties will first be determined in the foreign currency of the country in which the Sale was made and then converted into equivalent United States dollars. The exchange rate will be that quoted in the *Wall Street Journal* on the last business day of the reporting period.
- 5.4 Payments due for Sales occurring in any country outside the United States will not be reduced by any taxes, fees, or other charges imposed by the government of such country on the remittance of royalty income. Licensee will also be responsible for all bank transfer charges.
- 5.5 Licensee will make all payments under this Agreement either by check or electronic transfer, payable to "The Regents of the University of California" and Licensee will forward such payments to The Regents at the address shown in Paragraph 20.1 below.

- 5.6 No Earned Royalties will be collected or paid hereunder on Sales of Derived Products to, or for use by, the United States Government. Licensee will reduce the amount charged for such Sales by an amount equal to the Earned Royalties otherwise due The Regents as provided herein.
- 5.7 (a) Within [...***...] days after the [...***...], whichever occurs first, Licensee will pay to The Regents a one-time, non-refundable and non-creditable milestone fee of [...***...] dollars (\$[...***...]).
 - (b) Within [...***...] days after the [...***...], whichever occurs second and for which a milestone fee was not paid under Paragraph 5.7(a), Licensee will pay to The Regents a onetime, non-refundable and non-creditable milestone fee of [...***...] dollars (\$[...***...]).
 - (c) For clarity, the milestone fees in clauses (a) and (b) above shall each be payable only once, [...***...].

6. DILIGENCE

- 6.1 Licensee, upon execution of this Agreement, will use commercially reasonable efforts to proceed with the development, manufacture, and Sale of one or more Derived Products and will use commercially reasonable efforts to market such Derived Products in quantities sufficient to meet the market demand.
- 6.2 In addition to its obligations under Paragraph 6.1, Licensee specifically commits to obtain all necessary governmental approvals in each country where Derived Products are made, manufactured, used, Sold, imported, or offered for Sale.
- 6.3 If Licensee is unable to meet any of its diligence obligations set forth in Paragraphs 6.1 and 6.2, then The Regents will have the right and option to terminate this Agreement in accordance with Paragraph 10.1 below.

7. PROGRESS AND ROYALTY REPORTS

7.1 For the period beginning January 1, 2014, within sixty (60) days after each subsequent June 30 and December 31, Licensee will submit to The Regents a semi-annual progress report covering Licensee's Research Use Results and the test conditions used, activities related to the development and testing of all Derived Products, and the obtaining of necessary governmental approvals, if any, for marketing Derived Products in the United States. These progress reports will be made for all development activities. If Licensee fails to submit a timely progress report to The Regents, The Regents will be entitled to terminate this Agreement in accordance with Paragraph 10.1 below. If either Party terminates this Agreement before any Derived Products are Sold or before this Agreement's expiration, a final progress report covering the period prior to termination must be submitted within thirty (30) days of termination.

- 7.2 Each progress report will be a sufficiently detailed summary of activities of Licensee so that The Regents may evaluate and determine Licensee's progress in the development of Derived Product and Research Use, and in meeting its diligence obligations under Article 6, and will include (but not be limited to) the following: summary of work completed and in progress; current schedule of anticipated events and milestones; and anticipated market introduction dates.
- 7.3 In Licensee's progress report immediately subsequent to the first Sale by Licensee of Derived Products, Licensee will report the date of such first Sale.
- 7.4 After the first Sale of a Derived Product, Licensee will provide semi-annual royalty reports to The Regents on or before November 1 (for the six (6)-month period commencing March 1 of that year), and May 1 (for the six (6)-month period commencing September 1 of the prior calendar year). Each such royalty report will include at least the following:
 - (a) The number of Derived Products manufactured and the number of Derived Products Sold;
 - (b) Gross revenue from Sale of Derived Products;
 - (c) Net Sales pursuant to Paragraph 1.8;
 - (d) Itemized deductions pursuant to Paragraph 1.8;
 - (e) Listing of distributors Selling Derived Products; and
 - (f) Total Earned Royalties due to The Regents.
- 7.5 If no Sales of Derived Product have occurred during the reporting period, a statement to this effect is required in the royalty report for that period.

8. BOOKS AND RECORDS

Licensee will keep full, true, and accurate books of accounts containing all particulars that may be necessary for the purpose of showing the amount of Earned Royalties payable to The Regents and Licensee's compliance with other obligations under this Agreement. Said books of accounts will be kept at Licensee's principal place of business or the principal place of business of the appropriate division of Licensee to which this Agreement relates. Said books and the supporting data will be open at all reasonable times during normal business hours upon at least ten (10) business days' notice, for five (5) years following the end of the calendar year to which they pertain, to the inspection and audit by representatives of The Regents reasonably acceptable to Licensee for the purpose of verifying Licensee's royalty statement or compliance in other respects with this Agreement. Such representatives will be bound to hold all information in confidence except as necessary to communicate Licensee's noncompliance with this Agreement to The Regents. The Regents may conduct such an inspection and audit only once in any twelve (12)-month period, and may not conduct such an inspection and audit with respect to the same time period more than once.

3.2 The fees and expenses of The Regents' representatives performing such an examination will be borne by The Regents. However, if an error in underpaid royalties to The Regents of more than five percent (5%) of the total Earned Royalties due for any year is discovered, then the fees and expenses of these representatives will be borne by Licensee.

9. LIFE OF THE AGREEMENT

- 9.1 This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Article 6, Article 10, Article 11 or Article 25, this Agreement shall continue in effect until fifteen (15) years after the last-to-occur first Sale of a Derived Product (the effective period of the Agreement being referred to herein as the "Term"). Notwithstanding the foregoing, in no event will the Term extend beyond twenty-seven (27) years after the Effective Date. Upon expiration of this Agreement, the license set forth in Paragraph 2.1 shall become perpetual, irrevocable, royalty-free and fully paid-up, subject to Paragraph 9.2.
- 9.2 Any termination or expiration of this Agreement will not affect the rights and obligations set forth in the following Articles:

Article 1	Definitions
Article 8	Books and Records
Article 9	Life of the Agreement
Article 12	Disposition of Material, Modifications, and Derived Products on Hand upon Termination
Article 13	Use of Names and Trademarks
Article 14	Limited Warranties
Article 15	Indemnification
Article 19	Notices
Article 20	Payments
Article 22	Confidentiality
Article 27	Applicable Law; Venue; Attorneys' Fees
Article 28	Scope of Agreement

9.3 The termination or expiration of this Agreement will not relieve Licensee of its obligation to pay any monies owing at the time of such termination or expiration and will not relieve any obligations, of either Party to the other Party, established prior to termination or expiration.

10. TERMINATION BY THE REGENTS

10.1 If Licensee should violate or fail to perform any material term of this Agreement, then The Regents may give written notice of such default ("Notice of Default") to Licensee. If Licensee should fail to repair such default in accordance with Paragraph 10.3 and, if applicable, Paragraph 10.4, The Regents will have the right to terminate this Agreement and the license herein by providing a second written notice ("Notice of Termination") to Licensee. If a Notice of Termination is sent to Licensee, this Agreement will automatically terminate on the effective date of such notice. Such termination will not relieve Licensee of its obligation to pay any royalty or fees owing at the time of such termination and will not impair any accrued rights of The Regents. These notices will be subject to Article 19 (Notices).

- 10.2 Notwithstanding Paragraph 10.1 above, this Agreement will automatically terminate in the event of Licensee's insolvency or the filing of a petition for relief under the United States Bankruptcy Code (a) by Licensee as a debtor or (b) against Licensee as an alleged debtor, if such petition against Licensee has not been stayed or dismissed within sixty (60) days after filing.
- 10.3 After The Regents has given the Notice of Default, and if Licensee fails to repair such default within sixty (60) days after the effective date of such notice, if the Parties can mutually agree, no later than one hundred twenty (120) days after the effective date of the Notice of Default as to the measures Licensee is to take to adequately address the material term that has been breached by Licensee, then this Agreement will not terminate subject to Licensee's performance of such measures. If the Parties are unable to mutually agree on the measures Licensee is to take to address the material breach, then the Parties will submit the dispute to an unrelated third party arbitrator to determine the measures Licensee is to take to address the material breach, in accordance with Paragraph 10.4 ("Baseball Arbitration").
- 10.4 Any Baseball Arbitration shall be held in San Francisco, California, according to the then-current commercial arbitration rules of the American Arbitration Association ("AAA"), except to the extent such rules are inconsistent with this Paragraph 10.4. The Baseball Arbitration will be conducted by one (1) arbitrator who shall be reasonably acceptable to the Parties and who shall be appointed in accordance with AAA rules. If the Parties are unable to select an arbitrator, then the arbitrator shall be appointed in accordance with AAA rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of experience relevant to the nature of the matter in dispute. Within twenty (20) days after the selection of the arbitrator, each Party shall submit to the arbitrator and the other Party a proposal for the steps Licensee is to take to address the material breach, together with any relevant evidence in support thereof (the "Proposals"). Within fifteen (15) days after the delivery of the last Proposal to the arbitrator, each Party may submit a written rebuttal of the other Party's Proposal and may also amend and re-submit its original Proposal. The Parties and the arbitrator shall meet within fifteen (15) days after the Parties have submitted their Proposals, at which time each Party shall have one (1) hour to argue in support of its Proposal. The Parties shall not have the right to call any witnesses in support of their arguments, nor compel any production of documents or take any discovery from the other Party in preparation for the meeting. Within thirty (30) days after such meeting, the arbitrator shall select one of the Proposals so submitted by one of the Parties as the resolution of the dispute, but may not alter the terms of either Proposal and may not resolve the dispute in a manner other than by selection of one of the submitted Proposals. If a Party fails to submit a Proposal within the initial twenty (20) day time frame set forth above, the arbitrator shall select the Proposal of the other Party as the determination of the steps Licensee shall take to remedy the material breach. Any time period set forth in this Paragraph 10,4 may be extended by mutual agreement of the Parties. The content (but not

the existence or outcome) of the proceedings shall be confidential. Each Party shall bear its own costs incurred in Baseball Arbitration, and Licensee shall pay the costs of the arbitrator. The Regents shall have the right to issue the Notice of Termination in respect of the applicable material breach following Baseball Arbitration only if Licensee fails to perform the measures to address such material breach as set forth in the Proposal selected by the arbitrator.

11. TERMINATION BY LICENSEE

- 11.1 Licensee will have the right at any time to terminate this Agreement by giving notice in writing to The Regents. Such notice of termination will be subject to Article 19 (Notices) and termination of this Agreement will be effective sixty (60) days after the effective date of such notice.
- 11.2 Any termination pursuant to Paragraph 11.1 will not relieve Licensee of any obligation or liability accrued hereunder prior to such termination or rescind anything done by Licensee or any payments made to The Regents hereunder prior to the time such termination becomes effective, and such termination will not affect in any manner any rights of The Regents arising under this Agreement prior to such termination.

12. DISPOSITION OF MATERIAL, MODIFICATIONS AND DERIVED PRODUCTS ON HAND UPON TERMINATION

- 12.1 Upon termination of this Agreement, for a period of one hundred and twenty (120) days after the date of termination, Licensee may complete and Sell any partially made Derived Products; provided that all such Sales will be subject to the terms of this Agreement including, but not limited to, the payment of Earned Royalties and the rendering of royalty reports thereon. Licensee may not otherwise make, have made, use, Sell, have Sold, offer for Sale, or import Derived Products after the date of termination.
- 12.2 Upon termination of this Agreement for any reason, Licensee will destroy any Material or Modifications in its possession within fifteen (15) days following the effective date of termination. Licensee will provide The Regents within thirty (30) days following said termination date with written notice that the Material and Modifications have been destroyed.

13. USE OF NAMES AND TRADEMARKS

13.1 Nothing contained in this Agreement will be construed as conferring any right to use in advertising, publicity or other promotional activities any name, trademark, trade name, or other designation of either Party by the other (including any contraction, abbreviation, or simulation of any of the foregoing). Unless required by law or consented to in writing by The Regents, the use by Licensee of the name "The Regents of the University of California" or the name of any University of California campus in advertising, publicity or other promotional activities (other than as set forth in Paragraph 23.1) is expressly prohibited.

14. LIMITED WARRANTIES

- 14.1 The Regents warrants to Licensee that it has the lawful right to grant this license.
- 14.2 This license and the associated Property Rights and Material are provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. THE REGENTS MAKES NO REPRESENTATION OR WARRANTY THAT THE PROPERTY RIGHTS, DATA, MATERIAL, MODIFICATIONS OR DERIVED PRODUCTS, WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER PROPRIETARY RIGHT.
- 14.3 (a) EXCEPT FOR LICENSEE'S OBLIGATIONS REGARDING CLAIMS OF THIRD PARTIES PURSUANT TO ARTICLE 15 (INDEMNIFICATION), IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM EXERCISE OF THIS LICENSE OR THE USE OF THE DATA, MATERIAL, MODIFICATIONS, PROPERTY RIGHTS, OR DERIVED PRODUCTS.
 - (b) EXCEPT FOR LICENSEE'S OBLIGATIONS REGARDING CLAIMS OF THIRD PARTIES PURSUANT TO ARTICLE 15 (INDEMNIFICATION) AND EXCEPT AS MAY RESULT FROM A BREACH OF ARTICLE 22 (CONFIDENTIALITY), NEITHER PARTY WILL BE LIABLE FOR ANY LOST PROFITS, COSTS OF PROCURING SUBSTITUTE GOODS OR SERVICES, LOST BUSINESS, ENHANCED DAMAGES FOR INTELLECTUAL PROPERTY INFRINGEMENT, OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR OTHER SPECIAL DAMAGES SUFFERED BY THE OTHER PARTY OR ITS AFFILIATES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTY) EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
- 14.4 Nothing in this Agreement is or will be construed as:
 - (a) a warranty or representation by The Regents as to the validity, enforceability, or scope of any Property Rights;
 - (b) a warranty or representation that anything made, used, offered for Sale, imported, or Sold under any license granted in this Agreement is or will be free from infringement of patents of third parties;
 - (c) an obligation to bring or prosecute actions or suits against third parties for misappropriation of Data, Material, Modifications or Derived Products;
 - (d) conferring by implication, estoppel, or otherwise any express or implied license or rights under any patents, patent applications, data, copyrights or materials of The Regents, other than with respect to the Data or Material; or
 - (e) an obligation to furnish any know-how, technology, or technological information not provided in the Material.

15. INDEMNIFICATION

- 15.1 Licensee will indemnify, hold harmless, and defend The Regents and its officers, employees, and agents; sponsor(s) of the research that led to the Data and Material; and the creators and inventors of any Data and Material covered by Property Rights and their employers against any and all claims, suits, losses, damage, costs, fees, and expenses to the extent resulting from, or arising out of, any third party claim relating to the exercise of this license. This indemnification will include, but will not be limited to, any product liability. If The Regents, in its sole discretion, believes that there will be a conflict of interest with counsel chosen by Licensee, then The Regents may retain counsel of its choice to represent it, and Licensee will pay all expenses for such representation.
- 15.2 Licensee assumes all liability for damages that may arise from its use, storage or disposition of the Material or Modifications. The Regents shall not be liable to Licensee for any loss, claim or demand made by Licensee, or made against Licensee by any other party, due to or arising from the use, storage or disposition of the Material or Modifications by Licensee. Licensee shall be solely responsible for any use of the Material or Modifications at Licensee's facilities or otherwise by Licensee employees, agents, contractors, or other representatives. Licensee shall indemnify, defend, and hold The Regents and all The Regents' directors, officers, employees, agents, contractors and other representatives (collectively the "Indemnitees") harmless from any claim, litigation, liability, inspection, investigation, administrative proceeding, or other action initiated or threatened by a private party, a government agency, or any other person or entity (collectively "Claims") arising from receipt, storage, use, or disposition of Materials or Modifications by or on behalf of Licensee pursuant to this Agreement or otherwise, and regardless of the basis or cause of such Claim. Each Party shall promptly inform the other of any such Claim of which the Party becomes aware, and each shall communicate with the other's designated counsel regarding the management of such Claim. Licensee shall keep The Regents informed of, and consult with The Regents in connection with the selection of counsel to defend the any Claim and the progress of such litigation or settlement. Licensee shall not have any right to settle any Claim without the specific prior written approval from a designated legal representative of The Regents, Licensee acknowledges that any such settlement proposal submitted to The Regents for approval shall contain a full release of liability for The Regents.
- 15.3 Licensee, at its sole cost and expense, will insure its activities in connection with any work performed hereunder and will obtain, keep in force, and maintain the following insurance:
 - (a) Commercial Form General Liability Insurance (contractual liability included; Commercial Form General Liability Insurance will also include clinical trials insurance coverage when applicable, at the levels below) with limits as follows:

Each Occurrence	\$[***]
Products/Completed Operations Aggregate	\$[***]
Personal and Advertising Injury	\$[***]
General Aggregate	\$[***]

If the above insurance is written on a claims-made form, it will continue for three (3) years following termination or expiration of this Agreement. The insurance will have a retroactive date of placement prior to or coinciding with the Effective Date of this Agreement; and

- (b) Worker's Compensation as legally required in the jurisdiction in which Licensee is doing business.
- 15.4 The coverage and limits referred to in Subparagraph 15.3(a) and 15.3(b) above will not in any way limit the liability of Licensee under this Article 15. Upon the execution of this Agreement, Licensee will furnish The Regents with certificates of insurance evidencing compliance with all requirements, and Licensee will promptly notify The Regents of any material modification of the insurance coverages. Such certificates will:
 - (a) provide for thirty (30) days' (ten (10) days for non-payment of premium) advance written notice to The Regents of any cancellation of insurance coverages;
 - (b) indicate that The Regents has been endorsed as an additional insured under the coverage described above in Paragraph 15.3; and
 - (c) include a provision that the coverage will be primary and will not participate with, nor will be excess over, any valid and collectable insurance or program of self-insurance maintained by The Regents.
- 15.5 The Regents will promptly notify Licensee in writing of any claim or suit brought against The Regents for which The Regents intends to invoke the provisions of this Article 15. Licensee will keep The Regents informed of its defense of any claims pursuant to this Article 15.

16. COMPLIANCE WITH LAWS/EXPORT CONTROLS

- 16.1 Licensee will comply with all applicable international, national, state, regional, and local laws and regulations in performing its obligations hereunder and in Licensee's use, manufacture, offer for Sale, Sale, or import of the Derived Products. Licensee will observe all applicable United States and foreign laws and regulations governing the transfer of Derived Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations.
- 16.2 Licensee understands that The Regents is subject to United States laws and regulations (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979), controlling the export of technical data, computer software, laboratory prototypes and other commodities, and The Regents' obligations to Licensee under this Agreement are contingent on and subject to compliance with such laws and regulations.

The transfer of certain technical data and/or commodities may require a license from the cognizant agency of the United States Government and/or written assurances by Licensee that Licensee will not export such technical data and/or commodities to certain foreign countries without prior approval of such agency. The Regents neither represents that such a license will not be required nor that, if required, it will be issued.

17. GOVERNMENT APPROVAL OR REGISTRATION

17.1 If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee will assume all legal obligations to do so. Licensee will notify The Regents if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. Licensee will make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

18. ASSIGNMENT

18.1 This Agreement is binding upon and will inure to the benefit of The Regents, its successors and assigns. This Agreement is personal to Licensee and assignable by Licensee only with the written consent of The Regents, provided that Licensee may, on written notice to The Regents, assign this Agreement, including, without limitation, all obligations owed to The Regents hereunder, to an acquiror of all or substantially all of Licensee's stock or assets to which this Agreement relates.

19. NOTICES

19.1 All notices under this Agreement will be deemed to have been fully given and effective when done in writing and delivered in person, or mailed by registered or certified U.S. mail, or deposited with a carrier service requiring signature by recipient, and addressed as follows;

To The Regents: UC Davis InnovationAccess

1850 Research Park Drive, Suite 100

Davis, CA 95618-6134 Attn.: Executive Director, File No. [...***...]

To Licensee: Sage Therapeutics, Inc.

215 First Street

Cambridge, Massachusetts 02142 Attention: Chief Business Officer

Either Party may change its address upon written notice to the other Party.

20. PAYMENTS

20.1 Payments to The Regents that are not for the Material Fee will be made by check or bank wire transfer, to the following address:

Checks: The Regents of the University of California

Innovation Alliances and Services 1111 Franklin Street, 5th Floor Oakland, CA 94607-5200 Attention: Chief Financial Officer

Referencing: [...***...]

Bank wire (Licensee is responsible for all wire transfer fees):

Payments to The Regents for the Material Fee shall be made by check or bank wire transfer to the address below. Licensee is responsible for all wire transfer fees. Payments shall be made payable to "The Regents of the University of California".

In addition to the above, recipient shall return the chain of custody document signed by recipient to UC DAVIS at the above address within one (1) business day of receipt of shipment of the MATERIAL.

20.2 If monies owed to The Regents under this Agreement are not received by The Regents when due, Licensee will pay to The Regents interest charges at a rate of [...***...] percent ([...***...]%) per annum. Such interest will be calculated from the date payment was due until actually received by The Regents. Such accrual of interest will be in addition to, and not in lieu of, enforcement of any other rights of The Regents related to such late payment. Acceptance of any late payment will not constitute a waiver under Article 21 (Waiver) of this Agreement.

21. WAIVER

21.1 The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. None of the terms and conditions of this Agreement can be waived except by the written consent of the Party waiving compliance.

22. CONFIDENTIALITY

22.1 Subject to Paragraphs 22.2 and 22.3 below, each Party will hold the other Party's business and technical information, and other proprietary information, including the negotiated terms of this Agreement ("Confidential Information"), in confidence and against disclosure to third parties with at least the same degree of care as it exercises to protect its own information and data of a similar nature. This obligation will expire ten (10) years after the termination or expiration of this Agreement.

- 22.2 Nothing contained herein will in any way restrict or impair the right of Licensee or The Regents to use, disclose or otherwise deal with any information or data which:
 - (a) at the time of disclosure to a receiving Party is available to the public or thereafter becomes available to the public by publication or otherwise through no act of the receiving Party;
 - (b) the receiving Party can show by written record was in its possession prior to the time of disclosure to it hereunder and was not acquired directly or indirectly from the disclosing Party;
 - (c) is independently made available to the receiving Party without restrictions by a third party;
 - (d) is independently developed by employees of the receiving Party who did not have access to the information disclosed by the disclosing Party; or
 - (e) is subject to disclosure under the California Public Records Act or other requirements of law.
- 22.3 The Regents will be free to release to its inventors, senior administrators employed by The Regents, and individual Regents, the terms and conditions of this Agreement upon their request. Licensee will be free to disclose the terms and conditions of this Agreement in connection with the filing of INDs and to *bona fide* potential or actual advisors, consultants, investors, acquirers, lenders, investment bankers or other potential financial partners in connection with Licensee's proposed financing or business combination activities. If any such release described in this Paragraph 22.3 is made, the applicable Party will inform the recipient(s) of the confidentiality obligations set forth above and will request that they do not disclose such terms and conditions to others.
- 22.4 Licensee and The Regents agree to destroy or return to the disclosing Party Confidential Information received from the other in its possession within fifteen (15) days following the effective date of termination of this Agreement. However, each Party may retain one copy of Confidential Information of the other solely for archival purposes in non-working files for the sole purpose of verifying the ownership of the Confidential Information, provided such Confidential Information will be subject to the confidentiality provisions set forth in this Article 22. Licensee and The Regents agree to provide each other, within thirty (30) days following termination of this Agreement, with a written notice that Confidential Information has been returned or destroyed.

23. PUBLICATION OF RESEARCH USE RESULTS AND ACKNOWLEDGEMENT

23.1 Licensee may publish or present Research Use Results, provided Licensee provides The Regents with a copy of any proposed manuscript, abstract, poster session or presentation at least thirty (30) days prior to such publication or presentation. The Regents shall review such publication or presentation for Confidential Information or patentable material and may request a delay of the proposed publication or presentation for up to an additional thirty (30) days to allow for the removal of Confidential Information or the

filing of patent application(s). Notwithstanding the foregoing, the Parties agree that no publication or presentation shall contain Confidential Information with respect to which it has confidentiality obligations pursuant to Article 22 (Confidentiality) of this Agreement without prior written consent of the Party whose Confidential Information is to be disclosed. Unless The Regents directs otherwise, any publication or presentation including press releases reporting the research carried out with the Material, Modifications or Data shall contain proper referencing in academic journal format or appropriate format, acknowledging UC Davis and The Regents as the source of the Material and/or Data.

23.2 Notwithstanding the above, if either Party determines that a clinical investigation utilizing the Material must or should be listed with the National Library of Medicine (ClinicalTrials.gov) or other databases to satisfy the requirements of the FDA Amendments Act of 2007 ("FDAAA") or guidelines promulgated by the International Committee of Medical Journal Editors ("ICMJE"), the Parties shall meet and/or confer to create and upload one or more mutually agreeable listing(s).

24. DISCLOSURE, INVENTORSHIP, AND INTELLECTUAL PROPERTY RIGHTS

- 24.1 Licensee shall promptly notify The Regents of any potentially patentable discoveries or inventions made through the use of the Material, whether or not made within the specified limits of the approved Research Use. Licensee shall promptly supply The Regents with a copy of the invention disclosure.
- 24.2 Inventorship shall be determined according to United States patent law.
- 24.3 Collaborative efforts of The Regents and Licensee may create inventorship rights under United States patent law as well as under the law of any applicable jurisdiction in which a Party or both Parties may elect to file patent application(s). Each Party shall own its undivided interest in joint inventions. The Parties shall cooperate in discussing and securing patent rights to protect potentially patentable inventions.

25. FORCE MAJEURE

- 25.1 Except for Licensee's obligation to make any payments to The Regents hereunder, and subject to Paragraph 25.2, below, the Parties will be excused from any performance required hereunder if such performance is rendered impossible or infeasible due to any catastrophe or other major event beyond their reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, the Parties' respective obligations hereunder will resume.
- 25.2 Either Party to this Agreement will have the right to terminate this Agreement upon thirty (30) days' prior written notice if either Party is unable to fulfill its obligations under this Agreement due to any of the causes specified in Paragraph 25.1 above for a period of one (1) year.

26. SEVERABILITY

26.1 The provisions of this Agreement are severable, and in the event that any provision of this Agreement is determined to be invalid or unenforceable under any controlling body of law, such invalidity or enforceability will not in any way affect the validity or enforceability of the remaining provisions hereof.

27. APPLICABLE LAW; VENUE; ATTORNEYS' FEES

27.1 THIS AGREEMENT WILL BE CONSTRUED, INTERPRETED, AND APPLIED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, excluding any choice of law rules that would direct the application of the laws of another jurisdiction. Any legal action brought by the Parties relating to this Agreement will be conducted in San Francisco, California. The prevailing Party in any legal action under this Agreement will be entitled to recover its reasonable attorneys' fees in addition to its costs and necessary disbursements.

28. SCOPE OF AGREEMENT

- 28.1 This Agreement incorporates the entire agreement between the Parties with respect to the subject matter hereof and supersedes all previous communications, representations or understandings, whether oral or written, between the Parties relating to the subject matter hereof. The MTA specified in the Recitals above, effective July 9, 2013, is hereby superseded. For the avoidance of doubt, the IND Data Transfer Agreement has expired as of October 1, 2013; however, the surviving provisions of the IND Data Transfer Agreement will continue to exist.
- This Agreement may be altered or modified only by written amendment duly executed by the Parties. 28.2

In witness whereof, the Parties have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

SAGE THERAPEUTICS, INC.

By:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

/s/ Kiran Reddy /s/ David R. McGee Name: Kiran Reddy Name: David R. McGee

Title: Chief Business Officer Title: Executive Director, UC Davis InnovationAccess

Date: October 21, 2013 Date: October 23, 2013

First Amendment to the Non-Exclusive License Agreement between The Regents of the University of California and Sage Therapeutics, Inc. for Allopregnanolone in the Treatment of Status Epilepticus and Post-Partum Depression

UC Agreement Control No. 2014-01-0261

(File No. [...***...])

This first amendment to the Non-Exclusive License Agreement (UC Agreement Control No. 2014-01-0261; File No. [...***...]) for "Allopregnanolone in the Treatment of Status Epilepticus and Post-Partum Depression" ("First Amendment") is effective on the 14th day of May, 2014 ("First Amendment Effective Date") between The Regents of the University of California ("The Regents"), a California corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200, acting through UC Davis InnovationAccess, with an address at 1850 Research Park Drive, Suite 100, Davis, California 95618-6153, and Sage Therapeutics, Inc. ("Licensee"), a Delaware corporation, having a principal place of business at 215 First Street, Cambridge, Massachusetts 02142. The Regents and Licensee will be referred to herein, on occasion, individually as "Party" or collectively as "Parties".

Recitals

Whereas, a Non-Exclusive License Agreement for "Allopregnanolone in the Treatment of Status Epilepticus and Post-Partum Depression" was entered into between The Regents and Licensee on October 23, 2013, having UC Agreement Control Number 2014-01-0261; File No. [...***...] ("Agreement"); and

Whereas, the Parties desire to amend the Agreement by adding treatment of essential tremor to Derived Products, Licensed Field of Use and milestone fees provisions of the Agreement.

The Parties agree as follows:

- 1. The title of the Agreement is deleted in its entirety and replaced with the following:
 - Non-Exclusive License Agreement between The Regents of the University of California and Sage Therapeutics, Inc. for Allopregnanolone in the Treatment of Essential Tremor, Status Epilepticus, and Post-Partum Depression
- 2. Paragraph 1.4 of Article 1 (Definitions) of the Agreement is deleted in its entirety and replaced with the following:
- 1.4 "Derived Product" means a product containing Allopregnanolone produced by or on behalf of Licensee for Sale or Sold as a drug for essential tremor, status epilepticus, and/or post-partum depression.
- 3. Paragraph 1.6 of Article 1 (Definitions) of the Agreement is deleted in its entirety and replaced with the following:
- 1.6 "Licensed Field of Use" means the (a) use of Data for Reference Use as defined below and (b) use of Material or Modifications for Research Use as defined below.
 - (i) "Reference Use" means use of Data by the Licensee, and by affiliates, contractors, consultants, agents and/or vendors on behalf of Licensee, for the sole purpose of reference or incorporation to the extent that such reference or incorporation identifies, labels it as an excerpt from Data and acknowledges UC Davis as the source of the Data in Licensee's IND application(s) with the FDA for use of Allopregnanolone for the treatment of essential tremor, status epilepticus, and/or post-partum depression. [...***...].
 - (ii) "Research Use" means use of Material or Modifications to develop a clinically relevant pharmaceutical formulation and use of such pharmaceutical formulation for FDA-approved human clinical trials for treatment of essential tremor, status epilepticus, and/or post-partum depression. Research Use includes transfer of Material by Licensee to a third party who uses such Material to create a Modification on behalf of Licensee.
- 4. Paragraph 5.7 of Article 5 (Royalties and Milestones) of the Agreement is deleted in its entirety and replaced with the following:
- 5.7 (a) Within [...***...] days after the [...***...], whichever occurs first, Licensee will pay to The Regents a one-time, non-refundable and non-creditable milestone fee of [...***...] dollars (\$[...***...]).

- (b) Within [...***...] days after the [...***...], whichever occurs second and for which a milestone fee was not paid under Paragraph 5.7(a), Licensee will pay to The Regents a one-time, non-refundable and non-creditable milestone fee of [...***...] dollars (\$[...***...]).
- (c) Within [...***...] days after the [...***...], whichever occurs third and for which a milestone fee was not paid under Paragraph 5.7(a) or Paragraph 5.7(b), Licensee will pay to The Regents a one-time, nonrefundable and non-creditable milestone fee of [...***...] dollars (\$[...***...]).
- (d) For clarity, the milestone fees in clauses (a), (b), and (c) above shall each be payable only once, [...***...].

This First Amendment does not in any way affect the unamended provisions of the Agreement.

In witness whereof, the Parties have executed this First Amendment in duplicate originals by their duly authorized officers or representatives.

SAGE THERAPEUTICS, INC.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By:	/s/ Kimi Iguchi	By:	/s/ David R. McGee
Name:	Kimi Iguchi	Name:	David R. McGee
Title:	CFO	Title:	Executive Director, UC Davis InnovationAccess
Date:	5/12/14	Date:	5/14/14

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement") is made this 13th day of December, 2012 (the "Effective Date") between:

CYDEX PHARMACEUTICALS, INC., a Delaware corporation with offices at 11119 North Torrey Pines Road, Suite 200, La Jolla, California 92037 ("CyDex"); and

SAGE THERAPEUTICS INC., a Delaware corporation with offices at 29 Newbury Street, Suite 301, Boston, Massachusetts 02116 ("Sage").

RECITALS

WHEREAS, CyDex and Sage are also parties to that certain Commercial License Agreement of even date herewith (the "Commercial License Agreement") and that certain License Agreement dated October 13, 2011 (the "License Agreement"); and

WHEREAS, CyDex desires to sell Captisol[®] to Sage or its Contract Manufacturers (defined below), and Sage desires to obtain supplies of Captisol[®] from CyDex, for use in the Licensed Product, 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 are acknowledged, the parties, intending to be legally bound, agree as follows:

1. Definitions.

For the purposes of this Agreement, defined terms shall have the meanings defined in the Commercial License Agreement or as defined elsewhere in this Agreement. For reference purposes, "Affiliate", "Captisol", "Claim", "Clinical Grade Captisol", "Commercial Grade Gra

2. Purchase and Supply of Captisol.

- 2.1 **Clinical Quantities**. Sage shall have, subject to the terms and conditions of this Agreement, the right to purchase Clinical Grade Captisol and/or Commercial Grade Captisol from CyDex, at the purchase prices specified in Exhibit A hereto, as may be increased pursuant to Section 4.1(a); such purchase prices are EXW (Incoterms 2010) CyDex's production point or storage facilities.
- 2.2 **Purchase Commitment**. Subject to the provisions of this Agreement and during the Term of this Agreement, Sage agrees that Sage and its Affiliates and Sublicensees and their Contract Manufacturers shall purchase 100% of their requirements for Captisol for use in the formulation of Licensed Product exclusively from CyDex. Sage shall not itself, and will not permit its Affiliates and Sublicensees to, make, sell, offer to sell or import bulk Captisol. This

Agreement and the Commercial License Agreement do not grant Sage, its Affiliates or Sublicensees or their Contract Manufacturers the right to manufacture (or have manufactured on their behalf) Captisol, without CyDex's prior written consent. Sage covenants and agrees that it and its Affiliates, Sublicensees and Contract Manufacturers shall not re-sell any Captisol purchased pursuant to this Agreement (except as incorporated into the Licensed Product in and for the Field), and shall not use any Captisol purchased pursuant to this Agreement except in connection with the Licensed Product in and for the Field. Before entering into an agreement with any Sublicensees or Contract Manufacturers, Sage shall advise such Sublicensee or Contract Manufacturer of the foregoing restrictions and shall obtain such Sublicensee's or Contract Manufacturer's written agreement to observe and be bound thereby. Sage shall be responsible and liable for any actions by its Affiliates, Sublicensees and Contract Manufacturers which would have violated this Section 2.2 if committed by Sage itself.

- 2.3 **Supply Commitment**. CyDex agrees that CyDex shall produce (or have produced for it) and sell to Sage and its Affiliates and Sublicensees and their Contract Manufacturers 100% of Sage's and its Affiliates' and Sublicensees' and their Contract Manufacturers' requirements for Captisol for use in the formulation of Licensed Product in and for the Field, during the Term and subject to the provisions of this Agreement; *provided* that, and notwithstanding anything to the contrary in this Agreement, in no event shall CyDex be obligated to supply to Sage or its Affiliates or Sublicensees or their Contract Manufacturers more than an aggregate quantity of [...***...] kilograms of Captisol per year pursuant to this Agreement.
- 2.4 **Third-Party Manufacturers**. Without limiting CyDex's responsibility under this Agreement, CyDex shall have the right at any time to satisfy its supply obligations to Sage hereunder either in whole or in part through arrangements with third parties engaged by CyDex to perform services or supply facilities or goods in connection with the manufacture or testing of Captisol (each, a "**Third-Party Manufacturer**"). CyDex shall give Sage no less than 12 month's prior written notice of any such arrangement. The parties hereby agree that The Hovione Group is a Third-Party Manufacturer as of the Effective Date of this Agreement.

3. Supply Terms.

3.1 **Orders**. During the Term and subject to the provisions of this Agreement, Sage may place orders in customary form (or, to the extent so required by Section 3.2(d), in Section 3.2(d) form) for Captisol on behalf of its Affiliates and Sublicensees; *provided*, *however*, that: (a) Sage shall instruct CyDex as to the location for the shipment thereof; (b) Sage shall guarantee payment to CyDex of all amounts payable with respect thereto; and (c) if Sage requests that CyDex deliver such orders to Sage for re-delivery thereof by Sage to its Affiliates or Sublicensees, Sage shall comply with all applicable laws, rules and regulations applicable to the transportation of Captisol from Sage to its Affiliates and Sublicensees.

3.2 Supply Terms.

(a) **Long-term Forecast**. No later than 12 months before the anticipated Commercial Launch Date, Sage shall provide CyDex with a good-faith forecast setting forth Sage's estimate of the required quantities of Commercial Grade Captisol for each of the following three years. Such long-term forecast shall thereafter be updated by Sage at least once every 12 months. Such long-term forecasts shall not be binding and shall be for planning purposes only.

(b) **Detailed Forecast**. At least 4 months before the first order of Commercial Grade Captisol, Sage shall deliver to CyDex a detailed good-faith rolling forecast setting forth Sage's requirements and anticipated delivery schedules for Commercial Grade Captisol for the 12 month period following such first order (the "**Initial Detailed Forecast**"). The Initial Detailed Forecast shall thereafter be updated by Sage quarterly (each a "**Detailed Forecast**"), no later than the first day of each calendar quarter, so that each quarter CyDex shall have been provided with a rolling Detailed Forecast for each quarter during the 12-month period commencing on the first day of the next calendar quarter following the date on which such Detailed Forecast is submitted. Before the third anniversary of the Commercial Launch Date, the first 6 months of each Detailed Forecast shall be firm and binding on both parties, subject to the permissible variances set forth in Section 3.2(c)(i) below, while the final 6 months of each Detailed Forecast shall not be binding and shall be for planning purposes only. After the third anniversary of the Commercial Launch Date, the entire Detailed Forecast shall be firm and binding on both parties, subject to the permissible variances set forth in Section 3.2(c)(ii) below. If Sage fails to provide any updated Detailed Forecast in accordance with this Section 3.2(b), the Detailed Forecast last provided by Sage shall be deemed to be resubmitted as Sage's binding Detailed Forecast for the next succeeding 12-month period, and with the same quantity and timing as had been forecasted (or deemed to be forecasted) for the fourth quarter of the prior Detailed Forecast being repeated as the forecasted quantity and timing for the new Detailed Forecast's fourth quarter.

(c) Detailed Forecast Variances.

- (i) Until the 3rd anniversary of the first Commercial Launch Date, each updated Detailed Forecast may modify the amount of Commercial Grade Captisol estimated in the previous Detailed Forecast and the corresponding delivery timing in accordance with the following limitations (the "Purchase Volume Limitations"):
- (1) for the first through third calendar months covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases per month from the prior Detailed Forecast may be made without the prior express written consent of CyDex;
- (2) for the fourth through sixth calendar months covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases per month from the prior Detailed Forecast may be made without the prior express written consent of CyDex;
- (3) for the third calendar quarter covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases from the prior Forecast may be made without the prior express written consent of CyDex; and

(4) for the fourth calendar quarter covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases from the prior Forecast may be made without the prior express written consent of CyDex.

- (ii) After the 3rd anniversary of the Commercial Launch Date, the Purchase Volume Limitations shall be deemed modified as follows:
- (1) for the first calendar quarter covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases per month from the prior Detailed Forecast may be made without the prior express written consent of CyDex;
- (2) for the second calendar quarter covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases from the prior Detailed Forecast may be made without the prior express written consent of CyDex;
- (3) for the third calendar quarter covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases from the prior Forecast may be made without the prior express written consent of CyDex; and
- (4) for the fourth calendar quarter covered by such updated Detailed Forecast, there shall be no change in excess of a percentage to be agreed upon at a later date such that volume increases or decreases from the prior Forecast may be made without the prior express written consent of CyDex.
- (d) **Purchase Orders**. Together with each Detailed Forecast provided under Section 3.2(b) above, Sage shall place a firm purchase order with CyDex in a form mutually agreed upon by the parties, for Sage's order of Commercial Grade Captisol for the first calendar quarter of the Detailed Forecast for delivery consistent with the Detailed Forecast. Detailed Forecasts deemed delivered pursuant to the last sentence of Section 3.2(b) shall also be deemed to be accompanied by corresponding firm purchase orders for the first calendar quarter. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (*i.e.*, Commercial Grade Captisol or Clinical Grade Captisol); (ii) quantities; (iii) delivery dates; and (iv) reasonable shipping instructions. CyDex shall comply with Sage's requested delivery dates if the firm purchase order date is at least 90 days before the stipulated delivery date and is made in accordance with the quantities set forth in the latest Detailed Forecast. Any such firm purchase order for Commercial Grade Captisol provided by Sage, to the extent such order is in the form mutually agreed upon by the parties and does not request more or less than the Purchase Volume Limitations, shall be deemed accepted by CyDex upon receipt by CyDex. With respect to any quantities ordered under such purchase order that exceed the Purchase Volume Limitations, CyDex shall not be obligated to accept such orders but nevertheless shall use good faith efforts to fill such orders for such excess quantities from available supplies. If CyDex, despite the use of good faith efforts, is unable to supply such quantities that exceed the Purchase Volume Limitations to Sage, such inability to supply shall not be deemed to be a breach of this

Agreement by CyDex or a failure by CyDex to supply for any purpose. CyDex shall use reasonable efforts to notify Sage as soon as possible, but no less than within 30 days, after its receipt of Sage's purchase order of its ability to fill any amounts of such order that are in excess of the Purchase Volume Limitations. If any purchase order or other document submitted by Sage hereunder or any other document passing between the parties contains terms or conditions in addition to or inconsistent with the terms of this Agreement, the terms of this Agreement shall control and prevail and the parties hereby agree that such additional or inconsistent terms shall simply be ignored and deemed not to exist, unless they are handwritten and expressly identified as being additional to or inconsistent with this Section 3.2(d) and are signed by officers of both parties next to the handwriting.

- 3.3 **Delivery**. Sage acknowledges the inherent risk that a batch of Captisol may be lost in production or shipment, and Sage shall use commercially reasonable efforts to maintain a sufficient inventory of Captisol in the event of late delivery by CyDex. Quantities actually delivered to Sage or Sage's designee pursuant to an accepted purchase order may vary from the quantities reflected in such purchase order by up to 10% and still be deemed to be in compliance with such purchase order; *provided*, *however*, that Sage shall only be invoiced and required to pay for the quantities of Captisol that Sage actually ordered and CyDex actually delivered to Sage or Sage's designee. CyDex shall use Commercially Reasonable Efforts to include, in the next shipment of Captisol to Sage, any quantities ordered pursuant to an accepted purchase order but not delivered.
- 3.4 **Modified Specifications**. CyDex shall have the right to change the Specifications from time to time during the Term; *provided* that any change to the Specifications that would require Sage to (i) conduct additional process validation or (ii) comply with additional clinical study requirements from the FDA or other major-market regulatory agencies that would be beyond that required for the Licensed Product formulated with Captisol meeting the unmodified Specifications, will require Sage's prior written consent. In the event that CyDex desires to change the Specifications, CyDex shall give Sage at least 3 months' notice. If CyDex desires to change the Specifications or a regulatory agency requires a change to the Specifications where such change is generally applicable to Captisol, CyDex shall reimburse Sage for any Captisol purchased hereunder which is rendered unusable in all major markets by such change in Specifications. CyDex shall use Commercially Reasonable Efforts to cooperate with Sage to, if necessary, have any change approved by the FDA and other regulatory agencies having jurisdiction. CvDex will continue to provide Captisol with the unmodified Specifications under the terms of this Agreement until such time that Sage has obtained any required approvals for the Specification change by the FDA and other applicable major-market regulatory agencies. In the event that the FDA or another applicable major-market regulatory agency having jurisdiction requires Sage to implement any changes to the Specifications, CyDex shall use all reasonable efforts to make such changes. CyDex shall promptly advise Sage as to any lead-time changes or other terms that may result from a change to the Specifications. Sage shall bear the costs CyDex actually incurred for materials already purchased expressly for Sage, its Affiliates or Sublicensees and rendered unusable by a change in Specifications requested by Sage and agreed to by CyDex. If a regulatory agency requires a change to the Specifications where such change is not generally applicable to Captisol but is specific to the Licensed Product, or if Sage requests a change to the Specifications which CvDex agrees to, then Sage shall be responsible for the documented, reasonable costs incurred to generate such unique, modified Specifications. In all other instances, CyDex shall bear all costs associated with any change to the Specifications.

3.5 Inability to Supply.

- (a) **Notice**. CyDex shall notify Sage if CyDex is unable to supply the quantity of (i) Commercial Grade Captisol ordered by Sage within the Purchase Volume Limitations set forth in Section 3.2(c) or (ii) Clinical Grade Captisol ordered by Sage as set forth in Section 2.1 above: (1) as soon as possible but no less than within 15 days after CyDex's receipt of a purchase order from Sage; or (2) immediately upon becoming aware of an event of *force majeure* or any other event including, but not limited to, CyDex's failure to pass any regulatory inspections or as a result of modified Specifications that would render CyDex unable to supply to Sage the quantity of Captisol that CyDex is required to supply hereunder.
- (b) **Allocation**. If CyDex is unable to supply to Sage the quantity of Captisol that CyDex is required to supply hereunder, CyDex (i) shall allocate its available Captisol among Sage and any other purchasers of Captisol with which CyDex then has an on-going contractual relationship, in proportion to the quantity of Captisol for which each of them has orders pending at such time and (ii) shall take all reasonable steps necessary to minimize supply delays. The supply allocation provided in this Section 3.5(b) and the alternate suppliers provisions of Section 3.5(c) shall be CyDex's sole obligation and Sage's sole and exclusive remedy for any supply shortage.
- (c) **Alternate Suppliers**. If CyDex fails to supply to Sage, or if CyDex will be unable to supply Sage with 80% (*i.e.*, maximum shortfall of 20%) of the quantity of Captisol properly forecasted and ordered by Sage (and provided such order was within the Purchase Volume Limitations) in accordance with this Agreement, for a period of three consecutive months or longer or if any such failure occurs three or more times during any twelve month period ("**Supply Interruption**") then CyDex shall immediately provide written notice to Sage of the Supply Interruption. In the event of a Supply Interruption:
- (i) *Additional Site*. CyDex shall negotiate with its Third-Party Manufacturer for such Third-Party Manufacturer to validate and qualify an additional site for the manufacture of Captisol as soon as practicable, but in any event within 90 days from the first day of the Supply Interruption.
- (ii) *Additional Manufacturer*. If an additional site pursuant to <u>Section 3.5(c)(i)</u> does not resolve the Supply Interruption, then CyDex shall use its good faith efforts to qualify one or more alternate suppliers for the manufacture of Captisol as soon as practicable, but in any event within 90 days from the first day of the Supply Interruption.
- (iii) *Alternate Supply*. In the event of a Supply Interruption, Sage shall be permitted to purchase Captisol from any Third-Party Manufacturer on the terms provided hereunder until CyDex provides reasonably acceptable assurances to Sage that the cause of the Supply Interruption has been resolved.

3.6 Control; Acceptance and Rejection.

- (a) **Quality Control**. CyDex shall conduct or have conducted quality control testing of Captisol before shipment in accordance with the Specifications and other CyDex-approved quality control testing procedures that shall be set forth in the Specifications (the "**Testing Methods**"). CyDex shall retain or have retained accurate and complete records pertaining to such testing as well as samples (equal to at least twice the amount required to perform the full suite of Testing Methods) from each lot of Captisol shipped to Sage, for at least through the expiration date of such Captisol plus six months or longer if required by law. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for each lot of Captisol therein.
- (b) **Acceptance Testing**. Sage shall have a period of 45 days from the date of receipt to test or cause to be tested Captisol supplied under this Agreement. Sage or its designee shall have the right to reject any shipment of Captisol that does not conform in all respects with the Specifications at the time of delivery when tested in accordance with the Testing Methods. All shipments of Captisol shall be deemed accepted by Sage unless CyDex receives written notice of rejection from Sage within such 45-day period, describing the reasons for the rejection in reasonable detail. Once a delivery of Captisol is accepted or deemed accepted hereunder, Sage shall have no recourse against CyDex in the event Captisol is subsequently deemed unsuitable for use for any reason, except as provided in Section 10 below and except for Captisol that is not fit for use after the acceptance has occurred due to a defect in the Captisol that could not be detected through the performance of the Testing Method.
- (c) **Confirmation**. After its receipt of a notice of rejection from Sage pursuant to Section 3.6(b) above, CyDex shall notify Sage as soon as reasonably practical whether it accepts Sage's basis for rejection and Sage 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**. Sage may not return or destroy any batch of Captisol until it receives written notification from CyDex that CyDex does not dispute that the batch fails to meet the Specifications. CyDex will indicate in its notice either that Sage 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, Sage 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, Sage shall promptly return the rejected batch of Captisol to CyDex. In each case, CyDex will reimburse Sage for the documented, reasonable costs associated with the destruction or return of the rejected Captisol.
- (e) **Refund or Replacement**. Sage shall not be required to pay any invoice with respect to any shipment of Captisol properly rejected pursuant to this <u>Section 3.6</u>. Notwithstanding the foregoing, Sage shall be obligated to pay in full for any rejected shipment of

Captisol that is not returned or destroyed in accordance with Section 3.6(d) above and that is subsequently determined to meet the Specifications in all material respects, irrespective of whether Sage has already paid CyDex for a replacement shipment. If Sage pays in full for a shipment of Captisol and subsequently properly rejects such shipment in accordance with this Section 3.6, Sage shall be entitled, upon confirmation that such shipment failed to meet the Specifications in all material respects, either, at Sage's option: (i) to a refund or credit equal to the purchase price paid with respect to such rejected shipment (including without limitation, taxes paid and shipping expenses); or (ii) to require CyDex to promptly replace and deliver to Sage an amount of Captisol that conforms to the requirements of this Agreement to replace such rejected shipment at no additional cost to Sage. Sage acknowledges and agrees that, except for the indemnification obligations set forth in Section 10 below, Sage's rights to a refund or credit for or to receive replacement of properly rejected shipments of Captisol hereunder shall be Sage's sole and exclusive remedy, and CyDex's sole obligation, with respect to non-conforming Captisol delivered hereunder.

- (f) **Exceptions**. Sage's rights of rejection, return, refund and replacement set forth in this Section 3.6 shall not apply to any Captisol that is non-conforming due to damage (i) caused by Sage, 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 after 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 Sage with respect thereto.
- (g) **Inspections**. Authorized representatives of Sage shall be permitted to inspect those portions of all CyDex and Third-Party Manufacturer facilities that are used to manufacture, prepare, process, store or conduct testing of Captisol on an annual basis (scheduled at least 90 days in advance) during the term of this Agreement. Such representatives shall comply with the applicable rules and regulations for workers at such facilities and shall enter into reasonable confidentiality and non-use agreements if so requested by CyDex. Such audits shall be conducted in a manner that is intended to minimize any disruption to the operations at such facilities. CyDex shall promptly address and correct any deficiencies from cGMP's identified in connection with such inspections.
 - 3.7 Incoterms Delivery. All Captisol shall be delivered EXW (Incoterms 2010) CyDex's production point or storage facilities.

4. Compensation.

4.1 Pricing.

(a) **Captisol Purchase Price Increases and Quanta**. CyDex reserves the right to increase such purchase prices set forth in <u>Exhibit A</u> on each January 1 during the Term, upon no less than 180 days' written notice to Sage, by a percentage equal to the aggregate percentage increase, if any, in the [... ***...], U.S. Department of Labor, for the 12-month period ending March 31 of the prior year (or any applicable successor index). Ordered quantities of Commercial Grade Captisol shall be specified in multiples of [...***...] kilograms, subject to a minimum order quantity of [...***...] kilograms.

- (b) **Shortfall Reimbursement (Take or Pay)**. If Sage fails to order for the first calendar quarter of any Detailed Forecast (a "Q1") a quantity of Commercial Grade Captisol to be delivered during such Q1 (or within 100 days after the firm purchase order is placed) that is equal to or greater than the quantity of Commercial Grade Captisol Sage is obligated to purchase pursuant to the applicable Detailed Forecast (the difference between the quantity of Commercial Grade Captisol Sage is obligated to purchase in Q1 pursuant to the applicable Detailed Forecast and the amount of Commercial Grade Captisol that Sage actually orders for delivery in Q1 (or within 60 days after the firm purchase order is placed), the "**Shortfall**"), then Sage shall pay CyDex 60% of the purchase price hereunder for the Shortfall amount and shall not be entitled to receive delivery of such Shortfall amount. This <u>Section 4.1(b)</u> is based on the time stated for delivery in the original order, as opposed to the time delivery is actually made.
- (c) **Compound Supplies**. For clarity, Sage or its Contract Manufacturers shall at their cost arrange for supplies of the Compound and for all other items and services needed in connection with the manufacture and commercial delivery of Licensed Products.
- 4.2 **Invoicing; Payment**. CyDex shall invoice Sage 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 Sage 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 Sage are not known at the time CyDex invoices Sage for the purchase price for the Captisol ordered by Sage, CyDex may invoice such costs at a later date.
- 4.3 **Payments**. All amounts due hereunder are stated in, and shall be paid in, U.S. dollars. Payment of CyDex's invoices shall be made within 30 days of Sage's receipt of such invoices except in the event of a good faith rejection of a shipment of Captisol in accordance with this Agreement, in which event payment shall be made promptly after such shipment is determined to comply with the requirements of this Agreement, if applicable. Unpaid balances shall accrue interest, from due date until paid, at a rate equal to the prime rate, as reported in *The Wall Street Journal*, Eastern U.S. Edition, on the date such payment is due (or the last previous publication date if such date is not a publication date), plus an additional 200 basis points. If any amount due hereunder or under the Commercial License Agreement and not subject to a reasonable, good-faith dispute by Sage remains outstanding for more than 45 days after its due date, CyDex may, in addition to any other rights or remedies it may have, refuse to ship Captisol hereunder except upon payment by Sage in advance.
- 4.4 **Taxes**. All amounts due hereunder exclude all applicable sales, use, and other taxes, and Sage will be responsible for payment of all such taxes (other than taxes based on CyDex's income), fees, duties, and charges, and any related penalties and interest, arising from the payment of amounts due under this Agreement. Sage shall make all payments to CyDex under this Agreement free and clear of, and without reduction for, any withholding taxes; any such taxes imposed on payments of amounts to CyDex hereunder will be Sage's sole responsibility. Sage shall indemnify and hold CyDex harmless from any and all such taxes and any actions brought against CyDex by any taxing authority with respect to such taxes. The parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax

withholding or similar obligations in respect of payments made by Sage to CyDex under this Agreement. To the extent Sage is required to withhold taxes on any payment to CyDex, Sage shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CyDex may reasonably request, to establish that such taxes have been paid. CyDex shall provide Sage any tax forms that may be reasonably necessary in order for Sage to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. CyDex shall use reasonable efforts to provide any such tax forms to Sage at least 30 days before the due date for any payment for which CyDex desires that Sage apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or value added tax.

5. Representations and Warranties.

- 5.1 **Limited Warranty**. CyDex warrants solely to Sage that all Captisol sold to Sage pursuant to this Agreement (a) shall conform to the respective Specifications (as applicable for Clinical Grade Captisol or Commercial Grade Captisol) in all respects at the time of delivery, (b) shall have been manufactured, stored, packaged and (to the extent CyDex is responsible for shipping) shipped in accordance with cGMP's and all other applicable laws and regulations, (c) shall be delivered with good and marketable title, free and clear of any liability, pledge, lien, restriction, claim, charge, security interest or other encumbrance and (d) shall have not less than 75% of the remaining shelf life on the date of delivery. CyDex's sole obligation, and Sage's sole and exclusive remedies, for any breach of such warranty, shall be (i) for a refund or credit equal to the purchase price paid with respect to such rejected shipment, or for CyDex to replace such rejected shipment at no additional cost to Sage; and (ii) indemnification pursuant to Section 6.1 (Indemnification by CyDex) hereof. The term "cGMP's" shall mean current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for, the manufacture, preparation, packing and holding of pharmaceutical excipients, all as set forth from time to time by the U.S. Pharmacopoeia General Chapter <1078> Good Manufacturing Practices For Bulk Excipients and International Pharmaceutical Excipients Council's IPEC/PQG GMP Guide For Pharmaceutical Excipients, and any successors thereto.
- 5.2 **Representations and Warranties**. The provisions of <u>Section 9.1</u> (Mutual Representations and Warranties) and <u>Section 9.2</u> (CyDex Representation) of the Commercial License Agreement are incorporated herein by reference as if fully set forth herein, with references therein to "this Agreement" being understood to refer to this Supply Agreement rather than to the Commercial License Agreement.
- 5.3 **Disclaimer**. The warranties set forth in this <u>Section 5</u> are provided in lieu of, and each party hereby disclaims, all other warranties, express and implied, relating to the subject matter of this Agreement or Captisol, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, title and non-infringement of third party rights.

6. CONFIDENTIALITY.

- 6.1 **Definition**. Sage 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 <u>Section 6</u>. Neither Sage 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 which is obviously Confidential Information, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally is declared to be confidential by the Disclosing Party and confirmed in a writing delivered to the Receiving Party within 30 days of such disclosure, including but not limited to product specifications, data, know-how, formulations, product concepts, sample materials, business and technical information, financial data, batch records, trade secrets, processes, techniques, algorithms, programs, designs, drawings, and any other information related to a party's present or future products, sales, suppliers, customers, employees, investors or business. Without limiting the generality of the foregoing, CyDex's Confidential Information includes all materials provided as part of the Captisol Data Package, and Sage's Confidential Information includes Sage Patents and Sage Know-How.
- 6.2 **Obligation**. CyDex and Sage agree that they will disclose Confidential Information received from the other to its (or its respective parent's) own officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Neither party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent, and any such disclosure to a Third Party shall be pursuant to the terms of a non-disclosure agreement no less restrictive than this Section 6. The party which disclosed Confidential Information of the other to any Third Party shall be responsible and liable for any disclosure or use by such Third Party (or its disclosees) which would have violated this Agreement if committed by the party itself. Neither party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Unless otherwise specified in this Agreement and subject to terms and conditions in this Agreement, if so requested by the other party a party shall promptly return all relevant records and materials in its possession or control containing or embodying the other party's Confidential Information (including all copies and extracts of documents); provided, however, that each party may retain one archival copy (and such electronic copies that exist as part of the party's computer systems, network storage systems and electronic backup systems) of such records and materials solely to be able to monitor its obligations that surviv

- 6.3 **Exceptions**. The use and non-disclosure obligations set forth in this <u>Section 6</u> shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by appropriate documentation:
 - (i) at the time of disclosure is in the public domain;
- (ii) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees:
 - (iii) is independently developed by Receiving Party personnel with no reference or access to the Confidential Information; or
- (iv) is made available to the Receiving Party by an independent third party without obligation of confidentiality; *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 Securities and Exchange Commission, or in the course of litigation; *provided* that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) 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.

- 6.4 **Injunction**. Each party agrees that should it breach or threaten to breach any provisions of this <u>Section 6</u>, 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 <u>Section 6</u>, the Disclosing Party shall be entitled to seek temporary, preliminary and/or permanent injunctive relief in addition to any other remedy which it may have, without need to post any bond or security, in addition to any and all other legal and equitable rights and remedies available to the Disclosing Party.
- 6.5 **Third Party Information**. The parties acknowledge that the defined term "Confidential Information" shall include not only a disclosing party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a disclosing party.

Sage acknowledges that CyDex's Confidential Information includes information developed by Pfizer that is confidential to both CyDex and Pfizer. In so far as Confidential Information of Pfizer is disclosed, Pfizer is a third-party beneficiary of this Section 6 of this Agreement and may enforce it or seek remedies pursuant to it in accordance with its terms.

Sage agrees not to disclose to CyDex any Confidential Information of a Third Party which is in the possession of Sage, unless CyDex has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information. If CyDex refuses to provide such consent, then any obligation of Sage to provide such information to CyDex under this Agreement shall be deemed waived by CyDex.

6.6 **Public Announcements**. The parties will mutually agree on a press release to be issued upon execution of this Agreement or reasonably soon thereafter. Neither party shall make any subsequent public announcement concerning this Agreement or the terms hereof not previously made public without the prior written approval of the other party with regard to the form, content, and precise timing of such announcement, except as may be required to be made by either party in order to comply with applicable Law, regulations, court orders, or tax, securities filings, financing arrangements, acquisitions, or sublicenses. Such consent shall not be unreasonably withheld or delayed by such other party. Before any such public announcement, the party wishing to make the announcement will submit a draft of the proposed announcement to the other party in sufficient time to enable such other party to consider and comment thereon.

7. Indemnification.

- 7.1 **By CyDex**. CyDex shall defend, indemnify and hold Sage and its Affiliates and Sublicensees, and each of their respective directors, officers, agents and employees, harmless from and against any and all losses, judgments, damages, liabilities, settlements, penalties, fines, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively "**Losses**") incurred by Sage as a result of any claim, demand, action or other proceeding (each, a "**Claim**") by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Captisol by CyDex and its Affiliates (including without limitation, the sale of Captisol by CyDex to Sage hereunder); (b) infringement of any person's intellectual property rights in Captisol *per se*; (c) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in <u>Sections 5.1</u> and <u>5.2</u> and (d) CyDex's negligence or misconduct.
- 7.2 **By Sage**. Sage shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers, agents and employees, harmless from and against any and all Losses incurred by CyDex as a result of any Claim by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of the Licensed Product by Sage, its Affiliates and Sublicensees; (b) any acts or omissions by Sage in connection with pre-clinical studies and clinical studies of actual or potential Licensed Products; (c) infringement of any person's intellectual property rights in connection with the subject matter of this Agreement (other than intellectual property rights in Captisol *per se*); (d) Sage's breach of this Agreement, including without limitation any of its representations and warranties set forth in Section 5.2 and (e) Sage's negligence or misconduct.
- 7.3 **Expenses**. As the parties intend complete indemnification, all costs and expenses of enforcing any provision of this <u>Section 7</u> shall also be reimbursed by the Indemnifying Party.

7.4 Procedure.

(a) The person intending to claim indemnification under this Section 7 (an "Indemnified Party") shall promptly notify the other party (the "Indemnifying Party") of any Claim in respect of which the Indemnified Party intends to claim such indemnification, and a reasonable explanation of the basis for the Claim and the amount of alleged Losses to the extent

of the facts then known by the Indemnified Party. (Notwithstanding the foregoing, no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency.) The Indemnifying Party shall assume the defense thereof whether or not such Claim is rightfully brought; *provided*, *however*, that if the Indemnifying Party assumes the defense, the Indemnified Party shall have the right to employ counsel separate from counsel employed by the Indemnifying Party in any such action and to participate in the defense thereof, but the fees and expenses of such counsel employed by the Indemnified Party shall be at the sole cost and expense of the Indemnified Party unless the Indemnifying Party consents to the retention of such counsel or unless the named parties to any action or proceeding include both the Indemnifying Party and the Indemnified Party and a representation of both the Indemnifying Party and the Indemnified Party by the same counsel would be inappropriate due to the actual or potential differing interests between them. And *provided further* that, if the Indemnifying Party shall fail to assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.

- (b) The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; *provided*, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (A) there is no finding or admission of any violation of law or any violation of the rights of any Person by an Indemnified Party, no requirement that the Indemnified Party admit fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (B) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.
- (c) Regardless of who controls the defense, the other party hereto shall reasonably cooperate in the defense as may be requested. Without limitation, the Indemnified Party, and its directors, officers, advisers, agents and employees, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

8. Limitation of Liability.

EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 7 ABOVE, EACH PARTY SPECIFICALLY DISCLAIMS 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 (PURSUANT TO OR IN CONNECTION WITH THE

RIGHTS GRANTED UNDER THIS AGREEMENT) OF THE LICENSED PATENTS AND CAPTISOL DATA PACKAGE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN SECTION 7 ABOVE, IN NO EVENT SHALL EITHER PARTY'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS SUPPLY 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 PURSUANT TO OR IN CONNECTION WITH THE RIGHTS GRANTED UNDER THIS AGREEMENT, EXCEED THE GREATER OF (I) \$250,000 AND (II) THE TOTAL AMOUNTS ACTUALLY PAID BY SAGE TO CYDEX UNDER THIS AGREEMENT AS OF THE DATE SUCH CLAIMS ARISE; PROVIDED, THAT THE FOREGOING LIMITATIONS SHALL NOT LIMIT CYDEX'S RIGHT TO TAKE ACTION TO ENFORCE THIS SUPPLY AGREEMENT TO COLLECT AMOUNTS THAT ARE PROPERLY DUE AND OWING UNDER ARTICLE 4 HEREOF. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN TWO YEARS AFTER SUCH PARTY HAS KNOWLEDGE OF THE LEGAL AND FACTUAL BASIS FOR SUCH CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER. FOR AVOIDANCE OF DOUBT, THE PARTIES' RESPECTIVE RIGHTS AND OBLIGATIONS WITH RESPECT TO ANY LIABILITY THAT MAY ACCRUE UNDER THE LICENSE AGREEMENT, ANY COMMERCIAL LICENSE AGREEMENT OR ANY SUPPLY AGREEMENT (OTHER THAN THIS AGREEMENT) OR IN CONNECTION WITH ACTIVITIES CONDUCTED PURSUANT TO OR CONTEMPLATED BY ANY SUCH AGREEMENTS SHALL BE DETERMINED PURSUANT TO THE TERMS OF THOSE AGREEMENTS AND NOT BY THE TERMS AND CONDITIONS SET FORTH IN THIS AGREEMENT.

9. Term and Termination.

9.1 **Term**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and shall continue in effect unless and until terminated as set forth herein.

9.2 Termination for Breach.

(a) **Notice**. If either party believes that the other is in material breach of this Agreement, then the party holding such belief (the "**Non-breaching Party**") may deliver notice of such breach to the other party (the "**Notified Party**"). The Notified Party shall have [...***...] days to cure such breach to the extent involving non-payment of amounts due hereunder, and [...***...] days to either cure such breach for all other material breaches, or, if cure of such breach other than nonpayment cannot reasonably be effected within such [...***...] day period, to deliver to the Non-breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing but in no event in excess of an additional [...***...] day period. Following delivery of such a plan, the Notified Party shall diligently carry out the plan and cure the breach and the cure period shall be extended by the time period provided in such plan but in no event to exceed [...***...] days from the date of any initial breach notice delivered under this Section 9.2.

- (b) <u>Failure to Cure</u>. If the Notified Party fails to cure a material breach of this Agreement as provided for in <u>Section 9.2</u>, then the Non-Breaching Party may terminate this Agreement upon written notice to the Notified Party.
- 9.3 **Termination with Commercial License Agreement**. This Agreement shall automatically terminate upon the termination, for whatever reason, of the Commercial License Agreement.
- 9.4 **Survival**. Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions before the termination of this Agreement shall survive the termination of this Agreement, including Sage's obligation to pay CyDex sums due in respect of Captisol shipped before termination of this Agreement. And, such termination shall not relieve either party from obligations that are expressly indicated to survive termination of this Agreement. Sections 2.2 (Purchase Commitment) (final two sentences only), 3.4 (Modified Specifications) (final two sentences only), 3.6 (Control; Acceptance and Rejection), 4.1(b) (Shortfall Reimbursement (Take or Pay)), 4.3 (Payments), 4.4 (Taxes), 5.3 (Disclaimer), 6 (Confidentiality), 7 (Indemnification), 8 (Limitation of Liability), 9.4 (Survival), and 10 (General Provisions) shall survive termination of this Agreement. [...***...].

10. General Provisions.

- 10.1 **Non-Solicitation**. During the Evaluation Period and for a period of one year thereafter, neither party shall solicit 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.
- 10.2 **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 have the right to, and each party agrees not to purport to, incur any debts or make any commitments or contracts for the other.
- 10.3 **Compliance with Law**. Each of the parties shall comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing product quality and safety and patent, copyright and trade secret protection.

10.4 Arbitration.

(a) **Procedure**. 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 Boston, Massachusetts. The arbitration shall be conducted by an arbitrator reasonably

knowledgeable about the pharmaceutical industry and acceptable to CyDex and Sage. If CyDex and Sage cannot agree on a single arbitrator within 30 days after a demand for arbitration has been made, CyDex shall appoint an arbitrator, Sage shall appoint an arbitrator, the two arbitrators shall appoint a third arbitrator, and the three arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within 45 days after service of the demand for arbitration, then the arbitrator appointed by the other party shall arbitrate any controversy in accordance with this Section 10.4(a). Except as to the selection of arbitrators, the arbitration proceedings shall be conducted promptly and in accordance with the rules of the American Arbitration Association then in effect. The expenses of any arbitration, including the reasonable attorney fees of the prevailing party, shall be borne by the party deemed to be at fault or on a pro-rata basis should the arbitration conclude in a finding of mutual fault.

- (b) **Confidentiality of Proceedings**. All arbitration proceedings hereunder shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each party's Confidential Information. Except as required by law, 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.
- (c) **Interim Equitable Relief**. Notwithstanding <u>Section 10.4(a)</u>, but subject to the limitations set forth in <u>Article 8</u>, each party shall not be precluded from seeking equitable relief (including but not limited to interim injunctive relief) in any court having jurisdiction to protect its interests.
- (d) **Binding Effect**. The provisions of this <u>Section 10.4</u> shall survive any 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.
- 10.5 **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.
- 10.6 **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 or 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 and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

10.7 **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 <u>Section 10.7</u>. Unless otherwise provided, all notices shall be sent:

If to CyDex, to:

CyDex Pharmaceuticals, Inc. 11119 North Torrey Pines Road, Suite 200 La Jolla, CA 92037 Attention: President Fax: (858) 550-7272

With a copy to:

General Counsel Ligand Pharmaceuticals Incorporated 11085 North Torrey Pines Road, Suite 200 La Jolla, CA 92037 Fax: (858)550-7272

If to Sage, to:

Sage Therapeutics, Inc. 29 Newbury Street, Suite 301 Boston, MA 02116 Attention: President Fax: (617) 859-2891

With a copy to:

Goodwin Procter LLP Exchange Place Boston, MA 02109 Attention: Christopher Denn

Fax: (617)523-1231

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.

- 10.8 **Use of Name; Publicity**. No party shall use the name, trademark, trade name or logo of the other party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other party, except as may be required by law or the rules of NASDAQ. The parties agree that a party may disclose this Agreement's existence and terms, and material developments or material information generated under this Agreement, in (i) securities filings with the Securities and Exchange Commission (or equivalent foreign agency) to the extent required by law, or (ii) under conditions of confidentiality/nonuse in connection with investment and similar corporate transactions. Notwithstanding the above, once a public announcement has been made, either party shall be free to disclose to third parties any 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 before 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.
- 10.9 **Governing Law**. This Agreement shall be governed by and construed in accordance with the internal laws of the State of California (without giving effect to any conflicts of law principles that require the application of the law of a different state).
- 10.10 **Entire Agreement; Amendment**. The Supply Agreement and all Exhibits attached hereto contain the entire agreement of the parties relating to the subject matter hereof and thereof and supersede any and all prior or contemporaneous agreements, written or oral, between CyDex (and/or any of its Affiliates) and Sage (and/or any of its Affiliates) relating to the subject matter hereof and thereof; *provided*, that any confidentiality/nonuse provisions of any prior agreement are not superseded and will remain in effect in addition to the confidentiality/nonuse provisions hereof. This Agreement cannot be amended except by way of an express writing signed by both parties.
- 10.11 **Binding Effect**. This Agreement shall be binding upon, and the rights and obligations hereof shall apply to, CyDex and Sage 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.
- 10.12 **Waiver**. The rights of either party under this Agreement may be exercised from time to time, singularly or in combination, and the exercise of one or more such rights shall not be deemed to be a waiver of any one or more of the others. No waiver of any breach of a term, provision or condition of this Agreement shall be deemed to have been made by either party unless such waiver is addressed in writing and signed by an authorized representative of that party. The failure of either party to insist upon the strict performance of any of the terms, provisions or conditions of this Agreement, or to exercise any option contained in this Agreement, shall not be construed as a waiver or relinquishment for the future of any such term, provision, condition or option or the waiver or relinquishment of any other term, provision, condition or option.
- 10.13 **Severability**. If any provision of this Agreement is determined by a final and binding court or arbitration judgment to be invalid, illegal or unenforceable to any extent, such provision shall not be not affected or impaired up to the limits of such invalidity, illegality or

unenforceability; the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any way; and the parties agree to negotiate in good faith to replace such invalid, illegal and unenforceable provision (or portion of provision) with a valid, legal and enforceable provision that achieves, to the greatest lawful extent under this Agreement, the economic, business and other purposes of such invalid, illegal or unenforceable provision (or portion of provision). This Agreement shall not be invalidated by any future determination that any or all of the Licensed Patents have expired or been invalidated.

- 10.14 **Assignment**. Sage may not 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 CyDex, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, Sage may assign its rights and delegate its obligations under this Agreement to an Affiliate or to a third party successor, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise, without CyDex's prior written consent. As a condition to any permitted assignment hereunder, the assignor must guarantee the performance of any assignee to the terms and obligations of this Agreement. Any assignment by Sage not in accordance with this Section 10.14 shall be void. CyDex has the right to 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 any requirement for consent of Sage; provided that CyDex also assigns all of its right, title and interest in all assets, including without limitation, intellectual property rights, pertaining to its Captisol business to the same third party contemporaneous with the assignment of this Agreement.
- 10.15 **Third Party Beneficiaries**. Except for the rights of Indemnified Parties pursuant to <u>Section 7</u> hereof, and subject to <u>Section 6.5</u> hereof, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective successors or permitted assigns and it is not the intention of the parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CyDex under this Agreement shall only be pursued by Sage or such Indemnified Party, and not Sublicensees.
- 10.16 **Remedies Cumulative**. Subject to the limitations set forth in <u>Article 8</u> and <u>Section 10.4</u>, any enumeration of a party's rights and remedies in this Agreement is not intended to be exclusive, and a party's rights and remedies are intended to be cumulative to the extent permitted by law and include any rights and remedies authorized in law or in equity.
- 10.17 **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.
- 10.18 **Interpretation**. The language used in this Agreement is the language chosen by the parties to express their mutual intent, and no provision of this Agreement will be interpreted for or against any party because that party or its attorney drafted the provision.
- 10.19 **Counterparts**. This Agreement may be executed in 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 Supply Agreement as of the Effective Date.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman

Name: Charles Berkman Title: VP and Secretary

SAGE THERAPEUTICS, INC.

By: /s/ Kiran Reddy

Name: Kiran Reddy Title: Chief Business Officer

EXHIBIT A: PURCHASE PRICES FOR CAPTISOL

[...***...]

AMENDMENT TO SUPPLY AGREEMENT

THIS AMENDMENT TO SUPPLY AGREEMENT (this "Amendment") is made this "21th day of August, 2013 (the "Amendment Effective Date") between CYDEX PHARMACEUTICALS, INC., a Delaware corporation ("CyDex") and SAGE THERAPEUTICS, INC., a Delaware corporation ("Sage").

- 1. This Amendment amends the Supply Agreement dated December 13, 2012 between CyDex and Sage (the "Agreement").
- 2. On page 1 of the Agreement, the first recital is hereby amended and replaced in its entirety with the following:

WHEREAS, CyDex and Sage are also parlies to that certain Commercial License Agreement of December 13, 2012 (the "Old Agreement") which the parties are terminating as of the Amendment Effective Date, that Commercial License Agreement of August 21, 2013 (the "Commercial License Agreement") and that certain License Agreement dated October 13, 2011 (the "License Agreement"); and.

3. Except as expressly set forth herein, the Agreement remains unchanged and in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Agreement to Supply Agreement as of the date first above written.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman
Name: Charles Berkman
Title: VP and Secretary

SAGE THERAPEUTICS, INC.

By: /s/ Kimi Iguchi
Name: Kimi Iguchi
Title: CFO

August 21, 2013

AMENDMENT NO. 2 TO SUPPLY AGREEMENT

THIS AMENDMENT No. 2 TO SUPPLY AGREEMENT (this "Amendment") is made this 30th day of April, 2014 (the "Amendment Effective Date") between:

CYDEX PHARMACEUTICALS, INC., a Delaware corporation ("CyDex"); and

SAGE THERAPEUTICS INC., a Delaware corporation ("**Sage**").

RECITALS

WHEREAS, CyDex and Sage entered into a Supply Agreement as of December 13, 2012, as amended on August 21, 2013, (the "Agreement");

WHEREAS, CyDex and Sage wish to amend the Agreement in accordance with Section 10.10 thereof;

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

- **1. DEFINITIONS.** All terms used, but not defined, in this Amendment shall have the meaning set forth in the Agreement.
- **2. PURCHASE VOLUME LIMITATIONS.** Section 3.2(c) of the Agreement is hereby amended to read as follows:
 - (c) Detailed Forecast Variances.
- (i) Until the [...***...] anniversary of the first Commercial Launch Date, each updated Detailed Forecast may modify the amount of Commercial Grade Captisol estimated in the previous Detailed Forecast and the corresponding delivery timing in accordance with the following limitations (the "Purchase Volume Limitations"):
- (1) for the first through third calendar months covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease per month from the prior Detailed Forecast may be made without the prior express written consent of CyDex; and
- (2) for the fourth through sixth calendar months covered by such updated Detailed Forecast, no change in excess of a [...***..]% volume increase or decrease per month from the prior Detailed Forecast may be made without the prior express written consent of CyDex.
- (3) for the third calendar quarter covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease from the prior Forecast may be made without the prior express written consent of CyDex; and

- (4) for the fourth calendar quarter covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease from the prior Forecast may be made without the prior express written consent of CyDex.
 - (ii) After the [...***...] anniversary of the Commercial Launch Date, the Purchase Volume Limitations shall be deemed modified as follows:
- (1) for the first calendar quarter covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease per month from the prior Detailed Forecast may be made without the prior express written consent of CyDex;
- (2) for the second calendar quarter covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease from the prior Detailed Forecast may be made without the prior express written consent of CyDex;
- (3) for the third calendar quarter covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease from the prior Forecast may be made without the prior express written consent of CyDex; and
- **(4)** for the fourth calendar quarter covered by such updated Detailed Forecast, no change in excess of a [...***...]% volume increase or decrease from the prior Forecast may be made without the prior express written consent of CyDex.

3. PRICING.

3.1 The first sentence of section 4.1(a) is hereby amended to read:

CyDex reserves the right to increase such purchase prices set forth in Exhibit A on each January 1 during the Term, upon no less than 180 days' written notice to Sage, by a percentage equal to the aggregate percentage increase, if any, in the [...***...] as reported by the Bureau of Labor Statistics, U.S. Department of Labor, for the 12-month period ending March 31 of the prior year (or any applicable successor index); provided, however, that [...***...].

3.2 Exhibit A of the Agreement is hereby amended to read:

[...***...]

Portion of Cumulative Amount of Commercial Grade Captisol Purchased by Sage	Price per kilogram
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]

[...***...]

4. NOTICES. Sage's address is hereby revised to read:

If to Sage, to: Sage Therapeutics, Inc. 215 First Street Cambridge, Massachusetts 02142

Attention: President Fax: (617) 299-8379

5. INTERPRETATION. The following sentence is added to the end of Section 10.18 of the Agreement:

Except as the context otherwise requires, (a) the word "including" or correlatives thereof, means "including without limitation," and (b) the word "or" means "and/or."

- **6. ENTIRE AGREEMENT/AMENDMENTS.** Except as amended by this Amendment, the Agreement shall remain in full force and effect. After the Amendment Effective Date, every reference in the Agreement to the "Agreement" shall mean the Agreement as amended by this Amendment.
- **7. Counterparts**. This Amendment may be executed in 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 Amendment No. 2 to Supply Agreement as of the Amendment Effective Date.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman
Name: Charles Berkman
Title: VP and Secretary

SAGE THERAPEUTICS, INC.

By: /s/ Jeffrey Jonas Name: Jeffrey Jonas

Title: CEO



April 15, 2014

Thomas D. Anderson 721 Willow Run Road P.O. Box 232 Gwynedd Valley, PA 19437

Re: Employment by Sage Therapeutics. Inc.

Dear Tom:

Sage Therapeutics, Inc. (the "Company") is pleased to confirm its offer to employ you as Chief Commercial Strategy Officer reporting to the Chief Executive Officer.

In this role, you will:

- · Serve as an executive leadership team member to help drive company strategy, including interfacing with SAGE's Board of Directors.
- Oversee commercial strategy, development of commercial models to facilitate portfolio prioritization, and oversee business development in conjunction with the global development lead.
- Key contributor to business development strategy and operations
- · Maximize the commercial value of the SAGE portfolio across all territories providing an adequate return to shareholders.
- Be expected to thrive in a fast-paced, dynamic and nimble environment of an emerging start-up company that depends on strong links and collaboration with SAGE colleagues, suppliers, business partners, academia and non-profit organizations.
- · Serve as commercial and business strategy leader for CNS/Neurology products at various stages of development.
- Create, develop and further refine the commercial strategies for long-term planning at a cross-functional level for product, consistent with the corporate and franchise objectives.
- Assist and support CEO with preparing the commercial business case(s) to investors, Board members, analysts, external parties as requested.



- Collaborate with the Head of Business Development in determining the value of products and the portfolio as it pertains to developing
 negotiation strategies with potential partners.
- Provide commercial leadership in determining the franchise products' strategy, positioning and co-positioning, pricing and reimbursement, market access, launch preparedness and sales and marketing execution planning globally.
- Provide commercial and business guidance in support of global clinical trials.
- Develop deep relationships with key stakeholders in the CNS/Neurology marketplace including KOL's, payers, patient advocacy groups, etc.
- Proactively identify issues that will impact programs and provide strategies to address them and communicate to the executive leadership and project teams.
- · Drive decision making in the cross-functional teams with respect to business strategy and commercial issues.
- With approvals, commission marketing research, pricing & reimbursement, sales sizing & deployment, etc. to provide new insights into clinical trial designs and for developing target markets.
- Create a commercial development and execution plan.
- Hire, develop, manage and retain top talent across Strategy, Commercial and Business Development.

Your effective date of hire as a regular, full-time employee (the "Start Date") will be May 5, 2014.

Your compensation for this position will be at the rate of \$300,000 per year, payable monthly in accordance with the Company's normal pay schedule. You will be eligible to participate each year in any annual bonus plan adopted by the Company, and the Company shall adopt and implement such a plan, if reasonable in light of financial, business and other circumstances as factors. All payments are subject to legally required tax withholdings.

Subject to the approval of the Board of Directors of the Company (the "Board"), in connection with the commencement of your employment, the Board will grant you an option to purchase 575,000 shares of the Company's common stock (the "Option"). The Option will be granted following the commencement of your employment. The exercise price of the Option will be at least equal to the fair market value of the Company's common stock on the date of grant, and the Board of Directors may elect to seek a third party valuation of such fair market value, which could delay the date that the Option is granted. The Option will be subject to the terms and conditions of the Company's then-current stock option plan and form of stock option agreement. These options will vest as follows: one quarter of the shares will vest on the first

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anniversary of the Start Date, and following that, 1/48th of the shares will vest on a monthly basis, in arrears. Vesting is contingent on your continued full-time employment with the Company.

To help you relocate from Pennsylvania to Massachusetts, you will be eligible for a relocation bonus not to exceed \$100,000. Typical costs associated with relocation include the moving of household goods, storage, temporary living and transportation to your final move destination. Corporate relocation can have personal tax implications. Please contact your tax advisor for more information related to the tax implications of your relocation. If you leave Sage within two (2) years of receiving reimbursement of these expenses, you are required to repay Sage for the total of such amounts within one week of your termination date, and any money owed may be deducted from your last paycheck and/or expense report.

You will perform your services from the Company's offices in Cambridge, MA. It is understood that you are an "at-will" employee. You are not being offered employment for a definite period of time, and either you or the Company may terminate the employment relationship at any time and for any reason, with or without cause or prior notice and without additional compensation to you.

Enclosed for your review is a "Non-Solicitation, Confidentiality and Assignment Agreement" (the "Agreement").

This offer of employment is conditioned on your willingness to sign and abide by the terms of the Agreement. You will be expected to sign the Agreement before you report for work.

In making this offer, the Company understands, and in accepting it you represent that you are not under any obligation to any former employer or any person or entity which would prevent, limit, or impair in any way the performance by you of your duties as an employee of the Company.

The Immigration Reform and Control Act requires employers to verify the employment eligibility and identity of new employees. You will be required to complete a Form I-9 which will be provided to you before the Start Date. Please bring the appropriate documents listed on that form with you when you report for work. We will not be able to employ you if you fail to comply with this requirement. Also, this offer is subject to satisfactory reference checks if necessary.

This letter agreement and the Agreement referenced above constitute the complete agreement between you and the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company, although your job duties, title, reporting relationship, compensation and benefits may change from time to time, at the Company's option.

Please indicate your acceptance of this offer by signing and returning the enclosed copy of this letter no later than April 18, 2014.



Very truly yours,

4/15/14 Date

Please indicate your acceptance of this offer by signing and returning the enclosed copy of this letter to Teresa Regan. We look forward to your joining the Company and are pleased that you will be working with us.

/s/ Jeff Jonas
Jeff Jonas
President & Chief Executive Officer
Sage Therapeutics, Inc.
Accepted and Agreed:
/s/ Thomas D. Anderson
Thomas D. Anderson

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