

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

AMENDMENT NO. 1  
TO  
**FORM S-1**  
**REGISTRATION STATEMENT**  
UNDER  
*THE SECURITIES ACT OF 1933*

**JAZZ PHARMACEUTICALS, 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)

**05-0563787**  
(I.R.S. Employer  
Identification Number)

**3180 Porter Drive  
Palo Alto, CA 94304  
(650) 496-3777**

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

**Samuel R. Saks, M.D.  
Chief Executive Officer  
3180 Porter Drive  
Palo Alto, CA 94304  
(650) 496-3777**

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

*Copies to:*

**Suzanne Sawochka Hooper, Esq.  
John M. Geschke, Esq.  
Cooley Godward Kronish LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306-2155  
(650) 843-5000**

**Carol A. Gamble, Esq.  
Philip J. Honerkamp, Esq.  
Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
(650) 496-3777**

**Bruce K. Dallas, Esq.  
Davis Polk & Wardwell  
1600 El Camino Real  
Menlo Park, CA 94025  
(650) 752-2000**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

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

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

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

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

**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 that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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## EXPLANATORY NOTE

This Pre-Effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-141164) of Jazz Pharmaceuticals, Inc. is being filed solely for the purpose of (a) amending “Part II—Item 16. Exhibits and Financial Statement Schedules” and “Part II—Exhibit Index” and (b) filing herewith Exhibits 10.30 through 10.53, the omitted portions of which have been filed separately with the Securities and Exchange Commission in connection with the request for confidential treatment of such omitted portions.

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the NASD filing fee and the NASDAQ Global Market filing fee.

	<b>Amount to be Paid</b>
SEC registration fee	\$ 5,296
NASD filing fee	17,750
NASDAQ Global Market initial listing fee	150,000
Blue sky qualification fees and expenses	15,000
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	20,000
Miscellaneous expenses	*
Total	\$ *

\* To be filed by amendment.

**Item 14. Indemnification of Directors and Officers.**

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties 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 such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses that such officer or director has actually and reasonably incurred. Our third amended and restated certificate of incorporation and our amended and restated bylaws, each of which will become effective upon the closing of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our third amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and officers that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of Jazz Pharmaceuticals or any of its affiliated enterprises, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to us or our stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise. Messrs. Clammer, Michelson and Momtazee are further insured by liability insurance that has been purchased by Kohlberg Kravis Roberts & Co. L.P. on their behalf for any excess liabilities that are not covered by our liability insurance. Mr. Colella is insured by liability insurance purchased on his behalf by, and indemnified pursuant to the governing agreements of, Versant Ventures for his service on our board of directors.

We plan to enter into an underwriting agreement that provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

## Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities sold by us since our inception through January 31, 2007.

- (1) Since our inception through January 31, 2007, we have granted options under our 2003 Stock Equity Incentive Plan, to purchase 18,810,045 shares of common stock to employees and directors, having exercise prices ranging from \$.10 to \$4.09 per share. Of these, options to purchase 463,924 shares of common stock have been exercised for aggregate consideration of \$52,536.02, at exercise prices ranging from \$.10 to \$1.36 per share. As of January 31, 2007, we have cancelled options to purchase 773,347 shares of common stock.
- (2) On March 20, 2003, we issued and sold an aggregate of 3,960,000 shares of common stock to two of our executive officers for aggregate consideration of \$9,108.
- (3) On March 31, 2003, we issued and sold 815,000 shares of common stock to one of our executive officers for aggregate consideration of \$1,874.50.
- (4) On April 18, 2003, we issued and sold 300,000 shares of common stock to one of our executive officers for aggregate consideration of \$1,500.
- (5) On April 23, 2003, we issued and sold 330,000 shares of common stock to one of our executive officers for aggregate consideration of \$3,300.
- (6) On April 30, 2003, we issued and sold an aggregate of 2,150,000 shares of Series A preferred stock to a total of six accredited investors for aggregate consideration of \$2,150,000.
- (7) On August 29, 2003, we issued and sold an aggregate of 5,000,000 shares of Series A preferred stock to a total of five accredited investors for aggregate consideration of \$5,000,000.
- (8) On October 30, 2003, we issued and sold 660,000 shares of common stock to one of our executive officers for aggregate consideration of \$66,000.
- (9) On January 9, 2004, we issued and sold an aggregate of 232,500 shares of common stock to one of our executive officers for aggregate consideration of \$23,250.
- (10) On January 14, 2004, we issued and sold an aggregate of 7,850,000 shares of Series A preferred stock to a total of five accredited investors for aggregate consideration of \$7,850,000.
- (11) On February 18, 2004, we issued and sold an aggregate of 17,307,128 shares of Series B preferred stock to a total of thirty-one accredited investors for aggregate consideration of \$23,599,999.74.
- (12) On February 18, 2004, we issued and sold an aggregate of 19,067,175 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of \$25,999,999.83.
- (13) On April 6, 2004, we issued and sold an aggregate of 293,341 shares of Series B preferred stock to a total of two accredited investors for aggregate consideration of \$399,999.79.
- (14) On September 24, 2004, we issued and sold an aggregate of 146,671 shares of common stock to one of our directors for aggregate consideration of \$200,000.58.
- (15) On June 20, 2005, we issued and sold an aggregate of 35,200,937 shares of Series B preferred stock to a total of thirty-four accredited investors for aggregate consideration of \$47,999,997.69.
- (16) On June 20, 2005, we issued and sold an aggregate of 38,134,351 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of \$52,000,001.02.
- (17) On June 24, 2005, in connection with the issuance of our senior secured notes in the aggregate principal amount of \$80,000,000, we issued and sold warrants to purchase an aggregate of 8,695,652 shares of Series BB preferred stock to a total of eight accredited investors. Pursuant to the terms of

the agreement governing the issuance of the senior secured notes and warrants, the aggregate consideration allocated to the warrants was \$5,360,000.00.

- (18) On January 26, 2006, we issued and sold an aggregate of 12,320,326 shares of Series B preferred stock to a total of thirty-two accredited investors for aggregate consideration of \$16,799,996.53.
- (19) On January 26, 2006, we issued and sold an aggregate of 13,347,023 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of \$18,200,000.56.
- (20) On December 14, 2006, we issued and sold an aggregate of 22,880,598 shares of Series B preferred stock to a total of thirty-two institutional and accredited investors for aggregate consideration of \$31,199,983.44.
- (21) On December 14, 2006, we issued and sold an aggregate of 24,787,326 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of \$33,799,997.74.

The offers, sales and issuances of the securities described in Item 15(1) were exempt from registration under the Securities Act under Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees or directors and received the securities under our 2003 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment or business relationships, to information about us.

The offers, sales, and issuances of the securities described in Items 15(2) through 15(21) were exempt from registration under the Securities Act under Section 4(2) of the Securities Act and Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

#### **Item 16. Exhibits and Financial Statement Schedules.**

*(a) Exhibits.*

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1†	Form of Underwriting Agreement.
2.1*	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.
3.1*	Second Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2†	Form of Third Amended and Restated Certificate of Incorporation of the Registrant to be effective upon the closing of this offering.
3.3*	Amended and Restated Bylaws of the Registrant, currently in effect.
3.4†	Form of Amended and Restated Bylaws of the Registrant to be effective upon the closing of this offering.
4.1	Reference is made to exhibits 3.1 through 3.4.
4.2†	Specimen Common Stock Certificate.
4.3+*	Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
4.4*	Senior Secured Note and Warrant Purchase Agreement, dated as of June 24, 2005, by and among the Registrant, Twist Merger Sub, Inc. and the Purchasers.

<u>Exhibit Number</u>	<u>Description of Document</u>
4.5*	Form of Senior Secured Note of the Registrant.
4.6*	Form of Series BB Preferred Stock Warrant of the Registrant.
5.1†	Opinion of Cooley Godward Kronish LLP.
10.1+*	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce Cozadd.
10.3+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel Saks.
10.4+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert Myers.
10.5+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew Fust.
10.6+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol Gamble.
10.7+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne Wissel.
10.8+*	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.
10.9+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce Cozadd.
10.10+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce Cozadd.
10.11+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.12+*	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.13+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel Saks.
10.14+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel Saks.
10.15+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel Saks.
10.16+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert Myers.
10.17+*	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert Myers.
10.18+*	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert Myers.
10.19+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew Fust.
10.20+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol Gamble.

<b>Exhibit Number</b>	<b>Description of Document</b>
10.21+†	2003 Equity Incentive Plan, as amended.
10.22+†	Form of Stock Option Agreement and Form of Option Grant Notice under the 2003 Equity Incentive Plan.
10.23+†	2007 Equity Incentive Plan.
10.24+†	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.
10.25+†	2007 Non-Employee Directors Stock Option Plan.
10.26+†	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.
10.27+†	2007 Employee Stock Purchase Plan.
10.28+†	Form of 2007 Employee Stock Purchase Plan Offering Document.
10.29+*	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.
10.30#	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.
10.31#	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32#	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.
10.33#	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34#	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35#	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36#	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.37#	Xyrem Supply Agreement, dated as of June 30, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.38#	Letter Amendment No. 1, dated as of November 9, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.39#	Amendment No. 2 to the Xyrem Supply Agreement, dated as of August 19, 2002, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.40#	Amendment No. 3 to the Xyrem Supply Agreement, dated as of March 21, 2005, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.41#	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.42#	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.



<u>Exhibit Number</u>	<u>Description of Document</u>
10.43#	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.44#	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.45	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.46#	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47#	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48#	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49#	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.
10.50#	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51#	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.52	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.53	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Independent Auditors.
23.3†	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see page II-10 to the Registration Statement on Form S-1 (File No. 333-141164) filed with the SEC on March 9, 2007).

\* Previously filed.

† To be filed by amendment.

+ Indicates management contract or compensatory plan.

# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(b) *Financial Statement Schedules.* The following financial statement schedule is included herewith:

**Schedule II**  
**Valuation and Qualifying Accounts**  
**(In thousands)**

	<u>Balance at beginning of period</u>	<u>Additions(3)</u>	<u>Additions charged to costs and expenses(4)</u>	<u>Deductions</u>	<u>Balance at end of period</u>
<b>For the year ended December 31, 2006</b>					
Allowance for doubtful accounts(1)	\$ 25	\$ —	\$ 28	\$ (3)	\$ 50
Allowance for sales discounts(1)	71	—	880	(857)	94
Allowance for chargebacks(1)	26	—	212	(233)	5
Allowance for customer rebates(1)	—	—	44	(26)	18
Allowance for wholesaler fees(1)	153	—	203	(325)	31
Allowance for government rebates(2)	88	—	229	(254)	63
<b>For the year ended December 31, 2005</b>					
Allowance for doubtful accounts(1)	\$ —	\$ 25	\$ 14	\$ (14)	\$ 25
Allowance for sales discounts(1)	—	62	381	(372)	71
Allowance for chargebacks(1)	—	25	57	(56)	26
Allowance for customer rebates(1)	—	—	—	—	—
Allowance for wholesaler fees(2)	—	134	64	(45)	153
Allowance for government rebates(2)	—	115	135	(162)	88
<b>For the year ended December 31, 2004</b>					
Allowance for doubtful accounts	\$ —	\$ —	\$ —	\$ —	\$ —
Allowance for sales discounts	—	—	—	—	—
Allowance for chargebacks	—	—	—	—	—
Allowance for customer rebates	—	—	—	—	—
Allowance for wholesaler fees	—	—	—	—	—
Allowance for government rebates	—	—	—	—	—

**Notes**

- (1) shown as a reduction of accounts receivable  
(2) included in accrued liabilities  
(3) amounts represent the liabilities assumed as a result of the acquisition of Orphan Medical, Inc. on June 24, 2005  
(4) all charges except doubtful accounts are reflected as a reduction of revenue

All other schedules are omitted because they are inapplicable or the requested information is shown in the consolidated financial statements of the registrant or related notes thereto.

**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes to 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.

Insofar as indemnification for liabilities arising under the Securities Act 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 and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) 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.
- (2) 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.



Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ SAMUEL R. SAKS, M.D. Samuel R. Saks, M.D.	Chief Executive Officer and Member of the Board of Directors ( <i>Principal Executive Officer</i> )	March 27, 2007
/s/ MATTHEW K. FUST Matthew K. Fust	Senior Vice President and Chief Financial Officer ( <i>Principal Accounting and Financial Officer</i> )	March 27, 2007
* Adam H. Clammer	Director	March 27, 2007
* Samuel D. Colella	Director	March 27, 2007
* Bruce C. Cozadd	Director	March 27, 2007
* Bryan C. Cressey	Director	March 27, 2007
* Michael W. Michelson	Director	March 27, 2007
* James C. Momtazee	Director	March 27, 2007
* Kenneth W. O'Keefe	Director	March 27, 2007
* Alan M. Sebulsky	Director	March 27, 2007
* James B. Tananbaum, M.D.	Director	March 27, 2007

\*By: /s/ MATTHEW K. FUST  
Matthew K. Fust  
*Attorney-in-Fact*

## EXHIBIT INDEX

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5.1†	Opinion of Cooley Godward Kronish LLP.
10.1+*	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce Cozadd.
10.3+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel Saks.
10.4+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert Myers.
10.5+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew Fust.
10.6+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol Gamble.
10.7+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne Wissel.
10.8+*	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.
10.9+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce Cozadd.
10.10+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce Cozadd.
10.11+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.12+*	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.

<u>Exhibit Number</u>	<u>Description of Document</u>
10.13+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel Saks.
10.14+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel Saks.
10.15+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel Saks.
10.16+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert Myers.
10.17+*	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert Myers.
10.18+*	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert Myers.
10.19+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew Fust.
10.20+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol Gamble.
10.21+†	2003 Equity Incentive Plan, as amended.
10.22+†	Form of Stock Option Agreement and Form of Option Grant Notice under the 2003 Equity Incentive Plan.
10.23+†	2007 Equity Incentive Plan.
10.24+†	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.
10.25+†	2007 Non-Employee Directors Stock Option Plan.
10.26+†	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.
10.27+†	2007 Employee Stock Purchase Plan.
10.28+†	Form of 2007 Employee Stock Purchase Plan Offering Document.
10.29+*	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.
10.30#	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.
10.31#	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32#	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.
10.33#	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34#	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35#	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36#	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.

<b>Exhibit Number</b>	<b>Description of Document</b>
10.37#	Xyrem Supply Agreement, dated as of June 30, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.38#	Letter Amendment No. 1, dated as of November 9, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.39#	Amendment No. 2 to the Xyrem Supply Agreement, dated as of August 19, 2002, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.40#	Amendment No. 3 to the Xyrem Supply Agreement, dated as of March 21, 2005, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.41#	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.42#	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.43#	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.44#	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.45	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.46#	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47#	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48#	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49#	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.
10.50#	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51#	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.52	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.53	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Independent Auditors.
23.3†	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see page II-10 to the Registration Statement on Form S-1 (File No. 333-141164) filed with the SEC on March 9, 2007).

\* Previously filed.

† To be filed by amendment.

+ Indicates management contract or compensatory plan.

# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.



[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

### ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (the "Agreement") is made as of this 4th day of October, 2004 by and between Glaxo Group Limited, a company incorporated under the laws of England and Wales with offices at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, UK ("GGL"), SmithKline Beecham Corporation, doing business as GlaxoSmithKline, a company incorporated under the laws of the Commonwealth of Pennsylvania with offices at One Franklin Plaza, 200 North 16<sup>th</sup> Street, Philadelphia, Pennsylvania 19101 U.S.A. ("SB") (GGL and SB are collectively referred to in this Agreement as "GSK"), and Jazz Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware with offices at 3180 Porter Drive, Palo Alto, California 94304, U.S. ("Jazz Pharmaceuticals"). GSK and Jazz Pharmaceuticals are referred to herein on occasion separately as a "Party" or together as the "Parties".

### RECITALS

WHEREAS, GSK owns intellectual property rights covering a type IIa sodium channel antagonist compound, designated by GSK [ \* ], and other related compounds (hereinafter defined together as the "Compounds");

WHEREAS, Jazz Pharmaceuticals desires to purchase, and GSK desires to sell, the rights to the Compounds and certain assets [ \* ] including the intellectual property rights covering the Compounds; and

WHEREAS, Jazz Pharmaceuticals desires to [ \* ] under the intellectual property rights covering the Compounds for [ \* ], as further provided herein.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### ARTICLE 1—DEFINITIONS; INTERPRETATION

1.1 Definitions. The following terms will have the following meanings in this Agreement:

- 1.1.1. "Additional Consideration Payment" has the meaning ascribed to it in Section 3.5.
- 1.1.2. "Additional Consideration Payment Statement" has the meaning ascribed to it in Section 4.2.
- 1.1.3. "Affiliate" of a Party means any corporation or other business entity which is directly or indirectly controlling, controlled by, or under common control with such Party for so long as such control exists. For purposes of this definition, "control" means the direct or indirect ownership of at least fifty percent (50%) of the

outstanding shares or voting interest in such corporation or other entity having the power to vote or direct the affairs of the entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a Party of at least fifty percent (50%), “control” will be deemed to exist at the maximum level of ownership allowed by such jurisdiction. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals, such as financial institutions, venture capital funds and private equity investors, will not be its “Affiliates” for purposes of this Agreement.

- 1.1.4. “Agreement” means this Asset Purchase Agreement, together with the Schedules hereto, and any instrument amending this Agreement as referred to in Section 12.7. The expressions “Article” and “Section” followed by a number mean and refer to the specified Article or Section of this Agreement.
- 1.1.5. “Asset Transfer Period” has the meaning ascribed to it in Section 2.4.
- 1.1.6. “Business Day” means any day other than Saturday or Sunday on which the New York Stock Exchange is open for business. If not designated as a “Business Day”, a “day” shall include Saturdays, Sundays and holidays.
- 1.1.7. “Closing Date” means the date provided for in Section 5.1.
- 1.1.8. “Combination Product” means a product that is a pharmaceutical preparation for human use incorporating two or more therapeutically active ingredients, including a Compound, as active ingredients. Notwithstanding the foregoing, additives and excipients, including, but not limited to, drug delivery vehicles and formulations, adjuvants, carriers, bulking, stabilizing and flavoring agents, taste-masking agents, surfactants, antimicrobial agents and antioxidants will not be deemed to be “therapeutically active ingredients,” and their presence will not be deemed to create a Combination Product under this Section 1.1.8.
- 1.1.9. “Compound(s)” means GSK’s type IIa sodium channel antagonist compound [ \* ], any compound covered by the Patents, and all derivatives, and salts of such Compounds to the extent covered by the Patents.
- 1.1.10. “Confidential Information” has the meaning ascribed to it in Section 11.1.
- 1.1.11. “Diligent Efforts” means the carrying out of obligations in a sustained manner consistent with the efforts a Party devotes to [ \* ], and [ \* ] resulting from [ \* ] efforts, with the objective of launching a Product. Diligent Efforts requires that: (i) the Party promptly [ \* ] for such [ \* ] who are [ \* ] an on-going basis, (ii) the Party [ \* ] objectives for carrying out such obligations, and (iii) the Party consistently [ \* ] designed to advance progress with respect to such objectives.
- 1.1.12. “Effective Date” means the date of this Agreement as set forth above, which shall be the same date as the Closing Date.

- 1.1.13. "EMEA" means the European Medicines Evaluation Agency (European Medicines Agency) and the Committee for Proprietary Medicinal Products (Committee for Medicinal Products for Human Use) or any successor agency thereof.
- 1.1.14. "Europe" or the "EU" means the countries comprising the European Union and includes any of the following twenty-five (25) countries that are members of the European Union as of the Effective Date, and any other countries that subsequently become part of the European Union as of the date such membership becomes effective, including, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia.
- 1.1.15. "FDA" means the U.S. Food and Drug Administration and any successor agency thereof.
- 1.1.16. "First Commercial Sale" of a Product means the first invoiced commercial sale by Jazz Pharmaceuticals, its Affiliates or sublicensees (excluding, however, sales made by one such entity to another such entity) to a Third Party for commercial purposes in a country after Marketing Approval to market such Product in such country has been granted by the governing health regulatory authority of such country.
- 1.1.17. "[ \* ]" has the meaning ascribed to it in Section 6.1.
- 1.1.18. "Gross Sales" has the meaning ascribed to it in Section 1.1.28.
- 1.1.19. "Gross Selling Price" means the gross price at which a product is sold to a Third Party before discounts, deductions, credits, taxes, and allowances.
- 1.1.20. "[ \* ]" means GSK's type IIa sodium channel antagonist compound with the chemical structure shown in Schedule 1.1.20.
- 1.1.21. "Know-How" means technical and other information that is not subject to published patent rights and that is not in the public domain, including, but not limited to, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, assays, research, procedures, designs for experiments and tests and results of experimentation and testing, including results of research and development, manufacturing processes specifically related to [ \* ], specifications and techniques, chemical, pharmacological, toxicological, clinical, analytical, and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries relating to the quantities of [ \* ] being transferred hereunder, and information contained in submissions to and information from regulatory authorities. Know-How includes documents containing Know-How. Except as set forth above with respect to manufacturing process specifically related to [ \* ], Know-How does not include GSK Know-How relating to manufacturing processes.

- 1.1.22. "Licensed GSK Patents" means those GSK patents set forth in Schedule 2.6, attached hereto and incorporated herein.
- 1.1.23. "Marketing Approval" means, in any country, all approvals, licenses, registrations or authorizations, (including, in Europe and Canada only, governmental pricing approvals and governmental formulary acceptance based on pricing approval (but excluding formulary acceptance of private parties)), of any federal regulatory agency, department, bureau or other governmental entity, necessary for the sale of the Product. Marketing Approval in a country shall be deemed to occur upon first receipt of notice from the FDA, EMEA or similar agency in such country that sale of a Product in such country has been approved, including governmental pricing approval and governmental formulary acceptance based on pricing approval in Europe and Canada. Marketing Approval in Europe shall include the approval of any Central Marketing Authorization that is filed through the centralized procedure for the EU and approved by the European Commission. If a Central Marketing Authorization is filed through the centralized procedure for the EU and approved by the European Commission, Marketing Approval for the EU shall be deemed to have occurred when pricing approval is received in at least one country in the EU. In the countries of Europe and in Canada, "Marketing Approval" shall not be deemed to occur until pricing or formulary approval is obtained. Marketing Approval shall be deemed to have occurred in such country where government approval of pricing has not been obtained if, at any time, Jazz Pharmaceuticals, its Affiliates or sublicensees makes the First Commercial Sale of Product in the country without obtaining pricing approval, with the date of MAA approval deemed to have occurred on the date of the First Commercial Sale of the Product in the country.
- 1.1.24. "Marketing Approval Application" or "MAA" shall mean a New Drug Application ("NDA") (as defined in 21 C.F.R. § 314.50 *et. seq.*), or a comparable filing for Marketing Approval in a country, in each case with respect to a Product in the Territory.
- 1.1.25. "Major Market Country" means any one of the [ \* ].
- 1.1.26. "Milestones" mean the events identified in Section 3.3.
- 1.1.27. "Milestone Payments" mean the payments to be made by Jazz Pharmaceuticals to GSK pursuant to Section 3.3.
- 1.1.28. "Net Sales" means the aggregate gross sales amount ("Gross Sales") invoiced for Product, as applicable, in the countries of the Territory on which Additional Consideration Payments are due hereunder, by Jazz Pharmaceuticals, its Affiliates and sublicensees, to Third Parties,
- (a) less the following deductions:
- (i) trade, quantity and cash discounts and rebates allowed and taken by Jazz Pharmaceuticals (and its Affiliates and sublicensees);

- (ii) any adjustments on account of price adjustments, billing errors, rejected goods, damaged goods and returns;
  - (iii) credits, charge-backs and prime vendor rebates, fees, reimbursements, and similar payments granted or given to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations or other customers; and
  - (iv) rebates or other price reductions provided, based on sales by Jazz Pharmaceuticals (and its Affiliates and sublicensees) of Product, as applicable, to any governmental or regulatory authority in respect of any state or federal Medicare, Medicaid or similar programs; and
- (b) less an amount equal to all freight, insurance and handling costs, import costs, duties, tariffs, taxes, excises and other governmental charges incurred and paid by Jazz Pharmaceuticals (and its Affiliates and sublicensees).

The foregoing deductions from Gross Sales will only be deducted once and only to the extent not otherwise deducted from Gross Sales. Net Sales shall not include any sales among Jazz Pharmaceuticals, its Affiliates and sublicensees.

- 1.1.29. "Patents" means all the GSK granted patents and pending applications covering the Compounds and the processes for making a Compound, or any formulation or use thereof in the Territory, including any patent term extensions, supplementary protection certificates, registrations, extensions, reissues, reexaminations or divisionals thereof, and including any granted patents arising from the pending applications, which are listed in attached Schedule 1.1.29.
- 1.1.30. "Phase I Clinical Trial" means clinical trials for the first introduction into humans of a Product, including small scale clinical studies conducted in normal volunteers and/or patients to obtain information on the Product's safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. 312.21(a).
- 1.1.31. "Phase II Clinical Trial" means a human clinical trial that is intended to initially evaluate the effectiveness of a Product in the targeted patient population for a particular indication or indications in human subjects with the disease or indication under study, as more fully defined in 21 C.F.R. 312.21(b).
- 1.1.32. "Phase III Clinical Trial" means a pivotal efficacy trial whose primary objective is to obtain a definitive evaluation of the therapeutic efficacy and safety of a Product in patients for the particular indication in question that is needed to evaluate the overall risk-benefit profile of a Product and to provide adequate basis for obtaining requisite Marketing Approval(s) and product labeling, as more fully defined in 21 C.F.R. (S) 312.21(c).

- 1.1.33. "Product" means any pharmaceutical product that includes a Compound as an active pharmaceutical ingredient. "Product" shall include Combination Products.
- 1.1.34. "Purchase Price" has the meaning ascribed to it in Section 3.1.
- 1.1.35. "Purchased Assets" means the following Assets to be acquired by Jazz Pharmaceuticals pursuant to this Agreement on the Closing Date:
- (a) the Patents and information and hard-copy (i.e., non-electronic) records used by GSK's Corporate Intellectual Property group in filing, prosecuting, reviving, maintaining, renewing, enforcing and defending the Patents, and file wrappers and hard-copy (i.e., non-electronic) correspondence with the patent office in all jurisdictions in which the Patents are pending or granted;
  - (b) data (including without limitation, all pharmacological, pre-clinical, clinical, analytical and quality control data), manufacturing data (including batch records and technical reports) for the quantities of [ \* ] being transferred hereunder, results and material correspondence, and other documents relating to the Purchased Assets, all of which are listed on Schedule 1.1.35, all in electronic form;
  - (c) quantities of [ \* ] set forth on Schedule 1.1.35(c), and, to the extent they exist, retained stability samples [ \* ] and tissue samples used in the toxicology work relating to [ \* ]; and
  - (d) any Know-How specifically relating to [ \* ] developed, acquired or licensed by GSK prior to the Closing Date, as set forth in Schedule 1.1.35.

The Purchased Assets do not include laboratory notebooks or other specific information pertaining to proof of invention or reduction to practice of [ \* ] or the inventions claimed in the Patents. Should Jazz Pharmaceuticals require access to such information for purposes of responding to a challenge to the validity or enforceability of the Patents, or in order to initiate or participate in an interference proceeding in the United States (or a similar proceeding elsewhere), or to assert the Patents affirmatively against Third Parties, then in each case GSK shall promptly make such information available at no charge upon the reasonable request of Jazz Pharmaceuticals.

- 1.1.36. "ROW" means all countries and territories of the world except the U.S. and Europe.
- 1.1.37. "Territory" means all countries and territories of the world.
- 1.1.38. "Third Party" means any Party other than GSK or Jazz Pharmaceuticals or each of their respective Affiliates.

1.1.39. "Time of Closing" means 10:00 A.M. (Pacific Daylight Time) on the Closing Date or such other time and date as the Parties will mutually agree in writing at which time the Parties are to deliver the closing documents described in Section 5.2.

1.1.40. "U.S." means the United States of America, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

1.1.41. "Valid Claim" means a claim of an issued, unexpired Patent which has not been revoked, held to be invalid or unenforceable by a final judgment of a court or other government agency of competent jurisdiction from which no appeal can be or is taken within the time allowed for appeal and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

1.2 Interpretation. In this Agreement, words importing the singular number only will include the plural and vice versa, words importing a specific gender will include the other genders and references to persons will include corporations and one or more persons, their heirs, executors, administrators or assigns as the case may be. In addition, the division of this Agreement into Sections and the insertion of headings are for convenience of reference only and will not affect the interpretation hereof.

## **ARTICLE 2—PATENT ASSIGNMENT; POST-CLOSING ASSISTANCE; LICENSE GRANT**

2.1 Assignment of Patents. On the Closing Date, and subject to the terms and conditions of this Agreement, GSK will sell, assign, convey, transfer and deliver to Jazz Pharmaceuticals, and Jazz Pharmaceuticals will purchase and accept from GSK, the entire ownership, right title and interest of GSK in and to the Purchased Assets. Within fifteen (15) Business Days of the Closing Date, GSK will authorize and request the Commissioner or Director of Patents and Trademarks of the United States to issue all U.S. patents that may issue in the future as a result of the Purchased Assets to Jazz Pharmaceuticals, its successors and assigns, in accordance with this Agreement.

2.2 Registration of Purchased Assets. GSK will cooperate with and reasonably assist Jazz Pharmaceuticals in relation to Jazz Pharmaceuticals' registration as the new owner of the Purchased Assets in the registers of the respective patent offices in the Territory. GSK will execute and deliver, or cause to be executed and delivered, at no cost to Jazz Pharmaceuticals, any and all documents reasonably requested by Jazz Pharmaceuticals that may be necessary, in accordance with the rules and regulations of the various patent offices worldwide, to transfer to Jazz Pharmaceuticals, its successors or other legal representative, GSK's right, title and interest in and to the Purchased Assets and to register the transfer at the Patent and Trademark Office of the United States and patent offices in all other territories where patent rights have been granted or are pending. If Jazz Pharmaceuticals elects to record this Agreement or any other documents with the appropriate United States or foreign governmental authorities or registries, Jazz Pharmaceuticals will bear the costs and fees associated with recording, but GSK will provide timely cooperation to Jazz Pharmaceuticals as reasonably requested at no cost to Jazz Pharmaceuticals.

2.3 Post-Closing Assistance. Upon the reasonable request of Jazz Pharmaceuticals, GSK will provide reasonable support to Jazz Pharmaceuticals, at no cost to Jazz Pharmaceuticals, to

assist Jazz Pharmaceuticals with the transfer and registration of the Purchased Assets and to respond to official actions relating to the Purchased Assets. GSK's obligation to reasonably assist Jazz Pharmaceuticals as provided for under this Section 2.3 will terminate six (6) months after the Effective Date. Thereafter, if Jazz Pharmaceuticals requires the assistance of GSK, Jazz Pharmaceuticals shall reimburse GSK for the reasonable cost of any assistance provided, including direct costs for the time of internal GSK employees.

2.4 Transfer of Compound and Other Purchased Assets. Within ninety (90) days after the Closing Date (the "Asset Transfer Period") (which period may be extended by the mutual agreement of the Parties), GSK will transfer to Jazz Pharmaceuticals, at no additional cost to Jazz Pharmaceuticals, the quantities of [ \* ] and other Compounds identified in Schedule 1.1.35(c). Jazz Pharmaceuticals acknowledges that GSK and its Affiliates [ \* ] as permitted by this Agreement, certain [ \* ] in its [ \* ], pursuant to [ \* ] under Section 6.1.

2.5 Acknowledgement of Jazz Pharmaceuticals Regarding Purchased Assets. Jazz Pharmaceuticals acknowledges that GSK has not [ \* ], and that, as a result, the [ \* ] contained in the [ \* ] may be [ \* ]. Jazz Pharmaceuticals acknowledges that it is purchasing the Purchased Assets with this knowledge and with the understanding that successful development of [ \* ] or the other Compounds will require significant efforts and expense of Jazz Pharmaceuticals. In addition, Jazz Pharmaceuticals acknowledges that the quantities of [ \* ] and other Compounds identified in Schedule 1.1.35(c) transferred to Jazz Pharmaceuticals may not be suitable in their current condition for use in human clinical trials, and that Jazz Pharmaceuticals may need to conduct additional testing, without the assistance of GSK, on such quantities prior to any use in human clinical trials.

2.6 Non-Exclusive License Grant. Subject to the terms and conditions of this Agreement, effective as of the Closing Date, GSK grants Jazz Pharmaceuticals a worldwide, perpetual, royalty-free, non-exclusive license under the Licensed GSK Patents solely for the purpose of exploiting the rights granted under the Patents and developing and commercializing a Product; provided, however, that, pursuant to Sections 3.3 and 3.5, Jazz Pharmaceuticals shall be obligated to pay milestones and Additional Consideration Payments on Net Sales of Products for the indications covered by the Licensed GSK Patents. Such license granted hereunder shall be sublicensable by Jazz Pharmaceuticals in connection with activities relating to the development and commercialization of Products and Compounds. Additionally, should Jazz Pharmaceuticals require a license under any GSK patent relating to the composition of matter or method of manufacturing sodium channel antagonist compounds or other GSK patents that would block Jazz Pharmaceuticals from making and selling the Compounds as described in the Patents, GSK shall grant Jazz Pharmaceuticals a non-exclusive, royalty-free license under such GSK patents, to the extent GSK has the right to grant such license at the time of Jazz Pharmaceutical's request.

### **ARTICLE 3—PURCHASE PRICE; MILESTONE PAYMENTS AND ADDITIONAL CONSIDERATION**

3.1 Purchase Price. In consideration of GSK's assignment and transfer of the Purchased Assets to Jazz Pharmaceuticals pursuant to Section 2.1, Jazz Pharmaceuticals will pay a total of Two Million U.S. Dollars (U.S. \$2,000,000) (the "Purchase Price") on the Closing Date as follows: One Million U.S. Dollars (U.S. \$1,000,000) to GGL, and One Million U.S. Dollars (U.S. \$1,000,000) to SB. Of the Purchase Price, \$50,000 is paid in consideration of the transfer to



Jazz Pharmaceuticals of the quantities of [ \* ] and other Compounds identified in Schedule 1.1.35(c), which Jazz Pharmaceuticals, may use for research and development, including clinical activities.

3.2 Manner of Payment of Purchase Price. On the Closing Date, Jazz Pharmaceuticals will pay the Purchase Price to GGL and SB as set forth in Section 3.1 by electronic wire transfer into accounts that have been designated by GGL and SB in writing at least two (2) Business Days prior to the Closing Date.

3.3 Milestone Payments. As further consideration for the assignment and transfer of the Purchased Assets pursuant to Section 2.1, Jazz Pharmaceuticals shall pay GGL and SB the following non-refundable, non-creditable, irrevocable amounts (each, a "Milestone Payment") within ten (10) days after the first achievement by or on behalf of Jazz Pharmaceuticals, its Affiliates or sublicensees of the corresponding events set forth below (each, a "Milestone") for the first Product to reach such Milestone, regardless whether the development, promotion, or marketing of such Product is discontinued at any time after the achievement of such Milestone:

<u>PRE-COMMERCIAL MILESTONES</u>	<u>MILESTONE PAYMENT</u>
1. First patient enrolled in the first Phase I Clinical Trial for a Product anywhere in the Territory, for the first Product to reach this Milestone	(a) U.S. \$1,500,000 to GGL, and (b) U.S. \$1,500,000 to SB
2. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
3. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
4. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
5. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
6. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
7. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
<u>COMMERCIAL MILESTONES</u>	<u>MILESTONE PAYMENT</u>
1. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
2. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]

COMMERCIAL MILESTONES	MILESTONE PAYMENT
3. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
4. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
5. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]
6. [ * ]	(a) U.S. \$[ * ] and (b) \$[ * ]
7. [ * ]	(a) U.S. \$[ * ] and (b) U.S. \$[ * ]

### 3.4 Notes on Milestone Payments.

(a) Each Milestone Payment shall be made only once regardless of how many times such Milestones are achieved for each Product, except for Pre-Commercial Milestone number 5 and Commercial Milestone number 2 above which may be paid more than once (but only once for each [ \* ]). No payment shall be owed for a Milestone which is not reached (except that, upon achievement of a Milestone for a particular Product, any previous Milestone for that Product for which payment would have been due hereunder but was not yet made shall be deemed achieved and payment therefore shall be made), if such a payment was due under the terms hereof.

(b) In the event that more than one Milestone is achieved with respect to the same Product at one time, then all applicable payments under Section 3.3 shall be made.

(c) For purposes of Milestone payments, an “indication” means [ \* ].

(d) For purposes of [ \* ] in the event federal governmental pricing approval is required to commercialize the Product in the U.S., then the Milestone Payment for [ \* ] shall not become due until the earlier of (i) [ \* ] or (ii) [ \* ] of Marketing Approval.

3.5 Additional Consideration Payments. As further consideration for the assignment and transfer of the Purchased Assets pursuant to Section 2.1, Jazz Pharmaceuticals will pay GGL and SB the following percentage (each an “Additional Consideration Payment”) on Net Sales of Product in the Territory in each calendar year:

(a) with respect to Net Sales of Product (other than Combination Products) in countries of the Territory as to which payments are due, in each calendar year:

(i) [ \* ] percent ([ \* ]%) of annual Net Sales of Product up to and including [ \* ] U.S. Dollars (U.S. \$[ \* ]) in such calendar year; and

(ii) [ \* ] percent ([ \* ]%) of annual Net Sales of Product in excess of [ \* ] U.S. Dollars (U.S. \$[ \* ]) in such calendar year.

(b) After calculating the total Additional Consideration Payments due under Section 3.5(a) for all Net Sales in the Territory, Jazz Pharmaceuticals shall determine the

amount of Net Sales in the U.S. and shall pay SB [ \* ] percent ([ \* ]%) or [ \* ] percent ([ \* ]%) of such Net Sales in the U.S., as appropriate, at the Additional Consideration Payment level required by Section 3.5(a). After calculating the total Additional Consideration Payments due under Section 3.5(a) for all Net Sales in the Territory, Jazz Pharmaceuticals shall determine the amount of Net Sales in Europe and the ROW and shall pay GGL [ \* ] percent ([ \* ]%) or [ \* ] percent ([ \* ]%) of such Net Sales in Europe and the ROW, as appropriate, at the Additional Consideration Payment level required by Section 3.5(a). In no event will any calculations under this paragraph result in a larger payment by Jazz Pharmaceuticals than would have been made had the entire payment been made to one entity. Jazz Pharmaceuticals will use its Diligent Efforts to divide the Additional Consideration Payments as described above. If GSK believes that the division of the payment was not done correctly, GSK will, itself, reapportion the payments between the GSK entities and will not have any recourse to Jazz Pharmaceuticals or request any audits as to the allocation between the GSK entities, and Jazz Pharmaceuticals will have no liability to GSK with respect to any division of the payments as described above.

(c) With respect to Net Sales of Combination Products in the Territory in each reporting period in each country:

(i) if and to the extent all therapeutically active agents comprising the Combination Product are marketed and sold separately in such country in commercially relevant quantities in such Payment Period (as defined in Section 4.1) and the Gross Selling Price for each agent can be separately determined for such Payment Period, Net Sales of each Combination Product for determining the Additional Consideration Payment payable with respect to such Combination Product for such country shall be calculated by multiplying the Net Sales of the Combination Product by A divided by the sum of A plus B ( $A/(A+B)$ ), in which A is the Gross Selling Price of the single therapeutically active agent Product contained in the Combination Product sold in such country during such Payment Period and B is the Gross Selling Price of the other single therapeutically active agent(s) contained in the Combination Product sold in such country during such Payment Period. All Gross Selling Prices of the therapeutically active ingredients in the Combination Product shall be calculated as the average Gross Selling Price of the therapeutically active ingredients in such Combination Products during the applicable Payment Period for which the Net Sales are being calculated.

(ii) In the event that (a) separate sales, in commercially relevant quantities, in a particular country of the other therapeutically active agent (not the Product) comprising a single compound as a therapeutically active ingredient are made during the Payment Period in which the sale was made or if the Gross Selling Price for such other therapeutically active agent (not the Product) can be determined for a Payment Period, but (b) there are no such separate sales of the Product as the sole therapeutically active agent or such separate sales of the Product cannot be determined for such Payment Period, then the Net Sales of the Combination Product in such country for determining the Additional Consideration Payment payable with respect to such Combination Product for such country for such period shall be calculated by multiplying Net Sales of such Combination Product in such country by the number one (1) minus the result of

dividing X over Y (1—(X/Y)), in which X is the Gross Selling Price of the therapeutically active ingredient that is not a Product sold separately in commercially reasonable quantities during the Payment Period in question and Y is the Gross Selling Price of the Combination Product sold in the Payment Period in question in such country.

(iii) If neither of the single therapeutically active agent components of the Combination Product is sold separately in commercially relevant quantities in a country during a particular Payment Period, then the Additional Consideration Payment payable on such Combination Product in such country for such period will be [ \* ] percent ([ \* ]%) of the Additional Consideration Payment that would be due on a Product that is not a Combination Product.

(d) Any Additional Consideration Payment due on Combination Products shall be paid to SB for Net Sales of Combination Products in the U.S. and to GGL for Net Sales of Combination Products in the ROW. After determining the total Additional Consideration Payments due on Combination Products in accordance with Section 3.5(c) above, Jazz Pharmaceuticals shall determine the Additional Consideration Payments due on Net Sales in the U.S. and in ROW, respectively, and shall pay such amounts to SB and GGL, respectively.

3.6 Starting Date of Additional Consideration Payment Obligations. The obligation of Jazz Pharmaceuticals to pay Additional Consideration Payments to GGL and SB at the rates specified in Section 3.5 will become effective on a country by country basis on the date of the First Commercial Sale of a Product in such country.

3.7 Termination of Additional Consideration Payment Obligations. Additional Consideration Payments will be payable on Net Sales of Products in the U.S. until the expiration of the [ \* ]. Additional Consideration Payments will be payable on Net Sales of Products in all countries of Europe until the expiration of the [ \* ]. Additional Consideration Payments will be payable on Net Sales of Products in all countries in the ROW until the expiration of the [ \* ]. Additional Consideration on Net Sales of Products [ \* ] is being paid in this manner as an administrative convenience to the Parties as a result of the difficulty in allocating value for each of the Patents [ \* ].

3.8 Transfer and Other Taxes. Jazz Pharmaceuticals will be responsible for and will pay all foreign, federal, state and local taxes payable in connection with the acquisition and transfer of the Purchased Assets to Jazz Pharmaceuticals by GSK. GSK will be responsible for and will pay all foreign, federal, state and local taxes payable on any income or gain resulting from the sale of the Purchased Assets to Jazz Pharmaceuticals. Notwithstanding the foregoing, Jazz Pharmaceuticals shall not be required to pay (i) any VAT in connection with the transfer of the Purchased Assets, or (ii) any tax as a result of the separate payment to SB pursuant to Sections 3.3 or 3.5 that it would not have been required to pay if making only one payment to GGL. In the event that Jazz Pharmaceuticals is required to withhold and remit any tax to the revenue authorities in any country in the Territory regarding the Purchase Price, any Milestone payment or any Additional Consideration Payments payable to GGL or SB due to the laws of such country, such amount shall be withheld by Jazz Pharmaceuticals, and Jazz Pharmaceuticals shall notify GSK and promptly furnish GSK with copies of any documentation evidencing such withholding.

## **ARTICLE 4—MANNER OF PAYMENTS; REPORTS; DILIGENCE**

### **4.1 Manner of Additional Consideration Payments.**

- (a) Jazz Pharmaceuticals will deliver to GSK within sixty (60) days following the end of each “Payment Period”, meaning a calendar quarter ending on March 31<sup>st</sup>, June 30<sup>th</sup>, September 30<sup>th</sup> or December 31<sup>st</sup>, the Additional Consideration Payment Statements (as defined in Section 4.2), along with Jazz Pharmaceuticals’ payments to GGL and SB of any Additional Consideration Payment due and payable to GGL and SB for such Payment Period.
- (b) Each Additional Consideration Payment will be computed and paid in U.S. Dollars. Monetary conversion calculations from the currency of a foreign country in which a Product is sold into U.S. Dollars will be made on a quarterly basis on the last day of each applicable calendar quarter using the exchange rate reported on the last Business Day of such calendar quarter in the Wall Street Journal, eastern edition.
- (c) Whenever any Additional Consideration Payment is due on a day that is not a Business Day, such payment will be made on the immediately succeeding Business Day.
- (d) In the event that any payment due hereunder is not made when due, the payment shall accrue interest from that date due at the rate of [ \* ] percent ([ \* ]%) per month, or the maximum rate allowed by law, whichever is less, and shall be calculated based on the number of days that the payment is delinquent. The payment of such interest shall not limit GSK from exercising any other rights it may have as a consequence of the lateness of any payment.

### **4.2 Additional Consideration Payment Statements.** Each Additional Consideration Payment required hereunder will be accompanied by a report (“Additional Consideration Payment Statement”) for the preceding Payment Period containing the following information:

- (a) itemized accounting of the total Net Sales for Product during the applicable Payment Period in each country of sale in sufficient detail to permit confirmation of the accuracy of the Additional Consideration Payment;
- (b) adjustments and calculation of Net Sales for the applicable Payment Period in each country of sale; and
- (c) total Net Sales in U.S. dollars, together with the exchange rates used for conversion.

If no payment is due to GGL or SB for any Payment Period, the Additional Consideration Payment Statement will so state. All Additional Consideration Payment Statements will be considered Jazz Pharmaceuticals’ Confidential Information under this Agreement, but GSK may disclose such Confidential Information in accordance with Section 11.2 or Section 11.3.

### **4.3 Additional Consideration Payment Post-Termination Report.** Jazz Pharmaceuticals will make a written report to GSK within thirty (30) days after the date of any termination of

Additional Consideration Payment obligations under this Agreement, stating in such report the number, description and Net Sales of Products sold or otherwise disposed of and on which an Additional Consideration Payment is payable hereunder that was not previously reported to GSK.

4.4 Audit. Upon the written request of GSK (but not more frequently than [ \* ]), GSK will have the right, upon thirty (30) days advance notice to Jazz Pharmaceuticals and at a mutually agreeable time, to have an independent certified public accountant or like individual reasonably acceptable to Jazz Pharmaceuticals (the "Auditor") inspect, during normal business hours, Jazz Pharmaceuticals' directly applicable records for the preceding two (2) years for the purpose of determining the accuracy of Additional Consideration Payment Statements and the associated Additional Consideration Payment made to GGL and SB pursuant to this Agreement. The results of any such examination shall be made available to Jazz Pharmaceuticals. In the event the Auditor concludes that there was an underpayment of the total Additional Consideration Payment to GGL and SB together, the underpayment will be paid by Jazz Pharmaceuticals to GGL or SB or both, as applicable (but subject to the provisions of Section 3.5(b) concerning allocations between GGL and SB), within sixty (60) Business Days after the date Jazz Pharmaceuticals receives such Auditor's written report; provided, however, if Jazz Pharmaceuticals desires to contest such audit results, Jazz Pharmaceuticals may do so by submitting the results of the audit to arbitration through JAMS New York or San Francisco offices within thirty (30) days after the receipt of such audit, and the arbitration shall be final and binding on GSK and Jazz Pharmaceuticals. Pending the results of such arbitration, Jazz Pharmaceuticals shall be entitled to withhold any disputed amounts claimed by GSK as a result of the audit. In the event the Auditor concludes that there was an overpayment of Additional Consideration Payment to GGL or SB or both, as applicable, the overpayment will be credited toward the next Additional Consideration Payment to be paid by Jazz Pharmaceuticals to GGL or SB or both, as applicable, under this Agreement until fully credited; provided, however, that in the event no further Additional Consideration Payment will become due under this Agreement, such overpayment will be paid by GGL or SB or both, as applicable, to Jazz Pharmaceuticals within sixty (60) Business Days after the date GSK receives such Auditor's written report. If the underpayment of Additional Consideration is greater than [ \* ] percent ([ \* ]%) of the Additional Consideration Payment determined by the Auditor to be payable to GSK, the reasonable fees and expenses charged by the Auditor will be paid by Jazz Pharmaceuticals; otherwise GSK will pay the reasonable fees and expenses charged by such Auditor. The Auditor will report to GSK only its conclusions as to whether Jazz Pharmaceuticals is in compliance with its Additional Consideration Payment obligations and the amount of any underpayment or overpayment, and such report and the conclusions contained therein will constitute Jazz Pharmaceuticals' Confidential Information in accordance with Section 11.1.

#### 4.5 Diligence.

(a) Product Development Diligence. Jazz Pharmaceuticals shall exercise its Diligent Efforts to [ \* ]. In connection therewith, Jazz Pharmaceuticals shall use its Diligent Efforts to [ \* ] set forth below by the [ \* ] set forth below:

- (i) [ \* ];
- (ii) [ \* ]; and
- (iii) [ \* ].

(b) Commercialization Diligence. Jazz Pharmaceuticals shall devote its Diligent Efforts to [ \* ] within [ \* ] after the date on which [ \* ], subject to, with respect to each [ \* ], the [ \* ] and other [ \* ].

(c) Patent Diligence. Jazz Pharmaceuticals shall devote its Diligent Efforts to [ \* ] that have been transferred to Jazz Pharmaceuticals in accordance with [ \* ].

(d) Failure to Achieve Objectives. Failure to achieve any of the development objectives described in Section 4.5(a) or the commercial objective set forth in Section 4.5(b) at the times set forth therein shall not be a breach of this Agreement and shall not result in the availability of the remedies set forth in Section 9.2; provided, however, that the failure of Jazz Pharmaceuticals to exercise Diligent Efforts to achieve the development and commercial objectives set forth above shall constitute material breach of this Agreement and, upon such breach, GSK, in its discretion, may terminate the Agreement in accordance with Section 9.2. Any time period described in Section 4.5(a) or (b) shall be extended for the same period of time as any delay caused by GSK in transferring the Purchased Assets to Jazz Pharmaceuticals or any delay which was outside the control of Jazz Pharmaceuticals.

4.6 Cessation or Suspension of Development Efforts. If Jazz Pharmaceuticals ceases or suspends development efforts for [ \* ] and the other Products covered by the Patents (such that efforts have been suspended with respect to all of the Compounds) for [ \* ], such cessation or suspension of development efforts shall constitute a failure of Diligent Efforts by Jazz Pharmaceuticals and a material breach of this Agreement. Upon such material breach, GSK, in its discretion, may terminate this Agreement in accordance with Section 9.2.

4.7 Termination of Development or Commercialization by Jazz Pharmaceuticals.

(a) If Jazz Pharmaceuticals determines to cease Diligent Efforts (alone or with a Third Party) to develop and commercialize all Products prior to [ \* ] Jazz Pharmaceuticals shall so notify GSK in writing. In such event, GSK shall have a period of [ \* ] days after the date of Jazz Pharmaceuticals' notice to reacquire the rights to all the Products in their then-current condition, for a price equal to [ \* ]. If GSK reacquires the Products under this Section 4.7(a), Jazz Pharmaceuticals shall have no obligation to provide GSK with any data generated by Jazz Pharmaceuticals regarding the Products.

(b) If Jazz Pharmaceuticals determines to cease Diligent Efforts (alone or with a Third Party) to develop and commercialize all Products at any time after [ \* ] Jazz Pharmaceuticals shall so notify GSK in writing. In such event, GSK shall have a period of [ \* ] after the date of Jazz Pharmaceuticals' notice to reacquire the rights to the Products in their then-current condition, for a price equal to the sum of (a) [ \* ], plus (b) [ \* ]. In its notice to GSK, Jazz Pharmaceuticals shall advise GSK of the [ \* ]. If GSK reacquires the Products under this Section 4.7(b), Jazz Pharmaceuticals shall provide GSK with all data generated by Jazz Pharmaceuticals regarding the Products.

Upon receipt of notice from Jazz Pharmaceuticals under Section 4.7(a) or 4.7(b), GSK shall have the option, exercisable by written notice to Jazz Pharmaceuticals given within [ \* ] after Jazz Pharmaceuticals' notice, to reacquire the Product and all of Jazz Pharmaceuticals' rights to the Product. In the event that GSK exercises such option, the Parties shall work together

diligently to complete such reacquisition within the [ \* ] following GSK's exercise of such option, and Jazz Pharmaceuticals shall provide assistance to GSK, on a level commensurate to the assistance provided by GSK to Jazz Pharmaceuticals pursuant to Section 2.2 and 2.3, to transfer and assign the Purchased Assets to GSK. If the option is not exercised within the [ \* ] period described above, it will terminate, and GSK shall have no further right to reacquire any Products.

4.8 [ \* ] Reports. On a [ \* ] basis until [ \* ], Jazz Pharmaceuticals shall submit summary written reports to GSK describing Jazz Pharmaceuticals' [ \* ].

#### **ARTICLE 5—CLOSING**

5.1 Closing Date; Time and Place of Closing. The transfer of title to the Purchased Assets and the closing of the transactions contemplated by this Agreement will occur on October 4, 2004 (the "Closing Date") at or before the Time of Closing at 3180 Porter Drive, Palo Alto, California, U.S., or at such other place as may be agreed upon in writing by the Parties hereto.

5.2 Closing Arrangements.

(a) GSK's Delivery of Closing Documents. At the Time of Closing on the Closing Date, GSK will execute and deliver to Jazz Pharmaceuticals:

- (i) a Bill of Sale in the form of Schedule A attached hereto and incorporated herein, duly executed by GSK;
- (ii) an Assignment of Patent Rights in the form of Schedule B attached hereto and incorporated herein, duly executed by GSK; and
- (iii) this Agreement, duly executed by GSK.

In addition, at the Time of Closing, GSK will pay and satisfy the [ \* ] as provided in Section 6.1.

(b) Jazz Pharmaceuticals' Payment of Purchase Price and Delivery of Closing Documents: At the Time of Closing on the Closing Date, Jazz Pharmaceuticals will:

- (i) pay and satisfy the Purchase Price as provided in Section 3.1, payable via wire transfer to accounts that have been designated by GGL and SB at least two (2) Business Days prior to the Closing Date; and
- (ii) deliver this Agreement, duly executed by Jazz Pharmaceuticals.

5.3 Conditions of Obligations of Jazz Pharmaceuticals. The obligations of Jazz Pharmaceuticals to effect the transactions contemplated hereby are also subject to the satisfaction of the following conditions, unless waived in writing by Jazz Pharmaceuticals on or prior to the Closing Date:

(a) The representations and warranties of GSK set forth in this Agreement shall be true and correct as of the Time of Closing;



- (b) GSK shall have performed all conditions, obligations and covenants required to be performed by it under this Agreement prior to the Time of Closing;
- (c) Jazz Pharmaceuticals shall have received duly executed copies of all Third Party consents, approvals and assignments contemplated by this Agreement and necessary to transfer all of GSK's interest in the Purchased Assets, in form and substance reasonably satisfactory to Jazz Pharmaceuticals; and
- (d) Subject to Section 2.5, there shall have been no material change in the Compounds or the Purchased Assets.

5.4 Conditions of Obligations of GSK. The obligations of GSK to effect the transactions contemplated hereby are also subject to the satisfaction of the following conditions, unless waived in writing by GSK on or prior to the Closing Date:

- (a) The representations and warranties of Jazz Pharmaceuticals set forth in this Agreement shall be true and correct as of the Time of Closing;
- (b) Jazz Pharmaceuticals shall have performed all conditions, obligations and covenants required to be performed by it under this Agreement prior to the Time of Closing; and
- (c) There shall have been no material adverse change to the business or financial condition of Jazz Pharmaceuticals.

5.5 Transfer after Closing Date. While title to the Purchased Assets will pass to Jazz Pharmaceuticals on the Closing Date, the physical transfer of the Purchased Assets will take place during the Asset Transfer Period. In the event that Jazz Pharmaceuticals seeks additional data from GSK pertaining to the Purchased Assets, Jazz Pharmaceuticals may, during the Asset Transfer Period, make a specific request of GSK for copies of such additional data. GSK will endeavor to locate such data, where available, within a reasonable period of time. If, despite GSK's reasonable endeavors it cannot locate such additional data, GSK will promptly notify Jazz Pharmaceuticals in writing. GSK will be responsible for the physical transfer of the Purchased Assets (including compliance and costs associated with any export control laws or regulations and any required governmental authorizations) to Jazz Pharmaceuticals' chosen destination during the Asset Transfer Period. Risk of loss of the Purchased Assets will pass to Jazz Pharmaceuticals upon receipt of such by Jazz Pharmaceuticals.

5.6 Expenses for Transfer of the Purchased Assets. Except as provided in this Agreement, after the Time of Closing on the Closing Date, Jazz Pharmaceuticals will be responsible for all costs related to the recordation and perfection of the assignment of the Purchased Assets and Jazz Pharmaceuticals will bear all costs and fees imposed by governmental authorities related thereto and all postage costs. Except as otherwise expressly provided herein, all other costs, fees and expenses arising from the transfer of the Purchased Assets to Jazz Pharmaceuticals as contemplated by this Agreement will be paid by the Party incurring such costs and expenses.

## **ARTICLE 6—[ \* ]**

6.1 [ \* ] hereby grants to [ \* ] a [ \* ] and [ \* ] under the [ \* ], excluding [ \* ]. In accordance with Section 6.3, until [ \* ] shall have no right under the [ \* ] to [ \* ] or [ \* ] any [ \* ] in the [ \* ], respectively. [ \* ], respectively, should [ \* ] wish to [ \* ] in the [ \* ] where a [ \* ] to permit [ \* ], but [ \* ] will have no obligation to [ \* ].

6.2 [ \* ]. [ \* ] will have the right to [ \* ] to its [ \* ] and [ \* ] that enter into bona fide [ \* ]; provided that, in each instance (a) such [ \* ] shall be used solely for [ \* ], purposes only and (b) any such [ \* ] shall be [ \* ] to those set forth in [ \* ].

6.3 [ \* ] by [ \* ] of Products. [ \* ] will not [ \* ] or sell any Product in the U.S. [ \* ] any Product in any country in Europe [ \* ] any Product in any country in the ROW [ \* ]. This provision shall not prevent [ \* ] from researching any Compound covered by the Patents in accordance with the [ \* ] granted to [ \* ] in Section 6.1.

## **ARTICLE 7—REPRESENTATIONS AND WARRANTIES**

7.1 Representations and Warranties of Jazz Pharmaceuticals. Jazz Pharmaceuticals hereby represents and warrants to GSK and acknowledges that GSK is relying on such representations and warranties in connection with the transactions contemplated by this Agreement that, as of the Closing Date:

(a) Incorporation, Organization and Qualification of Jazz Pharmaceuticals. Jazz Pharmaceuticals is a corporation duly incorporated, validly existing and in good standing under the laws of the jurisdiction of its incorporation, and has the corporate power to own or lease its property and to carry on its business as now being conducted by it and to execute, deliver and perform this Agreement. Jazz Pharmaceuticals is duly qualified to do business as a foreign corporation and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except in such jurisdictions where the failure to so qualify does not in the aggregate have a material adverse effect on its respective businesses taken as a whole.

(b) Corporate Action. This Agreement, and any other agreements and instruments executed in connection herewith and therewith are the valid and binding obligations of Jazz Pharmaceuticals, enforceable in accordance with their respective terms, subject to bankruptcy, insolvency or similar laws of general application affecting the enforcement of rights of creditors, and subject to equitable principles limiting rights to specific performance or other equitable remedies and subject to the effect of federal and state securities laws on the enforceability of indemnification provisions relating to liabilities arising under such laws. The execution, delivery and performance of this Agreement and any other agreement and instruments executed in connection herewith and therewith have been duly authorized by all necessary corporate action.

(c) Governmental Approvals. No authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable laws, rules or regulations presently in effect, is or will be necessary for, or in connection with, the offer, issuance, sale, execution or delivery by Jazz Pharmaceuticals of the Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

(d) Sufficient Funds. Jazz Pharmaceuticals represents that it has, or will have at the Time of Closing, sufficient funds to fulfill its obligation to pay the Purchase Price and Milestone Payments to GSK.

(e) Compliance With Law. Jazz Pharmaceuticals has complied and is in compliance with all applicable foreign, federal, state and local laws, statutes, licensing requirements, rules and regulations, and judicial or administrative decisions applicable to Jazz Pharmaceuticals in connection with the transaction contemplated hereby.

7.2 Representations and Warranties of GSK. GSK hereby represents and warrants to Jazz Pharmaceuticals and acknowledges that Jazz Pharmaceuticals is relying on such representations and warranties in connection with the transactions contemplated by this Agreement that, as of the Closing Date:

(a) Incorporation, Organization and Qualification of GSK. Each of GGL and SB is a corporation duly incorporated, validly existing and in good standing under the law of the jurisdiction of its incorporation, and has the corporate power to own or lease its property and to carry on its business as now being conducted by it. Each of GGL and SB is duly qualified to do business as a foreign corporation and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except in such jurisdictions where the failure to so qualify does not in the aggregate have a material adverse effect on its respective businesses taken as a whole.

(b) Corporate Action. This Agreement, and any other agreements and instruments executed in connection herewith and therewith are the valid and binding obligations of each of GSK, enforceable in accordance with their respective terms, subject to bankruptcy, insolvency or similar laws of general application affecting the enforcement of rights of creditors, and subject to equitable principles limiting rights to specific performance or other equitable remedies. The execution, delivery and performance of this Agreement and any other agreement and instruments executed in connection herewith and therewith have been duly authorized by all necessary corporate action.

(c) Governmental Approvals. No authorization, consent, approval, license, exemption or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable laws, rules or regulations presently in effect, is or will be necessary for, or in connection with, the offer, issuance, sale, execution or delivery by GGL or SB of the Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

(d) Title to Purchased Assets.

(i) GSK is the sole and exclusive owner of the Purchased Assets, and the Purchased Assets are free and clear of any and all liens, pledges, mortgages, security interests, restrictions, and encumbrances. By virtue of the deliveries made at the Time of Closing, Jazz Pharmaceuticals will obtain good and marketable title to all of the Purchased Assets, free and clear of any and all liens,

pledges, mortgages, security interests, restrictions and encumbrances. To GSK's knowledge, no government funds, equipment, facilities, personnel or other resources were used in connection with the discovery or development of the Purchased Assets.

(ii) None of GSK, GGL or SB has granted and will not grant during the Term of this Agreement, any right to any Affiliate or Third Party which would conflict with the rights granted to Jazz Pharmaceuticals hereunder, and GSK will not take (or cause any other person or entity to take) any action that will conflict with, contravene or otherwise limit or restrict the rights of Jazz Pharmaceuticals hereunder or the right of Jazz Pharmaceuticals to enjoy the benefits of this Agreement.

(iii) The Purchased Assets constitute all of the material assets used by GSK and its Affiliates in the development of [ \* ] and the manufacturing Know-how specifically relating to [ \* ], other than manufacturing equipment. Except for the quantities of [ \* ] duly retained by GSK pursuant to Section 2.4, neither GSK nor its Affiliates will have any supply of [ \* ] at the expiration of the Asset Transfer Period, nor is GSK or its Affiliates in the process of, or planning to, manufacture any additional amounts of [ \* ], except for the purposes permitted by the [ \* ].

(iv) Schedule 1.1.29 lists all Patents related to the Compounds, or any formulation or process of manufacture or formulation specifically related to [ \* ], or use thereof in the Territory including any patent term extensions, supplementary protection certificates, registrations, extensions, reissues, reexaminations or divisionals thereof, and including any granted patents arising from the pending applications.

(e) Litigation. No action, claim, suit, proceeding or investigation is pending in respect of the Purchased Assets in the United States or Europe or, to GSK's knowledge, anywhere else in the Territory. To GSK's knowledge, no action, claim, suit, proceeding or investigation is threatened against GSK or its Affiliates in respect of the Purchased Assets anywhere in the Territory. There is no judgment, decree, injunction, rule or order of any court, governmental department, commission agency, instrumentality or arbitrator or other similar ruling outstanding against GSK or its Affiliates relating to the Purchased Assets. No action, claim, suit, proceeding or investigation is pending or threatened by GSK or its Affiliates, nor, to GSK's knowledge, is there any basis for such, against any Third Party relating to the Purchased Assets.

(f) No Existing Claims of Infringement. To the knowledge of GSK's Corporate Intellectual Property Group, there are no claims existing against GSK or its Affiliates asserting that the manufacture, use or sale of [ \* ] infringes, constitutes contributory infringement, inducement to infringe or misappropriation of any patent rights, trade secret rights or other intellectual property or proprietary rights of any Third Party. GSK hereby represents and warrants that GSK's Corporate Intellectual Property group referenced in this Agreement is the only group within GSK that prosecutes and maintains patents.

(g) Taxes; Maintenance Fees. All taxes imposed by the United States, any state, municipality, other local government or other subdivision or instrumentality of the United

States or the countries of EU that are due or payable by GSK or any of its Affiliates with respect to the Purchased Assets, and all interest and penalties thereon, whether disputed or not, and that would result in the imposition of a lien, claim or encumbrance on any of the Purchased Assets, other than taxes that are not yet due and payable, have been paid in full, all tax returns required to be filed in connection therewith with respect to the Purchased Assets have been accurately prepared and duly and timely filed in the United States and countries of the EU. To GSK's knowledge, all taxes imposed by any other country or any state or other government thereof, or any other taxing authority, that are due or payable by GSK or any of its Affiliates with respect to the Purchased Assets, and all interest and penalties thereon, whether disputed or not, and that would result in the imposition of a lien, claim or encumbrance on any of the Purchased Assets, other than taxes that are not yet due and payable, have been paid in full, all tax returns required to be filed in connection therewith with respect to the Purchased Assets have been accurately prepared and duly and timely filed. GSK is not delinquent in the payment of any foreign or domestic tax, assessment or governmental charge or deposits in the U.S. or the EU or, to GSK's knowledge, in any other country that would result in the imposition of a lien, claim or encumbrance on any of the Purchased Assets or against Jazz Pharmaceuticals, and neither GSK nor any of its Affiliates has a tax deficiency or claim outstanding, proposed or assessed against it, and, to GSK's knowledge, there is no basis for any such deficiency or claim, that would result in the imposition of any lien, claim or encumbrances on any of the Purchased Assets or against Jazz Pharmaceuticals. All maintenance fees and any other fees for the Patents have been timely paid.

(h) Compliance With Law. To GSK's knowledge, GSK and its Affiliates have complied and are in compliance with all applicable foreign, federal, state and local laws, statutes, licensing requirements, rules and regulations, and judicial or administrative decisions applicable to their ownership and use of the Purchased Assets, including without limitation all laws, rules and regulations regarding the development, clinical testing, manufacture, licensing, marketing, promotion, importation, exportation or other use of pharmaceutical products, except where such failure to do so would not materially adversely affect, or reasonably be expected to so affect, any of the Purchased Assets or the ability of GSK to consummate the transactions contemplated herein. GSK and its Affiliates have been granted any and all licenses, permits (temporary and otherwise), authorization and approvals from federal, state, local and foreign government regulatory bodies necessary to own and use the Purchased Assets, except where the failure to possess such license, permit, authorization or approval would not have a materially adverse effect, or reasonably be expected to so affect, any of the Purchased Assets or the ability of GSK, GGL and SB have to consummate the transactions contemplated herein.

(i) Full Disclosure. This Agreement and the Schedules attached hereto, when taken as a whole, do not contain any untrue statement of a material fact nor, to GSK's knowledge, information and belief, omit to state a material fact necessary in order to make the statements contained herein or therein not misleading.

(j) Limitations.

(i) EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 7.2, THE COMPOUNDS AND PURCHASED ASSETS ARE PROVIDED "AS IS," AND

GSK MAKES NO REPRESENTATIONS OR WARRANTIES (WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE COMPOUNDS OR PURCHASED ASSETS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, INCLUDING USE IN CLINICAL TRIALS, OR FREEDOM FROM INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. JAZZ PHARMACEUTICALS ACKNOWLEDGES THAT ALL CHARACTERISTICS OF THE COMPOUNDS ARE NOT FULLY UNDERSTOOD AND ANY USE THEREOF MAY INVOLVE RISKS OR DANGERS THAT ARE NOT KNOWN OR FULLY APPRECIATED.

(ii) NOTWITHSTANDING ANYTHING ELSE IN THIS AGREEMENT, JAZZ PHARMACEUTICALS WILL BE RESPONSIBLE FOR (AND GSK WILL HAVE NO RESPONSIBILITY FOR) ALL LIABILITIES ARISING SOLELY FROM ACTS OR OMISSIONS TO ACT BY JAZZ PHARMACEUTICALS, ITS AFFILIATES OR SUBLICENSEES AFTER THE TIME OF CLOSING RELATED TO THE PURCHASED ASSETS OR THE USE BY JAZZ PHARMACEUTICALS, ITS AFFILIATES OR SUBLICENSEES OF THE PURCHASED ASSETS TO IDENTIFY, RESEARCH, DEVELOP, MANUFACTURE, MARKET, PROMOTE, DISTRIBUTE, SELL OR IMPORT ANY PRODUCTS, EXCEPT WHERE SUCH LIABILITY, LOSS, DAMAGE, COST AND EXPENSE HAS BEEN INCURRED OR SUFFERED AS A RESULT OF A MATERIAL BREACH OF GSK'S REPRESENTATIONS, WARRANTIES OR OBLIGATIONS UNDER THIS AGREEMENT OR BY GROSS NEGLIGENCE OR WILLFUL MISCONDUCT ON THE PART OF GSK.

(k) Any representation or warranty by GSK herein will also be deemed to have been made by each of GGL and SB, individually as to itself, and the breach of any representation or warranty by any one of them will be deemed to be a breach by the others.

#### **ARTICLE 8—LIABILITY AND INDEMNIFICATION**

8.1 Indemnification by GSK. GSK will indemnify, defend and hold harmless Jazz Pharmaceuticals, its Affiliates, and each of their respective members, directors, officers, employees, advisors and agents (collectively, "Jazz Pharmaceuticals Indemnitees") from and against any and all suits, actions, damages, liabilities, claims (including death and bodily injury), demands, obligations, losses, fees, costs and expenses or money judgments (including reasonable attorneys' fees) (collectively, "Claims") incurred by or rendered against any Jazz Pharmaceuticals Indemnitee which arise out of or in connection with:

- (a) any Claims related to the Purchased Assets or against the Purchased Assets, in each case based upon events which occurred at or prior to the Time of Closing; or
- (b) liabilities of GSK or its Affiliates to the extent related to the Purchased Assets and existing as of, or prior to, the Closing Date or based on actions taken or omissions to act that occurred prior to the Time of Closing (including any infringement or misappropriation of Third Party patents or intellectual property);

(c) any breach or inaccuracy of any representation, warranty or covenant of GSK set forth in this Agreement; or

(d) the negligence or willful misconduct of any GSK Indemnitees;

provided, however, that in each case GSK will not be obligated to indemnify any Jazz Pharmaceuticals Indemnitee with respect to, and to the extent of, any Claims for which Jazz Pharmaceuticals is obligated to indemnify GSK pursuant to Section 8.2.

**8.2 Indemnification by Jazz Pharmaceuticals.** Jazz Pharmaceuticals will indemnify and hold harmless GSK and its Affiliates and each of their directors, officers, employees, advisors and agents (collectively, the “GSK Indemnitees”) from and against any and all Claims incurred by or rendered against any GSK Indemnitee which arise out of or in connection with:

(a) the development, manufacture, licensing, marketing, promotion, importation, exportation, sale or other use of the Purchased Assets from and after the Time of Closing by or on behalf of any Jazz Pharmaceuticals Indemnitees of any Product or service or any product or material embodying or made through the use of any part of the Purchased Assets; provided however, it is agreed by the Parties that such indemnification will not apply to the extent that any product or service arises from the exercise of the [ \* ] by GSK, its Affiliates, agents [ \* ];

(b) any breach or inaccuracy of any representation, warranty or covenant made by Jazz Pharmaceuticals pursuant to this Agreement; or

(c) the negligence or willful misconduct of any Jazz Pharmaceuticals Indemnitees;

provided, however, that in each case Jazz Pharmaceuticals will not be obligated to indemnify any GSK Indemnitees with respect to, and to the extent of, any Claims for which GSK is obligated to indemnify Jazz Pharmaceuticals Indemnitees pursuant to Section 8.1.

**8.3 Indemnification Process.** No Party against whom a claim of indemnity is made under this Agreement (the “Indemnifying Party”) will be liable unless the Party making such claim (the “Claimant Party”) (a) promptly notifies the Indemnifying Party in writing of such claim upon becoming aware of the existence or threatened existence of any such claim giving rise to or which may give rise to a claim of indemnity (provided, however that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnifying Party of any obligations hereunder, except to the extent that the Indemnifying Party is prejudiced by such failure), (b) permit the Indemnifying Party to assume direction and control of the defense of the claim, and (c) cooperates in the defense of such claim. Notwithstanding the foregoing, the Indemnifying Party shall not enter into any settlement or compromise of any claims without the express written consent of the Claimant Party in each instance where such settlement would include any admission of liability on the part of the Claimant Party, where the settlement would impose any material restriction on the conduct of the Claimant Party of any of its activities, or where the settlement would not include an unconditional release of the Claimant Party from all liability for claims that are the subject matter of such claim.

**8.4 Limitation on Indemnification.** NEITHER JAZZ PHARMACEUTICALS AND ITS AFFILIATES NOR GSK AND ITS AFFILIATES WILL BE LIABLE HEREUNDER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE REMEDIES FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS.

## **ARTICLE 9—TERM AND TERMINATION**

### **9.1 Term; Expiration.**

(a) This Agreement shall become effective as of the Effective Date, and GSK's sale, transfer and assignment of its rights to the Purchased Assets to Jazz Pharmaceuticals, and the transfer of title to such Purchased Assets shall be accomplished on the Closing Date, subject to satisfaction of the conditions set forth in Sections 5.3 and 5.4. As provided in Section 5.5, the physical transfer of the Purchased Assets will occur during the Asset Transfer Period. After the Closing Date, unless earlier terminated pursuant to Section 9.2, this Agreement shall expire on [ \* ].

(b) The period from the Effective Date to the expiration of the entire Agreement pursuant to this Section 9.1 shall be the "Term." The end of the Term shall not terminate or affect the transfer of Patents pursuant to Section 2.1 or the license granted under Section 2.6; and no Purchased Assets transferred to Jazz Pharmaceuticals hereunder shall be returned at the end of the Term.

### **9.2 Termination for Cause.**

(a) **Material Breach.** Either Party (the "Non-breaching Party") may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in its entirety in the event the other Party (the "Breaching Party") shall have committed a material breach, and such material breach shall have continued and/or remained uncured for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party. Any such termination shall become effective at the end of such sixty (60) day period, unless the Breaching Party has cured any such material breach prior to the expiration of such sixty (60) day period. The sixty (60) day cure period provided for herein shall be extended for as long as a Breaching Party is making Diligent Efforts to cure such material breach. The right of either Party to terminate this Agreement as provided in this Section 9.2 shall not be affected in any way by such Party's waiver or failure to take action with respect to any previous default.

(b) **Effect of Termination by Jazz Pharmaceuticals on GSK's Material Breach.** In the event Jazz Pharmaceuticals terminates this Agreement pursuant to Section 9.2(a) as a result of an uncured material breach by GSK, (i) all rights granted to Jazz Pharmaceuticals hereunder will continue unaffected, including the license granted to Jazz Pharmaceuticals pursuant to Section 2.6, (ii) no further payments will be due to GSK hereunder, (iii) Jazz Pharmaceuticals' diligence obligations under Section 4.5 will terminate, and (iv) Section 6.3 will continue in accordance with its terms.

(c) **Effect of Termination by GSK on Jazz Pharmaceutical's Material Breach.** In the event GSK terminates this Agreement pursuant to Section 9.2(a) as a result of an uncured material breach by Jazz Pharmaceuticals, (i) Jazz Pharmaceuticals shall cease all development and marketing of the Compounds or Products and immediately shall assign and transfer back to GSK all rights to the Purchased Assets; and (ii) the license



granted to Jazz Pharmaceuticals pursuant to Section 2.6 shall terminate. In consideration of the transfer of the Purchased Assets to it, GSK shall pay Jazz a sum equal to [ \* ] excluding the [ \* ]. In the event of such termination, the Parties will work together diligently to complete the reacquisition of the Purchased Assets by GSK within [ \* ] following GSK's notice of termination and intent to reacquire the Purchased Assets. Jazz Pharmaceuticals shall provide assistance to GSK, on a level commensurate to the assistance provided by GSK to Jazz Pharmaceuticals pursuant to Section 2.2 and 2.3, to transfer and assign the Purchased Assets to GSK. In addition, Jazz Pharmaceuticals shall transfer to GSK all data generated by Jazz Pharmaceuticals regarding the Purchased Assets prior to termination by GSK pursuant to Section 9.2(a).

9.3 Survival. Termination of this Agreement will terminate all outstanding obligations and liabilities between the Parties arising from this Agreement except those described in Sections 2.1, 2.3, 2.5, 2.6 (except with respect to termination pursuant to Section 9.2(c)), 4.3, 4.4, 6.1, 6.2 and 9.2(b) and (c), 9.3, and Articles 1, 7, 8, 10, 11, and 12. Additionally, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement will also survive, but only to the extent required for the full observation and performance of this Agreement.

#### **ARTICLE 10—DISPUTE RESOLUTION**

10.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the following procedures if and when a dispute arises under this Agreement:

(a) Any such disputes will be first referred by either Party to senior representatives designated by each Party. If such senior representatives are unable to resolve such a dispute within thirty (30) days of being requested by a Party to resolve the dispute, the matter will be presented to the chief executive officers of Jazz Pharmaceuticals and GSK, for resolution through good faith discussions. In the event that the chief executive officers of Jazz Pharmaceuticals and GSK cannot resolve the dispute within thirty (30) days of being requested by a Party to resolve a dispute, either Party may, by written notice to the other, invoke the mediation provisions of Section 10.1(b).

(b) Upon invocation as provided by Section 10.1(a), the Parties agree to try in good faith to resolve such dispute by non-binding mediation administered by the Center for Public Resources ("CPR") in accordance with the then current CPR Model Procedure for Mediation of Business Disputes, provided that specific provisions of this Section 10.1(a) will override inconsistent provisions of such CPR Model Procedure. The mediator will be selected from the CPR Panel of Neutrals and the location of the mediation be selected by mutual agreement of the Parties, and absent such mutual agreement, will be New York, New York. If the Parties cannot agree upon the selection of the mediator or its location within ten (10) Business Days of the initiation of the mediation, then CPR will appoint the mediator and the mediator will select the location. The Parties will attempt to resolve such dispute through mediation until one of the following occurs: (i) the Parties reach a written settlement; (ii) the mediator notifies the Parties in writing that

they have reached an impasse; (iii) the Parties agree in writing that they have reached an impasse; or (iv) the Parties have not reached a settlement within sixty (60) days of the initiation of the mediation. All aspects of any such mediation, including any resolution or decision relating thereto, will be non-binding, and will be held as confidential and all participants, including the mediator, will be bound by judicially enforceable obligations of strict confidentiality except to the extent the Parties agree in writing to waive in whole or part such confidentiality.

(c) If the Parties fail to resolve such dispute through mediation, then either Party may take such other action as such Party deems appropriate in its sole discretion, including pursuing litigation against the other Party.

10.2 Injunctive Relief. Notwithstanding the foregoing dispute resolution procedures, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek restraining orders, specific performance or other injunctive relief without submitting to such dispute resolution procedure.

10.3 Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the procedures set forth in this Article 10 are pending, and the Parties will cooperate in taking any and all actions necessary to achieve such a result.

#### **ARTICLE 11—CONFIDENTIALITY**

11.1 “Confidential Information” means all information disclosed by a Party to the other Party that would reasonably be regarded as of a confidential or commercially sensitive nature by the disclosing Party, including any matter relating to or arising in connection with this Agreement or the business or affairs of the disclosing Party. Without limitation, Confidential Information will include any confidential or commercially sensitive information relating to Jazz Pharmaceuticals and GSK and any of its or their Affiliates. For purposes of clarification, up to and on the Time of Closing, the Purchased Assets will be deemed the Confidential Information of GSK and thereafter will be deemed the Confidential Information of Jazz Pharmaceuticals and no longer the Confidential Information of GSK.

11.2 Exclusions. Confidential Information excludes the following:

- (a) information which at the time of disclosure hereunder is already in the public domain;
- (b) information which becomes available to the public after the date of disclosure hereunder through no fault of the receiving Party;
- (c) information which the receiving Party can demonstrate by written records that (i) it already possessed without any confidentiality obligation therefore at the time of receipt thereof from the disclosing Party or (ii) it or its employees independently developed without use of, or reliance on, the disclosing Party’s Confidential Information; or
- (d) information which the receiving Party receives from a Third Party which has no confidentiality obligation to the disclosing Party and duly possesses it.

11.3 Disclosure Required By Law. Notwithstanding the foregoing, Confidential Information may be disclosed to the extent required by law, regulation or order of a competent authority (including any regulatory or governmental body or securities exchange) to be disclosed by the receiving Party; provided that, where practicable, the disclosing Party is given reasonable advance notice of the intended disclosure and the right to attempt to protect the confidentiality of the Confidential Information before any governmental agency.

11.4 Confidential Information and the [ \* ]. With respect to Confidential Information of Jazz Pharmaceuticals that may be necessary for GSK to exercise [ \* ] the [ \* ], GSK, its Affiliates [ \* ] will maintain the confidentiality of such Confidential Information, and will only use such Confidential Information as may be required to exercise the [ \* ] thereof.

11.5 Publicity. Each of the Parties hereto agrees not to disclose to any Third Party the financial or other material terms of this Agreement without the prior written consent of the other Party hereto, except to advisors, investors and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law.

11.6 Publications. After the Closing Date [ \* ] shall submit any proposed publication (or other public disclosure, such as a lecture, presentation or seminar) related to the Purchased Assets containing Confidential Information of [ \* ] at least sixty (60) days prior to the proposed publication or public disclosure, to allow [ \* ] to review such planned publication or public disclosure. [ \* ] shall promptly review such proposed publication and respond in any event in writing to [ \* ] within forty-five (45) days and make any objections that it may have to the publication or public disclosure of Confidential Information contained therein and if no response is received from [ \* ] within such forty-five (45) day period, [ \* ] may conclusively presume that the publication may proceed without delay. Should [ \* ] make an objection to the publication or public disclosure of any such Confidential Information, then [ \* ] will have no right to include the Confidential Information in such publication or public disclosure.

## **ARTICLE 12—MISCELLANEOUS**

12.1 Assignment. This Agreement will not be assignable by either Party to any Third Party without the written consent of the other Party hereto. Notwithstanding the foregoing, either Party may assign this Agreement, without the written consent of the other Party, to an Affiliate or to an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains in connection with a merger, acquisition, sale or similar reorganization or the sale of all or substantially all of its assets or the sale of all or substantially all of its pharmaceutical and/or healthcare assets, and such Third Party agrees in writing to be bound by the terms and conditions of this Agreement. This Agreement will survive any such merger, acquisition or reorganization of either Party with or into, or such sale of assets to, another Third Party and no consent for such merger, acquisition, reorganization or sale will be required hereunder. This Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement will be void.

12.2 Consent/Approval. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval will not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval will not unreasonably be exercised.

12.3 Force Majeure. Neither Party will lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, earthquake, explosion, flood, strike, lockout, embargo, act of God, or any other similar or dissimilar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure.

12.4 Notices. All notices hereunder will be in writing and will be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as will be specified by like notice; provided, that notices of a change of address will be effective only upon receipt thereof). Further, any notice given by GGL and/or SB under this Agreement shall be deemed to have been given by GSK.

If to Jazz Pharmaceuticals:

Jazz Pharmaceuticals  
3180 Porter Drive  
Palo Alto, CA 94304  
U.S.A.  
Attn: General Counsel  
Fax: 650.496.3781

If to GGL:

Glaxo Group Limited  
Glaxo Wellcome House  
Berkeley Avenue  
Greenford, Middlesex, UB6 0NN,  
UK  
Attn: Corporate Secretary  
Fax: 011.44.(0).20.8047.6904

If to SB:

SmithKline Beecham Corporation  
One Franklin Plaza  
P.O. Box 7929  
Philadelphia, PA 19101  
U.S.A.  
Attn: Corporate Secretary  
Fax: 215.751.5349

with a copy to:

GlaxoSmithKline  
709 Swedeland Road  
King of Prussia, PA 19406  
UW 2214  
U.S.A.  
Attn: Head, Ventures Investment  
Fax: 610.270.6299

and

GlaxoSmithKline  
2301 Renaissance Blvd, RN0510  
King of Prussia, PA 19406  
U.S.A.  
Attn: SVP and Associate General Counsel  
R&D Legal Operations  
Fax: 610.787.7084

12.5 No Waiver. The waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy will not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement or excuse a similar subsequent failure to perform any such term or condition. Neither Party may waive or release any of its rights or interests in this Agreement except in writing.

12.6 Invalidity of Provisions/Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance will, to any extent, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, will not be affected thereby and each term, covenant or condition of this Agreement will be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

12.7 Entire Agreement. This Agreement, including the Schedules and hereto, constitutes the entire agreement between the Parties with respect to the transactions provided for herein and, except as stated in this Agreement and in the instruments and documents to be executed and delivered pursuant hereto, contains all of the agreements between the Parties and there are no verbal agreements or understandings between the Parties not reflected in this Agreement. This Agreement may not be amended or modified in any respect except by written instrument executed by each of the Parties.

12.8 Governing Law. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the laws of the State of New York, U.S., without reference to conflicts of laws principles.

12.9 Performance Warranty. Each Party hereby warrants and guarantees the performance of any and all rights and obligations by its Affiliate(s).

12.10 Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party will assume, either directly or indirectly, any liability of or for the other Party. Neither Party will have the authority to bind or obligate the other Party and neither Party will represent that it has such authority.

12.11 Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The Recitals and Annexes to this Agreement constitute an integral part of this Agreement. In the event of

any conflict or inconsistency between any of the terms and conditions of this Agreement, the conflict or inconsistency will be resolved according to the following order or priority: The Sections of the Agreement, the Annexes and the Recitals.

12.12 Payment of Transaction Expenses. All legal fees and other expenses incurred on behalf of GSK in connection with the negotiation of this Agreement and the consummation of the transactions contemplated herein will be borne by GSK, whether or not the Time of Closing shall have occurred. All legal fees and other expenses incurred on behalf of Jazz Pharmaceuticals in connection with the negotiation of this Agreement and the consummation of the transactions contemplated herein will be borne by Jazz Pharmaceuticals, whether or not the Time of Closing shall have occurred.

12.13 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing Party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such Party may be entitled.

12.14 Specific Performance. The Parties hereto agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof and that the Parties shall be entitled to specific performance of the terms hereof in addition to any other remedy at law or in equity.

12.15 Further Assurances. Each Party hereto shall execute and cause to be delivered to each other Party hereto such instruments and other documents, and shall take such other actions, as such other Party may reasonably request (prior to, at or after the Time of Closing) for the purpose of carrying out or evidencing any of the transactions contemplated by this Agreement.

12.16 Challenges by Each Party to the Agreement. Each of the Parties agrees that neither it nor any Affiliate will initiate or prosecute, or encourage or assist directly or indirectly any Third Party in initiating or prosecuting, any lawsuit attempting to challenge the validity of the transactions undertaken pursuant to this Agreement under any applicable law. In addition, GSK agrees that neither it nor any Affiliate shall seek to contest, or encourage or assist directly or indirectly any Third Party in contesting, the transfer of the Purchased Assets to Jazz Pharmaceuticals pursuant to this Agreement under any applicable law. Jazz Pharmaceuticals agrees that neither it nor any Affiliate shall seek to contest, or encourage or assist directly or indirectly any Third Party in contesting, the payment obligations of Jazz Pharmaceuticals to GSK hereunder under any applicable law.

12.17 Finder's Fee. Each Party represents that it neither is, nor will be, obligated for any finder's fee or commission in connection with this transaction. GSK agrees to indemnify and to hold harmless Jazz Pharmaceuticals from any liability for any commission or compensation in the nature of a finders' fee (and the costs and expenses of defending against such liability or asserted liability) for which GSK or any of its officers, partners, employees, or representatives is responsible. Jazz Pharmaceuticals agrees to indemnify and to hold harmless GSK from any liability for any commission or compensation in the nature of a finders' fee (and the costs and expenses of defending against such liability or asserted liability) for which Jazz Pharmaceuticals or any of its officers, employees or representatives is responsible.

12.18 Counterparts. This Agreement may be executed in two counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

{Signatures continue on next page.}

IN WITNESS WHEREOF, the Parties have executed this Asset Purchase Agreement in duplicate originals by their duly authorized representatives as of the Effective Date.

**GLAXO GROUP LIMITED**

By: /s/ S. M. Bicknell  
Name: S. M. Bicknell  
Title: Company Secretary

**JAZZ PHARMACEUTICALS, INC.**

By: /s/ Carol Gamble  
Name: Carol Gamble  
Title: Senior Vice President and General Counsel

**SMITHKLINE BEECHAM CORPORATION  
d/b/a GLAXOSMITHKLINE**

By: /s/ Donald F. Parman  
Name: Donald F. Parman  
Title: Vice President and Secretary



**SCHEDULE 1.1.20**

**Chemical Structure of [ \* ]**

[ \* ]

33

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

SCHEDULE 1.1.29

PATENTS TRANSFERRED TO JAZZ PHARMACEUTICALS

[ \* ]

Second Priority Application for [ \* ]

<u>Country</u>	<u>App./Date</u>	<u>App.Date</u>	<u>Patent No.</u>	<u>Status/ Grant Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

[ \* ] Process Case

<u>Country</u>	<u>App./Date</u>	<u>App.Date</u>	<u>Patent No.</u>	<u>Status/ Grant Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**SCHEDULE 2.6**

**Licensed GSK Patents**

[ \* ]

<u>Country</u>	<u>App No.</u>	<u>App.Date</u>	<u>Patent No.</u>	<u>Status/ Grant Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

[ \* ]

<u>Country</u>	<u>App No.</u>	<u>App.Date</u>	<u>Patent No.</u>	<u>Status/ Grant Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**SCHEDULE 1.1.35**

**PURCHASED ASSETS**

**CLINICAL**

<u>#</u>	<u>Title</u>	<u>Author</u>	<u>Identifier</u>	<u>Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

**PRECLINICAL TOXICITY, SAFETY AND EFFICACY**

<u>#</u>	<u>Title</u>	<u>Author</u>	<u>Identifier</u>	<u>Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

**CHEMICAL AND PHARMACEUTICAL DEVELOPMENT**

<u>#</u>	<u>Title</u>	<u>Author</u>	<u>Identifier</u>	<u>Issue Date</u>
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

**SCHEDULE 1.1.35(c)**

**Quantities of [ \* ] and other Compounds  
Transferred to Jazz Pharmaceuticals**

[ \* ]

37

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**SCHEDULE A**

**BILL OF SALE**

This is a BILL OF SALE from Glaxo Group Limited, a company incorporated under the laws of England and Wales with its registered offices at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN England (“GGL”) and SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, a company incorporated under the laws of the Commonwealth of Pennsylvania with offices at One Franklin Plaza, 200 North 16<sup>th</sup> Street, Philadelphia, Pennsylvania 19101 U.S.A. (“SB”) (GGL and SB are collectively referred to in this Bill of Sale as “GSK”) to Jazz Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware with offices at 630 Hansen Way, Palo Alto, California 94304 U.S., (“Jazz Pharmaceuticals”) pursuant to that certain Asset Purchase Agreement dated October 4, 2004 by and between GSK and Jazz Pharmaceuticals (the “Agreement”).

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, GSK hereby sells, assigns, transfers, conveys, delivers and contributes to Jazz Pharmaceuticals, its successors and assigns, to have and to hold forever, all of its right, title and interest in and to the Purchased Assets (as defined in the Agreement), subject to all of the other provisions contained in the Agreement.

From and after the Closing Date (as defined in the Agreement) upon request of Jazz Pharmaceuticals, GSK will duly execute, acknowledge and deliver all such further acts, deeds, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably required to convey to and vest the Purchased Assets in Jazz Pharmaceuticals or its permitted assignees and as may be appropriate to protect Jazz Pharmaceuticals’ rights, title and interest in and enjoyment of all the Purchased Assets and as may be appropriate otherwise to carry out the transactions contemplated by the Agreement and this Bill of Sale.

IN WITNESS WHEREOF, and intending to be legally bound, the undersigned has duly executed and delivered this Bill of Sale as of \_\_\_\_\_, 2004.

**GLAXO GROUP LIMITED**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**JAZZ PHARMACEUTICALS, INC.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**SMITHKLINE BEECHAM CORPORATION  
d/b/a GLAXOSMITHKLINE**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**SCHEDULE B**

**ASSIGNMENT OF PATENT RIGHTS**

Glaxo Group Limited, a company incorporated under the laws of England and Wales with offices at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN England ("GGL") and SmithKline Beecham Corporation d/b/a GlaxoSmithKline, a company incorporated under the laws of the Commonwealth of Pennsylvania with offices at One Franklin Plaza, 200 North 16<sup>th</sup> Street, Philadelphia, Pennsylvania 19101 U.S.A. ("SB") (GGL and SB are collectively referred to in this Assignment as "Assignor"), hereby assign certain patent rights to Jazz Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware with offices at 630 Hansen Way, Palo Alto, California 94304 ("Assignee").

Whereas, Assignor is the sole owner of the United States and foreign patents set forth on Exhibit 1 hereto (the "Patents"); and

Whereas, Assignor has agreed with Assignee for the transfer to it of Assignor's whole right, title and interest in and to such Patents and inventions described and/or claimed therein.

Now This Assignment Witnesseth that, for the consideration provided for in, and pursuant to that certain Asset Purchase Agreement between the Assignor and the Assignee dated October 4, 2004, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor, as beneficial owner, hereby assign and transfer to Assignee with full title guarantee the whole right, title and interest in and to the Patents covering the Purchased Assets, and any and all other patents in the United States of America or other countries which may be granted therefore and thereon, and in and to any and all reissues or extensions of the Patents or of such other patents, and the full exclusive benefits thereof, and all rights, privileges and advantages appertaining thereto, including the right to claim priority therefrom, including any and all rights to damages, profits or recoveries of any nature for past infringement of the Patents, and the payment of any and all maintenance fees, taxes, and the like, to hold the same unto and to the use of Assignee, its successors and assigns absolutely during the residue of the respective terms for which the Patents and such other patents were granted and during any such terms.

Assignor hereby covenants that Assignor has not executed and will not execute any agreements inconsistent with this Assignment.



Promptly upon Assignee's written request, Assignor hereby agrees to execute such additional form(s) of assignment for the foregoing Patents covering the Purchased Assets as may be required by the appropriate governmental authority of the United States of America or any foreign country for recordation of this Assignment. Without limitation, Assignor grants to Assignee the power to insert on this Assignment any further identification that may be necessary or desirable in order to record this Assignment.

Executed at \_\_\_\_\_, \_\_\_\_\_ this \_\_ day of \_\_\_\_\_ 2004.

**GLAXO GROUP LIMITED**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Executed at \_\_\_\_\_, \_\_\_\_\_ this \_\_ day of \_\_\_\_\_ 2004.

**SMITHKLINE BEECHAM CORPORATION  
d/b/a GLAXOSMITHKLINE**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**EXHIBIT 1 TO SCHEDULE B OF THE ASSET PURCHASE AGREEMENT**

**ASSIGNMENT OF PATENT RIGHTS**

Assignor and Assignee hereby agree that this Exhibit 1 shall be identical to Schedule A to the Agreement. Assignee shall have the right to prepare multiple versions of this Exhibit 1 that list one or more of the Patents for a single country set forth on Schedule A for recordation with the appropriate governmental authority of such country.

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ORPHAN MEDICAL, INC.

**SODIUM GAMMA HYDROXYBUTYRATE**  
**DEVELOPMENT AND SUPPLY AGREEMENT**

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**ORPHAN MEDICAL, INC.**

**SODIUM GAMMA HYDROXYBUTYRATE DEVELOPMENT AND SUPPLY AGREEMENT**

THIS AGREEMENT ("Agreement") is made as of this 6th day of November, 1996 by and between ORPHAN MEDICAL, INC., a Minnesota corporation, having its principal offices at 13911 Ridgedale Drive, Minnetonka, Minnesota 55305 ("ORPHAN") and LONZA, INC., a New York corporation, having its principal offices at 17-17 Route 208, Fair Lawn, New Jersey 07410, ("Supplier").

**RECITALS**

1. Supplier develops and manufactures bulk pharmaceutical chemicals meeting the regulatory and governmental requirements for commercial use in pharmaceutical products.
2. ORPHAN develops and markets ethical Pharmaceuticals targeted to specified populations of patients.
3. ORPHAN and Supplier desire to cooperate in the transfer of the manufacture of a pharmaceutical chemical known as "Sodium Gamma Hydroxybutyrate" ("the Drug").
4. Supplier desires to manufacture the Drug exclusively for sale to ORPHAN.
5. Upon obtaining approval to market the DRUG, ORPHAN wishes to purchase all of its requirements of the Drug from Supplier and Supplier wishes to supply ORPHAN all of its requirements for the Drug in the Territory.
6. Supplier understands that the Drug will likely be scheduled by the Drug

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Enforcement Administration (DEA) upon approval by the FDA. While Orphan anticipates a Schedule IV designation, Orphan cannot guarantee the level of scheduling that will be required. Supplier agrees that the Drug Price estimate is based on Schedule IV handling. Supplier also agrees to provide Drug to Orphan if a more restrictive level of scheduling is ultimately required at a price to be mutually agreed upon.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

## **ARTICLE 1**

### **DEFINITIONS**

The following terms, when capitalized, shall have the following meanings in this Agreement, whether used in the singular or the plural.

1.1 "Acquisition Cost" in respect of a particular item means the [ \* ] price paid by either party to a Third Party for acquiring such item, including without limitation, [ \* ].

1.2 "Affiliate" means any corporation or non-corporate business entity which controls, is controlled by, or is under common control with a party to this Agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least forty-nine percent (49%) of the voting stock of another corporation, or (a) in the absence of the ownership of at least forty-nine percent (49%) of the voting stock of a corporation, or (b) in the case of a non corporate business entity, if it possesses, directly or indirectly, whether by virtue of an ownership interest of any kind, by contract or otherwise, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity or to elect or cause the election of a majority of the board of directors or other governing body of such corporation or non-corporate business entity.

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1.3 “Contract Year” means the twelve (12) month period beginning on the [ \* ]. For purposes of this Section 1.3, [ \* ] or a product containing the Drug by ORPHAN shall not be deemed to be [ \* ] thereof.

1.4 “Delivery” means delivery of the Drug to a drug product manufacturer or any other ORPHAN-designated Third Party.

1.5 “Technology Transfer/Development Program” means the multi-staged Technology Transfer/Development Program further described in Appendix A which is attached hereto and made a part hereof, as well as any additional process or analytical development activities or process or analytical development modifications for the Drug to be mutually agreed upon in good faith by the parties after the date this Agreement is signed and subsequently attached hereto as a replacement for or as an addition to Appendix A.

1.6 “DMF” means a Type II Drug Master File intended for filing with the FDA.

1.7 “Dollars” or “\$” means United States Dollars.

1.8 “Drug Price” means the price to ORPHAN, in [ \* ], for manufacture of the Drug.

1.9 “Drug” means bulk Sodium Gamma Hydroxybutyrate (GHB).

1.10 “Effective Date” means the date appearing at the beginning of this Agreement.

1.11 “FDA” means the US Food and Drug Administration or any successor entity.

1.12 “FD&C Act” means the US Federal Food, Drug and Cosmetic Act, together with all regulations issued thereunder, as the same may be amended from time to time.

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1.13 “GMPs” means the current Good Manufacturing Practices regulations promulgated by the FDA, and any applicable amendments thereto in effect at the time of the Drug’s manufacture.

1.14 “Manufacturing Cost” means Supplier’s costs of [ \* ] (including without limitation [ \* ] and [ \* ] and [ \* ] in the manufacture of the Drug, [ \* ] (i.e. [ \* ] and [ \* ] and [ \* ] of the [ \* ]), all determined in accordance with generally accepted accounting principles applied on a consistent basis in the country of manufacture.

1.15 “NDA” means a New Drug Application filed with the FDA or any equivalent successor application or entity.

1.16 “Notification” means the date on which mailed as evidenced by the U.S. Postal Service or other carrier.

1.17 “Production Batch” means a production size batch of the Drug with a specified kilogram weight range, the size and range of which is to be established and mutually agreed upon by the parties during the Technology Transfer/Development Program. Each Production Batch is to have uniform character and quality within specified limits produced according to a single manufacturing order during the same cycle of manufacture.

1.18 “Proprietary Information” means all non-public information or data relating to the subject matter hereof first communicated by or on behalf of one party to the other, whether in writing or orally, including without limitation, all scientific, clinical, commercial, financial and business information and data, know-how, compilations, formulae, processes, plans, technical information, new product information, compounds, formulations, methods of product delivery, test procedures, product samples, specifications and other information or data.

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1.19 "Registration" means any legally required approval by the relevant government authorities in a country of or community or association of countries included in the Territory (including, where applicable, price approvals) which must be granted for the Drug or a product containing the Drug to be manufactured and/or sold in such jurisdiction.

1.20 "Specifications" means the final specifications for the Drug attached hereto as Appendix C and made a part hereof, including the final NDA specifications as approved by the FDA, as well as any revised specifications and/or additional specifications for the Drug to be mutually agreed upon in good faith by the parties after the Effective Date and subsequently attached hereto as a replacement for or as an addition to Appendix C. Such additional specifications may include, but shall not be limited to specifications for degradation, identification of drug substance and physical appearance.

1.21 "Territory" means worldwide.

1.22 "Third Party" means any entity other than Supplier or ORPHAN or their respective Affiliates.

1.23 "Validation Protocol" means the written protocol which will be mutually approved by the parties in writing prior to the manufacture of the first Validation Batch and which will set forth the tests and acceptance criteria to demonstrate that a process used by Supplier in the manufacture of the Drug does what it purports to do and yields quantities of the Drug which consistently meet the Specifications. The Validation Protocol may be amended from time to time during the term of this Agreement upon mutual agreement of the parties hereto, giving due consideration to applicable legal and regulatory requirements pertaining to the Drug.

1.24 "Validation Batches" means the first three (3) Production Batches manufactured consecutively according to the approved Validation Protocol.

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**ARTICLE 2****TECHNOLOGY TRANSFER/DEVELOPMENT PROGRAM**

2.1 Supplier hereby agrees to conduct the Technology Transfer/Development Program in accordance with Appendix A, the goal of which is to transfer the current process for commercial manufacture of the Drug, develop protocols for testing the Drug, and finalize Specifications. The Technology Transfer/Development Program shall consist of two (2) main stages (individually, a "Stage" or collectively, the "Stages"). Supplier agrees to provide or purchase all materials and supplies.

In general, Supplier shall perform validations for the Drug at its Conshohocken, Pennsylvania facility, provide stability samples, prepare an environmental assessment report, and prepare the chemical manufacturing section for ORPHAN to file in an NDA with FDA. A more detailed description, including the time schedule for completion of each Stage of the Technology Transfer/Development Program, is set forth in Appendix A attached hereto and made a part hereof.

2.2 Promptly upon completion of the development activities conducted by Supplier during each Stage of the Technology Transfer/Development Program, to the extent it has not already done so, Supplier shall deliver to ORPHAN a complete written report or reports. A detailed description of such reports, as well as other reports to be provided by Supplier during the Technology Transfer/Development Program is set forth in Appendix B. Within thirty (30) working days after the delivery to ORPHAN of all reports relating to such Stage, ORPHAN shall either (a) accept such reports and notify Supplier if it intends to proceed with the Technology Transfer/Development Program or (b) send Supplier written notice of Supplier's failure to conduct such Stage in accordance with the requirements set forth in Appendix A. Supplier agrees to take such corrective actions and to conduct such additional work required to satisfy the requirements set forth in Appendix A for completion of such Stage.

During ORPHAN'S review of each Stage completion report, Supplier and ORPHAN may mutually agree to continue execution of the Technology Transfer/Development Program based on previous verbal and written correspondence. If ORPHAN advises Supplier with a written notice to stop execution activities, Supplier will cease all program activities and bill ORPHAN [ \* ].

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2.3 In consideration of Supplier's conduct of the Technology Transfer/Development Program, ORPHAN agrees to pay Supplier the cost for each Stage as set forth in Appendix A. ORPHAN shall only pay Supplier for Stages which are completed. A breakdown of costs for each Stage is set forth in Appendix A. Payments for each Stage will be made within [ \* ], as determined by [ \* ] after review of the associated stage completion summary reports as set forth in Appendix B and any other data generated through execution of the Technology Transfer/Development Program. Supplier shall not incur any costs in excess of the amounts set forth in this paragraph without the prior written consent of ORPHAN.

2.4 Supplier and ORPHAN agree to designate one individual who will serve as a central liaison to the other at all times. The person designated will have the capability and authority to assist with coordination and resolution of any and all issues that might arise.

### ARTICLE 3

### VALIDATION ACTIVITIES

3.1 Supplier Validation Responsibilities. Supplier shall be responsible for regulatory required validations of its manufacture of the Drug and its facilities and shall take all reasonable steps to pass government inspection by the FDA or other regulatory agencies in the Territory. Supplier shall also provide reasonable assistance in preparing and updating the chemical manufacturing portion of the Registrations and all other documents required by the FDA and other regulatory agencies in the Territory for approval of the Drug. In the event non-U.S. Territory regulatory agencies require process development testing beyond that required for the U.S., Supplier agrees to provide the additional process development testing and associated documentation revisions at terms to be negotiated in good faith by the parties.

3.2 Validation of Cvtec Manufacturing Process . As provided in Appendix A, Supplier shall manufacture ORPHAN'S three (3) consecutive Production Batches of the Drug in accordance with the pre-approved Validation Protocol for validation purposes.

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Supplier and ORPHAN will jointly review all process development and analytical test results, the Validation Protocol, and stability study results prior to manufacture of each Validation Batch.

3.3 Re-Validation of Larger Scale Batches. Supplier shall have the option to manufacture three additional commercial Validation Batches using larger scale equipment judged to be regulatorily appropriate by Supplier and ORPHAN, conduct appropriate validation testing, and prepare an updated Process Validation Report to improve manufacturing cost. Costs associated with efforts required for completion of such 'scale up' activities will be included in the Manufacturing Cost of the commercial quantities produced subsequent to the scaleup and within the first Contract Year thereafter.

If the larger scale Validation Batches may be sold commercially by ORPHAN and, if such Validation Batches meet the Specifications and the acceptance criteria set forth in the Validation Protocol at the time of FDA approval of a product containing the Drug, the Drug shall be sold, pursuant to the terms of this Agreement, by Supplier to ORPHAN in fulfillment of ORPHAN'S orders for the Drug.

3.4 Defective Or Deficient Validation Batches. If any of the Validation Batches do not meet the Specifications and the acceptance criteria set forth in the Validation Protocol, Supplier shall, at its own expense, for a reasonable period of time not to exceed ninety (90) days, make necessary modifications to its facilities, equipment, processes and/or procedures and, after such modifications, shall manufacture one or more additional Validation Batches which will meet the Specifications and the acceptance criteria set forth in the Validation Protocol. If ORPHAN concludes that such modifications cannot be made effectively and promptly or if the additional Validation Batches still do not meet the Specifications and the acceptance criteria set forth in the Validation Protocol, ORPHAN may terminate this Agreement upon written Notification to Supplier in accordance with Article 15 of this Agreement.

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**ARTICLE 4**

**MARKETING RIGHTS**

4.1 ORPHAN shall have the exclusive right, directly or through any Affiliate, to market, distribute and sell the Drug or any product containing the Drug in the Territory, if the required Registrations have been obtained and if ORPHAN determines in its business judgment to do so. Supplier shall not market, distribute, make or sell the Drug or any product containing the Drug, directly or indirectly anywhere in the Territory and, except in the performance of its duties under this agreement, Supplier shall not reference or otherwise utilize any DMF or other filing made by Supplier on ORPHAN'S behalf unless required by a governmental agency or reference or otherwise utilize any data or information contained in such filing.

**ARTICLE 5**

**SUPPLY OF PRODUCT**

5.1 Material Safety Data Sheets. Prior to commencement of development or manufacturing operations hereunder, ORPHAN shall provide Supplier with a Material Safety Data Sheet (MSDS) and toxicity information for the Drug and any other information reasonably available to ORPHAN which relates to the safe conduct of the manufacturing and/or packaging operations to be conducted by Supplier. When and as such information becomes available, ORPHAN shall promptly update such information pertinent to the manufacture and/or packaging of the Drug.

5.2 Manufacture and Supply. During the term of this Agreement, ORPHAN shall purchase from Supplier, and Supplier shall supply ORPHAN and its Affiliates their requirements of the Drug for sale or other distribution in the Territory. Supplier and Orphan agree to cooperate closely to ensure that the Drug meets FDA, European, and Japanese standards and specifications. The International Conference on Harmonisation (ICH) guidelines will be followed for development and manufacturing decisions.

Supplier commits to provide the following [ \* ] per year for the [ \* ] and will use best efforts to provide any additional quantities that are required:

[ \* ]

[ \* ]

[ \* ]

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In the event Supplier is not able to provide quantities required that exceed those stated above, Supplier will no longer be the exclusive supplier in the Territory and will provide technology transfer support per the terms of 5.6 below, to a second supplier chosen by Orphan.

Supplier shall provide or purchase all materials and supplies necessary to manufacture the Drug. Supplier shall manufacture the Drug in accordance with the Specifications, the Validation Protocol and applicable cGMPs and shall package, label and/or otherwise prepare the Drug for bulk delivery to an ORPHAN-designated drug product manufacturer.

5.3 Packaging. Supplier shall furnish all packaging supplies and labels for the Drugs after such materials have been approved by ORPHAN prior to use. All such packaging and labels shall conform to applicable requirements and regulations of FDA or other regulatory authorities in the Territory. Packaging supplies and labels furnished by Supplier hereunder shall be timely approved by ORPHAN prior to use.

5.4 Qualification of Alternate Supplier Manufacturing Site. Supplier will develop a plan for qualification of an alternate Supplier site for manufacture of the Drug within one year of FDA approval of the Drug. If the plan allows for preparation to manufacture in 120 days or less, it will not be executed prior to determination of need. If the timeline for provision of the Drug from an alternate site is greater than 120 days, one year after approval of the Drug for commercial use by the FDA, Supplier agrees to take such actions as are reasonably necessary to qualify a second Supplier manufacturing site in addition to the current facility at Conshohocken, Pennsylvania. Supplier will provide regulatory documentation of processes or activities as required by each country of the Territory within which ORPHAN applies for approval of the Drug. ORPHAN will be responsible for determining the regulatory requirements for each submission. Supplier agrees to provide any additionally required development process testing at terms to be negotiated in good faith by the parties.

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5.5 Conditions Requiring Backup Manufacture. Supplier agrees to support the successful transfer of manufacturing technology as set forth in Section 5.6 to a second bulk drug manufacturer chosen by ORPHAN to make, have made, use and sell the Drug if Supplier (a) for a period of [ \* ], is unable to manufacture substantially all of ORPHAN'S orders for any reason covered by Section 16.1 hereof, or (b) if Supplier otherwise fails or refuses to meet ORPHAN'S orders for the Drug pursuant to the terms hereof.

5.6 Supplier Responsibility in Transfer of Technology to Back-Up Manufacturer. Subject to the provisions of Section 5.5, Supplier agrees to provide information and qualified personnel ([ \* ]) to support the successful transfer of all analytical and manufacturing development, to include know-how and patent processes (the "Background Technology") and the right to reference any DMF filed with the FDA relating to the Drug. Supplier agrees to render all reasonable technical assistance to the secured contract manufacturer and to provide, [ \* ], sources of or supplies of raw materials necessary to manufacture the Drug. ORPHAN shall [ \* ] for its [ \* ] incurred in rendering such [ \* ] for which ORPHAN prior approval has been obtained for each day in excess of [ \* ]. In addition, ORPHAN and Supplier will negotiate in good faith any additional time and cost for the successful transfer of manufacture to a backup supplier.

## **ARTICLE 6**

### **FORECASTS, ORDERS AND DELIVERIES**

6.1 Forecasts. ORPHAN shall provide Supplier with forecasts of ORPHAN'S anticipated [ \* ] requirements of the Drug for distribution and sale in the United States commencing with the [ \* ] period that begins at the time of an FDA approval. Such forecast will be provided [ \* ] in advance of anticipated FDA approval of the NDA and ORPHAN shall update such [ \* ] forecast on a [ \* ] basis thereafter. Once FDA approval of the Drug is received, ORPHAN will provide Supplier, prior to the beginning of each [ \* ], with forecasts of its anticipated requirements of the Drug for the following [ \* ]. Supplier will provide [ \* ] anticipated schedule for manufacture and will consult with ORPHAN on schedule changes.

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- (a) The forecasts provided to Supplier pursuant to this Section 6.1 are for planning purposes only and do not constitute a commitment by ORPHAN to have such or any quantity of Drug manufactured by Supplier or a commitment by Supplier to manufacture any quantity of the Drug for ORPHAN during [ \* ].
- (b) Supplier shall [ \* ] manufacture during any [ \* ] up to [ \* ] of the quantity of the Drug ORPHAN forecasted it would purchase from Supplier during such [ \* ] in its most recent forecast covering [ \* ]. Supplier will promptly communicate with ORPHAN as to its ability to produce quantities requested.
- (c) When and as ORPHAN proposes to commence its distribution and sale of the Drug outside the United States, ORPHAN shall supplement its [ \* ] forecast accordingly to indicate the additional requirements of the Drug for such purposes.
- (d) Supplier acknowledges that accurate forecasts of requirements are inherently difficult for a new pharmaceutical product. ORPHAN [ \* ]. Accordingly, if [ \* ], it will [ \* ] ninety (90) days [ \* ], in which case ORPHAN [ \* ]. The [ \* ] delivery of [ \* ] are that during such [ \* ] (i) ORPHAN shall be required to purchase [ \* ] the amount set forth in the [ \* ] and (ii) Supplier shall be required to manufacture [ \* ] such amount. If ORPHAN does not deliver a [ \* ], Supplier may accept [ \* ] use its [ \* ] to produce the Drug in accordance with ORPHAN'S purchase orders in a timely manner. It is agreed that this procedure will be used on an exception basis.
- (e) If Supplier manufactures the Drug with a lead time of more than [ \* ], ORPHAN shall not be required to pay any additional storage, or pay for the Drug sooner than as set forth in Section 7.5 nor shall any advance manufacture lead to a violation of the warranty of expiration date set forth in Section 8.1.

6.2 Orders. ORPHAN shall order the manufacturing of the Drug by Supplier

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pursuant to written purchase orders, including delivery dates, with not less than [ \* ] lead time prior to the requested delivery dates specified therein. Each purchase order for the Drug shall be in Production Batch sizes or whole multiples thereof. The terms contained in this Agreement shall govern over all purchase orders or sales orders of the Drug hereunder and shall not be varied by the terms of any ORPHAN purchase order or Supplier sales order or invoice. If ORPHAN requires manufacture of the Drug with less than [ \* ] lead time, Supplier shall use reasonable efforts to accommodate ORPHAN'S requirements. Supplier shall not manufacture the Drug except upon receipt of an ORPHAN purchase order to ensure a supply of the Drug with the maximum expiration dating.

6.3 Late Manufacture and Delivery. When ORPHAN submits a purchase order at least [ \* ] prior to the required delivery date, Supplier shall confirm delivery upon receipt of this order and provide Orphan with a manufacturing plan detailing timing within [ \* ]. Changes in this manufacturing plan which could affect the timing of deliveries will not be made without the written agreement of ORPHAN. In the event of unexpected delays owing to manufacturing problems associated with the Drug, Supplier will inform ORPHAN immediately and action to be taken will be jointly decided. A failure to provide supply of Drug on schedule will be considered a material breach of this Agreement and Supplier will no longer be the exclusive supplier in the Territory and will provide technology transfer support per the terms of Section 5.6 above, to a second supplier chosen by ORPHAN.

6.4 Delivery of Drug. Supplier shall arrange all shipments of the Drug [ \* ] to an ORPHAN designated location to be determined by ORPHAN prior to or upon regulatory approval of the Drug in accordance with reasonable commercial practices and, for shipments to be made in the United States, any applicable U.S. Department of Transportation regulations for pharmaceutical products to ensure against deterioration and damage of the Drug. ORPHAN shall approve any final shipping specifications subject to any stability findings for the Drug.

(a) Risk of loss of any shipment of the Drug shall pass to ORPHAN upon [ \* ].

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- (b) ORPHAN shall pay (or reimburse) Supplier for [ \* ]. Supplier may invoice ORPHAN for [ \* ] of the Drug paid by Supplier for ORPHAN'S account immediately upon each shipment of the Drug, provided all such charges or costs fall within the terms and conditions established [ \* ] for such shipment.
- (c) [ \* ] select one or more carriers for shipment of the Drug and to negotiate the terms and conditions for such shipment. Risk of loss of any shipment of the Drug would then [ \* ].
- (d) The quantity of Drug in any shipment may vary from the quantity reflected in the purchase order for such shipment by up to [ \* ] and still be deemed to be in compliance with such purchase order; provided, however, that ORPHAN shall [ \* ].
- (e) All Drug shall be shipped in bulk a) using suitable packaging as provided for in the approved NDA, or in other regulatory approvals obtained in the Territory, and b) in accordance with such other contract specifications as may be mutually agreed upon by the parties hereto.

6.5 Finished Bulk Inventory Storage. Supplier agrees to store Drug manufactured for ORPHAN, in quantities of up to [ \* ] for no longer than [ \* ] beyond the purchase order delivery date according to the requirements established through conduct of a stability study program as outlined in Appendix D at a charge [ \* ]. ORPHAN will [ \* ] for storage beyond [ \* ] at a cost to be negotiated in good faith upon FDA approval. Supplier shall have no responsibility for deterioration of Drug stored in accordance with such requirements.

6.6 Certifications. For each Validation Batch and upon request for Production Batches of the Drug manufactured for ORPHAN hereunder, Supplier shall furnish to ORPHAN at the time of its delivery copies of the following records. Originals are to be retained by Supplier:

- (a) representative samples of such batch for assay and other testing;

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- (b) batch records and quality assurance data for such batch; and
- (c) a Certificate of Analysis that such batch conforms to the Specifications and a Certificate of Manufacture which confirms that the Drug was manufactured, tested, and delivered in full compliance with all applicable laws and regulations.

**ARTICLE 7**

**PRICES AND PAYMENTS**

7.1 First Contract Year Manufacturing Price. After completion of Stage A of the Technology Transfer/Development Program, Supplier will quote the Drug Price that ORPHAN shall pay to Supplier for any orders of the Drug manufactured during the first Contract Year (including, if applicable, Validation Batches and any quantities ordered prior to the first Contract Year) as set forth in the Validation Protocol. The Drug Price for [ \* ] shall be [ \* ]. The Drug Price for the [ \* ] will be [ \* ].

7.2 Annual Price Adjustment Notification. At least [ \* ] days prior to the end of the first Contract Year of this Agreement and each Contract Year thereafter, Supplier shall notify ORPHAN of the proposed Drug Price for the next succeeding Contract Year provided, however, that the proposed Drug Price for each new Contract year shall be [ \* ], and (b) that ORPHAN will receive prior notification. Any increase or decrease in Drug Price shall be applicable only to those Production Batches of the Drug for which the production process is begun after the change in cost becomes effective and shall remain in effect until another price change becomes applicable.

In the event the cost of [ \* ] increases by [ \* ] within a single contract year, the Drug Price may be adjusted by the amount [ \* ] for that year. Likewise, if the cost of [ \* ] decreases by [ \* ] within a single contract year, the Drug Price will be adjusted down by the amount [ \* ] for that year. Any adjustments made as a result of [ \* ] price increases or decreases are separate from and in addition to the annual price adjustments described above.

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7.3 Justification of Price Increases. Supplier shall substantiate, upon ORPHAN'S request, Supplier's price increases for the Drug for any Contract Year. Supplier shall keep full and accurate books and records of account containing all particulars that may be necessary for the purpose of calculating the Manufacturing Cost of the Drug, including [ \* ] for any [ \* ] used in manufacturing the Drug. ORPHAN may, upon reasonable notice to Supplier and at ORPHAN'S expense, have an independent public accountant reasonably acceptable to Supplier conduct, during normal business hours, an examination of Supplier's books and records to verify the basis of such increases of the Drug Price for any Contract Year or Contract Years. If Supplier has increased Drug Price based on a claimed increase in Manufacturing Cost to ORPHAN in excess [ \* ] above what such independent certified public accountant finds to be justifiable for any Contract Year, or Contract Years, Supplier shall reimburse ORPHAN'S reasonable cost and expenses of such examination. In no event shall the Manufacturing Cost with respect to any period be audited [ \* ]. The independent public accountant used to conduct such audit shall enter into a confidentiality agreement satisfactory to Supplier and shall provide ORPHAN only with its conclusions.

7.4 Cost Reductions Through Process Improvements. To encourage active and open consideration of Manufacturing Cost reductions, it is agreed that [ \* ] of a cost reduction benefit will be [ \* ] to reduce cost. After the pilot campaign, the pricing offered shall be considered applicable to the process as then practiced (the "Baseline Process"). Any subsequent improvements which lead to realized manufacturing cost reductions [ \* ]. Proposals for improvement will be outlined in writing or communicated verbally and will detail how the improvement should be realized. In the event of improvements developed through a joint collaboration where the originator is unclear, improvements will be shared 50% to each party. This sharing of benefits will come into effect only after [ \* ] After realization of improvements and application of this mechanism, the Baseline Process will be redefined and the same calculation will be applied to any subsequent Manufacturing Cost reductions.

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7.5 Invoice Payment. Payment for each lot of the Drug shall be due net thirty (30) days from the date of the invoice therefor, provided that no invoice shall be dated prior to the date of actual release of the Drug reflected therein. ORPHAN will accept title to the Drug at the earlier of (a) when risk of loss passes pursuant to Section 6.4, and (b) the date of the payment of the invoice thereof. Supplier will retain liability for the safe keeping of the Drug until [ \* ].

## ARTICLE 8

### REPRESENTATIONS, WARRANTIES AND INSPECTIONS

#### 8.1 Representations and Warranties.

(a) ORPHAN represents and warrants to Supplier that:

(i) The execution of this Agreement and the performance by ORPHAN of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of ORPHAN; and

(ii) The processes transferred to Supplier by ORPHAN pursuant to the Technology Transfer/Development Program do not [ \* ].

(b) Supplier represents and warrants to ORPHAN that:

(i) The execution of this Agreement and the performance by Supplier of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of Supplier;

(ii) Subject to ORPHAN'S warranty set forth in Section 8.1 (a)(ii), Supplier warrants that [ \* ];

(iii) Supplier shall not use in any capacity persons, or the services of persons that are debarred, are on the Debarment List, or that have been convicted of actions that could lead to debarment as described in Section 306(a) and (b) of the Federal Food, Drug, and Cosmetic Act;

(iv) at the time of its delivery to a designated drug product manufacturer or other ORPHAN designated location, each Production Batch of the Drug manufactured by Supplier will:

(A) have an expiration date at the time of shipment equal to that approved by the FDA, via the initial NDA submission or via extended stability study data subsequently submitted;

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(B) conform to the Specifications and will be stored under proper conditions ;

(C) have been manufactured in conformance with the Validation Protocol and the DMF or NDA CMC Section on file with the FDA for manufacture of the Drug at Supplier's facilities and in compliance with all other applicable laws and regulations, including, without limitation, the then-current FDA GMP's;

(D) not to be adulterated or misbranded by Supplier within the meaning of the FD&C Act, as amended, or be an article which may not be introduced into interstate commerce under Sections 404 or 505 of such Act. This guarantee shall be continuing and shall be applicable to any Drug shipped [ \* ] drug product manufacturer [ \* ] ORPHAN of written notice of revocation thereof;

(E) be free from all liens and encumbrances of any kind provided, however, THE WARRANTIES SET FORTH HEREIN ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND SUPPLIER EXPRESSLY DISCLAIMS AND NEGATES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

8.2 ORPHAN Inspection Rights. ORPHAN shall have the following inspection rights with respect to Supplier's manufacture of the Drug:

- (a) During the Technology Transfer/Development Program, upon five (5) days' prior written notice, ORPHAN'S authorized representatives may, during normal business hours, inspect Supplier's facilities at which the Technology

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Transfer/Development Program is being conducted to monitor the progress of the Technology Transfer/Development Program. Supplier shall provide all data and records relating to the conduct of the Technology Transfer/Development Program reasonably requested by ORPHAN'S authorized representatives.

- (b) Prior to commencement of manufacture and/or packaging of the Drug and [ \* ] each Contract Year, upon [ \* ] prior written notice, ORPHAN'S authorized representatives may, during normal business hours, review Supplier's governmental licenses and permits relating to the facilities and operations utilized by Supplier in the manufacture and/or packaging of the Drug.
- (c) ORPHAN'S authorized representatives may inspect Supplier's manufacturing facilities during each production run of the Drug and at any other time upon reasonable notice to Supplier to audit any manufacturing, packaging, storage, and testing operations that ORPHAN deems reasonably appropriate to confirm that each batch of Drug has been manufactured, handled, and stored in accordance with the terms hereof. Upon ORPHAN'S request, Supplier shall notify ORPHAN at least thirty (30) days in advance of any production run of the Drug.
- (d) Supplier shall provide ORPHAN'S authorized representatives with copies of all data and records relating to (i) process validation for the Drug including, without limitation, validation of associated automated systems, information systems and any other systems associated with process control, promptly after completion thereof and, promptly thereafter, following any revalidation; and (ii) the production of the Drug, including, without limitation, raw materials, additional validations, production batch records, packaging components, stability data and quality assurance records.
- (e) Supplier shall keep ORPHAN updated on Supplier's internal audit and approval process for raw material suppliers, including, without limitation, an annual review of Supplier's audit reports of suppliers for materials to be used in the manufacture of the Drug.
- (f) ORPHAN shall perform assays on samples from each Production Batch of

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the Drug and may perform such other tests as ORPHAN deems necessary or appropriate from any production run of the Drug manufactured for ORPHAN hereunder, and, without charge, Supplier shall furnish such samples, the analytical methodology and specifications relating thereto approved by FDA or other appropriate regulatory authorities and other testing materials as ORPHAN may reasonably request for such purposes.

- (g) ORPHAN'S authorized representatives who are to conduct inspection or to review any Supplier records pursuant to this Section 8.3 shall execute a nondisclosure agreement substantially in the form attached hereto as Appendix E prior to conducting such inspections or reviewing such records.

8.3 Regulatory correspondence and Inspections. Supplier shall promptly inform ORPHAN of any regulatory correspondence or inspection with respect to Supplier's manufacture of the Drug as follows:

- (a) Supplier shall provide ORPHAN with copies of any correspondence and other documentation received or prepared by Supplier in connection with the manufacture and testing of the Drug in the Territory, including, but not limited to, copies of the proposed NDA (but only of those portions for which Supplier is responsible) and of the potential DMF for the Drug and of annual submissions to the FDA and other regulatory authorities in the Territory. Copies of all such correspondence or other documentation prepared by Supplier shall be reviewed and approved by ORPHAN prior to its submission.
- (b) If Supplier receives any regulatory correspondence or comments from any federal, state, or local regulatory agency in connection with its manufacture of the Drug requiring a response or action by Supplier, including, without limitation, receipt of an FDA Form 483 (Inspectional Observations) or an FDA "Warning Letter", Supplier shall immediately provide ORPHAN with a copy of each such regulatory correspondence or comment and a copy of Supplier's proposed response thereto for ORPHAN'S review and approval prior to its submission if Supplier's manufacture of additional products are not involved. In cases where Supplier's manufacture of additional products are involved, a good faith effort will be made to reach joint approval within an appropriate timeframe.

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- (c) If Supplier's manufacturing facility is inspected by representatives of any federal, state, or local regulatory agency in connection with Supplier's manufacture of the Drug, including, but not limited to, any pre-NDA approval inspection by the FDA, Supplier shall notify ORPHAN within [ \* ] (by telephone and, if possible, by fax or letter) upon learning of such inspection, and shall supply ORPHAN with copies of any correspondence or portions of correspondence which relate to such regulatory inspection. ORPHAN may send representatives to Supplier's manufacturing facility to observe any portion of such regulatory inspection relating to the Drug.

## **ARTICLE 9**

### **ACCEPTANCE, REJECTION, AND CLAIMS**

9.1 Acceptance and Rejection. Each shipment shall be considered to conform to the Specifications and the other warranties set forth in Section 8.1(b) unless ORPHAN gives Supplier notice in writing that it does not consider a particular shipment to conform, together with supporting documentation, within [ \* ] of receipt of such shipment (or, [ \* ] within [ \* ]). ORPHAN will analyze (or cause to be analyzed by its designated product manufacturer) each shipment of Drug using the validated methods approved by FDA for release of Drug. Such testing will be done for acceptance or rejection of the lot. If ORPHAN gives Supplier such notice, Supplier shall thereupon be given access to the shipment in question to conduct its own analysis thereof, and the parties will endeavor to agree amicably as to whether or not the shipment does conform to the Specifications and such other warranties and, if not, whether such non-compliance was due any action or inaction on the part of Supplier.

In the event that the parties are unable to agree as to whether or not the shipment conforms with the Specifications or other warranty, the question will be submitted to an independent quality control laboratory as the parties may mutually agree upon. Cost for the independent quality control laboratory shall be [ \* ].

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During the pendency of a dispute that requires settlement by an independent laboratory under this section, if requested to do so by ORPHAN, Supplier will replace the portion of such shipment under dispute until such dispute is resolved.

9.2 Rejected Shipments. If the nonconformity in a rejected shipment of the Drug was due to any action or inaction of ORPHAN, its carrier or its designated drug product manufacturer subsequent to delivery ([ \* ]) of the Drug by Supplier, Supplier shall have no liability for such rejected shipment. If the nonconformity in a rejected shipment of the Drug was due to any action or inaction of Supplier prior to shipment delivery ([ \* ]), Supplier at its cost shall either credit ORPHAN for the full Manufacturing Cost of such shipment or replace it with a conforming shipment within thirty (30) days of the notice of rejection. Such credit or replacement will be ORPHAN'S sole remedy for such rejected Drug provided Supplier provides replacement or credit within thirty (30) days of notice of rejection.

9.3 Disposal; Return Material Authorization. If ORPHAN expects to make a claim against Supplier with respect to a rejected shipment of the Drug, ORPHAN shall not dispose or allow the disposal of such Drug shipment without the express written authorization and instructions of Supplier. ORPHAN or any ORPHAN designated drug product manufacturer shall not return any rejected shipment of the Drug to Supplier without a Return Material Authorization ("RMA") from Supplier (Appendix F). Upon written request of ORPHAN or the ORPHAN designated drug product manufacturer, as the case may be, Supplier shall promptly issue a RMA for any rejected shipment, provided, however, appropriate samples may be retained as evidence of the basis for such rejection.

9.4 Product Recalls. Each party shall promptly notify the other party if any batch of the Drug is alleged or proven to be the subject of a recall, market withdrawal or correction ordered by the FDA or any other regulatory authority in the Territory. The parties shall cooperate in good faith to handle and dispose of such recall, market withdrawal or correction; provided, however, that in the event of a disagreement as to any

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matters related to such recall, market withdrawal or correction, ORPHAN'S decision shall prevail. ORPHAN shall bear [ \* ] costs of any such recall, market withdrawal or correction unless such recall, market withdrawal or correction was the result of Supplier's breach of any of its representations and warranties set forth in Article 8 above, in which case Supplier shall bear [ \* ] of such recall, market withdrawal, or correction. Supplier will not bear the cost for recalls made as a result of errors that could have been detected by Orphan through acceptance and rejection testing as outlined in Article 9.

## ARTICLE 10

### INDEMNIFICATION

10.1 Supplier's Indemnification to ORPHAN. Subject to Suppliers warranty and ORPHAN'S compliance with its obligations in Section 10.3 hereof, Supplier hereby indemnifies, defends, and holds ORPHAN and its directors, officers, employees, agents, and Affiliates harmless against any and all losses, damages, expenses, reasonable attorneys' fees (regardless of outcome), settlement costs and judgments arising out of or resulting from Supplier's material breach of any of its representations or warranties under Article 8 above, including, but not limited to, development, manufacture, testing, shipping, storage, delivery and/or other handling or processing of the Drug, except to the extent that such losses, damages, expenses, fees, settlement costs and judgments result from the material breach by ORPHAN of its covenants or warranties under this Agreement or the negligence or willful misconduct of ORPHAN, its employees or agents. Supplier shall defend and indemnify ORPHAN for any injuries or claims of injuries which may arise during manufacturing of the Product.

10.2 ORPHAN Indemnification of Supplier. Except as provided in Section 10.1 above, and subject to Supplier's compliance with its obligations in Section 10.3 hereof, ORPHAN hereby indemnifies, defends, and holds Supplier and its directors, officers, employees, agents and Affiliates harmless against any and all claims, losses, damages, expenses, reasonable attorneys' fees (regardless of outcome), settlement costs and judgments (a) to which Supplier may be subject with respect to the Drug, except those which arise under facts and circumstances pursuant to which Supplier would be required to indemnify ORPHAN under the provisions of Section 10.1, or (b) arising out of or resulting from any subsequent formulation, repackaging, distribution or other use of the Drug supplied hereunder, including third party liability claims relating thereto.

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10.3 Indemnification Procedures. A party (the “Indemnitee”) which intends to claim indemnification under this Article 10 shall promptly notify the other party (the “Indemnitor”) in writing of any action, claim or other matter in respect of which the Indemnitee or any of its directors, officers, employees, agents or Affiliates intend to claim such indemnification. The Indemnitee shall permit, and shall cause its directors, officers, employees, agents and Affiliates to permit, the Indemnitor, at its discretion, upon providing the Indemnitee with a written acknowledgment of full and complete responsibility for the indemnification of the Indemnitee with respect to any such action, claim or other matter, to settle any such action, claim or other matter; and to complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement shall not adversely affect the Indemnitee’s rights hereunder or impose any obligations on the Indemnitee in addition to those set forth herein in order for it to exercise such rights. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its directors, officers, employees, agents and Affiliates at the Indemnitor’s expense shall cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

## **ARTICLE 11**

### **INVENTIONS AND PATENTS**

11.1 Inventions by Supplier. Supplier hereby assigns, releases, and transfers to ORPHAN its entire right, title and interest in and to any invention, discovery or improvement relating to the Drug (whether patentable or not) made or conceived by Supplier employees or contractors, including, without limitation, manufacturing, manufacturing processes and procedures, analytical process, procedure or method,

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analytical results, and any route(s) of synthesis provided, however, ORPHAN hereby grants to Supplier a paid-up, worldwide, nonexclusive, nontransferable license to use patented inventions, discoveries, or improvements [ \* ] for purposes of this Agreement, [ \* ].

11.2 Inventions by ORPHAN. ORPHAN shall own all right, title and interest in and to any invention, discovery or improvement relating to the Drug (whether patentable or not) made or conceived solely by ORPHAN employees or by any ORPHAN contractor other than Supplier, including, without limitation, any manufacturing or analytical process, procedure or method or any source of synthesis given to Supplier.

11.3 Supplier shall promptly disclose to ORPHAN any and all inventions, discoveries and improvements relating to the Drug (collectively "Inventions"), by Supplier's employees or contractors, either alone or together with ORPHAN'S employees or contractors, and shall assign all its interests to ORPHAN or its designee in accordance with Section 11.1. Supplier shall execute at ORPHAN'S expense any assignments, applications or other instruments or documents reasonably requested by ORPHAN in accordance with this Article 11 and, at ORPHAN'S expense, give testimony which shall be deemed necessary to apply for and obtain Letters Patent of the United States or of any other country and otherwise to perfect ORPHAN'S interest therein. Supplier's and ORPHAN'S obligations hereunder shall survive termination of this Agreement. All data obtained in the Technology Transfer/Development Program and the stability program described in Appendix D—Requirements for Stability Studies, are the property of ORPHAN and cannot be used without its consent except for the performance by Supplier of its obligations hereunder.

## ARTICLE 12

### TRADEMARKS

12.1 ORPHAN Trademarks. ORPHAN may originate, select and apply to register one or more trademarks ("ORPHAN Trademarks") under which the Drug will be sold and distributed by ORPHAN or its Affiliates and distributors. ORPHAN shall own all

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right, title, and interest in the ORPHAN Trademarks, subject to the limited license granted to Supplier in this Article 12. ORPHAN shall be solely responsible for all prosecution, defense, maintenance and costs relating to the ORPHAN Trademarks.

12.2 Limited Trademark License. ORPHAN hereby grants Supplier a paid-up, worldwide, nonexclusive, nontransferable license to the ORPHAN Trademarks solely for purposes of manufacturing and distributing the Drug under this Agreement. Supplier shall comply with ORPHAN'S standard policies and procedures for the use of the ORPHAN Trademarks and shall furnish ORPHAN with copies of any packaging, or other materials incorporating the ORPHAN Trademarks for ORPHAN'S review and approval prior to any use thereof. Supplier shall make any changes or additions reasonably requested by ORPHAN to comply with ORPHAN'S standard policies and procedures for the use of the ORPHAN Trademarks. Upon termination of this Agreement, Supplier shall promptly cease any use of the ORPHAN Trademarks.

12.3 Limitations. Supplier shall not use, or assert any claims to, any of the ORPHAN Trademarks or any trademark confusingly similar to any ORPHAN Trademarks, provided that ORPHAN shall not choose a trademark which is the same as, or confusingly similar to, a trademark previously used by Supplier.

12.4 Infringement. Supplier shall promptly notify ORPHAN if Supplier knows or reasonably suspects that a Third Party is infringing any ORPHAN Trademark and shall provide ORPHAN with any evidence thereof. At ORPHAN'S expense, Supplier shall reasonably cooperate in any investigation or other legal action with regard to such infringement.

## **ARTICLE 13**

### **CONFIDENTIALITY**

13.1 Proprietary Information. During the term hereof and for a period of [ \* ] years thereafter, any Proprietary Information disclosed by the one party (the "Disclosing Party"), directly or indirectly, to the other party (the "Receiving Party") under this

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Agreement shall be deemed confidential and trade secret information, whether so designated or not, and shall not be disclosed by the Receiving Party to any Third Party, except as set forth below. Access to such Proprietary Information will be limited to employees, agents, consultants or contractors of the Receiving Party who reasonably require such Proprietary Information for purposes of performing the Receiving Party's obligations hereunder and who are bound to the Receiving Party by similar obligations in respect of confidentiality and use. Such employees, agents, consultants or contractors will be advised of the nature and existence of the undertakings in respect of such Proprietary Information pursuant to this Agreement and of the applicability of such undertakings to them. The Receiving Party will use such Proprietary Information only to carry out its obligations or to exercise its rights hereunder and will not use such Proprietary Information for its own benefit or for the benefit of others or in any way inconsistent with this Agreement.

13.2 Exceptions. Information shall not be deemed Proprietary Information which:

- (a) at the time of disclosure, is already in the public domain or thereafter becomes part of the public domain by publication or otherwise through no fault or act of the Receiving Party;
- (b) was demonstrably in the possession of the Receiving Party prior to the time of the disclosure to it and was not acquired, directly or indirectly, from the Disclosing Party;
- (c) is independently disclosed to the Receiving Party by a third party who has not violated any confidential obligation owed to the Disclosing Party;
- (d) was independently developed by the Receiving Party without any use of or reliance on any Proprietary Information of the Disclosing Party;
- (e) is required to be disclosed by legal process; provided that, in each case the party so disclosing information timely informs the other and uses its best efforts to limit the disclosure and maintain confidentiality to the extent possible and permits the other party to attempt by appropriate legal means to limit such disclosure;
- (f) is information which is required to be included in patent applications filed

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hereunder or required to be provided to the FDA or any other regulatory authority in the Territory in order for ORPHAN or Supplier to obtain Registrations for the Drug or otherwise to comply with applicable regulatory requirements, or for Supplier to manufacture the Drug for ORPHAN hereunder; provided, however, that no Proprietary Information of ORPHAN or Supplier will be disclosed in any such patent application without the prior written consent of the other Disclosing Party, which consent will not be unreasonably withheld; or

- (g) is information which is required to be disclosed to customers, users, and prescribers of the Product or which is reasonably necessary to disclose in connection with the ethical marketing of the Product, if applicable.

13.3 Disclosure by the Receiving Party to a Third Party shall be made only to the extent necessary to enable the Receiving Party to comply with its contractual obligations to the disclosing party.

13.4 Each Third Party to which Proprietary Information is disclosed other than a governmental agency will agree in writing prior to such disclosure to keep the Proprietary Information in strict confidence and to comply with the terms of this Article 13.

13.5 Both parties agree to limit access of Proprietary Information to those of its officers, directors, or employees, or any Third Party who must have Proprietary Information to carry out the terms of any agreement made between the parties.

13.6 Neither party shall utilize the Proprietary Information disclosed to it by the Disclosing Party after the completion of the Agreement between the parties, either in its own development work or for commercial purposes, without advance written consent of the Disclosing Party.

13.7 The party receiving Proprietary Information will obtain no right or license of any kind under any patent applications, patent or otherwise by reason of this Agreement and all Proprietary Information will remain the sole property of the Disclosing Party unless provided otherwise in this Agreement.

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13.8 Except as otherwise required by law, applicable regulations or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat as confidential the terms, conditions, and existence of this Agreement.

13.9 Prior Confidentiality Agreement. The Confidentiality Agreement between the parties hereto dated February 27, 1996, is hereby superseded and terminated. Any disclosure of Proprietary Information by either party pursuant to such Confidentiality Agreement shall be deemed to have been made hereunder and shall be subject to this Article 13.

13.10 Terms of Agreement; Press Releases. Except as otherwise required by law or the rules and regulations of any stock exchange on which a party's securities may be publicly traded or in disclosures made in confidence to a party's professional or financial advisors, applicable regulations or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat the terms, conditions and existence of this Agreement as Proprietary Information. The parties shall cooperate in good faith in the preparation of any press releases or other public disclosures of their business relationship, and neither party shall issue any such press release or other disclosure without the prior approval of the other party, which approval shall not be unreasonably held.

#### **ARTICLE 14**

#### **TERM OF AGREEMENT**

14.1 Unless sooner terminated pursuant to Article 15 below, the initial term of this Agreement shall commence on the Effective Date and end upon expiration of the third (3rd) Contract Year. Supplier and ORPHAN may mutually agree to extend this Agreement on a for one or more additional three year terms. Supplier or ORPHAN must provide a written notice of intent to terminate the Agreement at least eighteen (18) months prior to the expiration of the initial or any extended term. All references herein to "term of this Agreement" shall be deemed to include both the initial and any extended terms.

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**ARTICLE 15****TERMINATION**

15.1 Termination by Either Party. In addition to any other legal or equitable remedies it may have, either party may terminate this Agreement prior to the expiration of the term of this Agreement upon ten (10) days' written notice to the other party:

- (a) If the other party breaches any material term or condition of this Agreement, including any term or condition in any appendix attached hereto, provided such other party has not cured such breach within thirty (30) days of written notice thereof; provided, further, that if at the end of such thirty (30) day period the party in breach is making a good faith effort to cure, a reasonable time thereafter (not to exceed an additional thirty (30) days) shall be allowed for such cure.
- (b) If the other party is declared bankrupt or insolvent, or makes an assignment for the benefit of its creditors, or if a receiver is appointed or any proceedings are commenced, voluntary or involuntary, by or against either party under any bankruptcy or similar law, and such status is not cured within thirty (30) days from its occurrence.
- (c) If an event of force majeure continues for more than six (6) months, either party, at its option, may elect to treat such continued suspension of performance as a material breach and may terminate this Agreement.

15.2 Termination by ORPHAN. In addition to any other legal or equitable remedies it may have, ORPHAN may terminate this Agreement upon thirty (30) days' written notice to Supplier:

- (a) If the minimum requirements for the Drug or the timeframes for performance set forth in Appendix A hereto are not met by Supplier and no amendment thereof is acceptable to ORPHAN; or
- (b) If ORPHAN determines, in its sole discretion, not to proceed further with the investigation of the Drug for the treatment of narcolepsy or any other indication.

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15.3 Termination by Supplier. In addition to any other legal or equitable remedies it may have. Supplier may terminate this Agreement upon thirty (30) days' written notice to ORPHAN if [ \* ], Supplier determines that solely, in order [ \* ] under the terms of this Agreement, it will have to [ \* ]. [ \* ].

15.4 Effects of Expiration or Termination. Upon expiration or termination of this Agreement for any reason:

- (a) Supplier shall manufacture and ship, and ORPHAN shall purchase, Production Batches of the Drug ordered by ORPHAN prior to the effective date of such expiration or termination.
- (b) Supplier shall continue to provide manufacturing and quality assurance support and support of the stability studies for the Drug until the expiration date of the last production Batch of the Drug purchased by ORPHAN hereunder or the date required by any applicable law or regulation in the Territory, whichever is later, provided, however, if ORPHAN terminates this Agreement, ORPHAN shall [ \* ] of any required support of the stability studies.
- (c) Supplier shall take all steps reasonably requested by ORPHAN to confirm the assignment to ORPHAN all of Supplier's right, title and interest in the Inventions, including, without limitation, to execute or cause its employees or contractors to execute such documents as may be reasonably requested by ORPHAN to vest all such right, title and interest in such Inventions in ORPHAN, provided ORPHAN shall pay all reasonable expenses, including any of time and travel of Supplier's employees, in connection with steps.
- (d) Each party shall return to the other party any Proprietary Information of the other party except for one (1) archival copy as may be required for purposes of compliance with any FDA regulation or other applicable law or regulation in the Territory.

15.5 Survival. The provisions of Articles 4 (Marketing Rights), 7 (Prices and Payments), 8 (Representations, Warranties, and Inspections), 9 (Acceptance, Rejection and Claims), 10 (Indemnification), 11 (Inventions and Patents), 12 (Trademarks), 13

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(Confidentiality), 14 (Term of Agreement), 15 (Termination), 16 (Force Majeure), 17 (Dispute Resolution) and 18 (Miscellaneous) shall survive the expiration or termination of this Agreement and shall remain in full force and effect in accordance with the terms thereof.

## ARTICLE 16

### FORCE MAJEURE

16.1 Events of Force Majeure. Either party shall be excused from the performance of its obligations in the event such performance is prevented by a cause beyond the reasonable control of such party, including, without limitation, any act of God; regulation or law of any government or an agency thereof; war; insurrection or civil commotion; earthquake, tornado, fire, flood or storm; epidemic; or failure of suppliers, public utilities or common carriers. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such condition, such party shall promptly resume performance hereunder.

16.2 Notice. A party affected by an event of force majeure shall give the other party prompt written notice of the occurrence of any event of force majeure and the nature and duration thereof. An affected party shall use all reasonable efforts to resume performance as quickly as possible and to give the other party prompt written notice when it is again fully able to perform such obligations. If Supplier is the affected party, such notice of resumption of performance shall state the quantities of Drug manufactured but not shipped by Supplier due to any event of force majeure and the expiration dates thereof.

16.3 Cover. During any suspension of performance by Supplier under Section 16.1 above, ORPHAN may, at its option, purchase elsewhere the quantities of the Drug ORPHAN has ordered which Supplier is unable to deliver.

16.4 Short Supply Allocation. If Supplier is unable to supply all of ORPHAN'S orders for the Drug hereunder in a timely manner, Supplier shall [ \* ] available resources and production capacity [ \* ],

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taking into consideration the respective requirements of [ \* ] during a reasonable time period [ \* ].

## ARTICLE 17

### DISPUTE RESOLUTION

17.1 Negotiation. The parties intend that any dispute, controversy or claim arising out of or relating to this Agreement, or any breach thereof, shall be resolved under the procedures set forth in this Section, including, as a final method of resolution, binding arbitration. The amount involved in any such dispute, controversy, or claim shall be conclusively determined for the sole purpose of determining whether such dispute, controversy, or claim is subject to the provisions of this Article 17, by the amount set forth in an initial letter from the party making the claim to the other party.

17.2 Mediation. If attempts to resolve the dispute pursuant to Section 17.1 are unsuccessful, before commencing arbitration, mediation shall be conducted by a single mediator appointed by mutual agreement of the parties. The mediator shall not have the power to bind the parties to the resolution. The mediation session shall take place in [ \* ], on [ \* ] and shall be attended by a representative of each party with full authority to settle the matter, along with any other representatives reasonably necessary to discuss and address the issues involved in the Dispute. On the [ \* ] day of mediation, each party shall be allotted [ \* ] with other representatives necessary to discuss and address the issues involved in the Dispute to state its views of the Dispute to the mediator and to the other party. On the [ \* ] day of mediation, the parties shall attempt to resolve the Dispute with the aid of the mediator in a format agreed to by the parties or imposed by the mediator. If the parties cannot agree upon a mutually acceptable mediator within [ \* ] of the end of the [ \* ] negotiation period in Section 17.1 or if the Dispute is not resolved by mediation within [ \* ] after completion of the mediation session, either party may give notice in writing that the Dispute shall be decided by final and binding arbitration.

17.3 Arbitration. Final and binding arbitration of any Dispute shall be conducted

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in [ \* ], before three (3) arbitrators selected by mutual agreement of the parties or, if no such agreement is possible, appointed by the American Arbitration Association (“AAA”). The arbitration shall be conducted in accordance with the AAA Commercial Arbitration Rules then in effect, subject to the modifications set forth below, and judgment upon the award may be entered in any court of competent jurisdiction. At least one arbitrator shall have experience in the pharmaceutical industry, and at least one arbitrator shall be an attorney with experience in pharmaceutical industry licensing and contractual matters. The arbitration shall be closed to any Third Party. Notwithstanding any provision to the contrary in the AAA’s Commercial Arbitration Rules, the parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:

- (a) Each party shall have the right to request from the arbitrators, and the arbitrators shall order upon good cause shown, reasonable and limited pre-hearing discovery as permitted in civil matters in the courts of [ \* ], , including (i) exchange of witness lists, (ii) depositions under oath of named witnesses, (iii) written interrogatories, and (iv) document requests;
- (b) If a party is asked to reveal material in the arbitration which the party considers to be Proprietary Information, the party shall bring the matter to the attention of the arbitrators, who shall make such protective orders as are reasonable and necessary;
- (c) Upon conclusion of the pre-hearing discovery, the arbitrators shall promptly hold a hearing upon the evidence to be presented by the parties and shall promptly render a written opinion and award but in no event later than sixty (60) days after the conclusion of the hearing.
- (d) The arbitrators shall not add to, detract from, or alter the provisions of the Agreement of any applicable law or rule of civil procedure;
- (e) The arbitrators may not award or assess punitive damages against either party;
- (f) The arbitrators may require either party to specifically perform its obligations under this Agreement; and
- (g) Each party shall bear its own costs and expenses of the arbitration and [ \* ], subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees, including, without limitation, attorney’s fees, to the prevailing party.

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**ARTICLE 18**

**MISCELLANEOUS**

18.1 Choice of Law. This Agreement shall be governed by and interpreted in accordance with the laws of [ \* ], without regard to its conflict of laws provisions and the courts of [ \* ] shall have exclusive jurisdiction over all matters arising out of this agreement.

18.2 Notices. Any and all notices provided for shall be sent to the respective parties at the following addresses by certified or registered mail or sent by a national courier service with proof of delivery, by personal delivery or by facsimile with an electronic and verbal confirmation of receipt:

If to Supplier:     General Manager  
                          Special Fine Chemicals  
                          Lonza Inc.  
                          Corporate Headquarters  
                          17-17 Route 208  
                          Fairlawn, New Jersey 07410-2821  
                          Fax: (201)794-2695

If to ORPHAN:     [ \* ]  
                          Orphan Medical, Inc. 3911  
                          Ridgedale Drive Minnetonka,  
                          Minnesota 55305  
                          Fax: (612)541-9209

with a copy to each President's office, or to such other addresses as may be subsequently furnished by one party to the other in writing. Any such notice shall be deemed effective three (3) days after mailing or upon receipt if sent by courier service, personal delivery or facsimile.

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18.3 Severability. If any term or condition of this Agreement is found by a court of competent jurisdiction in a final unappealed or unappealable order to violate the provisions of any applicable statute, law or regulation, the remainder of this Agreement shall remain in full force and effect. The parties shall then negotiate in good faith to modify this Agreement, but only to the extent necessary to make the affected term or condition of this Agreement valid and enforceable, having full regard for applicable laws and the intent and purposes of the parties entering into this Agreement.

18.4 Integration; Amendment. This Agreement and all appendices hereto constitute the entire agreement between the parties relating to the subject matter of this Agreement and supersedes all prior agreements, representations, and understandings. This Agreement may not be amended, modified, or varied except in writing signed by a duly authorized representative of each party. In the event of a conflict between the terms of this Agreement, and any appendix hereto, the terms of this Agreement shall control.

18.5 Assignment. Neither party may assign this Agreement without the prior written consent of the other party except that either ORPHAN or Supplier may assign this Agreement (a) to an Affiliate or (b) in connection with the sale or transfer of all or substantially all of the assets of such party or the division of such party manufacturing or marketing of the Drug, as the case may be, provided, however, any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of the foregoing sentence shall be null and void. No assignment shall relieve either party of responsibility for the performance of any accrued obligation under this agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Supplier and ORPHAN respectively.

18.6 Waiver. No course of dealing between Supplier and ORPHAN or delay or failure to exercise any rights hereunder shall operate as a waiver of such rights or preclude the exercise of any other rights hereunder.

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18.7 Relationship. Each of the parties hereto is an independent contractor and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the parties hereto.

18.8 Captions. The captions to the several Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles hereof and shall not affect the meaning or interpretation hereof.

18.9 Counterparts. Two (2) or more counterparts of this Agreement may be signed by the parties, each of which shall be an original, but all of which together shall constitute the same instrument.

18.10 Diligence. Each party agrees to use due diligence in preparing full disclosure of relevant information, in reviewing information when available, and in committing decisions necessary to enable completion of Stages within target timeframes.

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IN WITNESS WHEREOF, the parties have caused this Agreement to be entered into by their duly authorized representatives as of the Effective Date.

SUPPLIER

ORPHAN MEDICAL, INC.

By: /s/ Peter Pollak  
Print: Peter Pollak  
Its: VP/GM Fine Chemicals  
Date: November 8, 1996

By: /s/ Bert Spilker  
Print: Bert Spilker  
Its: President  
Date: November 6, 1996

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**APPENDIX A**  
**GHB TECHNOLOGY TRANSFER/DEVELOPMENT PROGRAM**

Cost/Timeline

Stage A, Part I: [ \* ]

[ \* ]

Stage A, Part II

[ \* ]

TOTAL [ \* ]

\$[ \* ]

\$[ \* ]

- 
- 1) Raw Material Specifications and Acceptance Criteria—[ \* ]
  - 2) Process Validation Protocol—[ \* ]

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APPENDIX A (continued)

Stage B [ \* ]  
[ \* ]

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## **APPENDIX B**

### **REPORTING REQUIREMENTS**

The following items represent minimum content requirements. Actual reports should include all information that is relevant in assessing the status of the development program and in completing documentation that is required by regulatory agencies. Any documentation that is required for preparation of the CMC Section, Process Certification Report, Process Validation Report, etc. should not be rewritten as part of a stage completion report.

Progress reports on development will be discussed with ORPHAN on an agreed upon schedule depending on the level of activity at any point in time. Decisions, issues, and significant findings will be documented for review and concurrence. Reasonable efforts will be used to take corrective actions and conduct such additional work as is necessary to achieve the Required Specifications as outlined in Appendix C. The parties will mutually agree upon the time impact of any changes. Additional resources will be committed to conduct of the GHB Technology Transfer/Development Program if necessary to ensure completion of the project as close to the overall time frame specified as possible.

### **STAGE A: [ \* ] COMPLETION REPORT**

A "Stage A Completion Report" will contain the data and analytical results from all processing and testing conducted to include the manufacture of one (1) Validation Batch. This report will also include a copy of the following for ORPHAN review and approval if approval has not already been obtained:

- 1) Manufacturing Validation Protocol and Report  
[ \* ]
- 2) Re-validation of analytical methods, tests and specifications (to include validation documentation to support all analytical methods)  
[ \* ]

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- 3) Additional Testing  
[ \* ]
  - 4) Raw Material Vendor and Specs, and Final Product Specifications and Methods Manual
  - 5) Copies of executed Batch Record(s) and Certificate(s) of Analysis
  - 6) Stability Report (See—‘Requirements For Stability Studies’)
  - 7) Description of manufacturing facilities, personnel, Standard Operating Procedures, and appropriate supporting validation documentation as required for the NDA.
    - Training
    - Util and Support Systems
    - Environmental Standards
    - Process Conditions
  - 8) Update estimates for cost of goods

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COMPLETION REPORT

- 1) Mutually approved Bulk Drug Manufacturer Contract Release Specifications [ \* ].
- 2) Subsequent to FDA approval, ORPHAN will be notified for prior approval of any updates made through standard operating "Change Control" procedures. Changes requiring notification for approval will include and not be limited to the following:  
[ \* ]

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REQUIRED DRUG SPECIFICATIONS

[ \* ]

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**APPENDIX D**

**REQUIREMENTS FOR STABILITY STUDIES**

**REQUIREMENTS FOR DEVELOPMENT PROGRAM STABILITY STUDIES**

[ \* ]

**REQUIREMENTS FOR PRODUCTION STABILITY STUDIES**

- I. A Production Stability Protocol to be jointly approved. The protocol will meet requirements of the “Stability Testing of New Drug Substances and Products’ endorsed by the ICH Steering Committee.
- II. Reporting
  - Written stability study reports will be provided which include, but are not limited to, the following information for all Drug batches used for stability.
  - A) Certificate of analysis (include batch size, date of manufacture)
  - B) Batch numbers
  - C) Stability study results past two (2) consecutive failures or to 60 months, whichever is shortest, including both initial and data at the designated time points for analysis with references to analytical procedures used.

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**PROPOSED DEVELOPMENT PROGRAM STABILITY PLAN**  
**REQUIRED TESTS, STORAGE CONDITIONS AND FREQUENCY**

[ \* ]

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**PRODUCTION STABILITY STUDY PLAN**

[ \* ]

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**APPENDIX E**

CONFIDENTIAL DISCLOSURE AGREEMENT FOR INFORMATION EXCHANGED  
BETWEEN LONZA AND AN EXTERNAL SOURCE

This Agreement is made and entered into this \_\_\_\_ day \_\_\_\_\_ of 19\_\_\_\_, by and between Lonza Inc., a company \_\_\_\_\_ located in Fair Lawn, New Jersey ("LONZA") and \_\_\_\_\_ a company (the "POTENTIAL-COLLABORATOR") located in \_\_\_\_\_.

A. LONZA and the "POTENTIAL-COLLABORATOR" have entered into certain discussions the purpose of which is to explore and consider the possibilities of a business relationship between, or other transaction involving, LONZA and the "POTENTIAL-COLLABORATOR".

B. In this connection with and in furtherance of this possible business relationship, it is anticipated that both of the undersigned parties (i.e. LONZA and the POTENTIAL-COLLABORATOR) at various times will disclose (the "DISCLOSING PARTY") and receive (the "RECEIVING PARTY") certain information with each other which the undersigned parties consider proprietary and confidential.

The undersigned RECEIVING PARTY in consideration for the use of certain information, knowledge, software, data and/or know-how (hereinafter called "INFORMATION") related to the possible contract manufacturing of Sodium Gamma Hydroxybutyric Acid made available to it by DISCLOSING PARTY hereby agrees as follows:

1. RECEIVING PARTY agrees to keep in confidence and not to use the INFORMATION for its commercial benefit (except for technical and economic evaluation) for a period of [ \* ] years from the date hereof.
2. RECEIVING PARTY further agrees that it shall keep in confidence and not disclose any part of INFORMATION to a third party for a period of five (5) years from the date hereof.
3. Obligations of RECEIVING PARTY shall not apply to any information, knowledge, software, data and/or know-how which:
  - (a) is or hereafter becomes a part of the public domain other than through a breach of this Agreement by RECEIVING PARTY;
  - (b) RECEIVING PARTY can demonstrate was in its possession prior to the time of disclosure by DISCLOSING PARTY or can demonstrate was received by it from a third party who shall not have received same from DISCLOSING PARTY
  - (c) is required by a court or other governmental authority with competent jurisdiction to be disclosed in a non- confidential manner.
4. Each party warrants and represents that the terms of this Agreement are not inconsistent with other contractual or legal obligations it may have, or with the policies or rules of any institution or company with which it is associated.
5. Each party agrees that, without the other party's prior written consent, it will not disclose the existence of this Agreement or the fact that each party is evaluating the Information.
6. RECEIVING PARTY agrees to obligate its employees who shall have access to any portion of INFORMATION to protect the confidential and proprietary nature of INFORMATION. If either or both parties are not interested in proceeding with the establishment of a manufacturing contract, or if a commercial arrangement is not entered into, each party shall return the Information of the other party to the other party, subject to retention of one copy for archival purposes.

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7. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Minnesota.

Accepted and Agreed by Both Parties

Lonza, Inc.

Third Party

Signature: \_\_\_\_\_

Authorized Signature: \_\_\_\_\_

Name (Print): \_\_\_\_\_

Name (Print): \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

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**Return Material Authorization (RMA)**

For material return, Lonza operates a paperless, computer-supported system. The following procedure will be followed:

1. Orphan can request return authorization by calling Lonza at [ \* ] and requesting the “Customer Service Department”.
2. Lonza will issue material return authorization number generated by its quality performance database according to standard work practices in effect within Lonza at that time.
3. Lonza will organize transport of material through coordination with Orphan. The appropriate contact will be given by Orphan at the time of request for return of material.
4. Upon receipt of returned material, Lonza will send a confirmation of this to the designated contact at Orphan.

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PROCEDURE FOR RETURNED MATERIALS

- 1.0 This procedure is to describe the system for accepting customer returned goods or return of material for salvaging.
- 2.0 Customer return calls for regulated products will be forwarded to the Quality Control Department either through direct customer contact or through communications with Shipping, Receiving, or the Manufacturing Department.
- 2.1 The Quality Control then reviews verbal return policy and forwards a preprinted Notice of Authorization to Return Form to the customer.
- 2.2 The customer will fill in the required information and forward the form to the Quality Control Department. The Quality Control Department will circulate the return goods form to Shipping & Receiving, Manufacturing, Purchasing, Accounting, and the Warehouse for information on return.
- 2.3 Upon receipt of the returned goods form, the material is authorized for return. The GMP Department will communicate authorization to customer approving the return.
- 2.4 Once the material is physically returned it shall be labeled "*Hold Pending Investigation*" by the Quality Control Department.
- 2.5 The disposition of the returned goods will be indicated on a Returned Goods Form by the Quality Control Department.
- 2.6 A Returned Goods Form will be circulated for approval by the Plant Manager, Project Engineer, and Quality Control Manager, indicating disposition of material.
- 2.7 Salvaging or rework shall be within the GMP guidelines and meet DMF and/or NDA considerations.

Approved:

Production Manager	_____	Date	_____
Quality Control	_____	Date	_____
Plant Manager	_____	Date	_____

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APPENDIX G

CHANGE CONTROL REQUEST

Change Control Number \_\_\_\_\_

Date of Request: \_\_\_\_\_

Name and address of person making request:

Requested by: \_\_\_\_\_

Company Name: \_\_\_\_\_

Company address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Product/Process Affected: \_\_\_\_\_

Requested change: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Reason for change: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Change Request approved

Change Request not approved

Approved Signatures:

\_\_\_\_\_  
Orphan Medical Regulatory Affairs Date

\_\_\_\_\_  
Orphan Medical QA Date

\_\_\_\_\_  
Orphan Medical Director of New Medicine Date

\_\_\_\_\_  
Contract Vendor Date

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APPENDIX H

[ \* ] DRUG PRICE ESTIMATES  
according to Section 7.4

[ \* ]

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Amendment No. 1  
to  
Sodium Gamma Hydroxybutyrate  
Development and Supply Agreement

Amendment No. 1, dated February 7, 2005 (this "Amendment"), between Orphan Medical, Inc., a Delaware corporation ("Orphan"), and Lonza, Inc., a New York corporation ("Supplier").

**Recitals**

1. Orphan and Supplier are parties to a Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated November 6, 1996 (the "Agreement").

2. Orphan and Supplier wish to extend the term of the Agreement and to amend certain provisions of the Agreement.

3. Each capitalized term used in this Amendment and not defined herein shall have the meaning ascribed to it in the Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Orphan and Supplier agree as follows:

1. Acknowledgments. Orphan and Supplier acknowledge and agree that the initial Contract Year of the Agreement commenced [ \* ], and that each Contract Year consists of the twelve-month period commencing [ \* ] and extending through the following [ \* ].

2. Amendments to the Agreement. Effective as of the date of this Amendment, the Agreement shall be amended and modified as follows:

a. Section 14.1 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

14.1. Unless terminated pursuant to Article 15, the initial term of this Agreement shall commence on the Effective Date and end upon expiration of the third (3rd) Contract Year. Following the expiration of the initial term and any renewal terms, this Agreement shall be automatically extended for an additional term of three (3) Contract Years unless either party delivers a written notice of termination at least eighteen (18) months prior to the expiration of the initial or any renewal term. All references herein to the "term of the Agreement" shall be deemed to include both the initial and any renewal terms.

b. Appendix C {Required Drug Specifications} of the Agreement shall be amended in its entirety and shall be replaced by the Appendix C attached to this Amendment.

c. Section 18.2 of the Agreement is amended to replace the address for Orphan set forth in Section 18.2 with the following address:

Orphan Medical, Inc.  
13911 Ridgedale Drive  
Suite 250  
Minnetonka, MN 55305  
Attn: Vice President of Regulatory Affairs

d. Appendix H {Quality Agreement}. The Quality Agreement herein attached is incorporated within the overall Development and Supply Agreement.

3. **Ratification.** As modified by this Amendment, the Agreement is hereby ratified and confirmed in all respects.

IN WITNESS WHEREOF, each of Orphan and Supplier has caused this Amendment to be executed by a duly authorized representative as of the date set forth in the first paragraph.

LONZA, INC.

ORPHAN MEDICAL, INC.

/s/ Simon Edwards Feb 7, 2005

/s/ John Howell Bullion

By (print): Simon Edwards  
Its VP Sales & Business Development

By: John Howell Bullion  
Its Chief Executive Officer

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**APPENDIX C**

Orphan Medical, Inc.  
Bulk Drug Substance Specification

[ \* ]  
[ \* ]

[ \* ]

Orphan Medical, Inc.  
Bulk Drug Substance Specification

[ \* ]

[ \* ]

[ \* ]

Orphan Medical, Inc.  
Bulk Drug Substance Specification

[ \* ]

[ \* ]

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**APPENDIX H**

**QUALITY AGREEMENT  
BY AND BETWEEN**

**ORPHAN MEDICAL, INC.**  
13911 Ridgedale Drive, Suite 250  
Minnetonka, Minnesota 55305  
(hereafter called "ORPHAN")

Approved by: **Orphan  
Medical, Inc.**

By: Illegible

Date: April 25, 2005

**And**

**LONZA, INC.**  
900 River Road  
Conshohocken, PA 19428  
(hereafter called "LONZA")

Approved by:  
**Lonza, Inc.**

By: Illegible

Date: April

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## 1. QUALITY AGREEMENT

### 1.1 Purpose

- 1.1.1 This agreement (this “Agreement”) defines the roles and responsibilities for the Quality Assurance and Regulatory Affairs Department (“Quality Assurance”) of Lonza (LONZA) when providing services for Orphan Medical, Inc. (“ORPHAN”).
- 1.1.2 This Agreement also defines how ORPHAN Quality Assurance and the LONZA Quality Department will interact with each other.

### 1.2 Relationship to Supply Agreement

- 1.2.1 This Agreement shall be incorporated within and constitute a part of the Supply Agreement by and between LONZA and ORPHAN.
- 1.2.2 In the event of a conflict between any of the provisions of this Quality Agreement and the Supply Agreement, the provisions of this Quality Agreement shall govern.

## 2. PRODUCT

The PRODUCT prepared for ORPHAN by LONZA are described in **Appendix I**.

## 3. ADMINISTRATIVE INFORMATION

### 3.1 ORPHAN Contact Names

See **Appendix II**.

### 3.2 LONZA Contact Names

See **Appendix II**.

## 4. TERM OF AGREEMENT

This Quality Agreement will expire with termination of the Supply Agreement (except for quality issues that may extend past the Supply Agreement; i.e. complaints). This Agreement can be modified as needed with the written approval of both parties.

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## 5. MANUFACTURING GMP COMPLIANCE

### 5.1 General

The manufacturing operations for the PRODUCT to be performed by LONZA are defined in the Supply Agreement.

### 5.2 Premises

5.2.1 LONZA will perform required operations for manufacturing activities at approved sites.

5.2.2 The premises and equipment used to manufacture the PRODUCT will be maintained according to current regulatory requirements and in accordance with the controlled documentation approved by ORPHAN.

5.2.3 The manufacture of the PRODUCT will be conducted in a suitably controlled environment and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with (i) applicable GMP guidelines and (ii) any conditions registered in the manufacturing authorization (NDA or investigational application).

5.2.4 LONZA will maintain controlled access to the premises. All visitors must sign in and are escorted during any visit to the areas of the premise.

### 5.3 GMP Guidelines

The principles detailed in the US Current Good Manufacturing Practices (21 CFR 210 and 211) that govern the standards of manufacture for active pharmaceutical ingredients, as well as the product Guidance for Industry “Q7A Good Manufacturing Practice, Guidance for Active Pharmaceutical Ingredients”, will govern (i) the standards of manufacture of the PRODUCT, (ii) the product specifications, (iii) any applicable product license, and (iv) the NDA/ANDA application, pharmacopoeia or formulatory requirements.

### 5.4 Materials

5.4.1 LONZA will use only chemical materials, packaging, and labeling components approved by ORPHAN and tested and approved in accordance with the documentation reviewed and approved by ORPHAN.

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5.4.2 Prior to commercial use, all materials used in the PRODUCT shall meet ORPHAN'S requirements for production use.

5.5 Materials procured by LONZA

5.5.1 LONZA is responsible for auditing and qualifying vendors of actives and raw materials used in PRODUCT and will provide ORPHAN with a Certificate of Conformance statement for such vendors when requested. LONZA shall audit raw material vendors/suppliers at regular intervals according to a defined program; and the documentation of the vendors/suppliers audited and date of audit shall be available for review by ORPHAN upon request.

5.5.2 LONZA is responsible for ensuring that all materials and components procured by LONZA for use in the PRODUCT are in full compliance with the specifications listed in documentation reviewed and approved by ORPHAN. Raw Materials are given a repeat test date upon the satisfactory completion of all initial testing. Repeat testing will be performed at defined time intervals to ensure the chemical and physical stability of the raw materials unless ORPHAN provides an official expiration date.

5.5.3 LONZA is responsible for ensuring that all materials are labeled (for ID and current status) and stored properly, used correctly, appropriately tested upon receipt, and traceable to the relevant Certificate of Analysis for the materials.

5.6 Materials Provided by ORPHAN for LONZA

ORPHAN is responsible for ensuring that all materials and components provided by ORPHAN for use in the PRODUCT are in full compliance with the specifications registered, ORPHAN will provide LONZA with a Certificate of Compliance statement for the vendors that ORPHAN is responsible for qualifying.

5.7 Master Production Records

LONZA may transcribe the manufacturing information (i.e., bulk manufacturing) into its own format and will obtain written approval from ORPHAN for major changes to the process before manufacturing. Additionally Lonza will provide Orphan with all changes to process documentation, analytical methods, and specifications. Agreed upon changes to documentation will be handled as outlined by Change Management (see Section 10) of this agreement.

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**5.8 Standard Operating Procedures**

LONZA is responsible for writing and approval of any SOPs required to manufacture, test, and store the PRODUCT in accordance with applicable GMP guidelines.

**5.9 Methods Validation**

5.9.1 ORPHAN is responsible for providing to LONZA approved copies of the most current and complete filed analytical methods relating to the PRODUCT for receipt of API and raw materials, in-process product testing, product lot release, and drug and product stability and cleaning validation.

5.9.2 ORPHAN is responsible for providing to LONZA a Certification of Methods Validation for all critical methods practiced by LONZA (raw materials testing, in-process product testing, product lot release, and drug and product stability) . The certifications should state, *“The methods are appropriate for the intended purpose, are validated per relevant regulatory guidelines, and are readily available in case of a regulatory inspection.”*

**5.10 Batch Numbers**

5.10.1 The convention for LONZA “Batch Identification Number” (BIN) is as follows:

- [ \* ]

**5.11 Dates of Manufacture and Expiration**

5.11.1 Date of Manufacture: LONZA will allocate the Date of Manufacture based on the date that drying is complete for the PRODUCT.

5.11.2 Expiration Date: LONZA will calculate the expiry date from the Date of Manufacture using the currently approved expiry period. The expiration date will be the last day of the month assigned. Changes to the expiration date will be handled by Change Management (see Section 10).

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### 5.12 Manufacturing and Equipment Data

LONZA is responsible for keeping records of equipment usage (previous PRODUCT produced in non-dedicated equipment), cleaning, and any maintenance/calibration performed.

### 5.13 Storage and Shipment

5.13.1 Storage: LONZA will store the PRODUCT under conditions approved by ORPHAN. LONZA will ensure that during storage before shipping of the PRODUCT, appropriate controls are in place to insure that there is no interference, theft, product contamination, or mixture with any other product or materials. ORPHAN will provide details of any labeling requirements and storage and shipping conditions for the PRODUCT.

5.13.2 Packaging and Labeling for Transit: The PRODUCT will be labeled and packaged for transit pursuant to instructions timely provided to LONZA in writing by ORPHAN and complying with cGMP.

5.13.3 Segregation of PRODUCT: LONZA will maintain proper segregation of the PRODUCT according to systems reviewed and approved by ORPHAN. Different lots of a single product or different types of product will not be mixed on a pallet.

5.13.4 Shipment of Product to ORPHAN: Only approved, finished (unless required by ORPHAN), labeled PRODUCT will be shipped by LONZA to ORPHAN. LONZA will not ship any product that is unapproved or under quarantine without prior written approval from Orphan Medical, Inc.

## 6. QUALITY CONTROL

### 6.1 General

The testing of the PRODUCT is to be performed by LONZA as defined in the PRODUCT Specification, see Appendix I. Following LONZA's release of the PRODUCT to ORPHAN, the ORPHAN Quality Control Unit shall be responsible for approving or rejecting drug product manufactured, processed, or packed by LONZA.

### 6.2 In-Process and Finished Product Testing

6.2.1 A method transfer of any validated test method developed by ORPHAN will be completed prior to product release by LONZA.

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## APPENDIX H

- 6.2.2 LONZA will perform all in-process and finished product testing using approved specifications and methods of analysis. Laboratory notebook pages and representative sample chromatograms can be reviewed on LONZA's site by ORPHAN.
- 6.2.3 A LONZA Qualified Person/QA Representative will sign a Certificate of Conformity confirming that the lots produced in a campaign have been manufactured, packaged, tested, and meets the requirements of the Master Batch Record and Drug Product Specification. The current release documentation information can be found in Appendix III.
- 6.2.4 Any reference standards that are supplied by ORPHAN or its Affiliates must be accompanied by a COA listing the expiration date and any correction factors that need to be applied.
- 6.2.5 ORPHAN may perform testing to confirm the LONZA data. ORPHAN may perform confirmatory testing during the initial term of this Agreement to validate the LONZA data. Periodically thereafter, ORPHAN may test material to confirm the LONZA data. Dispute resolutions in conflicting test data will be handled according to the provisions of Section 9.
- 6.2.6 ORPHAN may perform release testing at a contract laboratory. Copies of all related documentation will be provided to LONZA upon request to support final disposition by LONZA.

### 6.3 Retain Samples

- 6.3.1 LONZA will retain samples of the active ingredients for a [ \* ] beyond the ingredient date manufactured. LONZA will retain samples of raw materials for [ \* ]. The amount of sample retained will be [ \* ] quantity required to carry out all of the tests required to determine if the material meets its specifications, with the exception of sterility and pyrogen testing (CFR 211.170a).

### 6.4 Routine Stability Program

- 6.4.1 ORPHAN is responsible for maintaining a Stability Program and will request samples from Drug Product lots to be placed on stability as required.

### **Quality Agreement: Page 6**

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#### 6.5 Out-of-Specification (OOS) Investigations

LONZA is responsible for investigating any testing performed that fails to meet specifications. Each investigation will be reviewed by LONZA's Quality Assurance designee, and will follow internal procedures that are in accordance with regulatory guidelines. LONZA will inform ORPHAN of OOS results and any subsequent retest results.

#### 6.6 Contract OC Laboratories

ORPHAN is responsible for ensuring the compliance and documented qualification of any QC lab contracted to perform testing of the Raw Materials and PRODUCT used in the manufacture of the finished PRODUCT through an appropriate laboratory audit for compliance.

### 7. QUALITY ASSURANCE

#### 7.1 Deviations and Investigations

7.1.1 Deviations: Any deviation from the process during manufacture or OOS result must be carefully documented and approved by LONZA Quality Assurance and appropriate area management. ORPHAN will be informed at the time of all Pharmaceutical Process/Formulation Exception Reports (PFERs) and reserves the right to participate in the investigation. A copy of the final investigation report will be included in the Release Documentation package provided to ORPHAN.

7.1.2 LONZA will notify ORPHAN of the disposition of any rejected PRODUCT [ \* ].

7.1.3 LONZA will notify ORPHAN immediately, in writing, if any problems are discovered that may impact PRODUCT lots previously shipped to ORPHAN.

7.1.4 Some investigations may require additional testing, stability, or validation to be conducted. This work will be performed by LONZA as agreed by both parties.

#### 7.2 Lot Disposition

For each lot, LONZA will provide the release documentation required in **Appendix III**.

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**7.3 Quality Assurance Certificate of Compliance/Analysis**

- 7.3.1 LONZA will provide a standard Certificate of Analysis indicating the test results of each test performed as well as a signed Certificate of Compliance for the campaign confirming that the PRODUCT has been manufactured, tested, and stored according to the requirements of the Master Production Record.
- 7.3.2 LONZA will provide complete copies to ORPHAN of the lot documentation (Executed batch record and analytical data). Shipment of the lots will require written prior authorization by ORPHAN.

**7.4 Product Release**

- 7.4.1 Shipment of the PRODUCT, once dispositioned as “Approved” by LONZA, is the absolute responsibility of ORPHAN’S quality department. ORPHAN’S approval will be undertaken by ORPHAN, based on ORPHAN’S internal procedures, the full document package provided by LONZA, and completion of any release testing required by ORPHAN Quality Control for their internal release criteria.
- 7.4.2 Any problem discovered by ORPHAN likely to cause rejection of the PRODUCT will be communicated to LONZA within [ \* ] from receipt of the full release documentation package (see Appendix III).

**7.5 Product Complaints and Recalls**

- 7.5.1 Product Complaints: ORPHAN is responsible for receiving and initially investigating any PRODUCT complaints. ORPHAN will notify LONZA of any problems thought to be due to manufacture which are found during the distribution of the PRODUCT. When LONZA receives notice of manufacturing problems from ORPHAN, LONZA will promptly perform investigations for alleged problems. Investigation reports will be forwarded to ORPHAN within [ \* ]. ORPHAN is responsible for reporting any complaint to the appropriate regulatory authority including adverse drug events reports. Any PRODUCT complaint received by LONZA will be immediately forwarded to ORPHAN.

Product Recall: ORPHAN, with data and assistance provided by LONZA, is responsible for filing Field Alerts and initiating PRODUCT recalls due to any defect considered sufficiently serious. ORPHAN will provide LONZA with a copy of any regulatory correspondence related to field alerts or recalls. ORPHAN will notify LONZA of any recall. LONZA will provide a [ \* ].

**7.6 Records Retention**

- 7.6.1 LONZA will retain, [ \* ], lot production records for the PRODUCT and materials for [ \* ] from manufacture of lots. Validation records may need to be held for [ \* ].

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## APPENDIX H

7.6.2 LONZA will retain lot records for the expiry date of the Clinical Trial Materials for [ \* ] of [ \* ] unless notified of a shorter retention period by ORPHAN, [ \* ] of [ \* ] past the stop use date.

### 7.7 Quality Assurance Presence in the Manufacturing Facility

7.7.1 LONZA will maintain adequate Quality Assurance presence in the manufacturing facility during the manufacture of the PRODUCT to ensure compliance with GMPs.

7.7.2 LONZA will permit ORPHAN'S presence in the manufacturing facility during the manufacture of the PRODUCT if requested by ORPHAN'S quality group.

## 8. REGULATORY COMPLIANCE

### 8.1 Regulatory Inspections

8.1.1 LONZA will immediately inform ORPHAN of any regulatory inspections that may involve the PRODUCT and permit a representative from ORPHAN Quality to be present, if required by ORPHAN.

8.1.2 LONZA will secure ORPHAN'S agreement prior to making any commitment to a regulatory agency regarding ORPHAN'S PRODUCT.

8.1.3 Additionally, LONZA will immediately forward to ORPHAN any regulatory correspondence on the PRODUCT or on other system related issues that support manufacturing, packaging, or testing for ORPHAN'S PRODUCT.

8.1.4 ORPHAN will immediately inform LONZA in writing of any regulatory issue that impacts LONZA's ability to manufacture the PRODUCT.

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8.2 Regulatory Actions

- 8.2.1 ORPHAN will notify LONZA of any regulatory actions on the PRODUCT that may impact LONZA.
- 8.2.2 LONZA is responsible for supporting all lot record investigations associated with regulatory actions.
- 8.2.3 LONZA agrees to supply ORPHAN with any manufacturing, testing, or storage data [ \* ], if requested, as the result of a regulatory inspection, or a potential regulatory exposure such as a recall or significant product complaint.

8.3 Regulatory Affairs

- 8.3.1 ORPHAN is responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with regulatory agencies prior to shipment/human administration.
- 8.3.2 LONZA Quality Assurance will act as the point of contact between ORPHAN'S regulatory affairs staff or consultant regarding issues that impact the CMC registration information for the drug substances and/or drug product.
- 8.3.3 LONZA Quality Assurance will perform a technical/regulatory review of all documentation provided to ORPHAN to support regulatory submission.
- 8.3.4 ORPHAN will be responsible for making final decisions regarding CMC regulatory strategy.
- 8.3.5 ORPHAN will provide a copy of final regulatory submissions to LONZA Quality Assurance for reference during inspections.
- 8.3.6 LONZA will provide support for ORPHAN with respect to proposing appropriate CMC regulatory strategies and identifying potential regulatory consequences for issues involving drug substance.

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**8.4 Right to Audit**

- 8.4.1 LONZA will allow representatives from ORPHAN Quality to have access to their manufacturing, warehousing, laboratory premises, and records for audit purposes pursuant to this Section 8.4. ORPHAN representatives will be escorted at all times by LONZA personnel.
- 8.4.2 ORPHAN will provide a [ \* ] notification for all planned audits.
- 8.4.3 LONZA will permit ORPHAN Quality to conduct preparatory audits either for initiation of GMP manufacture of the PRODUCT or for pre-approval inspections (PAI).
- 8.4.4 LONZA will permit ORPHAN Quality to conduct audits to address significant product quality or safety problems.
- 8.4.5 LONZA will permit ORPHAN Quality to perform [ \* ] GMP compliance audit per [ \* ] and [ \* ] of [ \* ] each. This includes audits required by ORPHAN'S commercial partners.

**8.5 Audit Closeout**

- 8.5.1 An exit meeting will be held with representatives from LONZA and ORPHAN to discuss significant audit observations.
- 8.5.2 ORPHAN will provide a written report of all observations within [ \* ] to LONZA. Within [ \* ] of the audit report receipt, LONZA will provide a written response to all findings that details corrective action to be implemented. LONZA will follow up to ensure that all corrective actions are implemented.

**9. DISPUTE RESOLUTION****9.1 Non-Conformity Dispute**

In the event that a dispute arises between LONZA and ORPHAN in the nonconformity of a lot of the PRODUCT, the supervisors of the Quality departments from both companies shall in good faith promptly attempt to reach an agreement. ORPHAN may only dispute a lot of PRODUCT which has been dispositioned and released by LONZA. Whatever the outcome, ORPHAN Quality retains the absolute right to determine product release status. Financial liability shall be determined according to the Supply Agreement.

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## 9.2 Other Disputes

Other disputes shall be resolved in accordance with the Supply Agreement.

## 10. CHANGE MANAGEMENT

### 10.1 Technical & cGMP Impact Assessment

- 10.1.1 All changes shall proceed through a technical and cGMP impact assessment by the LONZA expert groups coordinated by LONZA's Quality Assurance change management personnel. The documents that contain ORPHAN'S intellectual property or changes that may affect (i) ORPHAN'S regulatory submissions or (ii) the support system that has a direct impact on the quality systems that will affect ORPHAN'S product, will also go through ORPHAN'S assessment for regulatory advice and implementation requirements, as per the agreements between ORPHAN and LONZA.
- 10.1.2 Any changes to documentation will be coordinated with ORPHAN by the responsible project scientist or project leader.
- 10.1.3 The scope of such a Change Management process includes Chemical Manufacturing, Pharmaceutical Manufacturing and Packaging processes. The associated changes may relate to: the Master Production Control Records (e.g. Master Formulas, Filling Work Orders, Packaging Work Orders); Bills of Materials; Analytical Standards and Test Methods (for Raw Materials and Finished Product); Stability Protocols; Purchase Specifications (for Raw Materials and Packaging Components); and ORPHAN specific Validated Equipment, Facilities, Utilities or Computer Systems.
- 10.1.3.1 All manufacturing, testing, and storage operations performed by LONZA for the PRODUCT will have ORPHAN Quality review and written approval within [ \* ] of notification. ORPHAN'S Quality review and approval signifies the conformance of LONZA documents to ORPHAN'S CMC regulatory submissions.
- 10.1.3.2 Any significant changes will be mutually agreed upon in writing prior to implementation. All required regulatory approvals will be obtained prior to implementation.

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- 10.1.3.3 Changes to the controlled documents or to validated equipment and systems specific to the PRODUCT must have ORPHAN Quality written approval, prior to implementation.
- 10.1.3.4 Administration changes to the controlled documents (e.g., typo corrections, formatting) do not require ORPHAN Quality written approval prior to implementation, but these changes must be submitted to ORPHAN Quality in a timely manner for review and approval.

## 11. PRODUCT AND PROCESS VALIDATION

### 11.1 Process Validation

LONZA is responsible for ensuring that the manufacturing process is validated. The validation should ensure that the process is capable of consistently achieving the PRODUCT acceptance specification.

### 11.2 Cleaning Verification/Validation

LONZA is responsible for ensuring that adequate cleaning is carried out between lots of different product to prevent contamination. Data should be available to support the campaign of lots of the same product and the type of cleaning that will be performed in between manufacturing of the same product. ORPHAN will provide information (i.e. [ \* ]) to establish cleaning limits. The cleaning procedure and analytical methodology will be reviewed before the first product lots are made.

### 11.3 Equipment, Computer, Facility, and Utilities Qualification

LONZA is responsible for all equipment, computer, facility, and utility qualification activities associated with the PRODUCT.

### 11.4 Laboratory Qualification

LONZA is responsible for ensuring that all laboratories are in compliance with applicable cGMP's guidelines. If analytical work is performed at LONZA then ORPHAN will also provide any existing analytical documentation to assist in methods transfer or methods validation. In addition, if analytical work is not performed at the Conshohocken, Pennsylvania site, LONZA may elect to perform an audit on vendors to be used for analytical testing. LONZA will be responsible for insuring that the vendor is practicing within cGMP compliance.

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**12. ANNUAL PRODUCT REVIEW, ANNUAL REPORT AND DRUG LISTING****12.1 Annual Product Review**

- 12.1.1 LONZA will perform an Annual Product Review for the PRODUCT and will issue a report to ORPHAN. This report will cover all manufacturing, testing, and storage activities performed by LONZA. It will be a review of any changes at LONZA in the manufacturing, testing, storage or validation of the PRODUCT in the previous calendar year and a summary of lots made, released, and rejected. Also, control charting or trend analysis of key product parameters will be performed. Any abnormalities will be explained in the annual review.
- 12.1.2 ORPHAN is responsible for preparing any Annual Report as required by applicable regulations, including 21 CFR 314.70, 314.81, and/or 601.12. At [ \* ] calendar days before the Annual Report due date, ORPHAN shall request in writing from LONZA the chemistry, manufacturing, and controls data required for submission of the Annual Report. LONZA will provide the requested information to ORPHAN within [ \* ].

**12.2 Drug Listing**

- 12.2.1 LONZA is responsible for drug listing as the manufacturer of the PRODUCT for ORPHAN, while ORPHAN is responsible for drug listing as the distributor of the PRODUCT. ORPHAN will provide LONZA with all required information needed to register the PRODUCT. ORPHAN will notify LONZA of the scheduled PRODUCT launch.

{Appendices are attached}

**Quality Agreement: Page 14**

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**APPENDIX I: PRODUCT—SODIUM OXYBATE Specification**

[ \* ]

**Quality Agreement: Page 15**

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**Sampling:**

[ \* ]

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**Contractual Release Specifications:**

Some specification requirements for release of the bulk drug substance will be more restrictive than those approved in the NDA to ensure drug adequacy upon analytical retesting or anticipated degradation over time. Sodium Oxybate Powder must meet BP/EP/EC/Japan standards. Orphan Medical Quality Assurance will issue a certificate of analysis as the final release for the bulk drug substance.

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**APPENDIX II: LIST OF QUALITY CONTACTS**

<u>ISSUE</u>	<u>ORPHAN</u>	<u>LONZA</u>
Product Release	[ * ]	[ * ]
QC Testing	[ * ]	[ * ]
Investigations	[ * ]	[ * ]
Regulatory Affairs	[ * ]	[ * ]
Validation	[ * ]	[ * ]
Compliance Audits	[ * ]	[ * ]
Product Complaints	[ * ]	[ * ]
Change Management	[ * ]	[ * ]

Note: \*[ \* ], as the Product Manager for SXB is the backup for all contacts.

**Quality Agreement Appendix: Page 1**

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**APPENDIX III: RELEASE DOCUMENTATION**

The lot release document package will include copies of the batch record prior to release, analytical test data, a-Certificate of Analysis (“CO A”) and a campaign Certificate of Compliance (“COC”) and any deviations (manufacturing or laboratory).

Certificate of Analysis: A COA which is automatically generated by LONZA Quality Assurance will be provided and will include the name of the PRODUCT, lot number, date of manufacture, retest date, and analytical specifications. The COA will list the release tests performed by LONZA laboratories and actual test results.

Certificate of Compliance: The COC will attest to the fact that the PRODUCT lots produced during a campaign was performed in accordance with all applicable regulations, licenses, and company policies.

**Quality Agreement Appendix: Page 2**

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## AMENDED AND RESTATED SERVICES AGREEMENT

THIS AMENDED AND RESTATED SERVICES AGREEMENT (this "Agreement"), dated the 31<sup>st</sup> day of May, 2005 and effective as of January 1, 2005 (the "Effective Date"), is by and between EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC., a Delaware corporation ("SDS"), having a business address at 13900 Riverport Drive, Maryland Heights, Missouri 63043, and ORPHAN MEDICAL, INC. ("Orphan"), a Delaware corporation, having a business address at 13911 Ridgedale Drive, Suite 250, Minnetonka, Minnesota 55305.

### RECITALS

WHEREAS, Orphan manufactures Product (as defined below), and desires to enter into an agreement with SDS, whereby SDS will facilitate the dispensing and distribution of Product, and perform certain services associated therewith;

WHEREAS, SDS has experience in providing the services desired by Orphan, and is willing to provide such services for Orphan on the terms set forth in this Agreement;

WHEREAS, SDS and Orphan are parties to a Services Agreement dated as of July 29, 2002 (the "Original Services Agreement"); and

WHEREAS, the parties wish to amend and restate in its entirety the Original Services Agreement.

NOW, THEREFORE, in consideration of the premises and mutual promises herein stated, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree that the Original Services Agreement shall be amended and restated in its entirety to read as follows:

### TERMS OF AGREEMENT

#### ARTICLE I DEFINITIONS

As used in this Agreement, each of the following terms (and the plural or singular thereof, when appropriate) shall have the meaning set forth herein, except where the context makes it clear that such meaning is not intended:

"Act" shall mean the United States Federal, Food, Drug and Cosmetic Act, as amended from time to time.

“Additional Services” shall mean services relating to Product and the Xyrem Success Program(SM) to be performed by SDS as specified and agreed upon by the parties using an Additional Services Request Form included as Exhibit D to this Agreement. Such Additional Services Request Form shall be mutually agreed to and executed by both parties and, once so executed, shall be incorporated by reference and made a part of this Agreement.

“AWP” shall mean the average wholesale price of Product as reported by First Data Bank.

“Business Rules” shall mean the written documents related to the Xyrem Success Program(SM) that are mutually agreed upon by the parties which further describe the SOPs relating to how the Covered Services are to be performed.

“Confidential Information” shall have the meaning assigned to it in Section 5.1.

“Covered Services” shall mean those services to be performed by SDS relating to Product and the Xyrem Success Program(SM) as set forth in: (a) Exhibit A, (b) the SOPs and Business Rules as they existed on the Effective Date, and as modified during the term of this Agreement; provided that such modifications do not constitute a material change thereto, and (c) an Additional Services Request Form executed by both parties.

“DEA” shall mean the United States Drug Enforcement Administration.

“Facility” shall mean a distribution facility (or facilities) located in the United States that is owned and/or operated by SDS, and utilized by SDS in connection with performance of the Covered Services.

“FDA” shall mean the United States Food and Drug Administration.

“Fees” shall mean the fees as described in Section 4.2 hereof below to be paid by Orphan to SDS hereunder.

“HIPAA” shall mean Health Insurance Portability and Accountability Act of 1996, as further defined in the United States Code of Federal Regulations (CFR) 45, Part 164 – Security and Privacy section.

“Non-PAP Order” shall mean each shipment of Product by SDS to any Person other than a PAP Patient in accordance with applicable law and FDA guidelines.

“Non-PAP Patient” shall mean a Patient who is not eligible to participate in the PAP, as determined: (a) by NORD with respect to the financial eligibility of a patient; or (b) by Orphan with respect to other, non-financial criteria, and for whom SDS dispenses Product pursuant to a Non-PAP Order.

“NORD” shall mean the National Organization of Rare Disorders, which is responsible for determining whether individuals are eligible for participation in the PAP, based on financial criteria established by NORD, and for communicating such eligibility to SDS.

2.

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“PAP” shall mean the patient assistance program established by Orphan, pursuant to which SDS will provide dispensing services pursuant to the applicable SOPs and Business Rules.

“PAP Patient” shall mean a Patient who has been approved by NORD as eligible to participate in the PAP.

“PAP Order” shall mean a valid prescription indicating the dose, amount and strength of Product properly prescribed to a PAP Patient by a health care practitioner who is licensed to prescribe Product, and which is submitted to SDS in accordance with the relevant SOPs and Business Rules.

“Patient” means an individual who: (a) properly completes all necessary intake and Xyrem Patient Success forms (the form and content of which shall be mutually agreed upon by Orphan and SDS, and which shall comply with applicable laws and all applicable FDA requirements), as described in the relevant SOPs and Business Rules; and (b) is either deemed eligible by NORD to participate in the PAP, or is otherwise approved by SDS to receive Product.

“Patient Confidential Information” means individually-specific medical or prescription information and any other individually-identifiable information which may be deemed to be confidential or protected under federal or state law or regulations, including, without limitation, information that constitutes Protected Health Information under HIPAA.

“Person” shall mean any natural person, corporation, organization, association, partnership, limited liability company, HMO, or similar entity.

“Product” shall mean Orphan’s proprietary Xyrem® (sodium oxybate) oral solution and dosing kit.

“SOPs” shall mean the written standard operating procedures mutually agreed upon by the parties which further describe the operational processes of SDS as they relate to the requirements of the Xyrem Success Program (SM) as required by Orphan and the FDA.

“Territory” shall mean the United States of America, including its territories where SDS is allowed to legally distribute and ship the Product.

“Marks” shall mean those registered and common law trademarks of Orphan that are listed in Exhibit C.

“VA FSS” shall mean the Veteran’s Administration Federal Supply Schedule pricing contract provided to Orphan for the Product.

“WAC” shall mean the wholesale acquisition cost of Product,

“Xyrem Success Program(SM)” shall mean the pharmaceutical program for patients taking Xyrem® for which SDS shall perform the Covered Services hereunder, and which Orphan represents to be developed and implemented by, and proprietary to, Orphan.

3.

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**ARTICLE II  
SERVICES**

Section 2.1 Covered Services. From and after the Effective Date, SDS shall provide the Covered Services for the benefit of Orphan.

Section 2.2 Exclusive Distributor. During the term of this Agreement, and for so long as the FDA mandates single central pharmacy administration of the Xyrem Success Program, all Product sold or made available through the PAP in the Territory will be distributed exclusively through SDS pursuant to this Agreement. If, during the term of this Agreement, the FDA no longer mandates single central pharmacy administration of the Xyrem Success Program and Orphan chooses to engage another distributor in addition to SDS (thus making SDS' distributorship hereunder non-exclusive), Orphan shall provide SDS one hundred eighty (180) days written notice thereof.

Section 2.3 Warehousing. All Product sold, or made available through the PAP, in the Territory shall be warehoused by SDS at the Facility in accordance with Exhibit A and any related SOPs and Business Rules.

**ARTICLE III  
SUPPLY OF PRODUCT; AUDIT**

Section 3.1 Non-PAP Orders.

(a) General. Subject to direction from SDS regarding available space at the Facility, Orphan shall deliver to SDS at the Facility, at Orphan's own expense and on a consignment basis, sufficient quantities of Product to fulfill Non-PAP orders. The Product to be shipped pursuant to Non-PAP Orders will be furnished to, and held by, SDS on a consignment basis at the Facility at all times, except as provided in Subsection 3.1(b). The consignment of Product hereunder shall at no time be construed as a loan or other debt financing or secured transaction arrangement between the parties, and title to consigned Product shall remain with Orphan until transferred pursuant to Subsection 3.1(b).

(b) Transfer of Title. Upon confirmation of a Non-PAP Order in SDS' internal order processing system, SDS shall purchase from Orphan such Product being shipped from the Facility pursuant to such Non-PAP Order. Title to the consigned Product so purchased by SDS in connection with a Non-PAP Order shall pass to SDS at the time of such purchase.

(c) Pricing for Non-PAP Orders. Subject to the restrictions set forth in Subsection 4.1(d) of this Agreement or any FDA requirements, SDS shall have sole authority to determine pricing for Non-PAP Orders.

Section 3.2 PAP Orders. Subject to direction from SDS regarding available space at the Facility, Orphan shall deliver to SDS at the Facility, at Orphan's own expense, sufficient quantities of Product to fulfill PAP Orders. The Product to be shipped by SDS pursuant to PAP Orders shall be for the account of Orphan, and title to such Product shall remain with Orphan

4.

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until confirmation of the PAP order in SDS' internal order processing system, at which time title will pass to the PAP Patient. Once NORD approves a Patient as meeting the PAP financial criteria and eligible to participate in the PAP, SDS shall treat such Patient as so eligible until SDS (a) is notified otherwise by NORD or (b) determines that such Patient does not meet (i) the criteria established by NORD for financial eligibility, or (ii) other non-financial criteria established by Orphan as set forth in the Business Rules. SDS acknowledges and agrees that any determination made by SDS pursuant to Clause (b) above may be overruled by Orphan and the affected patient shall then be considered a PAP Patient and the relevant order treated as a PAP Order hereunder. SDS shall fulfill PAP Orders as set forth in the applicable SOP and Business Rule.

Section 3.3 Risk of Loss. All risk of Product loss or damage during the time that such Product is at the Facility, after receipt in good condition by SDS at the Facility, including inventory shortages which are unaccounted for, shall be borne by SDS, except to the extent caused by the negligence or willful misconduct of Orphan. Payment to Orphan by SDS for consigned Product lost or damaged while at SDS' Facility shall be based on Orphan's reasonable replacement costs, as reasonably determined and documented by Orphan.

Section 3.4 Financial Audit. During the term of this Agreement (excluding the months of December and January) and for a period of ninety (90) days after the expiration or termination of this Agreement, upon reasonable prior notice and during normal business hours, Orphan, or any third party auditor designated by Orphan, shall be entitled to audit and inspect those books and records of SDS which are maintained by SDS in connection with its performance of the Covered Services, subject to confidentiality constraints and applicable law. Such third party auditor (a) shall not have a conflict of interest with SDS or any of its affiliates (as determined by SDS in good faith), and (b) will be required to sign a confidentiality agreement in a form reasonably acceptable to SDS prior to commencing such audit. Neither Orphan nor its auditor shall have access to any Patient Confidential Information in the context of an audit.

Section 3.5 Regulatory and Compliance Audits and Information Requests.

(a) SDS shall provide to Orphan and/or the FDA, DEA or any other governmental body all documents and information requested by the FDA, DEA or any other governmental body in support of Orphan's regulatory filings or any governmental investigations or inquiries. Copies of all documents to be provided to the FDA or DEA shall be provided to Orphan in advance, if practicable, or otherwise within two (2) business days of delivery to the FDA or DEA. SDS shall notify Orphan immediately upon receipt of notice of any inspection by the FDA or DEA directed specifically toward Product, and Orphan shall have the right to have an employee present at any such inspection, if allowed by law. In addition, SDS shall notify Orphan of any FDA or DEA correspondence or inspections that concern SDS generally and which are related to any SDS compliance issues that may adversely impact SDS' ability to perform the services contemplated by this Agreement. SDS shall notify Orphan immediately of any notices, requests for information or other communications related to Product or SDS' ability to perform the Covered Services contemplated by this Agreement from the U.S. Department of Health and Human Services or any other government agency or any state healthcare program or other state agency and, to the extent permitted under applicable law, shall give Orphan copies of such communications.

5.

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(b) SDS shall from time to time submit to audits and inspections by Orphan during normal business hours or at any other time during which the services being audited are ongoing, including but not limited to, audits of regulatory and quality assurance SOPs and of records of contacts with regulatory agencies, provided the scope of any such audit or inspection shall be limited to information and facilities pertaining to Orphan's program. Orphan shall give SDS at least 2 business days' prior notice of any such inspection and at least 30 days' prior notice for any such audit, and Orphan shall bear the out of pocket costs of such audit or inspection.

(c) No employee of SDS who has been the subject of any disciplinary action by any State Board of Pharmacy shall be entitled to perform Covered Services.

Section 3.6 Returns and Replacement. In the event that Product is damaged in transit as a result of SDS' negligence or its designated shipper, SDS will replace the Product to the Patient free of charge once the damaged Product is returned to SDS. SDS will monitor all reports of lost Product for the potential for abuse and diversion. SDS will cooperate with state and federal authorities fully in any investigations of lost Product, and will provide reports of such loss to Orphan on a monthly basis for the purpose of allowing Orphan to track the Product and satisfy its FDA reporting requirements. SDS will investigate the loss of Product by interviewing the Patient, and/or physician, report the loss to Orphan and to the appropriate regulatory authorities, as required by law, and record the loss in the Patient's file. Where there is suspicion of abuse or diversion, SDS will contact the Orphan designee responsible for DEA issues, and lost Product will not be replaced without Orphan's approval. Where abuse or diversion is not suspected, SDS will replace the lost Product at no charge to the Patient in the event such loss is the result of SDS' negligence or its designated shipper and record the shipment in the Patient file. SDS will treat a repeat request for lost Product as suspicion of abuse or diversion and report it to the Orphan designee responsible for DEA issues, and SDS will not replace the lost Product without Orphan's approval. For damaged Product, SDS will make a good faith effort to arrange for the damaged Product to be returned to SDS. Upon receipt of damaged Product, SDS will keep the damaged Product in a secure locked area, and will dispose of it at SDS' cost in compliance with the applicable SOP for destruction of Product. If Product is returned to SDS due to a complaint of Product quality (i.e., Product taste, appearance, or faulty PIBA), Orphan shall reimburse SDS for the price paid by SDS to Orphan, if any, for such Product and for shipping costs associated with return of Product and SDS' sending of Product for quality assurance testing at Orphan's request. SDS shall not be required to disclose any Patient Confidential Information to Orphan pursuant to this Section 3.6 to the extent such disclosure is not permitted under HIPAA and other federal and state law.

6.

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Section 3.7 Recalls. If Orphan is required to recall or, on its own initiative, recalls or withdraws Product sold in the Territory, SDS shall reasonably assist Orphan in such recall in accordance with applicable laws and regulations. For such purposes, SDS shall maintain a complete and current list of all Patients and other third parties to whom SDS has shipped (or dispensed) Product, as well as from whom SDS has accepted returns of Product, with the lot numbers of Product dispensed/distributed or returned. Orphan shall pay for all reasonable costs and expenses incurred by SDS solely as a result of any such recall. SDS shall provide to Orphan, at Orphan's request, any information reasonably requested by Orphan in connection with Orphan investigations relating to recalled Product, subject to the confidentiality constraints imposed by HIPAA and any other federal or state law.

Section 3.8 Expired Product. Orphan will at its cost replace Product that expires prior to the purchase thereof by SDS. Orphan will not replace expired Product once it has been purchased by SDS. SDS will dispose of, or return, expired Product as reasonably directed by Orphan, subject to applicable law, and Orphan shall promptly reimburse SDS for all reasonable expenses incurred in complying with this Section 3.8.

Section 3.9 Territory. SDS shall use commercially reasonable efforts to obtain all necessary licenses and approvals to distribute Product in those areas of the Territory which, as of the Effective Date, SDS has not obtained such licenses and approvals. If SDS reasonably determines that there are one or more areas in the Territory in which SDS is likely able to obtain such licenses and approvals, but such distribution is not commercially feasible, the parties shall discuss SDS' concerns and mutually determine whether they will proceed with distribution in such area(s) of the Territory.

Section 3.10 Facility. Orphan reserves the right to inspect and approve any Facility used for Xyrem distribution prior to any change in the aforementioned Facility. The Facility shall be selected by SDS in its discretion and is subject to change from time to time upon no less than ninety (90) days prior written notice to Orphan. If there is an event of force majeure, as more fully described in Section 10.5, SDS shall provide such notice to Orphan as soon as reasonably practicable.

#### **ARTICLE IV PURCHASE PRICE OF PRODUCT; FEES**

##### Section 4.1 Purchase Price of Product.

(a) With respect to all Product purchased by SDS pursuant to Section 3.1, SDS shall pay a purchase price to Orphan equal to [ \* ] as it may be changed by Orphan annually with at least five (5) days prior written notice to SDS. Orphan shall so notify SDS, First Data Bank and any other relevant drug pricing indices on the same date. Notwithstanding the foregoing, SDS shall pay Orphan the [ \* ] for any Product for which SDS is required to charge such [ \* ].

7.

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(b) The purchase price for Product purchased by SDS shall be due and payable to Orphan within thirty (30) days from the date of confirmation of the relevant orders for Product in SDS' internal order processing system. SDS shall provide Orphan with written confirmation of sales of Product on a weekly basis. If SDS makes payment in full of the purchase price of Product within the applicable time period, it shall be [ \* ] of such Product, and the [ \* ] by SDS by [ \* ] to Orphan by [ \* ].

(c) SDS shall be responsible for any sales tax or similar taxes payable in connection with the sale of Product to SDS.

(d) SDS shall have the right to establish the price at which it resells Product to Non-PAP Patients, and shall have all right, title and interest in and to any amounts that SDS receives from third parties in connection with Product dispensed or distributed pursuant to Non-PAP Orders; provided, however, that the price at which SDS sells Product shall not exceed the greater of (i) [ \* ] percent of [ \* ] for Product or (ii) the [ \* ] Product.

Section 4.2 Fees. As compensation for the Covered Services performed by SDS, Orphan shall pay SDS the Fees described in Exhibit B or in an Additional Services Request Form executed by both parties. SDS shall invoice Orphan for the Fees on a monthly basis, and such Fees shall be due and payable to SDS within 30 days of the date of SDS' invoice. In the event that SDS has provided inaccurate information as listed under "Reporting" in the Covered Services, Orphan shall be credited at a rate of \$[ \* ] per hour for each hour expended by Orphan in correcting any such inaccuracies uncovered in the data received. Such credit shall be against the invoice for the month following the month in which such error(s) occurred and shall not exceed [ \* ]. On the first anniversary of the Effective Date, and each anniversary thereafter, SDS shall be entitled to increase each of the Fees by no more than a percentage which is equal to the percentage increase to the then current 12 month Consumer Price Index (all items) as published by the U.S. Department of Labor, Bureau of Labor Statistics during such 12 month period. SDS shall notify Orphan in writing within 30 days after the effective time of any such increase in Fees.

Section 4.3 Late Penalty. Any amount not paid by the owing party on or before the respective due date thereof shall bear interest at the rate of [ \* ] percent per annum ([ \* ] percent per month) or, if lower, the highest interest rate permitted by law.

Section 4.4 Adjustment. In December 2006, and annually thereafter, the parties will, in good faith, re-evaluate the pricing set forth on Exhibit B to determine whether an adjustment thereto is warranted in light of certain unanticipated expenditures, efficiencies, reductions or other circumstances that may necessitate such an adjustment; provided, however, in no event shall either party be obligated at such time to agree to any such adjustment. Notwithstanding the foregoing, nothing in this Section 4.4 shall limit SDS' ability to increase Fees pursuant to Section 4.2 of this Agreement.

8.

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**ARTICLE V**  
**CONFIDENTIAL INFORMATION; OWNERSHIP**

Section 5.1 Nondisclosure Commitments. The parties acknowledge that, as a result of this Agreement, each may learn confidential and proprietary information, including, but not limited to, information about Orphan's operations, business, and products, and information about SDS' report formats, computer software, business, and operations (all of which shall collectively be considered the "Confidential Information" of the respective party). Except as specifically provided herein, neither Orphan nor SDS shall disclose any Confidential Information of the other to any person or entity, or use, or permit any person or entity to use, any of such Confidential Information, excepting only: (a) disclosures to and use by the employees of Orphan or SDS who have a reasonable need to know such information in connection with performance of this Agreement, (b) disclosures which are required by law, and (c) disclosures that are made on a confidential basis to the attorneys, accountants, and other professional advisors of Orphan or SDS in connection with matters relating to this Agreement. Notwithstanding the foregoing, Confidential Information shall not include: (x) information which is public or becomes public through no fault of the receiving party, (y) information of which the receiving party has knowledge prior to receipt, and (z) information which is received by one party from a third person not under an obligation of confidentiality to the other party to this Agreement.

Section 5.2 Patient Confidential Information. Except as otherwise provided in Section 6.7, Orphan shall neither have access to nor be entitled to receive any Patient Confidential Information, except to the extent Orphan must have access to such Patient Confidential Information to satisfy its FDA reporting requirements associated with Product. Each party shall maintain the confidentiality of all information and records, including patient information if such party receives Patient Confidential Information in any form or manner, to the extent required by applicable law, including, but not limited to, HIPAA. All patient-related data and information obtained by SDS hereunder shall be and remain the property of SDS and shall be deemed the Confidential Information of SDS. SDS will not utilize Patient Confidential Information it comes into possession of as a result of this Agreement outside the scope of this Agreement. SDS will not engage in any activity designed to expand its information of individual Patients through the use of third parties for a purpose other than to effectuate the uses and disclosures contemplated by this Agreement. There shall be no prior use of Patient Confidential Information outside of the scope of this Agreement. Notwithstanding anything to the contrary, however, SDS and/or its affiliates may use any such Patient Confidential Information in the aggregate and on a de-identified basis with other drug-use data, to the extent permitted by law, without charge, for research, cost analysis, and other business purposes of SDS and its affiliates, so long as there is no specific disclosure of the Confidential Information of Orphan. Notwithstanding anything to the contrary herein, with respect to any information or documents that are subject to disclosure or that are requested pursuant to Section 3.5 or otherwise, and which contain Patient Confidential Information, SDS shall only be required to disclose such information and documents to the extent permitted by federal and state confidentiality laws and regulations, including, but not limited to, HIPAA and, in connection with any such disclosure to Orphan pursuant to Section 3.5 or otherwise which involves Patient Confidential Information, Orphan hereby represents that such disclosure is required by law or is intended for one of the purposes described in 45 C.F.R. § 164.512(b) and that such documents and information received by Orphan will be used solely to comply with such law or with one of the intended purposes under 45 C.F.R. § 164.512(b).

9.

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Section 5.3 Ownership. The parties acknowledge and agree that: (a) each party shall own all right, title, and interest in, to, and under, any and all Intellectual Property (Intellectual Property shall mean inventions, patents, copyrights, trade secrets, and other forms and types of intellectual property related to the distribution of sodium oxybate or gamma hydroxybutyrate, excluding trademarks, service marks, and/or trade dress) that it has independently made, conceived, and/or reduced to practice; (b) to the extent the parties have in the past or during the term of this Agreement, jointly invented any inventions, and/or jointly developed any other Intellectual Property, the parties shall jointly own, and have the right to use and/or otherwise exploit (on a non-exclusive basis), all right, title, and interest in, to, and under, any and all such Intellectual Property (however, under no circumstances shall there be any duty to account to the other party for any use and/or exploitation of any jointly owned Intellectual Property), and, further, the parties hereby grant to each other a non-exclusive, non-terminable, royalty-free, assignable license to any and all such jointly invented and/or jointly developed other Intellectual Property; and (c) this Agreement shall not constitute and/or be deemed to constitute either party's acknowledgement and/or agreement that any of the other party's alleged inventions, patent applications, patents, or other alleged Intellectual Property, is/are new, unobvious, valid, or enforceable, or that either party, any of its employees, and/or any of its independent contractors, are the inventors and/or owners of any patent applications that it has filed and/or any alleged inventions claimed in any such patent applications. Notwithstanding the foregoing, SDS disclaims any and all rights it may have in and to the mark Xyrem Success Program(SM).

## **ARTICLE VI TERM AND TERMINATION**

Section 6.1 Initial Term; Renewal. The term of this Agreement shall begin on the Effective Date and continue through July 31, 2007, unless terminated earlier or automatically extended in accordance with the terms hereof. Not less than 120 days prior to the end of the initial or any renewal term of this Agreement, either party may notify the other party in writing that it desires to terminate this Agreement, effective as of the end of the then current term. If no such written notification is given, this Agreement shall automatically continue with the same terms and conditions as set forth herein for an additional 1 year term, subject to the right of termination as otherwise provided herein.

Section 6.2 Termination for Bankruptcy. Either party shall have the right to terminate this Agreement upon 5 days' written notice, if (a) the other party files a petition for reorganization or liquidation under any federal or state bankruptcy law, or any such petition is filed against such other party and, in either case, the petition is not withdrawn or dismissed within 60 days after filing, or (b) a receiver is appointed for any part of the other party's assets and said appointment is not vacated within 60 days.

Section 6.3 Termination for Noncompliance. Orphan shall have the right to terminate this Agreement upon 5 days' written notice to SDS if SDS is cited as non-compliant with regulatory requirements as determined by an audit of SDS facilities by Orphan and confirmed by a third-party audit, or if SDS is cited as non-compliant as determined by a regulatory body, and appropriate corrective action cannot be mutually agreed to by the parties within 30 days after such determination of non-compliance or such earlier date as is specified by the regulatory body.

10.

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Section 6.4 Termination for Cause. Notwithstanding anything to the contrary herein, either party may give the other written notice of a material breach of this Agreement. If the breaching party has not cured said breach within 30 days from the date such notice was sent, this Agreement may be terminated at the option of the non-breaching party. If the amount of time commercially reasonable for the breach to be cured is longer than 30 days, this Agreement may not be terminated by the non-breaching party pursuant to this provision until such commercially reasonable period of time has elapsed; provided, however, that in no event shall such cure period exceed 60 days from the date such notice was sent. Notwithstanding the foregoing, Orphan may terminate this Agreement under Section 10.5 if SDS is precluded from rendering Covered Services as a result of an event of force majeure.

Section 6.5 Transition of Covered Services. Upon termination or expiration of this Agreement, the parties shall mutually agree on an expeditious schedule of transition of the Covered Services. If Orphan terminates this Agreement pursuant to Section 6.2, 6.3 or 6.4, SDS shall be responsible for all costs and expenses incurred by SDS that are associated with such transition. If SDS terminates this Agreement pursuant to Section 6.2 or 6.4, Orphan shall be responsible for all costs and expenses incurred by SDS that are associated with such transition. If this Agreement expires pursuant to the terms of Section 6.1, each Party shall be responsible for its own costs and expenses incurred in connection with such transition. SDS shall promptly return to Orphan (or to any other third party in the Territory that can accept the Product as directed by Orphan) all Product then in SDS' possession or control which has not been purchased by SDS pursuant to Subsection 3.1(b).

Section 6.6 Return of Confidential Information. Upon termination or expiration of this Agreement, each party shall, if requested by the other party, promptly: (a) return to the other party all documentation and other materials (including all copies of original documentation or other materials) containing any Confidential Information, and (b) certify to the other party as to the destruction or return of all such documentation and other materials public through no fault of the receiving party.

Section 6.7 Transfer of Patient Information, Etc. Upon termination or expiration of this Agreement, for whatever reason, Orphan shall have the right to transfer all mutually-developed Xyrem Success Program(SM) SOPs and Business Rules and the toll free Xyrem telephone number to another specialty pharmacy and/or distributor of its choice, and SDS shall cooperate with Orphan in the transfer of such items to another qualified specialty pharmacy and/or distributor. Notwithstanding the foregoing, SDS shall not be required to, and Orphan shall not, disclose SOPs and Business Rules that contain Confidential Information of SDS to such other qualified specialty pharmacy and/or distributor, except to the extent required by law. In addition, Orphan may request that SDS also transfer Patient Confidential Information to such other specialty pharmacy for the purpose of continuing "treatment" (as that term is defined under HIPAA) of such Patients, and SDS shall expeditiously honor such request to the extent disclosure of such Patient Confidential Information by SDS is permitted under applicable law, including, but not limited to, HIPAA. If this Agreement has been terminated by Orphan under Sections 6.2, 6.3 or 6.4, SDS shall be responsible for all expenses incurred by SDS in connection

with the transition described in this Section 6.7. If SDS terminates this Agreement pursuant to Section 6.2 or 6.4, Orphan shall be responsible for all costs and expenses incurred by SDS that are associated with such transition. If this Agreement expires pursuant to the terms of Section 6.1, each Party shall be responsible for its own costs and expenses incurred in connection with such transition.

## **ARTICLE VII COMPLIANCE WITH LAW; REPRESENTATIONS AND WARRANTIES**

Section 7.1 Compliance With Law. Each party agrees that it will perform its respective obligations hereunder in accordance with applicable federal, state and local laws, including but not limited to applicable DEA, FDA, state and local retail and wholesale pharmacy requirements. Orphan agrees that it will not use language stating that any entity other than SDS is the licensed pharmacy that distributes Product pursuant to this Agreement in any written materials that SDS is requested by Orphan to send to Patients as part of the Covered Services. Orphan may, without restriction, use any language referring to the Xyrem Success Program(SM), as well as any references to "pharmacy" in, or in conjunction with, any written materials that SDS is not requested by Orphan to send to Patients or any other party; provided that Orphan shall not use SDS' name in connection with such references. If SDS reasonably believes that any correspondence from Orphan to Patients that Orphan requests SDS to send to Patients as part of the Covered Services does not comply with any applicable federal, state, or local law, SDS shall notify Orphan and provide reasonable detail as to its determination. The parties shall discuss SDS' reasonable concerns and agree upon an alternative mailing or other course of action, if necessary. FDA laws are not limited to section 505 of the Federal Food, Drug and Cosmetic Act, but also include any special considerations required by the FDA for approval of any additional indication for the Product. SDS will be notified of such requirements in writing by Orphan. In the event any such special FDA requirements cause SDS' obligations under this Agreement to be materially more burdensome or expensive, the parties shall promptly negotiate an appropriate modification to the Fees, and if the parties cannot agree on such a modification, or SDS in good faith views such additional responsibility as too burdensome to continue with the Agreement, SDS shall have the right to terminate this Agreement without penalty upon 5 days' written notice to Orphan.

### Section 7.2 Representations and Warranties.

(a) Each party hereby represents and warrants to the other party that: (i) it has all requisite corporate power and authority to enter into this Agreement and perform and observe all obligations and conditions required to be performed or observed by that party under this Agreement; (ii) neither the execution and delivery of this Agreement nor the performance by that party of its respective obligations under this Agreement will conflict with or result in a breach of any covenant or agreement between that party and any third party; (iii) this Agreement represents the legal, valid and binding obligation of that party; and (iv) such party has (or will have at such time as performance of its obligations under this Agreement may require) obtained all of the local, state and federal permits, licenses or other regulatory registrations or approvals necessary for the performance of its obligations under this Agreement. In the future, if necessary, SDS shall make a good faith effort to apply and obtain the requisite DEA license necessary in order for SDS to distribute Product to Persons other than the end-user; provided, however, that the foregoing obligation shall not apply if such license is not available.

12.

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(b) Orphan hereby represents and warrants that Product at the time of shipment to SDS' facility: (i) shall not be adulterated or misbranded within the meaning of the Act, or within the meaning of any applicable state or municipal law in which the definitions of adulteration or misbranded are substantially the same as those contained in the Act, as the Act and such laws are constituted and effective at the time of shipment; and (ii) shall not be a product which may not, under the provisions of the Act or FDA guidelines pertaining to the Product, be introduced into interstate commerce.

## **ARTICLE VIII INDEMNIFICATION AND INSURANCE**

### **Section 8.1 Indemnification.**

(a) SDS shall indemnify and hold harmless Orphan and its directors, officers, employees, and affiliates from and against all third party claims, liabilities, losses, damages, costs, and expenses (including without limitation reasonable attorney's fees) arising out of: (i) any material breach by SDS of this Agreement, including, but not limited to, its representations and warranties; (ii) the negligent act or negligent omission, or the willful misconduct, of SDS or any of its employees or agents in connection with the performance of its obligations under this Agreement; and (iii) SDS' use of patient information in violation of applicable laws governing confidentiality; except to the extent any of the foregoing claims arise out of Orphan's negligence or willful misconduct or breach hereunder, including, but not limited to, a breach of Orphan's representations and warranties hereunder.

(b) Orphan shall indemnify and hold harmless SDS and its directors, officers, employees and affiliates from and against all third party claims, liabilities, losses, damages, costs, and expenses (including without limitation reasonable attorneys' fees) arising out of: (i) any material breach by Orphan of this Agreement, including, but not limited to, its representations and warranties; (ii) the negligent act or negligent omission, or the willful misconduct, of Orphan or any of its employees or agents in connection with the performance of its obligations under this Agreement; (iii) any claim relating to the manufacturing of the Product or use of the Product by a Patient or other individual; and (iv) use by SDS of a Mark in accordance with the terms of this Agreement; except to the extent any of the foregoing claims arise out of SDS' negligence or willful misconduct or breach hereunder, including, but not limited to, a breach of SDS' representations and warranties hereunder.

Section 8.2 Insurance. Each party shall procure and maintain during the term of this Agreement, comprehensive general liability insurance in the amount of [ \* ] per claim made, and in the aggregate, including but not limited to, for contractual liability, personal and bodily injury, and product liability. Each party shall provide the other party with evidence of such insurance upon request. A party may not cause or permit such insurance to be canceled without obtaining comparable replacement coverage or modified to materially reduce its scope or limits of coverage during the term of this Agreement.

**ARTICLE IX  
TRADEMARKS**

Section 9.1 Grant of License. Orphan grants to SDS a nonexclusive, royalty-free, nontransferable license to use the Marks in the Territory in connection with the rendering of the Covered Services and sale of Product contemplated by this Agreement, and SDS accepts the license subject to the following terms and conditions.

Section 9.2 Ownership of the Service Marks. SDS acknowledges that Orphan is the exclusive owner of the Marks and that all use of the Marks by SDS will inure to the benefit of and be on behalf of Orphan. SDS will do nothing inconsistent with such ownership and will reasonably assist Orphan in recording the evidence of this license arrangement with any appropriate government authorities. Nothing in this Agreement shall give SDS any right, title, or interest in the Marks other than the right to use the Marks in accordance with this Agreement, and SDS will not attack the title of Orphan to the Marks.

Section 9.3 Quality Standards. All use of the Marks by SDS will be in compliance with the quality control standards that are furnished from time to time by Orphan or its agents. SDS will reasonably cooperate with Orphan in facilitating Orphan's ultimate control of such nature and quality standards, will permit reasonable inspection of SDS' operation, and, upon request of Orphan, will supply Orphan with specimens of all uses by SDS of the Marks.

Section 9.4 Marking. SDS' use of the Marks will comply with all marking requirements and other laws pertaining to trademarks in force during the term of this Agreement.

Section 9.5 Form of Use. SDS will use the Marks only in the form and manner and with appropriate legends as prescribed from time to time by Orphan.

Section 9.6 Infringement Proceedings. SDS will promptly notify Orphan of any unauthorized uses of the Marks by others that come to SDS' attention. Orphan will have the sole right and discretion to bring infringement, dilution or unfair competition proceedings involving the Marks.

Section 9.7 Effect of Termination. Upon termination of this Agreement, SDS will immediately discontinue all use of the Marks and any term or symbol confusingly similar thereto, will cooperate with Orphan or its agents to apply to the appropriate authorities to cancel any recording of evidence of this Agreement from all government records, and will destroy all printed materials bearing the Marks.



**ARTICLE X  
MISCELLANEOUS**

Section 10.1 Notices. Except as otherwise specified in this Agreement any notice or other communication required or contemplated under the provisions of this Agreement shall be in writing and (a) delivered in person, evidenced by a signed receipt, (b) deposited in the United States mail, first class postage prepaid, (c) sent by electronic facsimile transmission, or (d) sent via Federal Express, Airborne, or any other similar express delivery service, to the addresses indicated below or to such other persons or addresses as the parties may provide by written notice to the other. The date of the notice shall be (x) the date of delivery if the notice is personally delivered or sent via Federal Express or similar express delivery service, or (y) three (3) days after the date of mailing if the notice is mailed by United States mail.

If to SDS: Express Scripts Specialty Distribution Services, Inc.  
13900 Riverport Drive  
Maryland Heights, Missouri 63043  
Attn: Vice President and General Manager  
Fax No. (314) 702-7120

*with a copy to:* Express Scripts, Inc.  
13900 Riverport Drive  
Maryland Heights, Missouri 63043  
Attn: General Counsel  
Fax No. (314) 702-7120

If to Orphan: Orphan Medical, Inc.  
13911 Ridgedale Drive, Suite 250  
Minnetonka, Minnesota 55305  
Attn: Vice President of Commercial Operations  
Fax No. (952) 541-9209

Section 10.2 Invalidity. Should any of the provisions hereof become legally invalid or unenforceable, the remainder of this Agreement shall remain effective, provided that the essential purpose of the Agreement can still be carried out. In such event, the parties agree to negotiate a mutually acceptable amendment to the terms and conditions of this Agreement.

Section 10.3 Non-Waiver. A failure by either party to insist upon strict compliance with any term of this Agreement, to exercise any option, to enforce any right, or to seek any remedy upon any default of the other party shall not affect, or constitute a waiver of, the first party's right to insist upon strict compliance with that term, to exercise that option, to enforce that right, or to seek that remedy with respect to that default or any prior, contemporaneous, or subsequent default. No custom or practice of the parties at variance with any provision of this Agreement shall affect, or constitute a waiver of, a party's right to demand strict compliance with all provisions of this Agreement.

Section 10.4 Remedies. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY PUNITIVE, SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR ANY LOSS OF PROFIT OR REVENUES RESULTING FROM EITHER PARTY'S BREACH OF THIS AGREEMENT; PROVIDED, HOWEVER, THAT NOTHING IN THIS SECTION 10.4 SHALL LIMIT EITHER PARTY'S RIGHT TO INDEMNIFICATION UNDER SECTION 8.1 OF THIS AGREEMENT AGAINST ANY CLAIM BROUGHT BY A THIRD PARTY. The rights and remedies of each party under this Agreement shall be cumulative and in addition to any other rights or remedies available to such party, whether under any other agreement, at law, or in equity, including without limitation specific performance, a temporary restraining order, and temporary or permanent injunctions.

Section 10.5 Force Majeure. If the performance of any part of this Agreement by either party shall be affected for any length of time by fire or other casualty, government restrictions, war, riots, strikes, or labor disputes, lock out, transportation delays, and acts of God, or any other similar causes which are beyond the reasonable control of such party, such party shall not be responsible for delay or failure of performance of this Agreement for such length of time; provided, however, that the obligation of the parties to pay amounts then due shall not be suspended or delayed; and provided, further, that if SDS is precluded from rendering Covered Services for a continuous period in excess of 10 business days, Orphan shall be entitled to terminate this Agreement upon 5 days' written notice to SDS.

Section 10.6 Governing Law. This Agreement and performance hereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to choice of law principles.

Section 10.7 Successors and Assigns. This Agreement may not be assigned by any party hereto without the prior written consent of the other parties, which consent shall not be unreasonably withheld.

Section 10.8 Relationship of the Parties. The parties are independent contractors and shall not be considered as an employee, agent or legal representative of any other party for any purposes whatsoever. Nothing herein shall be construed to create a partnership, joint venture or general agency. Except as expressly provided for herein, the parties shall have no authority to act for or on behalf of the any party or to sign or otherwise enter into any kind of contract, undertaking or agreement, or make any promise, warranty or representation, with respect to the Product or any other matter on behalf of any other party, and no other party shall be bound by or liable for any acts, obligations, or defaults of the other party, its employees or agents. Each party shall have exclusive liability and responsibility for workers' compensation insurance, taxes and other obligations with respect to itself, its employees and agents.

Section 10.9 Equal Opportunity. This contract is subject to the equal opportunity clause set forth in 41 C.F.R.s. 61-1.4(a), which is incorporated herein by reference.

Section 10.10 Complete Agreement; Amendment. This Agreement (together with the exhibits, Business Rules, and SOPs, all of which are hereby incorporated herein by reference) contains the entire agreement between the parties and supersedes all prior or contemporaneous discussions, negotiations, representations, warranties, or agreements relating to the subject matter of this Agreement. This Agreement may not be amended or changed in any of its provisions except by a subsequent written agreement between the parties.

Section 10.11 Headings. The article, section and paragraph headings used in this Agreement are for convenience only and are not part of the agreement between the parties.

Section 10.12 Survival. Notwithstanding any provision of this Agreement to the contrary, Section 3.3, Section 3.5(a), Article IV, Article V, Section 6.5, Article VII, Sections 8.1, 8.2, 10.3, 10.4, 10.6 and 10.12 shall survive the expiration or termination of this Agreement for any reason.

IN WITNESS WHEREOF, the parties have signed this Agreement as of the date indicated below.

**EXPRESS SCRIPTS SPECIALTY  
DISTRIBUTION SERVICES, INC.**

**ORPHAN MEDICAL, INC.**

By: /s/ Gerard A. Carino  
Name: Gerard A. Carino  
Title: President PBS & SDS  
Date: 5/31/05

By: /s/ John H. Bullion  
Name: John H. Bullion  
Title: CEO  
Date: 6/1/05

EXHIBIT A

COVERED SERVICES

• **Administration of the Xyrem Success Program**<sup>SM</sup>

- Call Center Services
  - [ \* ]
- Drug Information and Fulfillment Services
  - [ \* ]
- Physician and Patient Registries
  - [ \* ]
- Xyrem Patient Assistance Program as described in Section 3.2, and as outlined the Business Rules.
- [ \* ]
- [ \* ]
- Dispensing Services
- Pharmacy Services
  - [ \* ]
- Distribution Services
- Provision of a Xyrem program manager

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- **Inventory Management**
  - Orphan monitors production cycles and expected inventories and communicates information with SDS
  - SDS' inventory system tracks Product production cycles and planned availability
  - Inventory reports monthly to Orphan
  
- **Master Warehouse**
  - Distribution agent for Xyrem within the Territory
  - Sole source distribution agent for Xyrem within the Territory
  - Separate storage, dispensing distribution and security area for Xyrem
  - Inventory of Xyrem
  - Inventory storage in compliance with Orphan's reasonable requirements
  - Maintaining mutually agreed upon inventory levels.
  - Tracking of Xyrem, by lot #, NDC# and expiration date.
  - Maintaining an FIFO inventory
  - Full Class I Recall capabilities
  - Management of a database of lot numbers
  - Return goods-storage, processing and disposal
  
- **Reporting**
  - Reporting that has been mutually agreed upon by the parties and verified by SDS for accuracy shall include the following:
    - Reporting as agreed on Product inventory (non-patient identifiable)
    - [ \* ]
    - Adverse event reporting as required by Orphan and agreed to by SDS
    - [ \* ]
    - Additional reports mutually agreed upon by the parties and within expectations that SDS is able to provide
    - Custom and ad hoc reports reasonably requested by Orphan
  
- **Other Covered Services**
  - Free Trial Program
  - Opt-In Program (business reply cards processing of patients who have agreed to receive further correspondence from Orphan)
  - InSights Newsletters
  - Patient Surveys
  - Voucher Program
  - Relabeling of Xyrem bottles
  - Xyrem pallet shipments
  - Any other services as mutually agreed upon by the parties by completing and executing an Additional Services Request Form.

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EXHIBIT B

FEES

Type of Fee	Amount Owed by Orphan
Base Business Non-PAP Administrative Fee*	[ * ]
Supplemental Business Non-PAP Administrative Fee**	[ * ]
PAP Administrative Fee	[ * ]
PAP Order Dispensing Fee	[ * ]
Custom and ad hoc reports	[ * ]
Enrollment Fee***	[ * ]
Shipment Fee****	[ * ]
Faxes or e-mails to Orphan's sales force	[ * ]
Re-verification of Patient insurance benefits under Free Trial Program	[ * ]
Obtaining new prescription under Free Trial Program	[ * ]
Production of offer letters under Free Trial Program	[ * ]
Processing of Patient Business Reply Cards for opting-in to Patient correspondence from Orphan	[ * ]
Processing and mailing of "inSIGHTS" Patient newsletters for new patients	[ * ]
Processing and mailing of "inSIGHTS" Patient newsletters for pending/approved Patients	[ * ]
Patient surveys	[ * ]
Bottle re-labelling of [ * ]*****	[ * ]
Bottle re-labelling of [ * ]	[ * ]
Shipment of Xyrem pallets	[ * ]
Preparation of Reimbursement letters to Patients (sent via Fed Ex)	[ * ]
Preparation of Pharmacy letters to Patients (sent via Fed Ex)	[ * ]

Orphan shall reimburse SDS for all [ \* ], on a pass-through basis, meaning that Orphan shall reimburse SDS for the actual amount billed to SDS by its [ \* ]. If the [ \* ] cost is related to an SDS error (e.g., [ \* ]), Orphan will not be responsible for [ \* ] related to such errors.

Orphan shall pay SDS for any Additional Services as mutually agreed upon in an Additional Services Request Form executed by both parties.

\*Payable on first [ \* ] bottles of Product shipped by SDS per calendar year on Non-PAP Orders

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\*\*Payable on bottles of Product shipped by SDS per calendar year on Non-PAP Orders in excess of [ \* ] bottles

\*\*\*Orphan shall pay this Enrollment fee for [ \* ], including but not limited to insurance verification and processing of a patient's prescription, regardless of whether Product is ultimately shipped.

\*\*\*\*Orphan shall pay this Shipment Fee on the [ \* ].

\*\*\*\*\*Orphan shall pay at this rate for re-labelling of bottles in [ \* ], whether the occurrence of such re-labelling is before or after the Effective Date.

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**EXHIBIT C**

**XYREM**

**XYREM & DESIGN** (As identified in U.S. Reg. No. 2,472,156)

**XYREM & DESIGN** (Color) (As identified in U.S. Reg. No. 2,423,880)

**XYREM CIII SODIUM OXYBATE ORAL SOLUTION & DESIGN**

**XYREM SUCCESS PROGRAM**

**XYREM PATIENT SUCCESS PROGRAM**

**XYREM PHYSICIAN SUCCESS PROGRAM**

**1-866-XYREM88**

**O ORPHAN MEDICAL & Design** (As shown in U.S. Reg. No. 1,906,107)

**ORPHAN**

**ORPHAN MEDICAL**

**ORPHAN MEDICAL, INC.**

C-1

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**EXHIBIT D**

**ADDITIONAL SERVICES REQUEST FORM**

This Additional Services Request Form relates to and is part of the Amended and Restated Services Agreement between Express Scripts Specialty Distribution Services, Inc. and Orphan Medical, Inc. effective as of January 1, 2005.

**1. Description of Additional Services to be Provided**

**2. Fees for Additional Services**

Accepted and Agreed:

EXPRESS SCRIPTS SPECIALTY  
DISTRIBUTION SERVICES, INC.

ORPHAN MEDICAL, INC.

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

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**CONSENT AND ADDENDUM TO  
AMENDED AND RESTATED MASTER SERVICES AGREEMENT**

This Addendum (the “**Addendum**”) to the **AMENDED AND RESTATED MASTER SERVICES AGREEMENT** dated as of May 31, 2005, as amended (collectively, the “**Agreement**”), by and between **EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC.** (“**ESSDS**”) and **ORPHAN MEDICAL, INC.** (“**Orphan Medical**”), is entered into as of the 1st day of June 2006 (the “**Effective Date**”) by and between ESSDS and Jazz Pharmaceuticals, Inc. (“**Jazz Pharmaceuticals**”). Capitalized terms not otherwise defined herein shall have the same meanings as in the Agreement.

**RECITALS**

**WHEREAS**, Jazz Pharmaceuticals acquired Orphan Medical on June 24, 2005 and desires to assume all rights and obligations of Orphan Medical under the Agreement; and

**WHEREAS**, pursuant to Section 10.7 of the Agreement, such assignment requires the written consent of ESSDS, which consent cannot be unreasonably withheld; and

**WHEREAS**, the parties further desire to clarify and describe in more detail the provision by ESSDS of certain Voucher Program Services (as defined in Section 2 of this Addendum) to Jazz Pharmaceuticals; and

**WHEREAS**, Section 10.10 of the Agreement provides that the Agreement may be amended by a written instrument signed by both parties; and

**WHEREAS**, ESSDS desires to consent to the assignment to Jazz Pharmaceuticals and the parties desire to supplement the Agreement as provided herein.

**NOW, THEREFORE**, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein and in the Agreement, the parties hereto agree as follows:

**AGREEMENT**

**1. Incorporation of Recitals.** The Recitals are hereby incorporated into the Addendum.

**2. Assignment.** In accordance with Section 10.7, ESSDS hereby consents to the assignment of the Agreement to Jazz Pharmaceuticals; provided, however, in the event that (i) the Xyrem<sup>®</sup> (sodium oxybate) License Agreement dated January 1, 2006 by and between Jazz Pharmaceuticals and Orphan Medical terminates and (ii) Orphan Medical notifies ESSDS in writing that the rights to Xyrem<sup>®</sup> (sodium oxybate) have reverted back to Orphan Medical, ESSDS hereby further consents to the assignment of the Agreement back to Orphan Medical. Jazz Pharmaceuticals accepts the foregoing assignment of the Agreement and all covenants and



(c) The Voucher Program Services will be performed in accordance with all applicable laws, rules and regulations.

7. **Continuation of Agreement.** Except as expressly set forth herein, all of the terms and conditions of the Agreement shall remain in full force and effect.

{SIGNATURE PAGE FOLLOWS}

3.

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IN WITNESS WHEREOF, the parties have executed or caused this Addendum to be executed as of this \_\_ day of June, 2006.

EXPRESS SCRIPTS SPECIALTY  
DISTRIBUTION SERVICES, INC.

JAZZ PHARMACEUTICALS, INC.

Name: /s/ Gerard A. Carino  
Its: President PBS & SDS

Name: /s/ Matthew K. Fust  
Its: Chief Financial Officer

4.

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---

**EXHIBIT A**  
**VOUCHER PROGRAM SERVICES**

**See attached.**

A-1

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**Document Information**

Author: [ \* ]  
 Procedure Title: Jazz Pharmaceuticals Program Enrollment  
 Procedure Number: JPP-0022-07-02  
 Revision Date: 04/27/06  
 Effective Date: 06/05/06  
 Owner: [ \* ]

**SOP Approval**

<u>Department</u>	<u>Name</u>	<u>Title</u>	<u>Date</u>	<u>Signature</u>
Compliance	[ * ]	Sr. Compliance Manager		Signature on File
Admissions	[ * ]	Director of Patient Care Coordination		Signature on File
Pharmacy	[ * ]	Patient Direct Pharmacy		Signature on File

**Procedure Section Titles**

<u>Section Number</u>	<u>Section Name</u>	<u>Page</u>
1	Enrollment	2
2	Voucher Processing	3

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Page 1 of 6

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**Purpose**

This SOP outlines the process in which patient enrollments are completed in a consistent manner as individuals contact the program for consideration.

**Procedure**

1. Enrollment  
[ \* ]
2. Voucher Processing  
[ \* ]

**Definitions**

Word/Acronym	Definition
New Patient	[ * ]
Admissions Team	[ * ]

**Applicable Documents**

Document Number	Document Name
[ * ]	[ * ]

**Change Control History**

Change Implemented	Revision Date	Effective Date
[ * ]	[ * ]	[ * ]

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**EXHIBIT B**

**FEES**

<b>Services</b>	<b>Fees</b>
Voucher Program Administrative Fee	\$[ * ]/per patient
Voucher Program Dispensing Fee	\$[ * ]/per prescription
Voucher Program Shipment Fee	\$[ * ]/per prescription

The fee associated with enrolling a new patient into the Xyrem Success Program shall be billed in accordance with Exhibit B, Fees of the Agreement.

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**ADDENDUM No. 2 TO  
AMENDED AND RESTATED MASTER SERVICES AGREEMENT**

This Addendum No. 2 (the “**Addendum**”) to the **AMENDED AND RESTATED MASTER SERVICES AGREEMENT** dated as of May 31, 2005, as amended (collectively, the “**Agreement**”), by and between **EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC.** (“**ESSDS**”) and **ORPHAN MEDICAL, INC.** (“**Orphan Medical**”) and assigned to **JAZZ PHARMACEUTICALS, INC.** (“**Jazz Pharmaceuticals**”), is entered into as of the 22<sup>nd</sup> day of June, 2006 (the “**Effective Date**”) by and between ESSDS and Jazz Pharmaceuticals. Capitalized terms not otherwise defined herein shall have the same meanings as in the Agreement.

**RECITALS**

**WHEREAS**, Jazz Pharmaceuticals desires ESSDS to provide certain Nursing Program Services (as defined in Section 2 of this Addendum) as a trial pilot program for its product, Xyrem, and related PAP; and

**WHEREAS**, the parties desire to include and describe in more detail the provision by ESSDS of certain Nursing Program Services as a trial pilot program under the PAP to Jazz Pharmaceuticals as described herein; and

**WHEREAS**, Section 10.10 of the Agreement provides that the Agreement may be amended by a written instrument signed by both parties; and

**WHEREAS**, the parties desire to supplement the Agreement as provided herein.

**NOW, THEREFORE**, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein and in the Agreement, the parties hereto agree as follows:

**AGREEMENT**

1. **Incorporation of Recitals.** The Recitals are hereby incorporated into the Addendum.

2. **Definitions.** As used in this Addendum, the following term (and the plural thereof, when appropriate) shall have the meaning set forth herein, except where the context makes it clear that such meaning is not intended:

- a. “**Nursing Program Services**” shall mean those services set forth in Exhibit A, attached hereto and incorporated herein by reference that are

- b. provided as a trial pilot program for the Jazz Pharmaceutical product, Xyrem and related PAP.
- c. Capitalized terms used herein but not defined herein shall have the meaning ascribed to them in the Agreement.

3. **Performance of Nursing Program Services.** ESSDS shall perform the Nursing Program Services set forth in Exhibit A as a trial pilot program for Jazz Pharmaceuticals for its product, Xyrem and related PAP. ESSDS agrees to perform such Nursing Program Services with due care in accordance with the standards and practices which are generally accepted in the industry and exercised by other persons engaged in performing similar services in the local area and in accordance with all applicable federal and state laws and regulations. In the event the pilot program is transitioned into a permanent program under the PAP, the parties agree to renegotiate, in good faith, an agreement under which Nursing Program Services will be provided as a permanent program under the PAP.

4. **Term and Termination.** The term of this Addendum shall commence on the Effective Date, and continue through November 30, 2006, unless this Addendum is earlier terminated as provided herein or extended by the parties. Either party may terminate this Addendum on thirty (30) days' prior written notice to the other party, provided, however, that neither party may terminate this Addendum prior to August 31, 2006.

5. **Fees.** Jazz Pharmaceuticals shall pay ESSDS the fees described in Exhibit B in consideration of the performance of Nursing Program Services. The fees described on Exhibit B shall constitute full and complete payment for performance of the Nursing Program Services by ESSDS under the Agreement.

6. **Miscellaneous.**

- a. Except as expressly set forth in this Addendum, all of the terms and conditions of the Agreement shall remain in full force and effect.
- b. To the extent there is a conflict between the terms and conditions of this Addendum and the terms and conditions of the Agreement, this Addendum shall control.
- c. This Addendum may be executed in one or more counterpart copies, each of which shall be deemed an original, and all of which shall together be deemed to constitute one agreement. Facsimile execution and delivery of this Addendum is legal, valid and binding execution and delivery for all purposes.

{SIGNATURE PAGE FOLLOWS}

2.

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IN WITNESS WHEREOF, the parties have executed or caused this Addendum to be executed as of this 22<sup>nd</sup> day of June, 2006.

EXPRESS SCRIPTS SPECIALTY  
DISTRIBUTION SERVICES, INC.

JAZZ PHARMACEUTICALS, INC.

By: /s/ Gerard A. Carino  
Its: President PBS & SDS

By: /s/ Janne L. T. Wissel  
Its: SR VP Development

3.

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**EXHIBIT A**  
**NURSING PROGRAM SERVICES**

**Population**

- Patients to whom Nursing Program Services will be offered under the trial pilot program (the “pilot patient population”) will include all new enrollees on a given day of the week (e.g., every Tuesday or such other day as determined by the parties) over a recommended period of [ \* ].

**Contact**

- ESSDS nurses will contact a random, select group of the pilot patient population at designated intervals over the course of the first 90 days of such individual’s Xyrem therapy. There will be [ \* ] “touch points” with the patient through the [ \* ] refill: [ \* ]

The patient may contact the nurse at other intervals throughout the pilot program. Additionally, it may be necessary for the nurse to contact the patient’s physician throughout the pilot program for clarification of orders and/or compliance issues.

**Documentation**

- ESSDS will document all contact with the patients selected from the pilot patient population and their physicians’ offices.

**Reporting**

- ESSDS will provide a monthly report to include patient [ \* ].

**Program Continuation**

- Outcomes for improvement in length of therapy will be measured and reported to determine whether permanent PAP program-wide implementation should occur.

A-1

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**EXHIBIT B**  
**FEES**

<u>Services</u>	<u>Fees</u>
Monthly Management Fee (prorated for partial months)	\$[ * ]

The fee schedule listed above is subject to the following qualifications:

- The fees apply to the Nursing Program Services only.
- In the event the Nursing Program Services are canceled and this Addendum terminated, the nursing staff will continue to contact patients through the [ \* ] refill.
- SDS will be paid the Monthly Management Fee each month until all patients have cycled through the [ \* ] refill.
- Pricing will be re-evaluated upon permanent program-wide implementation.

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**ADDENDUM No. 3  
TO AMENDED AND RESTATED MASTER SERVICES AGREEMENT**

THIS ADDENDUM NO. 3 TO AMENDED AND RESTATED MASTER SERVICES AGREEMENT (this "Addendum") is entered into as of the 17<sup>th</sup> day of August, 2006 (the "Effective Date") by and between **Express Scripts Specialty Distribution Services, Inc.** ("SDS") and **Jazz Pharmaceuticals, Inc.**

**RECITALS**

**WHEREAS**, this Addendum relates to and is hereby incorporated into the Amended and Restated Services Agreement between Express Scripts Specialty Distribution Services, Inc. and Orphan Medical, Inc., dated May 31, 2005, which was effective as of January 1, 2005, as assigned to Jazz Pharmaceuticals, Inc., together with the Consent and Addendum dated June 1, 2006 and the Addendum No. 2 dated June 22, 2006 (hereinafter collectively referred to as the "Agreement"); and

**WHEREAS**, the NDC code for Xyrem (the "Product") has been changed due to the change in marketing company from Orphan Medical, Inc. to Jazz Pharmaceuticals, Inc.; and

**WHEREAS**, Jazz Pharmaceuticals, Inc. is awaiting a rebate agreement acceptance ("Acceptance") from Centers for Medicare and Medicaid Services ("CMS") which would provide rebates for the Product under the new NDC code ("New Lot"); and

**WHEREAS**, Jazz Pharmaceuticals, Inc. desires SDS to provide to Medicaid Patients (as defined below) the Product under the prior NDC code ("Prior Lot"), as opposed to the New Lot, until such Acceptance is completed; and

**WHEREAS**, Article 1, Additional Services, allows additional services to be incorporated into the Agreement through use of an Additional Services Request Form as described on Exhibit D of the Agreement; and

**WHEREAS**, the parties desire to supplement the Agreement through this Addendum.

**NOW, THEREFORE**, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein and in the Agreement, the parties hereto agree as follows:

**AGREEMENT**

1. Incorporation of Recitals. The Recitals are hereby incorporated into the Addendum.

2. Interim Management of Medicaid Patients. SDS shall provide the Prior Lot to Medicare Patients (as defined below) as further detailed below ("Additional Services").

1.

SDS will manage and provide the Covered Services, described in the Agreement and on Exhibit A of the Agreement, for the specific provision, to Non-PAP Patients who have Medicaid coverage and are approved by Medicaid to receive the Product ("Medicaid Patients"), of the Prior Lot, as opposed to the New Lot, until such time as notification is received from Jazz Pharmaceuticals, Inc. that the Acceptance is finalized. Additional Services will require SDS to perform system program changes to ensure the accuracy of selection and provision of the Prior Lot for this particular group of Patients. In addition, the SDS operations team will need to develop the processes necessary and train staff to effectively transition the Medicaid Patients, These programming changes will have an impact on reporting, purchase orders, inventory management and other associated program aspects.

3. Fees for Additional Services:

- a. A one time \$[ \* ] set up fee.
- b. Medicaid Patients will be billed at \$[ \* ] per order for shipments from the Prior Lot to such patients.

**IN WITNESS HEREOF, the parties have executed or caused this Addendum to be executed as of the date indicated above.**

**EXPRESS SCRIPTS SPECIALTY  
DISTRIBUTION SERVICES, INC.**

**JAZZ PHARMACEUTICALS, INC.**

By:  /s/ Gerard A. Carino  
Name: Gerard A. Carino  
Title: President, PBS & SDS

By:  /s/ Carol Gamble  
Name: Carol Gamble  
Title: Sr. Vice President & General Counsel

2.

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ORPHAN MEDICAL, INC.  
AND CATALYTICA PHARMACEUTICALS, INC.

XYREM  
SUPPLY AGREEMENT

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## XYREM SUPPLY AGREEMENT

THIS AGREEMENT ("Agreement") is made as of this 30<sup>th</sup> day of June, 2000 by and between ORPHAN MEDICAL, INC., a Minnesota corporation, having its principal offices at 13911 Ridgedale Drive, Minnetonka, Minnesota 55305 ("ORPHAN") and Catalytica Pharmaceuticals, Inc., a Delaware corporation, having its principal offices at Intersection US 13/NC11 and US 264, Greenville, North Carolina 27834 ("Catalytica").

### RECITALS

1. Catalytica manufactures pharmaceuticals meeting regulatory and governmental requirements for commercial use.
2. ORPHAN develops and markets ethical pharmaceuticals targeted to specified populations of patients.
3. ORPHAN and Catalytica desire to cooperate in the transfer of the manufacture of an oral pharmaceutical product, Xyrem<sup>®</sup> (sodium oxybate) Oral Solution, containing the active ingredient sodium gamma hydroxybutyrate.
4. In anticipation of the above-referenced transfer, ORPHAN and Catalytica entered into a Technical Services Agreement, dated November 20, 1999, pursuant to which Catalytica would undertake certain technical services in order to prepare its facilities for performance of this Agreement.
5. Catalytica desires to manufacture the Product exclusively for sale to ORPHAN.
6. Upon obtaining approval to market the Product, ORPHAN wishes to purchase all of its requirements for the Product in the United States from Catalytica and Catalytica wishes to supply ORPHAN all of its requirements for the Product in the United States.

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7. Catalytica understands that Public Law 106-172 has designated that Product will be scheduled by the Drug Enforcement Administration (DEA) upon approval by the FDA, as Schedule III, and that ARCOS reporting will be required. ORPHAN and Catalytica agree that the Product Price estimate is based on Schedule III security requirements. Catalytica shall have no obligation to supply the Product pursuant to this Agreement if Schedule I security requirements are required. Orphan reserves the right to review Catalytica's SOPs regarding handling of Controlled Substances and company policies related to employees who handle controlled substances.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

#### **ARTICLE 1**

#### **DEFINITIONS**

The following terms, when capitalized, shall have the following meanings in this Agreement, whether used in the singular or the plural.

1.1 "Acquisition Cost" in respect of a particular item means the [ \* ] price paid by either party to a Third Party for acquiring such item, including without limitation, [ \* ].

1.2 "Active Ingredient" means sodium gamma hydroxybutyrate in bulk form.

1.3 "Affiliate" means any corporation or non-corporate business entity which directly or indirectly controls, is controlled by, or is under common control with a party to this Agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty (50%) of the voting stock of another corporation, or (a) in the absence of the ownership of at

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least fifty (50%) of the voting stock of a corporation, or (b) in the case of a non-corporate business entity, if it possesses, directly or indirectly, whether by virtue of an ownership interest of any kind, by contract or otherwise, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity or to elect or cause the election of a majority of the board of directors or other governing body of such corporation or non-corporate business entity.

1.4 “Contract Year” means the twelve (12) month period beginning on the [ \* ], and each successive twelve (12) month period thereafter.

1.6 “Services” means the Services as defined and further described in the Technical Services Agreement which is attached hereto as Appendix A and made a part hereof, as well as any additional process or analytical development activities or process or analytical development modifications for the Product to be mutually agreed upon in good faith by the parties after the Effective Date and subsequently attached hereto. Such modifications will include timing and cost factors.

1.7 “DMF” means a Type II Product Master File intended for filing with the FDA.

1.8 “Dollars” or “\$” means United States Dollars.

1.9 “Product Price” means the price to ORPHAN, in Dollars per unit (for purposes of this Agreement, a “unit” is a [ \* ] bottle), for manufacture of the Product as such price may be amended from time to time during the term of, and pursuant to, this Agreement.

1.10 “Product” means Xyrem, an oral liquid pharmaceutical product containing the Active Ingredient packaged in [ \* ] bottles or such other package sizes as may be mutually agreed by the parties from time to time.

1.11 "Effective Date" means the date appearing at the beginning of this Agreement.

1.12 "FDA" means the US Food and Drug Administration or any successor entity.

1.13 "FD&C Act" means the US Federal Food, Drug and Cosmetic Act, together with all regulations issued thereunder, as the same may be amended from time to time.

1.14 "cGMPs" means the current Good Manufacturing Practices regulations promulgated by the FDA, and any applicable amendments thereto in effect at the time of the Product's manufacture.

1.15 "Manufacturing Price" means Catalytica's costs of [ \* ] and [ \* ], [ \* ] (including without limitation [ \* ] and [ \* ] and [ \* ] in the manufacture of the Product), [ \* ] (i.e. [ \* ] and [ \* ] and [ \* ] of the [ \* ]), all determined in accordance with generally accepted accounting principles applied on a consistent basis .

1.16 "NDA" means a New Drug Application filed with the FDA or any equivalent successor application or entity relating to the formulation of the Product.

1.17 "Notification" shall have the meaning prescribed in Section 19.2 hereof.

1.18 "Production Batch" means a production size batch of the Product with a specified number of units, the size and range of which is to be established and mutually agreed upon by the parties. Each Production Batch is to have uniform character and quality within specified limits produced according to a single manufacturing order during the same cycle of manufacture.

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1.19 "Proprietary Information" means all information or data relating to the subject matter hereof first communicated by or on behalf of one party (the "Disclosing Party") to the other (the "Receiving Party"), whether in writing, orally, or otherwise, including without limitation, all scientific, clinical, commercial, financial and business information and data, know-how, compilations, formulae, processes, plans, technical information, new product information, compounds, formulations, methods of product delivery, test procedures, product samples, specifications and other information or data. Information shall not be deemed Proprietary Information which: (a) at the time of disclosure, is already in the public domain or thereafter becomes part of the public domain by publication or otherwise through no fault or act of the Receiving Party; (b) was demonstrably in the possession of the Receiving Party prior to the time of the disclosure to it and was not acquired, directly or indirectly, from the Disclosing Party; (c) is independently disclosed to the Receiving Party by a Third Party who has not violated any confidential obligation owed to the Disclosing Party or any Third Party; (d) was independently developed by the Receiving Party without any use of or reliance on any Proprietary Information of the Disclosing Party as shown by competent evidence; (e) is required to be disclosed by legal process; provided that, in each case the party so disclosing information timely informs the other and uses its best efforts to limit the disclosure and maintain confidentiality to the extent possible and permits the other party to attempt by appropriate legal means to limit such disclosure; or (f) is information which is required to be included in patent applications filed hereunder or required to be provided to the FDA or any other regulatory authority in the Territory in order for ORPHAN to obtain registrations for the Product or otherwise to comply with applicable regulatory requirements, or for Catalytica to manufacture the Product for ORPHAN hereunder; provided, however, that no Proprietary Information of ORPHAN or Catalytica will be disclosed in any such patent application without the prior written consent of the other Disclosing Party, which consent will not be unreasonably withheld. Written Proprietary Information shall be identified by the Disclosing Party as being confidential by stamping the cover pages of such information "Confidential." Proprietary Information disclosed orally, visually and/or in another tangible form shall be identified by the Disclosing Party to

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the Receiving Party as confidential at the time of such disclosure and confirmed to the Receiving Party within thirty (30) days after such disclosure in a writing marked "Confidential."

1.20 "Specifications" means the final specifications for the Product attached hereto as Appendix B and made a part hereof, including the final NDA specifications as approved by the FDA, packaging specifications, as well as any revised and/or additional specifications for the Product to be developed and mutually agreed to by the parties after the Effective Date and subsequently attached hereto as a replacement for or as an addition to Appendix B.

1.21 "Territory" means worldwide. Catalytica will be granted manufacturing exclusivity for US.

1.22 "Third Party" means any entity other than Catalytica or ORPHAN or their respective Affiliates.

1.23 "Quality Agreement" shall mean the Quality Agreement, as further defined in Section 8.5, which shall be substantially in the form of Exhibit F hereto.

1.24 "CMC" means Chemistry Manufacturing and Control.

1.25 "Orphan Product Exclusivity" shall refer to any period of exclusivity (including but not limited to manufacturing, marketing and advertising exclusivity) provided by the FDA. As of the date of this Agreement, ORPHAN has applied for an "ORPHAN drug" designation from the FDA, which, if approved, will entitle ORPHAN to a period of seven (7) years exclusivity on the Product, calculated from the date of Product approval.

1.26 "Lonza" refers to LONZA Group.



**ARTICLE 2****VALIDATION ACTIVITIES**

2.1 Catalytica's Validation Responsibilities. Catalytica shall be responsible for regulatory required validations of its manufacture of the Product and its facilities and shall take all reasonable steps to pass inspections by the FDA and DEA or other regulatory agencies in the Territory. In the event non-U.S. Territory regulatory agencies require process development testing beyond that required in the U.S., Catalytica agrees to provide the additional process development testing per mutually approved protocols at terms to be negotiated in good faith by the parties.

**ARTICLE 3****EXCLUSIVITY**

3.1 ORPHAN, as between Catalytica and ORPHAN, shall have the exclusive right, directly or through any Affiliate, to apply for registrations and to market, distribute and sell the Product or any product containing the Active Ingredient in the Territory, if ORPHAN determines in its business judgment to do so. Catalytica shall not market, distribute, make or sell the Product or any product containing the Active Ingredient, directly or indirectly anywhere in the Territory, except to ORPHAN, during [ \* ], or [ \* ], whichever is longer.

**ARTICLE 4****SUPPLY OF PRODUCT**

4.1 Information Provided by ORPHAN. Prior to commencement of manufacturing operations hereunder, ORPHAN shall provide Catalytica with a Material Safety Data Sheet ("MSDS"), toxicity information for the Product, any other information reasonably available to ORPHAN which relates to the safe conduct of the manufacturing and/or packaging operations to be conducted by Catalytica, and any other documents necessary for Catalytica to manufacture the Product. When and as such information becomes available, ORPHAN shall promptly update such information pertinent to the manufacture and/or packaging of the Product.

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4.2 Manufacture and Supply.

During each Contract Year of this Agreement, and subject to the provisions of Section 7.2 hereof as well as other provisions herein, ORPHAN agrees to purchase all of its requirements for the Product in the United States from Catalytica, but no less than the minimum quantities of Product indicated below:

<u>Contract Year</u>	<u>Orphan's Minimum Purchase of Units</u>
Year 1	[ * ]
Year 2	[ * ]
Year 3	[ * ]
Year 4	[ * ]
Year 5	[ * ]
Year 6	[ * ]
Year 7	[ * ]

Catalytica shall be the exclusive supplier of Product in the United States to ORPHAN. Subject to Section 6.1, Catalytica shall provide or purchase all materials and supplies necessary to manufacture the Product. Catalytica shall manufacture the Product in accordance with the Specifications and applicable cGMPs and shall package, label and/or otherwise prepare the Product for bulk delivery to an ORPHAN-designated distribution site.

4.3 Packaging. Catalytica shall furnish the packaging supplies and labels for the Products, which shall meet the Specifications, as specified in Appendix D and as required by ORPHAN at a mutually agreed to price. All such packaging and labels shall conform to applicable requirements and regulations of FDA or other regulatory authorities in the Territory.

4.4 Artwork. At least ninety (90) days prior to (a) the date for which delivery of Product is stated in the first purchase order or (b) any modification to the artwork for the Product, as applicable, and from time to time thereafter with respect to the Product, as needed, ORPHAN shall provide [ \* ] to Catalytica, in a format acceptable to Catalytica and in a timely manner, digital artwork for all packaging components to be used in the manufacture of the Product, which artwork shall meet the Specifications. [ \* ].

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4.5 Conditions Requiring Backup Manufacture. Catalytica agrees to support the successful transfer of manufacturing technology to a second Product manufacturer chosen by ORPHAN to make, have made, use and sell the Product if Catalytica breaches this Agreement and fails to cure as provided in Section 16.1 (a).

**ARTICLE 5**

**FORECASTS, ORDERS AND DELIVERIES**

5.1 Forecasts. ORPHAN shall provide Catalytica with forecasts of ORPHAN'S anticipated [ \* ] requirements of the Product for distribution and sale in the United States commencing with the [ \* ] period that begins at the time of FDA approval of the Product. Such forecast will be provided [ \* ] in advance of anticipated FDA approval of the NDA and ORPHAN shall update such [ \* ] forecast on [ \* ] basis thereafter. Once FDA approval of the Product is received, ORPHAN will provide Catalytica, prior to the beginning of each [ \* ], with forecasts of its anticipated requirements of the Product for the following [ \* ] and the forecast for the first [ \* ] shall be firm and binding on ORPHAN. Catalytica will provide [ \* ] anticipated schedule for manufacture and will consult with ORPHAN on schedule changes.

- (a) Catalytica shall [ \* ] manufacture during any [ \* ] up to [ \* ] of the quantity of the Product ORPHAN forecasted it would purchase from Catalytica during such [ \* ] in its most recent forecast covering [ \* ]. Catalytica will promptly communicate with ORPHAN as to its ability to produce quantities requested.
- (b) When and as ORPHAN proposes to commence its distribution and sale of the Product outside the United States, ORPHAN shall supplement its [ \* ] forecast accordingly to indicate the additional requirements of the Product for such purposes.

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- (c) If Catalytica manufactures the Product with a lead time of more than [ \* ], ORPHAN shall not be required to pay any additional storage, or pay for the Product sooner than as set forth in Section 7.7 nor shall any advance manufacture lead to a violation of the warranty of expiration date set forth in Section 8.1.

5.2 Orders. ORPHAN shall order the manufacturing of the Product by Catalytica pursuant to written purchase orders, including delivery dates, with not less than [ \* ] "lead time" prior to the requested delivery dates specified therein. Each purchase order for the Product shall be in Production Batch sizes or whole multiples thereof and shall be for not less than [ \* ] batches totaling not less than [ \* ]. The terms contained in this Agreement shall govern over all purchase orders or sales orders of the Product hereunder and shall not be varied by the terms of any ORPHAN purchase order or Catalytica sales order or invoice. If ORPHAN requires manufacture of the Product with less than [ \* ] lead time, Catalytica shall use reasonable efforts [ \* ] to accommodate ORPHAN'S requirements. Catalytica shall not manufacture the Product except upon receipt of an ORPHAN purchase order to ensure a supply of the Product with the maximum expiration dating.

5.3 Late Manufacture and Delivery. When ORPHAN submits a purchase order at least [ \* ] prior to the required delivery date, or [ \* ] in the event the Product is to be shipped, used or sold outside the United States, Catalytica shall confirm receipt of this order. In the event of unexpected delays owing to manufacturing problems associated with the Product, Catalytica will inform ORPHAN promptly and action to be taken will be jointly decided.

5.4 Delivery Terms. The terms of delivery for (a) any Active Ingredients delivered by or on behalf of ORPHAN to Catalytica hereunder and (b) the Product shall be F.O.B. Catalytica's [ \* ] plant, [ \* ]. At its written request, ORPHAN may delay delivery of Product for up to [ \* ] from the issue date of COC/COA. [ \* ] shall select the carrier and arrange for shipment. Subject to any security interest reserved and granted pursuant to this Agreement, title and risk of loss and/or damage to the Product shall pass to ORPHAN upon delivery of the Product to the carrier at Catalytica's [ \* ] plant.

5.5 Purchase Quantities. Each purchase order shall specify the quantity of units of Product being ordered. Quantities actually shipped pursuant to a given purchase order may vary from the quantities reflected in such purchase order by up to [ \* ] and still be deemed to be in compliance with such purchase order; provided, however, ORPHAN shall only be invoiced and required to pay for the quantities of Product which Catalytica actually ships to ORPHAN.

5.6 Certifications. For each Production Batch of the Product manufactured for ORPHAN hereunder, Catalytica shall furnish the following to ORPHAN at the time of delivery. Originals are to be retained by Catalytica:

- (a) representative samples of such batch for assay and other testing;
- (b) batch records and quality assurance data for such batch; and
- (c) a certificate of analysis that such batch conforms to the Specifications and a certificate of compliance which confirms that the Product was manufactured, tested, and delivered in full compliance with all applicable laws and regulations.

In addition, ORPHAN shall ensure that Lonza furnishes to Catalytica with each shipment of Active Ingredients hereunder a certificate of analysis for each Active Ingredient reflecting that each Active Ingredient meets the Specifications.

#### **ARTICLE 6.**

#### **ACTIVE INGREDIENTS**

6.1 Active Ingredients Supply. On ORPHAN'S behalf, Catalytica shall submit purchase orders to Lonza for the Active Ingredients for the Product. ORPHAN shall be solely responsible for delivery of Active Ingredients to Catalytica [ \* ]. Within thirty (30) days after submitting each purchase order for Product, ORPHAN shall ensure that Lonza provides to Catalytica sufficient quantities of Active Ingredients

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necessary for Catalytica to manufacture Product thereunder , as well as the certificates of analysis as set forth in Section 5.6 hereof. In the event ORPHAN is unable to provide such Active Ingredients within any such thirty (30) day period, the [ \* ] “lead time” period for the manufacture of Product under the affected purchase order shall be extended for a period of [ \* ] for each day of delay in the supply of Active Ingredients by ORPHAN. Upon request by Catalytica, ORPHAN shall promptly send Catalytica all reference standards relating to the Active Ingredients developed by or for ORPHAN. ORPHAN shall ensure that all imported Active Ingredients or other materials supplied to Catalytica by or on behalf of ORPHAN comply with all applicable laws and regulations relating to the import of such Active Ingredients and materials and receive all required governmental and regulatory approvals, including without limitation customs and FDA approvals.

6.2 Supply by Catalytica. At ORPHAN’S request and upon ninety (90) days prior written notice, Catalytica shall supply the Active Ingredients for the Product and in that event, notwithstanding Section 7.1 hereof, the Product Price will be increased to reflect Catalytica’s Acquisition Costs of the Active Ingredients.

6.3 Manufacturing Loss. Catalytica shall [ \* ] to prevent manufacturing waste of the Active Ingredients supplied by ORPHAN for the manufacture of the Product and shall be accountable to ORPHAN for Catalytica’s use of such Active Ingredients. Accordingly, Catalytica shall grant credits or pay to ORPHAN its Acquisition Costs of Active Ingredients lost by Catalytica, due to Catalytica’s negligence or willful misconduct, in excess of normal manufacturing loss. For purposes of this Agreement, the normal manufacturing loss for any given Production Batch shall be mutually established by Catalytica and ORPHAN following Catalytica’s manufacture of [ \* ] Production Batches, not to exceed [ \* ]. Catalytica shall dispose of manufacturing waste consistent with its handling of other waste and in compliance with DEA requirements

6.4 Title to Active Ingredients Supplied by ORPHAN. ORPHAN shall retain title to all Active Ingredients supplied to Catalytica.

**ARTICLE 7**

**PRICES AND PAYMENTS**

7.1 First Contract Year Manufacturing Price. After completion of the Services as identified in the Technical Services Agreement attached as Appendix A, Catalytica will notify ORPHAN of the Product Price that ORPHAN shall pay to Catalytica for any orders of the Product manufactured during [ \* ]. Subject to Section 6.2 hereof, the Product Price for [ \* ] shall be [ \* ]. The Product Price for the [ \* ] will be [ \* ].

7.2 Minimum Purchase Requirements. In the event ORPHAN does not meet the minimum purchase requirements set forth in Section 4.2 hereof with respect to any Contract Year, ORPHAN shall within thirty (30) days after the end of such Contract Year pay Catalytica the Product Price less any packaging material costs applicable at the end of such Contract Year for the quantity of Product not purchased that would satisfy the applicable minimum purchase requirement.

7.3 Annual Price Adjustment Notification. At least [ \* ] days prior to the end of the first Contract Year of this Agreement and each Contract Year thereafter, Catalytica shall notify ORPHAN of the Product Price for the next succeeding Contract Year provided, however, that the Product Price for each new Contract Year shall be [ \* ]. [ \* ] in the Product Price pursuant to this Section 7.3 shall become effective as of the anniversary date of the Effective Date.

7.4 Specification Changes.

- (a) Specification Changes. In the event that ORPHAN wishes to change the Specifications, or in the event that ORPHAN is required to change the Specifications pursuant to applicable law or regulation or in response to the order or request of a governmental authority or regulatory body, the following provisions will apply.

- (1) ORPHAN shall promptly advise Catalytica in writing of any such change(s) to the Specifications, and Catalytica shall promptly advise ORPHAN as to any scheduling and/or Product Price adjustments which may result from any such change(s), if any. The notification and approval procedure shall be in accordance with APPENDIX F, as well as any additional standard operating procedures (*i.e.*, change control procedures) agreed upon by ORPHAN and Catalytica in writing from time to time.
- (2) Prior to implementation of such change(s) to the Specifications, ORPHAN and Catalytica shall negotiate in good faith in an attempt to reach agreement on (i) the new Product Price, if any, for any Drug Product and/or Finished Product provided hereunder by Catalytica which embodies such change(s) to the Specifications, giving due consideration to the effect of such change(s) on Catalytica's manufacturing costs for Drug Product and/or Finished Product and (ii) any other amendments to this Agreement which may be necessitated by such changes (*e.g.*, an adjustment to the lead time for Firm Orders). Implementation of such change(s) to the Specifications shall be as set forth in APPENDIX F.
- (3) ORPHAN will reimburse Catalytica for the reasonable and necessary expenses incurred by Catalytica as a result of any such change(s) to the Specifications [ \* ].
- (4) If any such change(s) to the Specifications renders obsolete or unusable any materials or components for Drug Product or Finished Product, and to the extent such materials or components may not be returned to the appropriate vendor for a credit [ \* ] that amount of inventory of materials or components, as the case may be, so rendered obsolete or unusable, not to exceed the amount of such materials or components which would have been required for [ \* ].

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7.5 Taxes. The Product Price does not include sales, use, consumption, or excise taxes of any taxing authority. The amount of such taxes, if any, will be added to the Product Price in effect at the time of shipment thereof and shall be reflected in the invoices submitted to ORPHAN by Catalytica pursuant to this Agreement. ORPHAN shall pay the amount of such taxes to Catalytica in accordance with the payment provisions of this Agreement.

7.6 Additional Payments. As additional consideration for Catalytica's performance of its obligations hereunder, ORPHAN shall pay Catalytica the amounts set forth below (with all payments being due within thirty (30) days of receipt of the relevant Catalytica invoice, unless otherwise provided below):

(a) ORPHAN shall pay Catalytica, at [ \* ] for regulatory consulting services performed in connection with this Agreement. These services are to be approved in advance by Orphan.

(b) ORPHAN shall reimburse Catalytica for all reasonable and necessary travel and lodging expenses incurred in the performance of this Agreement which have been requested or approved by ORPHAN.

7.7 Cost Reductions Through Process Improvements. To encourage active and open consideration of Manufacturing Price reductions, it is agreed that any cost reduction benefit will be shared based on [ \* ]. Proposals for improvements will be outlined in writing or communicated verbally and will detail how the improvement should be realized. This sharing of benefits will come into effect only after [ \* ]

7.8 Invoice Payment. Payment for the Product shall be due net thirty (30) days from the date of the invoice therefor, provided that no invoice shall be dated prior to the date of actual release of the Product reflected therein. All amounts not paid when due shall bear interest from the due date at the rate of [ \* ] percent ([ \* ]%) per month (or such other percentage, if lower, as shall not exceed the maximum rate permitted by law), and ORPHAN shall be responsible for reasonable attorneys' fees and expenses incurred by Catalytica in connection with the collection thereof.

8.1 Representations and Warranties.

(a) ORPHAN represents and warrants to Catalytica that:

(i) the execution of this Agreement and the performance by ORPHAN of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of ORPHAN;

(ii) the processes transferred to Catalytica by ORPHAN pursuant to the Services do not [ \* ];

(iii) at the time it releases or causes to be released the Active Ingredients to Catalytica for use in the manufacture of the Product, the Active Ingredients shall meet the specifications therefor and shall be suitable for use in the manufacture of the Product; and

(iv) that upon delivery to Catalytica, no Active Ingredients constituting or being part of any shipment or other delivery now or hereafter made to Catalytica will be adulterated or misbranded within the meaning of the FD&C Act or would be an article which may not be introduced into interstate commerce under the provisions of Section 404 or 505 of the FD&C Act.

(b) Catalytica represents and warrants to ORPHAN that:

(i) The execution of this Agreement and the performance by Catalytica of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of Catalytica;

(ii) To the best of its knowledge, Catalytica will not use in any capacity persons, or the services of persons that are debarred, are on the Debarment List, or that have been convicted of actions that could lead to debarment as described in Section 306(a) and (b) of the FD&C Act; and

(iii) at the time of sale and shipment by Catalytica, each Production Batch will:

(A) have an expiration date equal to that approved by the FDA, via the initial NDA submission or via extended stability study data subsequently submitted;

(B) conform to the Specifications; and will have been stored in accordance with storage specifications;

(C) have been manufactured in compliance with all applicable laws and regulations, including, without limitation, current cGMP regulations;

(D) not be adulterated or misbranded by Catalytica within the meaning of the FD&C Act, as amended, or be an article which may not be introduced into interstate commerce under Sections 404 or 505 of such Act;

(E) be free from all material liens and encumbrances provided, however, **THE WARRANTIES SET FORTH HEREIN ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND CATALYTICA EXPRESSLY DISCLAIMS AND NEGATES, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS' and**

(F) be shipped in accordance with Orphan's reasonable instructions.

(c) Catalytica shall have no responsibility for, or liability with respect to, any Product that fails to comply with the warranties set forth in Section 8.1(b) hereof due in whole or in part to the failure of any Active Ingredient to comply with the warranties set forth in this Section 8.1.

## 8.2 Manufacturing Audits and Observation Rights.

(a) Annual MA. With respect to any Contract Year, ORPHAN shall have the right to conduct [ \* ] Manufacturing Audit (as defined below) according to the terms specified in Sections 8.2(b) and 8.2(c) hereof (such [ \* ] Manufacturing Audit to be hereinafter referred to as an “[ \* ] MA”).

(b) Event MA. In addition to the [ \* ] MA referred to in Section 8.2(a) hereof, in the event that (i) Catalytica shall receive a “Warning Letter” from the FDA relating to the manufacture, packaging or labeling of the Product by Catalytica, (ii) ORPHAN has rejected a shipment of Product for a mutually agreed upon failure to meet Specifications or (iii) ORPHAN or Catalytica shall have received a series of complaints (i.e., 3 or more complaints on at least 2 Production Batches) from Third Parties within any Contract Year relating to the manufacturing process for the Product (individually or collectively, an “Event”), ORPHAN shall have the right to conduct an additional Manufacturing Audit or Audits according to the terms specified in Section 8.2(c) hereof (such Event Manufacturing Audit or Audits to be hereinafter referred to as an “Event MA”). It is understood and agreed, however, that with respect to any Contract Year, if ORPHAN has not yet conducted an [ \* ] MA and ORPHAN elects to exercise its rights with respect to an Event MA, then in such case, such Event MA and [ \* ] MA shall be conducted at the same time; provided, however, an [ \* ] MA shall not be conducted within [ \* ] of the immediately preceding [ \* ] MA.

(c) Definition. For purposes of this Agreement, the term “Manufacturing Audit” shall mean an audit by no more than [ \* ] of ORPHAN of that portion of Catalytica’s manufacturing facility where the Product is manufactured for purposes of reviewing Catalytica’s procedures and processes used in

manufacturing the Product. Any such employees and/or agent shall be accompanied by Catalytica personnel at all times, shall be qualified to conduct manufacturing audits, shall comply with Catalytica's rules and regulations relating to facility security, health and safety, and shall execute a written agreement to maintain in confidence all information obtained during the course of any such audit except for disclosure to ORPHAN. Each Manufacturing Audit shall be conducted during Catalytica's normal business hours and upon at least [ \* ] prior written notice to Catalytica in the case of an [ \* ] MA, or upon at least [ \* ] prior written notice to Catalytica in the case of an [ \* ] MA. The written notice shall identify any specific audit requests that ORPHAN intends to make of Catalytica and ORPHAN'S contact person with regard to the Manufacturing Audit. In no event shall a Manufacturing Audit exceed [ \* ] in duration (ORPHAN will be billed at Catalytica's standard full time equivalent rates for any Manufacturing Audit that, with Catalytica's permission, exceeds [ \* ], and in all cases ORPHAN shall ensure that its employees or agents will conduct each Manufacturing Audit so as not to interfere with the normal and ordinary operation of Catalytica's manufacturing facility. All Manufacturing Audits shall be at ORPHAN'S sole expense.

(d) Observation Rights. In addition to the [ \* ] MA and Event MA referred to in Sections 8.2(a) and (b) hereof, ORPHAN shall have the right to be present at and to observe up to [ \* ] production runs of the Product in any Contract Year. Such observations shall be conducted by no more than [ \* ] ORPHAN solely for purposes of observing Catalytica's manufacture of the Product. Any such employees and/or agent shall be accompanied by Catalytica personnel at all times, shall comply with Catalytica's rules and regulations relating to facility security, health and safety, and shall execute a written agreement to maintain in confidence all information obtained during the course of any such observation. Each observation shall be conducted during Catalytica's normal business hours and upon at least [ \* ] prior written notice to Catalytica. In all cases ORPHAN shall ensure that its employees or agents will conduct each observation so as not to interfere with the normal and ordinary operation of Catalytica's manufacturing facility. All observations shall be at ORPHAN'S sole expense. Upon ORPHAN'S request, Catalytica shall notify ORPHAN at least thirty (30) days in advance of any production run of the Product.

(e) Limitation. Except as set forth in this Section 8.2, neither ORPHAN nor its Affiliates, employees or agents shall have access to Catalytica's manufacturing facilities.

- 8.3 Regulatory correspondence and Inspections. Catalytica shall promptly inform ORPHAN of any regulatory correspondence or inspection with respect to Catalytica's manufacture of the Product as follows:
- (a) Catalytica shall provide ORPHAN with copies of any correspondence and other documentation received or prepared by Catalytica in connection with the manufacture and testing of the Product in the Territory, including, but not limited to, copies of the proposed NDA (but only of those portions for which Catalytica is responsible) and of the potential DMF for the Product and of annual submissions to the FDA and other regulatory authorities in the Territory. Copies of all such correspondence or other documentation prepared by Catalytica shall be reviewed and approved by ORPHAN prior to its submission, such approval not to be unreasonably withheld.
  - (b) If Catalytica receives any regulatory correspondence or comments from any federal, state, or local regulatory agency related to its manufacture of the Product, or affecting the Product, requiring a response or action by Catalytica, including, without limitation, receipt of an FDA Form 483 (Inspectional Observations) or an FDA "Warning Letter", Catalytica shall immediately provide ORPHAN with a copy of each such regulatory correspondence or comment and a copy of Catalytica's proposed response thereto for ORPHAN'S review and approval (such approval not to be unreasonably withheld or delayed) prior to its submission if Catalytica's manufacture of additional products are not involved. In cases where Catalytica's manufacture of additional products are involved, a good faith effort will be made to reach joint approval within an appropriate timeframe.

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- (c) If Catalytica's manufacturing facility is inspected by representatives of any federal, state, or local regulatory agency in connection with Catalytica's manufacture of the Product, including, but not limited to, any pre-NDA approval inspection by the FDA, Catalytica shall notify ORPHAN within one (1) working day (by telephone and, if possible, by fax or letter) upon learning of such inspection, and shall supply ORPHAN with copies of any correspondence or portions of correspondence which relate to such regulatory inspection. ORPHAN may send representatives to Catalytica's manufacturing facility to observe any portion of such regulatory inspection relating to the Product.

#### 8.4 Regulatory Support.

(a) Catalytica will provide ORPHAN with standard regulatory support as identified under the heading "Regulatory Support" in Appendix E attached hereto. In addition, Catalytica shall provide ORPHAN with regulatory consulting services as identified under the heading "Regulatory Consulting" in Appendix E attached hereto. Regulatory support services, as identified in Appendix E, shall be at no additional charge to ORPHAN; regulatory consulting services shall be billed at Catalytica's standard hourly rates and payable pursuant to Section 7.7 of this Agreement. Additional regulatory services and/or documentation may be provided by Catalytica, subject to agreement of the parties and subject to additional charges.

(b) Notwithstanding the above or anything in this Agreement or Appendix E to the contrary, ORPHAN is solely responsible for (i) its use of any documentation provided by Catalytica, including without limitation use in any regulatory submission to the FDA or any other regulatory agency inside or outside of the United States, (ii) document control and retention, (iii) determining the suitability of any documentation provided by Catalytica hereunder for use in any regulatory submission; and (iv) all regulatory submission, CMC and other regulatory strategies.

(c) Catalytica may, at its option, retain copies of any documentation

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provided to ORPHAN hereunder; provided, however, that Catalytica cannot and does not provide any assurances that Catalytica's records will match or otherwise correspond to any submission that ORPHAN may provide to the FDA or any other regulatory agency inside or outside the United States.

(d) ORPHAN shall provide Catalytica with all documents reasonably requested by Catalytica relating to the FDA's pre-approval inspection of Catalytica's manufacturing facility, including, but not limited to, development reports, CMC sections of ORPHAN'S NDA and stability data. In addition, ORPHAN shall provide to Catalytica at least thirty (30) days prior to filing with the FDA a copy of ORPHAN'S annual report (see 21 C.F.R. Section 314.81(b)(2)(iv)) with respect to the manufacture and control of the Product [ \* ]. Notwithstanding the foregoing or anything in this Agreement to the contrary, ORPHAN shall be solely responsible for the CMC regulatory strategy.

8.5 Quality Agreement. Catalytica and ORPHAN will negotiate in good faith and use their best efforts to arrive at a mutually acceptable Quality Agreement, which shall be substantially in the form attached hereto as Exhibit F, to further detail the quality assurance obligations and responsibilities of the parties with respect to the Product. Notwithstanding anything to the contrary in this Agreement or in any other document or agreement, in the event of a conflict between this Agreement and the Quality Agreement, this Agreement shall govern and control.

## ARTICLE 9

### ACCEPTANCE, REJECTION, AND CLAIMS

9.1 Placed on Hold. In the event that a production batch is placed on hold, Catalytica will work to resolve the hold within thirty (30) days. If the hold can not be resolved within (30) days a replacement production batch will be produced [ \* ]. A batch placed on hold will be handled as per sections 9.2 and 9.3 herein.

9.2 Acceptance and Rejection. Each shipment shall be deemed accepted by ORPHAN and considered to conform to the Specifications and the other warranties set forth in Section 8.1(b) which relate to quality unless ORPHAN gives Catalytica notice in



writing that it does not consider a particular shipment to conform, together with supporting documentation specifying the manner in which the Product fails to meet such warranties or the Specifications, within [ \* ] of receipt of such shipment (or, [ \* ] within [ \* ]). ORPHAN will analyze (or cause to be analyzed by its designated product manufacturer) each shipment of Product using the validated methods approved by the FDA for release of Product. Such testing will be done for acceptance or rejection of the lot. If ORPHAN gives Catalytica notice of rejection, Catalytica shall thereupon be given access to the shipment in question to conduct its own analysis thereof, and the parties will endeavor to agree amicably as to whether or not the shipment does conform to the Specifications and such other warranties and, if not, whether such non-compliance was due to any breach on the part of Catalytica.

In the event that the parties are unable to agree as to whether or not the shipment conforms with the Specifications or other warranties set forth in Section 8.1(b), the question will be submitted to an independent quality control laboratory which the parties shall mutually agree upon. Cost for the independent quality control laboratory shall be [ \* ]. During the pendency of a dispute that requires settlement by an independent laboratory under this section, if requested to do so by ORPHAN, Catalytica will replace [ \* ] the portion of such shipment under dispute until such dispute is resolved.

9.3 Rejected Shipments. If the nonconformity in a rejected shipment of the Product was due to any action or inaction of ORPHAN or the carrier subsequent to shipment (F.O.B. Catalytica's [ \* ] plant) of the Product by Catalytica or results from Active Ingredients supplied by ORPHAN, Catalytica shall have no liability for such rejected shipment. If the nonconformity in a properly rejected shipment of the Product was due to Catalytica's negligence or willful misconduct prior to shipment (F.O.B. Catalytica's [ \* ] plant), Catalytica at its cost and option shall either credit ORPHAN'S account for the full Manufacturing Price of such shipment or replace it with a conforming shipment within thirty (30) days of the Notification of rejection. Such credit or replacement will be ORPHAN'S sole remedy for such rejected Product provided Catalytica provides replacement or credit within thirty (30) days of Notification of rejection.

9.4 Disposal; Return Material Authorization. If ORPHAN expects to make a claim against Catalytica with respect to a rejected shipment of the Product, ORPHAN shall not dispose or allow the disposal of such Product shipment without the express written authorization and instructions of Catalytica. ORPHAN shall not return any rejected shipment of the Product to Catalytica without a Return Material Authorization (“RMA”) from Catalytica (Appendix C). Upon written request of ORPHAN, Catalytica shall promptly issue an RMA for any rejected shipment, provided, however, appropriate samples may be retained as evidence of the basis for such rejection. If the Product is returned to Catalytica, all risk of loss and/or damage to such Product shall remain with ORPHAN unless and until such Product is returned to such place as Catalytica designates in writing.

9.5 Product Recalls. Each party shall promptly notify the other party if any batch of the Product is alleged or proven to be the subject of a recall, market withdrawal or correction ordered by the FDA or any other regulatory authority in the Territory. The parties shall cooperate in good faith to handle and dispose of such recall, market withdrawal or correction; provided, however, that in the event of a disagreement as to any matters related to such recall, market withdrawal or correction, ORPHAN’S decision shall prevail. ORPHAN shall bear [ \* ] costs of any such recall, market withdrawal or correction unless such recall, market withdrawal or correction was solely the result of Catalytica’s negligence or willful misconduct, or breach of Article 8.1(b), in which case Catalytica shall [ \* ] bear [ \* ] cost of administering such recall, market withdrawal, or correction; provided, however, in no event shall Catalytica’s aggregate liability with regard to any recall, market withdrawal or correction exceed [ \* ]. Catalytica will not bear the cost for recalls made as a result of errors that could have been detected by ORPHAN through acceptance and rejection testing as outlined in this Article 9. ORPHAN shall in all events be responsible for conducting any recalls, market withdrawals or corrections with respect to the Product.

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**ARTICLE 10**

**INDEMNIFICATION**

10.1 Catalytica's Indemnification of ORPHAN. Catalytica hereby indemnifies, defends, and holds ORPHAN, its Affiliates and their respective directors, officers, employees, agents; successors and assigns harmless from and against any and all damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) resulting from any Third Party claims or suits arising solely out of (a) Catalytica's material breach of any of its warranties or representations hereunder or (b) Catalytica's negligent acts or omissions or willful misconduct in the manufacture or labeling of the Product; provided, however, [ \* ].

10.2 ORPHAN'S Indemnification of Catalytica. Except as otherwise provided in Section 10.1 above, ORPHAN hereby indemnifies, defends, and holds Catalytica, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any and all claims, damages, judgments, suits, actions, liabilities, costs and expenses (including, but not limited to reasonable attorneys' fees) arising out of or connected with (a) the use, handling, distribution, marketing or sale of the Product (except to the extent caused solely by Catalytica's negligent acts or omissions or willful misconduct in the manufacture or labeling of the Product), (b) ORPHAN'S material breach of any of its warranties or representations hereunder, (c) ORPHAN'S negligent acts or omissions or willful misconduct or (d) any proceeding instituted by or on behalf of a Third Party based upon a claim that the manufacture, use or sale of the Product infringes a United States patent or any other proprietary rights.

10.3 Indemnification Procedures. A party (the "Indemnitee") which intends to claim indemnification under this Article 10 shall promptly notify the other party (the

“Indemnitor”) in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees, or agents intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense and shall have the right to select counsel with respect thereto, provided that the Indemnitor shall promptly notify the Indemnitee of all developments in the matter. In no event shall the Indemnitor or Indemnitee compromise or settle any such matter without the prior written consent of the other party, which shall not be bound by any such compromise or settlement absent its prior consent, which shall not be unreasonably withheld or delayed. The Indemnitee, its Affiliates, and their respective directors, officers, employees, and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation, negotiation, compromise, settlement and defense of any action, claim or other matter covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

10.4 Survival of Indemnification Obligations. The provisions of this Article 10 shall survive the expiration or termination of this Agreement.

10.5 Limitation of Liability and Claims. In no event shall either party be liable to the other party for incidental, special, consequential or punitive damages, including, but not limited to, any claim for damages based upon lost profits. No action, regardless of form, arising out of or in any way connected with this Agreement or Products or services furnished by Catalytica may be brought by ORPHAN more than [ \* ] after the cause of action accrued.

10.6 Insurance. ORPHAN shall provide Catalytica, on request, documentation assuring Catalytica that ORPHAN maintains product liability and other insurance coverage in amounts reasonably satisfactory to Catalytica consistent with industry practices.

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**ARTICLE 11****INVENTIONS AND PATENTS**

11.1 Inventions by Catalytica. Catalytica hereby assigns, releases, and transfers to ORPHAN its entire right, title and interest in and to any invention (whether patentable or not) conceived, reduced to practice or created by Catalytica and/or its agents during the performance of the Services and relating to the Product (collectively "Inventions") provided, however, ORPHAN hereby grants to Catalytica an unlimited, worldwide, perpetual, royalty-free license to use the Inventions. Catalytica shall promptly disclose to ORPHAN any and all Inventions and shall assign all its interests to ORPHAN or its designee in accordance with this Section. Catalytica shall execute at ORPHAN'S expense any assignments, applications or other instruments or documents reasonably requested by ORPHAN in accordance with this Article 11 and, at ORPHAN'S expense, give testimony which shall be deemed necessary to apply for and obtain Letters Patent of the United States or of any other country and otherwise to perfect ORPHAN'S interest therein. Catalytica's and ORPHAN'S obligations hereunder shall survive termination of this Agreement. All data obtained during the Services are the property of ORPHAN and cannot be used without its consent except for the performance by Catalytica of its obligations hereunder.

11.2 Inventions by ORPHAN. ORPHAN shall own all right, title and interest in and to any invention, discovery or improvement relating to the Product (whether patentable or not) made or conceived solely by ORPHAN employees or by anyone other than Catalytica, including, without limitation, any manufacturing or analytical process, or procedure or method or any source of synthesis given to Catalytica.

**ARTICLE 12****CATALYTICA INTELLECTUAL PROPERTY**

12.1 ORPHAN acknowledges that Catalytica possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to procedures and techniques, computer technical expertise, software, and certain technical expertise and conceptual expertise in the area of drug processing and manufacturing, which have been independently developed by

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Catalytica or its Affiliates without the benefit of any information provided by ORPHAN (collectively “Catalytica Property”). ORPHAN and Catalytica agree that any Catalytica Property or improvements thereto which are used, improved, modified or developed by Catalytica under or during the term of this Agreement are the product of Catalytica’s technical expertise possessed and developed by Catalytica or its Affiliates prior to or during the performance of this Agreement and are the sole and exclusive property of Catalytica or its Affiliates, as the case may be.

**ARTICLE 13**

**TRADEMARKS**

13.1 ORPHAN Trademarks. ORPHAN may originate, select and apply to register one or more trademarks (“ORPHAN Trademarks”) under which the Product will be sold and distributed by ORPHAN or its Affiliates and distributors. ORPHAN shall own all right, title, and interest in the ORPHAN Trademarks, subject to the limited license granted to Catalytica in this Article 13. ORPHAN shall be solely responsible for all prosecution, defense, maintenance and costs relating to the ORPHAN Trademarks.

13.2 Limited Trademark License. ORPHAN hereby grants Catalytica an unlimited worldwide, perpetual, royalty-free license to the ORPHAN Trademarks solely for purposes of manufacturing and distributing the Product under this Agreement. In that regard, Catalytica shall be permitted to use ORPHAN’S Trademarks and name in connection with general advertising and promotional activities. Catalytica shall comply with ORPHAN’S reasonable policies and procedures for the use of the ORPHAN Trademarks and shall furnish ORPHAN with copies of any packaging, or other materials incorporating the ORPHAN Trademarks for ORPHAN’S review and approval prior to any use thereof. Catalytica shall make any changes or additions reasonably requested by ORPHAN to comply with ORPHAN’S standard policies and procedures for the use of the ORPHAN Trademarks. Upon termination of this Agreement, Catalytica shall promptly cease any use of the ORPHAN Trademarks.

13.3 Limitations. Catalytica shall not use, or assert any claims to, any of the ORPHAN Trademarks or any trademark confusingly similar to any ORPHAN Trademarks, provided that ORPHAN shall not choose a trademark which is the same as, or confusingly similar to, a trademark previously used by Catalytica.

13.4 Infringement. Catalytica shall promptly notify ORPHAN if Catalytica knows or reasonably suspects that a Third Party is infringing any ORPHAN Trademark. At ORPHAN'S expense, Catalytica shall reasonably cooperate in any investigation or other legal action with regard to such infringement.

#### ARTICLE 14

#### CONFIDENTIALITY

14.1 Proprietary Information. During the term hereof and for a period of [ \* ] years thereafter, any Proprietary Information disclosed by the Disclosing Party, directly or indirectly, to the Receiving Party under this Agreement shall be deemed confidential and trade secret information and shall not be disclosed by the Receiving Party to any Third Party or used by the Receiving Party, except as set forth below. Access to such Proprietary Information will be limited to employees, agents, or consultants of the Receiving Party who reasonably require such Proprietary Information for purposes of performing the Receiving Party's obligations hereunder and who are bound to the Receiving Party by similar obligations in respect of confidentiality and use. Such employees, agents, or consultants will be advised of the nature and existence of the undertakings in respect of such Proprietary Information pursuant to this Agreement and of the applicability of such undertakings to them. The Receiving Party will use such Proprietary Information only to carry out its obligations or to exercise its rights hereunder and will not use such Proprietary Information for its own benefit or for the benefit of others or in any way inconsistent with this Agreement.

14.2 Disclosure by the Receiving Party to a Third Party shall be made only to the extent necessary to enable the Receiving Party to comply with its contractual obligations to the Disclosing Party.

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14.3 Each Third Party to which Proprietary Information is disclosed other than a governmental agency must agree in writing prior to such disclosure to keep the Proprietary Information in strict confidence and to comply with the terms of this Article 14.

14.4 Both parties agree to limit access of Proprietary Information to those of its officers, directors, or employees, or any Third Party who must have Proprietary Information to carry out or enforce the terms of any agreement made between the parties.

14.5 Neither party shall utilize the Proprietary Information disclosed to it by the Disclosing Party after the completion of the Agreement between the parties, either in its own development work or for commercial purposes, without advance written consent of the Disclosing Party.

14.6 No Right or License. The Receiving Party will obtain no right or license of any kind under any patent applications, patent or otherwise by reason of this Agreement and all Proprietary Information will remain the sole property of the Disclosing Party unless provided otherwise in this Agreement.

14.7 Prior Confidentiality Agreement. The Confidential Disclosure Agreement between the parties hereto dated December 1, 1997 and the Mutual Non-Disclosure Agreement between the parties hereto dated November 23, 1998 , as well as the confidentiality provisions of the Technical Services Agreement dated November 20, 1999, are hereby superseded and terminated. Any disclosure of Proprietary Information by either party pursuant to such Confidentiality Agreements shall be deemed to have been made hereunder and shall be subject to this Article 14.

14.8 Terms of Agreement; Press Releases. Except as otherwise required by law or the rules and regulations of any stock exchange on which a party's securities may be publicly traded or in disclosures made in confidence to a party's professional or financial



advisors, applicable regulations or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat the terms, conditions and existence of this Agreement as Proprietary Information. The parties shall cooperate in good faith in the preparation of any press releases or other public disclosures of their business relationship, and neither party shall issue any such press release or other disclosure without the prior approval of the other party, which approval shall not be unreasonably held.

**ARTICLE 15**

**TERM OF AGREEMENT**

15.1 Unless sooner terminated pursuant to Article 16 below, the initial term of this Agreement shall commence on the Effective Date and end upon expiration of the seventh (7th) Contract Year. Unless otherwise terminated pursuant to Article 16 below, this Agreement shall be automatically renewed for additional one (1) year terms after the end of the initial term, unless either party provides written notice to the other at least eighteen (18) months prior to the expiration of the initial or any extended term, as the case may be, that this Agreement shall expire at the end of the initial term or such renewal term, as the case may be. All references herein to "term of this Agreement" shall be deemed to include both the initial and any extended terms.

**ARTICLE 16**

**TERMINATION**

16.1 Termination by Either Party. In addition to any other legal or equitable remedies it may have, either party may terminate this Agreement prior to the expiration of the term of this Agreement upon written notice to the other party:

- (a) If the other party breaches any material term or condition of this Agreement, including any term or condition in any appendix attached hereto, provided such other party has not cured such breach within ninety (90) days of written notice thereof (ten (10) days in the event of a payment breach by

ORPHAN); provided, further, that if at the end of such ninety (90) day period the party in breach is making a good faith effort to cure, a reasonable time thereafter (not to exceed an additional sixty (60) days) shall be allowed for such cure.

- (b) If the other party is declared bankrupt or insolvent, or makes an assignment for the benefit of its creditors, or if a receiver is appointed or any proceedings are commenced, voluntary or involuntary, by or against either party under any bankruptcy or similar law, and such status is not cured within thirty (30) days from its occurrence.
- (c) If an event of force majeure continues for more than six (6) months, either party, at its option, may elect to treat such continued suspension of performance as a material breach and may terminate this Agreement.

16.2 Effects of Expiration or Termination. Upon expiration or termination of this Agreement for any reason:

- (a) Catalytica shall manufacture and ship, and ORPHAN shall purchase, Production Batches of the Product ordered by ORPHAN prior to the effective date of such expiration or termination.
- (b) Other than termination by ORPHAN pursuant to Section 16.1(a) hereof, (i) [ \* ], ORPHAN shall purchase from Catalytica at [ \* ] all materials acquired by Catalytica hereunder, (ii) [ \* ], ORPHAN shall purchase from Catalytica all work-in progress for the Product at [ \* ], (iii) [ \* ], ORPHAN shall purchase all other finished Product then in Catalytica's possession, (iv) ORPHAN shall compensate Catalytica for all other uncancellable commitments made by Catalytica to satisfy the existing purchase orders, and (v) ORPHAN shall compensate Catalytica for [ \* ].
- (c) Catalytica shall take all steps reasonably requested by ORPHAN to confirm the assignment to ORPHAN all of Catalytica's right, title and interest in the Inventions, including, without limitation, to execute or cause its employees to execute such documents as may be reasonably requested by ORPHAN

to vest all such right, title and interest in such Inventions in ORPHAN, provided ORPHAN shall pay all reasonable expenses, including any of time and travel of Catalytica's employees.

- (d) Each party shall return to the other party any Proprietary Information of the other party except for one (1) archival copy as may be required for purposes of compliance with any FDA regulation or other applicable law or regulation in the Territory.

16.3 Survival. The provisions of Articles 7 (Prices and Payments), 8 (Representations, Warranties, Inspections, Regulatory and Quality), 9 (Acceptance, Rejection and Claims), 10 (Indemnification), 11 (Inventions and Patents), Article 12 (Catalytica Intellectual Property), 13 (Trademarks), 14 (Confidentiality), 15 (Term of Agreement), 16 (Termination), 17 (Force Majeure), 18 (Dispute Resolution) and 19 (Miscellaneous) shall survive the expiration or termination of this Agreement and shall remain in full force and effect in accordance with the terms thereof.

#### ARTICLE 17

#### FORCE MAJEURE

17.1 Events of Force Majeure. Either party shall be excused from the performance of its obligations [ \* ] in the event such performance is prevented by a cause beyond the reasonable control of such party, including, without limitation, any act of God; regulation or law of any government or an agency thereof; war; insurrection or civil commotion; earthquake, tornado, fire, hurricane, flood or storm; epidemic; or failure of suppliers, public utilities or common carriers. Such excuse shall continue as long as the Force Majeure Event and consequences to supply continue, except that Customer will have the right to (i) terminate the Agreement without further obligation in the event that Catalytica is not able to supply Customer with Product for a continuous period of six (6) months and (ii) seek an alternate supplier of the Product during the continuation of, and only during the continuation of, such a Force Majeure Event unless Customer can only secure an alternate supplier for a time period in excess of the Force Majeure Event period, in which case Customer

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will resume its exclusive supply relationship with Catalytica at the end of such period and extend the term of this Agreement by a maximum of six (6) months. If no such termination by Customer occurs, upon cessation of such Force Majeure Event, the Parties shall promptly resume performance hereunder.

17.2 Notice. A party affected by an event of force majeure shall give the other party prompt written notice of the occurrence of any event of force majeure and the nature and duration thereof. An affected party shall use all reasonable efforts to resume performance as quickly as possible and to give the other party prompt written notice when it is again fully able to perform such obligations. If Catalytica is the affected party, such notice of resumption of performance shall state the quantities of Product manufactured but not shipped by Catalytica due to any event of force majeure and the expiration dates thereof.

17.3 Cover. During, and only during, any suspension of performance by Catalytica under Section 17.1 above, ORPHAN may, at its option, purchase elsewhere the quantities of the Product ORPHAN has ordered which Catalytica is unable to deliver.

## **ARTICLE 18**

### **DISPUTE RESOLUTION**

18.1 Negotiation. The parties intend that any dispute, controversy or claim arising out of or relating to this Agreement, or any breach thereof, shall be resolved under the procedures set forth in this Article 18. The parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement which relates to either party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either party may, by notice to the other party, have such dispute referred to their respective officers designated below, or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Such designated officers are as follows:

For ORPHAN – [ \* ]

For Catalytica – [ \* ]

18.2 Mediation. If attempts to resolve the dispute pursuant to Section 18.1 are unsuccessful, mediation shall be conducted by a single mediator appointed by mutual agreement of the parties. The mediator shall not have the power to bind the parties to the resolution. The mediation session shall take place in [ \* ] if ORPHAN requests mediation or in [ \* ] if Catalytica requests mediation, on [ \* ] and shall be attended by a representative of each party with full authority to settle the matter, along with any other representatives reasonably necessary to discuss and address the issues involved in the dispute. On the [ \* ] day of mediation, each party shall be allotted [ \* ] with other representatives necessary to discuss and address the issues involved in the dispute to state its views of the dispute to the mediator and to the other party. On the [ \* ] day of mediation, the parties shall attempt to resolve the dispute with the aid of the mediator in a format agreed to by the parties or imposed by the mediator. If the parties cannot agree upon a mutually acceptable mediator within [ \* ] of the end of the [ \* ] negotiation period in Section 18.1 or if the dispute is not resolved by mediation within [ \* ] after completion of the mediation session, either party shall have the right to pursue any and all remedies available at law or in equity.

**ARTICLE 19**

**MISCELLANEOUS**

19.1 Choice of Law. This Agreement shall be governed by and interpreted in accordance with the laws of North Carolina, without regard to its conflict of laws provisions.

19.2 Notifications. Any and all notices provided for shall be sent to the respective parties at the following addresses by certified or registered mail or sent by a national courier service with proof of delivery, by personal delivery or by facsimile with an electronic and verbal confirmation of receipt:

If to Catalytica:      Chief Executive Officer  
                                 Catalytica Pharmaceuticals, Inc.  
                                 Intersection US 13/NC11 and US 264  
                                 Greenville, North Carolina 27834  
                                 Fax (252) 707-2450

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If to ORPHAN: Chief Executive Officer  
Orphan Medical, Inc.  
3911 Ridgedale Drive, Suite 250  
Minnetonka, Minnesota 55305  
Fax: (612) 541-9209

with a copy to each Legal Council's office, or to such other addresses as may be subsequently furnished by one party to the other in writing. Any such notice shall be deemed effective three (3) days after mailing or upon receipt if sent by courier service, personal delivery or facsimile.

19.3 Severability. If any term or condition of this Agreement is found by a court of competent jurisdiction in a final unappealed or unappealable order to violate the provisions of any applicable statute, law or regulation, the remainder of this Agreement shall remain in full force and effect. The parties shall then negotiate in good faith to modify this Agreement, but only to the extent necessary to make the affected term or condition of this Agreement valid and enforceable, having full regard for applicable laws and the intent and purposes of the parties entering into this Agreement.

19.4 Integration; Amendment. This Agreement and all appendices hereto constitute the entire agreement between the parties relating to the subject matter of this Agreement and supersedes all prior agreements, representations, and understandings. This Agreement may not be amended, modified, or varied except in writing signed by a duly authorized representative of each party. In the event of a conflict between the terms of this Agreement, and any appendix hereto, the terms of this Agreement shall control.

19.5 Assignment. Neither party may assign or otherwise transfer this Agreement without the prior written consent of the other party except that either ORPHAN or Catalytica may assign, without such consent, this Agreement (a) to an Affiliate, (b) in connection with the sale or transfer of all or substantially all of the assets of such party or the line of business of which this Agreement forms a part, or (c) in the event of the merger or consolidation of a party hereto with another company, provided, however, any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of the foregoing sentence shall be null and void. No assignment shall relieve either party of responsibility for the performance of any accrued obligation under this agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Catalytica and ORPHAN respectively.

19.6 Waiver. No course of dealing between Catalytica and ORPHAN or delay or failure to exercise any rights hereunder shall operate as a waiver of such rights or preclude the exercise of any other rights hereunder.

19.7 Relationship. Each of the parties hereto is an independent contractor and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the parties hereto.

19.8 Captions. The captions to the several Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles hereof and shall not affect the meaning or interpretation hereof.

19.9 Counterparts. Two (2) or more counterparts of this Agreement may be signed by the parties, each of which shall be an original, but all of which together shall constitute the same instrument.

IN WITNESS WHEREOF, the parties have caused this Agreement to be entered into by their duly authorized representatives as of the Effective Date.

CATALYTICA PHARMACEUTICALS, INC.

ORPHAN MEDICAL

By: /s/ Michael H. Thomas  
Print: Michael H. Thomas  
Its: CEO  
Date: 7/17/00

By: /s/ John Howell Bullion  
Print: John Howell Bullion  
Its: CEO  
Date: 6/30/00

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**APPENDIX A**

**TECHNICAL SERVICES AGREEMENT**

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## TECHNICAL SERVICES AGREEMENT

THIS AGREEMENT is made and entered into this day \_\_\_ of November, 1999 by and between Catalytica Pharmaceuticals, Inc., a Delaware corporation, having an address at Intersection US 13/NC11 and US 264, Greenville, North Carolina 27834 ("Catalytica") and Orphan Medical, Inc., a Minnesota corporation, having an address at 13911 Ridgedale Drive, Suite 475, Minnetonka, Minnesota 55305 ("Orphan") (Catalytica and Orphan may be referred to collectively as the "Parties" or individually as a "Party").

### WITNESSETH:

WHEREAS, the Parties are in the process of negotiating and intend to enter into a definitive Supply Agreement (the "Supply Agreement") pursuant to which Catalytica would manufacture and supply Orphan's Xyrem™ Oral Solution (the "Product"); and

WHEREAS, in anticipation of the Supply Agreement and the services that Catalytica will perform thereunder, the Parties desire to enter into a binding agreement pursuant to which Catalytica would undertake certain technical services in order to prepare its facilities for performance of the Supply Agreement.

NOW THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the Parties hereby agree as follows:

1. Best Efforts. Catalytica and Orphan will negotiate in good faith and use their best efforts to arrive at a mutually acceptable Supply Agreement not later than March 31, 2000, with terms consistent with those set forth in Catalytica's proposal dated October 1, 1999 (a copy of which is attached hereto as Exhibit 1), which includes a commercial per unit cost of [ \* ], (based on [ \* ]). Packaging material costs have been estimated at [ \* ] and includes the [ \* ]. Pricing is subject to confirmation upon completion of transfer activities.

#### 2. Services.

(a) Description of Services. Catalytica shall perform the services listed in Exhibit 1 hereto, including any modifications and additions thereto agreed upon in writing by the Parties, to develop and confirm the manufacturing process for the Product (the "Services") (Catalytica's performance of the Service is based on the assumptions set forth in Exhibit 1). In that regard, Catalytica shall use reasonable efforts to complete the Services in a timely fashion in accordance with a schedule to be mutually agreed upon by the Parties,

(b) Cost and Payment. The cost of the Services shall be [ \* ] (the "Cost"). Orphan shall make an fixed fee payment equal to one-half of the Cost [ \* ], upon execution of this Agreement, Orphan shall make [ \* ] subsequent equal payments equal to the balance of the Cost [ \* ], or such higher amount agreed to by the Parties in the event Catalytica performs services in addition to those identified in Exhibit 1, on September 30 and December 31, 2000; provided, however, Catalytica shall not perform services hereunder in addition to those identified in Exhibit 1 which cost more than [ \* ]

without Orphan's prior written consent. In addition, Orphan shall make an up-front payment of [ \* ] for the [ \* ] of [ \* ]. If the [ \* ] paid by Catalytica (including tax, shipping, insurance, etc.) for the [ \* ] exceeds [ \* ], Orphan shall promptly, upon receipt of [ \* ] for any such [ \* ]; provided, however, Catalytica shall not pay more than [ \* ] for the [ \* ] without Orphan's prior written consent. Catalytica shall own all of the [ \* ]

(c) Orphan's Responsibilities. To assist Catalytica in its performance of the Services, Orphan shall provide Catalytica, in a timely fashion, all relevant material, information and data in its possession which Orphan, in its good faith opinion, believes is necessary for Catalytica to carry out and complete the Services.

(d) Reporting. Catalytica shall respond to Orphan's reasonable inquiries regarding the status of the Services on an ongoing basis, including if requested periodic meetings at Catalytica's facility to discuss the results and progress of the Services.

(e) Validation Batches. At Orphan's option and request, after execution of the Supply Agreement, Orphan may purchase validation batches of Product prepared in connection with the Services, pursuant to the terms and conditions of the Supply Agreement (including without limitation the terms and conditions governing price, payment, warranty, indemnification and limitation of liability). Catalytica shall retain representative samples from each batch of the Products for record keeping, testing and regulatory purposes.

(f) Ownership of Tangible Materials. Orphan shall retain ownership of all information, documents and materials which Orphan provides to Catalytica in connection with the performance of the Services hereunder. Further, Orphan shall have full ownership, possession of, and all rights to use, any reports, documents and other tangible materials which Catalytica provides to Orphan as part of the Services,

(g) Ownership of Inventions. All inventions, whether patentable or not, conceived, reduced to practice or created by Catalytica and/or its agents during the performance of the Services and relating to the Product shall be owned by Orphan; provided, however, Catalytica shall have, and Orphan hereby grants to Catalytica, an [ \* ] license to [ \* ]. Orphan shall be responsible for the costs of filing, prosecution and maintenance for patents and patent applications with regard to inventions owned by Orphan pursuant to this paragraph.

3. Exclusive Dealing. In recognition of the substantial effort and expense to be incurred by Catalytica in undertaking a detailed analysis in anticipation of the Supply Agreement contemplated hereunder, neither Orphan nor any of its affiliates, shareholders, partners, directors, officers, employees or agents, shall discuss, negotiate, solicit, or in any manner encourage any transaction or proposal for a transaction involving the manufacture or supply of the Products, other than the transaction contemplated by this agreement, until March 31, 2000. Without limiting the foregoing, none of the foregoing shall directly or indirectly furnish to any third party any non-public information concerning the manufacture or supply of the Product, or otherwise engage in any act related to or likely to induce any actual or potential transaction inconsistent with this Agreement.

4. Confidentiality. Catalytica and Orphan, including all their respective representatives, agents, accountants and counsel, shall treat confidentially all of the information received from one another in connection with this Agreement that is not publicly available and will not, without the prior consent of the other party, disclose any information to any third party except as required by law and will not use any such information for purposes other than in furtherance of this Agreement. Information shall be deemed "publicly available" if, other than as a result of a breach of the obligation of this Agreement, it is or becomes generally available to the public or is or becomes a matter of public knowledge or if it is or becomes available to a party on a non-confidential basis from a source, other than from the other party, that is not known to be bound by a confidentiality agreement or otherwise prohibited from transmitting such information. Except to the extent inconsistent herewith, all prior agreements (if any) between the parties regarding confidentiality shall remain in full force and effect. The confidentiality obligations set forth in this paragraph 4 shall survive the termination or expiration of this Agreement for a period of [ \* ] years.

5. Termination. Unless extended by mutual agreement of the Parties, this Agreement shall terminate on March 31, 2000, or earlier upon the mutual agreement of the Parties.

6. Force Majeure. No failure or omission by the Parties in the performance of any obligation of this Agreement [ \* ] shall be deemed a breach of this Agreement nor shall it create any liability (other than as set forth herein), if the same shall arise from any cause or causes beyond the reasonable control of the affected Party (a "Force Majeure"), including, but not limited to, the following, which for purposes of this Agreement shall be regarded as beyond the control of the Party in question: acts of God; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; invasion; strikes; and lockouts or the like; provided that the Party so affected shall use its commercially reasonable best efforts to avoid or remove such causes of non-performance and shall continue performance hereunder with the utmost dispatch whenever such causes are removed.

7. Indemnification.

(a) Orphan shall indemnify, defend and hold Catalytica, its affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or connected with (a) the Services and the use, handling, distribution, marketing or sale of the Product (except to the extent caused solely by Catalytica's negligent acts or omissions or willful misconduct), (b) Orphan's breach of any of its warranties or representations hereunder, (c) Orphan's negligent acts or omissions or willful misconduct or (d) any proceeding instituted by or on behalf of a third party based upon a claim that the Services or the manufacture, use or sale of the Product infringes a United States patent or any other proprietary rights.

(b) Except as otherwise provided in Section 7(a), Catalytica shall indemnify, defend and hold Orphan, its affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) resulting from any third party claims or suits arising solely out of (i) Catalytica's material breach of any of

its warranties or representations hereunder or (b) Catalytica's negligent acts or omissions or willful misconduct in the performance of the Services or the manufacture of the Product; provided, however, [ \* ].

(c) A party (the "Indemnitee") which intends to claim indemnification under this Section 7 shall promptly notify the other party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees or agents intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee, its affiliates, and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation, negotiation, compromise, settlement, and defense of any action, claim or other matter covered by this indemnification. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense and shall have the right to select counsel with respect thereto, provided that the Indemnitor shall promptly notify the Indemnitee of all developments in the matter. In no event shall the Indemnitor or Indemnitee compromise or settle any such matter without the prior written consent of the other party, which shall not be bound by any such compromise or settlement absent its prior consent, which shall not be unreasonably withheld or delayed. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

(d) In no event shall either party be liable to the other for incidental, special, consequential or punitive damages, including, but not limited to, any claim for damages based upon lost profits. In addition, in no event shall the collective, aggregate liability of Catalytica and its affiliates and its and their respective directors, officers, employees and agents under this Agreement exceed the amount of compensation actually received by Catalytica from Orphan pursuant to this Agreement. No action, regardless of form, arising out of or in any way connected with this Agreement or Products or Services furnished by Catalytica may be brought by Orphan more than [ \* ] after the cause of action accrued.

(e) The provisions of this Section 7 shall survive the expiration or termination of this Agreement.

8. Governing Law. This agreement shall be governed by and construed in accordance with the laws of the State of North Carolina without reference to principles of conflicts of laws.

9. Assignment. This Agreement may not be assigned or otherwise transferred by either party without the prior written consent of the other; provided, however, either party may, without such consent, assign this Agreement (a) in connection with the transfer or sale of all or substantially all of the assets of such party or the line of business of which this Agreement forms a part, (b) in the event of the merger or consolidation of a party hereto with another company, or (c) to any affiliate of the assigning Party. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either party of responsibility for the performance of any obligation which accrued prior to the effective date of such assignment.

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10. Survivability. The following paragraphs shall survive the termination or expiration of this Agreement: 2(f), 2(g), and 7.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto as of the day and year first written above.

ORPHAN MEDICAL, INC.

CATALYTICA PHARMACEUTICALS, INC.

By: /s/ Dayton Reardan  
Title: Vice President

By: /s/ Gabriel Cipau  
Title: President & CEO

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EXHIBIT 1 PROPOSAL

(See attached)

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October 1, 1999

Orphan Medical  
13911 Ridgedale Drive  
Suite 475  
Minnetonka, Minnesota 55305

ATTN: Randy Tlachac Dear

Randy:

I am pleased to provide the attached proposal for the Xyrem™ Oral Solution. The proposal includes the commercial estimate, the associated transfer costs and the equipment requirements to produce your product at our [ \* ] facility.

Please note that Orphan would be responsible for the [ \* ] estimated at [ \* ]. Also, the commercial prices would be subject to annual price increases based on [ \* ].

Catalytica Pharmaceuticals, being the largest full-service pharmaceutical company in the world, provides a full spectrum of capabilities tailored to meet your needs. We are committed to delivering the finest products, services, and performance available to you including:

- full-service development, and manufacturing,
- access to the newest technology,
- assistance from professionals who are among the best in the business,
- unsurpassed regulatory expertise, and
- a workforce dedicated to continuous quality improvement and ongoing professional development.

Catalytica appreciates the opportunity to bid on this project and hope that arrangements can be made to expedite its transfer. If you have any questions or need further clarification, please don't hesitate to call. I will try to contact you next week to discuss the proposal and the next steps.

Sincerely,

David Hamby

cc: Dr. Cipau  
Tom Mulligan Bob Peoples  
File (2)

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Proposal Summary for Xyrem Oral Solution

Commercial Estimate:

<u>Product</u>	<u>Price/Unit</u>
<u>Xyrem Oral solution – [ * ]</u>	<u>[ * ]</u>

**Active and packaging materials are not included.**

**Subject to [ \* ] contract, minimum volumes and annual price increases.**

**Packaging material costs have been estimated at [ \* ] and includes the [ \* ]**

Transfer Estimate:

**Xyrem Transfer Costs [ \* ]**  
**(See activities attached)**

**Estimated Capital Requirements [ \* ]**  
**See attached for details**  
**Customer to assume**

---

Amy DelaCourt  
Vice President, Pharmaceutical Marketing & Sales

---

Proposal valid for 60 days. A change in scope will necessitate a re-evaluation of resources.

CONFIDENTIAL

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*Orphan Medical*  
*Xyrem Oral Solution*

Packaging Assumptions

[ \* ]

Equipment requirements (estimated);

Manufacturing

[ \* ] [ \* ]

Packaging

[ \* ] [ \* ]

Total cost [ \* ]

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**Transfer Activities**

<b>CATEGORY</b>	<b>ACTIVITY</b>
<b>Predevelopment</b>	Review product info. Establish scope Create 2 new raw material and 1 product item numbers, critical documents; SOPs, PWOs BOM, etc Pass raw materials
<b>Process Development</b>	Prepare/approve batch records
<b>Clinical Batch</b>	Perform validation activities to include VPS, PQ-mfg, PQ-pkg, PQ-cleaning Prepare Nonproduction formula Manufacture and package 1 x 100gallon batch. Activities include equipment set up, mfg, and cleaning. Perform in process testing Perform cleaning verification testing Transfer drug product analytical methods to AR&D Review final batch record and prepare report
<b>Validation Batches</b>	Prepare and approve Master Formula  Monitor manufacturing and packaging of 3 validation batches Perform cleaning validation testing Transfer drug product analytical methods to QC Perform cleaning validation testing
<b>Reports</b>	Prepare transfer report Prepare "Data Only" documentation for CMC section.

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## Development Assumptions

### ORPHAN MEDICAL - XYREM SOLUTION

1. One [ \* ] development batch will be manufactured to evaluate the processing parameters.
2. Orphan medical will provide suitable filter cartridges for processing.
3. All lab testing for the development and CTM batch will be performed by Orphan Medical.
4. Although the NDA has not been filed, this is considered a Tech Transfer that requires no formulation or analytical development activities.
5. Prior to the manufacture of the batches, AR&D will perform a collaborative type method transfer utilizing Orphan Medical's existing contract lab(s).
6. AR&D is responsible for the development of the method transfer protocol. Orphan Medical will review and approve the transfer protocol prior to implementation.
7. No stability testing is included in this estimate,
8. Regulatory documentation deliverables include:
  - [ \* ]

( Additional Regulatory support will be billed at [ \* ] )

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**Specifications**

[ \* ]

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## APPENDIX C

### **Return Material Authorization (RMA)**

For material return, Catalytica operates a paperless, computer-supported system. The following procedure will be followed:

1. ORPHAN can request return authorization by calling Catalytica at 252-707-2484 and requesting the "Customer Service Department".
2. Catalytica will issue a material return authorization number generated by its quality performance database according to standard work practices in effect within Catalytica at that time.
3. Catalytica will organize transport of material through coordination with ORPHAN. The appropriate contact will be given by ORPHAN at the time of request for return of material.
4. Upon receipt of returned material, Catalytica will send a confirmation of this to the designated contact at ORPHAN.

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**APPENDIX D**  
**PRODUCT PRICE ESTIMATES**  
according to Section 7.1

**Tiered pricing for Xyrem [ \* ]**  
**Volume Breaks Unit Price**

	<b>Conversion</b>	<b>Materials</b>	<b>Total</b>
[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]

The following assumptions apply:

[ \* ]

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**APPENDIX E**

**Regulatory Support**

Attend all Catalytica project team meetings

Provide the following documents to ORPHAN'S regulatory affairs department to support submissions under the Agreement:

[ \* ]

Perform regulatory review of the above-listed documents. Unless noted otherwise, such documents will not be suitable for submission to Regulatory Agencies.

**Regulatory Consulting**

[ \* ]

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**APPENDIX F**  
**Quality Agreement**

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**INTERCOMPANY QUALITY AGREEMENT**

ORPHAN MEDICAL, INC.  
13911 Ridgedale Drive, Suite 475  
Minnetonka, Minnesota 55305  
(hereafter called "ORPHAN")

Approved by: /s/ Randall Tlachac Date: 6/12/00

Director, Quality Assurance, ORPHAN

AND

Catalytica Pharmaceuticals, Inc.  
Greenville, North Carolina  
(hereafter called "C\*P")

Approved by: /s/ K.S. Manning Date: 14 June 2000

Vice President, Quality Operations, C\*P

The Products and Drug Substance Listed in Appendix  
(hereafter called "the PRODUCTS")  
are subject to the following conditions:

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1. QUALITY AGREEMENT

1.1 Purpose

1.1.1 This agreement defines the roles and responsibilities for Catalytica Pharmaceuticals (C\*P) Quality Operations in providing services to ORPHAN.

1.1.2 This agreement also defines how C\*P Quality Operations and ORPHAN Quality Department will interact with each other.

1.2 Relationship to Definitive Agreement

1.2.1 This agreement shall be incorporated within and constitute a part of the Definitive Agreement between the two companies.

1.2.2 In the event of a conflict between any of the provisions of the Quality Agreement and the Definitive Agreement, the provisions of the Definitive Agreement shall govern.

2. PRODUCTS

2.1 The PRODUCTS prepared for ORPHAN by C\*P are described in Appendix I.

3. ADMINISTRATIVE INFORMATION

3.1 ORPHAN contact names: See Appendix II

3.2 C\*P contact names: See Appendix II

3.3 Emergency contact names and numbers, during and outside working hours:

ORPHAN

[ \* ]

CATALYTICA

[ \* ]

4. DURATION OF AGREEMENT

The agreement will expire with termination of the Definitive Agreement. The agreement can be modified as needed with the written approval of both parties.

5. MANUFACTURING GMP COMPLIANCE

5.1 General

5.1.1 The manufacturing operations for the PRODUCTS to be performed by C\*P are defined in the Definitive Agreement.

## 5.2 Premises

- 5.2.1 C\*P will perform required operations for manufacturing activities at the [ \* ] site.
- 5.2.2 The premises and equipment used to manufacture the PRODUCTS will meet or exceed current regulatory requirements.
- 5.2.3 The production of the PRODUCTS will be conducted in a suitably controlled environment and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with applicable GMP guidelines, and any disclosed conditions registered in the manufacturing authorization.
- 5.2.4 C\*P will maintain controlled access to the premise.

## 5.3 GMP Guidelines

- 5.3.1 The principles detailed in the US Current Good Manufacturing Practices (21 CFR 200, 211, and 600) and the Rules Governing Medicinal Product in The European Community—Volume IV Good Manufacturing Practice for Medicinal Products Guidelines will cover the standards of manufacture of the PRODUCTS, as well as, the product specifications and any applicable product license or pharmacopoeia or formulary requirements.

## 5.4 Materials

- 5.4.1 C\*P will use only chemical materials, packaging, and labeling components approved by ORPHAN and tested in accordance with the documentation reviewed and approved by ORPHAN.
- 5.4.2 Materials procured by C\*P
  - 5.4.2.1 C\*P is responsible for ensuring that all DRUG SUBSTANCES, materials, and components procured by C\*P for use in the PRODUCTS are in full compliance with the specifications listed in the documentation reviewed and approved by ORPHAN.
  - 5.4.2.2 C\*P is responsible for ensuring that all materials are stored properly, used correctly, appropriately tested upon receipt, and traceable to the relevant Certificate of Analysis for the materials.
  - 5.4.2.3 C\*P is responsible for auditing and qualifying vendors of drug substances used in PRODUCTS and will provide ORPHAN with a Certificate of Conformance statement for such vendors when requested.



- The third through the sixth digits are four sequential numbers that are assigned from the reserved number series [ \* ] designated for routine pharmaceutical production.

## 5.8 Dates of Manufacture and Expiration

- 5.8.1 Date of Manufacture - C\*P will allocate the Date of Manufacture based on the completion of compounding the PRODUCT.
- 5.8.2 Expiration Date - C\*P will calculate the expiry date from the Date of Manufacture using the currently approved expiry period. The expiration date will be the last day of the month computed above.

## 5.9 Manufacturing and Equipment Data

- 5.9.1 C\*P is responsible for keeping records of equipment usage (previous PRODUCT produced in non-dedicated equipment), cleaning, and any maintenance/calibration performed.

## 5.10 Storage and Shipment

- 5.10.1 Storage - C\*P will store the PRODUCTS under conditions approved by ORPHAN as listed in the specifications. C\*P will ensure that during storage before shipping of the PRODUCTS that appropriate controls are in place to ensure no interference, theft, product contamination, or admixture with any other materials. ORPHAN will provide details of any labeling requirements and container sealing and integrity.
- 5.10.2 Packaging and Labeling for Transit - The PRODUCTS will be labeled and packaged for transit as per ORPHAN.
- 5.10.3 Mixing of PRODUCTS - C\*P will maintain proper segregation of the PRODUCTS according to systems reviewed and approved by ORPHAN.
- 5.10.4 Shipment of Product to ORPHAN - Only approved, finished (unless required by ORPHAN), labeled PRODUCTS will be shipped by C\*P to ORPHAN. Any shipment of product from C\*P which is Unapproved or under Quarantine requires prior written consent by the ORPHAN'S Quality Unit. This authorization will be on a lot by lot basis.

## 6. QUALITY CONTROL

### 6.1 General

- 6.1.1 The testing activities for the PRODUCTS are to be performed by C\*P as defined in the Definitive Agreement. In general, C\*P is responsible for final product assays and product release.

### 6.2 Materials supplied by C\*P

- 6.2.1 Quality control of materials supplied by C\*P will be undertaken by C\*P.



- 6.3 In-Process and Finish Product Testing
- 6.3.1 C\*P will perform all in-process and finished product testing using approved specifications and methods of analysis listed in the Definitive Agreement.
- 6.3.2 A C\*P Qualified Person/QA Representative will sign a Certificate of Conformity confirming that the product has been manufactured, packaged, tested, and meets the requirements of the Master Batch Record and Drug Product Specification. The current release documentation information can be found in Appendix III.
- 6.3.3 ORPHAN may perform testing to confirm the C\*P data. ORPHAN may perform confirmatory testing during the initial term of the agreement to validate the C\*P data. Periodically thereafter, ORPHAN may test material to confirm the C\*P data. Dispute resolutions in conflicting test data will be handled per Section 9.
- 6.3.4 ORPHAN may perform release testing at a contract laboratory. Copies of all related documentation will be provided to C\*P upon request to support final release.
- 6.4 Retained Samples
- 6.4.1 Active Ingredients - C\*P will retain samples of the active ingredients as agreed between C\*P and ORPHAN. The amount of sample retained will be [ \* ] required to carry out all of the tests required to determine if the material meets its specifications.
- 6.4.2 Products - C\*P will retain samples of the PRODUCTS for at least [ \* ] beyond the expiry period. The amount of sample retained will be [ \* ] required to carry out all of the tests required to determine if the material meets its specifications.
- 6.5 Routine Stability Program
- 6.5.1 ORPHAN is responsible for maintaining a Stability Program and will request samples from Drug Product lots to be placed on stability.
- 6.6 Out-of-Specification (OOS) Investigations
- 6.6.1 C\*P is responsible for investigating any testing performed by C\*P that fails to meet specifications. Each investigation will be reviewed by C\*P's designated Quality person per internal SOPs, and will comply with Section 7.1 (Deviations and Investigations) of this agreement. C\*P will inform Orphan of all Phase I OOS results and any subsequent retest results. C\*P will inform ORPHAN of all confirmed OOS (Phase II) Investigations prior to their resolution and final determination.
- 6.7 Contract QC Laboratories
- 6.7.1 ORPHAN is responsible for ensuring the compliance of any QC lab contracted to perform testing of the PRODUCTS used in the manufacture of the PRODUCTS.

7. QUALITY ASSURANCE

7.1 Deviations and Investigations

7.1.1 Deviations - Any deviation from the process during manufacture must be carefully explained and documented in the batch records, justified, and approved by C\*P Quality Assurance and Production Management and included in the document package. ORPHAN will be informed at the time of all PFERs and reserves the right to participate in the investigation. Deviations will be processed per C\*P SOP "Pharmaceutical Process/Formulation Exception Report (PFER)".

7.1.2 C\*P will notify ORPHAN of any batch of PRODUCTS rejected by C\*P.

7.1.3 C\*P will notify ORPHAN immediately, in writing, if any problems are discovered that may impact PRODUCTS batch(es) previously shipped to ORPHAN.

7.1.4 Some deviations/failures may require additional testing to be performed as agreed by both parties.

7.2 Batch Disposition

7.2.1 For each batch, C\*P will provide the documentation required in Appendix III.

7.2.2 Certificate of Compliance/Analysis

7.2.2.1 C\*P is responsible for ensuring and certifying that the PRODUCTS have been manufactured according to the specifications/procedures documented in the Master Production Records.

7.2.2.2 C\*P Qualified Person/QA Representative will sign a Certificate of Compliance confirming that the PRODUCTS have been manufactured, packaged, tested and stored according to the requirements of the Master Production Record and the Drug Product Specification.

7.2.2.3 C\*P will provide a Certificate of Analysis indicating the test result from each test performed.

7.3 Product Release

7.3.1 Release of the PRODUCTS is the absolute responsibility of ORPHAN Quality and will be undertaken by ORPHAN based on ORPHAN'S internal procedures, the full document package provided by C\*P, and completion of any release testing required by ORPHAN Quality Control.

7.3.2 Any problem discovered by ORPHAN likely to cause rejection of the PRODUCTS will be communicated to C\*P within 30 days from receipt of the full release documentation package (see Appendix III).

#### 7.4 Product Complaints and Recalls

- 7.4.1 Product Complaints - ORPHAN is responsible for receiving and initially investigating any PRODUCTS complaints. ORPHAN will notify C\*P of any problems thought to be due to manufacture, which are found during the distribution of the PRODUCTS. When requested by ORPHAN, C\*P will promptly perform investigations for these problems. Investigation reports will be forwarded to ORPHAN within 30 days.
- 7.4.2 Product Recall - ORPHAN is responsible for instituting a PRODUCTS recall due to any defect considered sufficiently serious. ORPHAN will notify C\*P of any recall which may be due to the manufacturing of PRODUCTS. C\*P will provide a [ \* ].

#### 7.5 Records Retention

- 7.5.1 C\*P will retain, at a minimum, batch production records for the PRODUCTS and materials for [ \* ] years.

#### 7.6 QA Presence in the Manufacturing Facility

- 7.6.1 C\*P will maintain adequate QA presence and permit ORPHAN'S presence in the manufacturing facility during the manufacture of the PRODUCTS to ensure compliance with applicable GMPs.

### 8. REGULATORY ;

#### 8.1 Regulatory Inspections

- 8.1.1 C\*P will immediately inform ORPHAN of any regulatory inspections that may involve the PRODUCTS and permit a representative of ORPHAN Quality to be present at such inspections, if required by ORPHAN.
- 8.1.2 C\*P will secure ORPHAN'S approval prior to making any commitment to a regulatory agency regarding ORPHAN'S PRODUCTS.
- 8.1.3 Additionally, C\*P will immediately forward any regulatory correspondence on the PRODUCTS to ORPHAN.
- 8.1.4 ORPHAN will inform C\*P in writing of any regulatory issue that impacts C\*P's ability to manufacture the PRODUCTS.

#### 8.2 Regulatory Actions

- 8.2.1 ORPHAN will notify C\*P of any regulatory actions on the PRODUCTS that may impact C\*P.
- 8.2.2 C\*P is responsible for supporting all batch record investigations associated with regulatory actions.

- 8.2.3 C\*P agrees to supply ORPHAN with any manufacturing, testing, or storage data within 48 hours, if requested, as the result of a regulatory inspection, or a potential regulatory exposure such as a recall or significant product complaint.
- 8.3 Regulatory Affairs
- 8.3.1 ORPHAN is responsible for ensuring all appropriate regulatory filings and export documentation are filed with Regulatory Agencies prior to shipment/human administration.
- 8.3.2 ORPHAN will be responsible for making final decisions regarding CMC regulatory strategy.
- 8.3.3 ORPHAN will provide a copy of final Regulatory Submissions to C\*P Regulatory Affairs for reference during inspections.
- 8.4 Right to Audit
- 8.4.1 C\*P will allow representatives of ORPHAN Quality to have access to relevant manufacturing, warehousing, laboratory premises, and records for audit purposes listed below in 8.4.2 through 8.4.4. ORPHAN representatives will be escorted at all times by C\*P personnel.
- 8.4.2 ORPHAN will give C\*P a [ \* ] day notification for all planned audits.
- 8.4.3 C\*P will permit representatives of ORPHAN Quality to conduct preparatory audits either for initiation of GMP manufacture of the PRODUCTS or for preapproval inspections (PAI).
- 8.4.4 C\*P will permit representatives of ORPHAN Quality to conduct audits to address significant product quality problems.
- 8.4.5 C\*P will permit representatives of ORPHAN Quality to perform [ \* ] per year not to exceed [ \* ]. This includes audits required by ORPHAN'S commercial partners.
- 8.5 Audit Closeout
- 8.5.1 An exit meeting will be held with representatives of C\*P and ORPHAN to discuss significant audit observations.
- 8.5.2 ORPHAN will provide a written report of all observations within 30 days to C\*P. Within 30 days of the audit report receipt, C\*P will provide a written response to all findings that details corrective action to be implemented. C\*P will follow up to ensure that all corrective actions are implemented.

9. DISPUTE RESOLUTION

9.1 Non-Conformity Dispute

9.1.1 In the event that a dispute arises between C\*P and ORPHAN in the nonconformity of a batch of the PRODUCTS, the heads of Quality from both companies shall in good faith promptly attempt to reach an agreement. Whatever the outcome, ORPHAN Quality retains the absolute right to determine product release status. Financial liability is determined in the Definitive Agreement.

9.2 Test Result Dispute

9.2.1 In the event that a dispute arises between C\*P and ORPHAN in the testing performed by C\*P for the PRODUCTS, the resolution will proceed in stages. The first stage requires direct communication between analysts from both parties to determine that the methods of analysis are the same and are being executed in the same manner at both sites. Second, carefully controlled and split samples should be sent from one site to another in an attempt to reach agreement. Should there be a failure to achieve resolution, analysts from both parties will be required to meet to work through the analysis of a mutually agreeable sample. If these actions fail to achieve resolution, and only after these avenues have been exhausted, a qualified referee laboratory will be used to achieve resolution. This laboratory must be agreeable to both parties prior to use. The results from this referee laboratory will be used as final authority to determine responsibilities, but whatever the outcome, ORPHAN retains the right to determine product release status. Financial liability is determined in the Definitive Agreement.

10. CHANGE MANAGEMENT

10.1 Controlled Documentation

10.1.1 All manufacturing, testing, and storage operations performed by C\*P for the PRODUCTS will have ORPHAN Quality review and written approval within five business days of notification. ORPHAN'S Quality review and approval signifies the conformance of C\*P documents to ORPHAN'S CMC regulatory submissions.

10.1.2 Any significant changes will be mutually agreed upon in writing prior to implementation. All required regulatory approvals will be obtained prior to implementation.

10.1.3 ORPHAN shall provide to C\*P a list of all documents referenced in the CMC submissions which are subject to Change Control. These documents will be required to be approved by both ORPHAN and C\*P, and both parties agree to subject these documents for approval per Change Control. ORPHAN shall be responsible for meeting regulatory submission requirements based on the status of these documents.

## 10.2 Change Control

10.2.1 Changes to the controlled documents or to validated equipment and systems specific to the PRODUCTS must have ORPHAN Quality written approval, prior to implementation.

10.2.2 Administration changes to the controlled documents (e.g., typo corrections, formatting) do not require ORPHAN Quality written approval prior to implementation, but these changes must be submitted to ORPHAN Quality in a timely manner for review and approval.

## 11. PRODUCT AND PROCESS VALIDATION

11.1 Process - C\*P is responsible for ensuring that the manufacturing process is validated. The validation should ensure that the process is capable of consistently achieving the PRODUCTS acceptance specification.

11.2 Cleaning Validation - C\*P is responsible for ensuring that adequate cleaning is carried out between batches of different products to prevent contamination. ORPHAN will provide information (i.e. [ \* ]) to establish cleaning limits. The cleaning procedure and analytical methodology will be reviewed before the first product batches are made.

11.3 Equipment, Computer, Facility, and Utilities Qualification - C\*P is responsible for all equipment, computer, facility, and utility qualification activities associated with the PRODUCTS.

11.4 Laboratory Qualification - C\*P is responsible for ensuring that all laboratories are in compliance with applicable GMP guidelines. If analytical work is performed at C\*P, then ORPHAN will also provide any existing analytical documentation to assist in methods transfer or methods validation. In addition, if analytical work is not performed at the [ \* ] site, C\*P may elect to perform an audit on vendors to be used for analytical testing appropriate to manufacture of the PRODUCTS.

## 12. ANNUAL PRODUCT REVIEW, ANNUAL REPORT AND DRUG LISTING

### 12.1 Annual Product Review

12.1.1 C\*P will perform an Annual Product Review for the PRODUCTS and will issue a report to ORPHAN. This report will cover all manufacturing, testing, and storage activities performed by C\*P. It will be a review of any changes at C\*P in the manufacturing, testing, storage or validation of the PRODUCTS in the previous calendar year and a summary of lots made, released, and rejected. Also, control charting or trend analysis of key product parameters will be performed. Any abnormalities will be explained in the annual review.

- 12.1.2 ORPHAN is responsible for preparing any Annual Report as required by applicable regulations, including 21 CFR314.7(g)(3), 314.81(b)(2), and/or 601.12(d), (f)(3). At least 90 calendar days before the Annual Report due date, ORPHAN shall request in writing from C\*P the chemistry, manufacturing, and controls data required for submission of the Annual Report. C\*P will provide the requested information to ORPHAN within 30 days.
- 12.2 Drug Listing
- 12.2.1 C\*P is responsible for drug listing as the manufacturer of the PRODUCTS, while ORPHAN is responsible for drug listing as the distributor of the PRODUCTS. ORPHAN will provide C\*P with all required information needed by them for their listing. ORPHAN will notify C\*P of the scheduled PRODUCTS launch date.

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APPENDIX I

The PRODUCTS

XYREM ORAL SOLUTION

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APPENDIX II

List of Quality Contacts  
(name, phone, fax, e-mail)

<u>ISSUE</u>	<u>ORPHAN</u>	<u>C*P</u>
Product Release	[ * ]	[ * ]
QC Testing	[ * ]	[ * ]
Investigations	[ * ]	[ * ]
Regulatory Affairs	[ * ]	[ * ]
Validation	[ * ]	[ * ]
Compliance Audits	[ * ]	[ * ]
Product Complaints	[ * ]	[ * ]
Change Management	[ * ]	[ * ]

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APPENDIX III

Release Documentation

The Batch/Lot Release Document Package will include a Certificate of Analysis and Certificate of Compliance.

Certificate of Analysis (COA)

This document will include the name of the PRODUCT, the batch number and the date of manufacture. The COA will list the In-Process QC tests performed by C\*P and actual test results. The COA will also list the product release QC tests performed by C\*P and actual test results.

Certificate of Compliance (COC)

This document will attest to the fact that the batch of PRODUCTS was made in accordance with all applicable regulations, product licenses, and company policies. This document will include the batch quantity approved, the batch yield, and the expiration date. It will also include a listing of all manufacturing variances and/or incidents for the batch.

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Catalytica  
Pharmaceuticals

November 9, 2000

Mr. Randall J. Tlachac  
Orphan Medical  
13911 Ridgedale Drive  
Suite 475  
Minnetonka, MN, 55305

Dear Randy,

I am pleased to provide this revised commercial pricing for Xyrem Oral Solution. The new pricing includes the requested component/packaging changes. I have also attached an amended "APPENDIX D" which includes the pricing, packaging details and related assumptions. All raw materials and packaging components are included, [ \* ].

Commercial Pricing

Volume Breaks	Conversion	Materials	Total Unit Price
[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]

- Volume price breaks based on [ \* ]
- Pricing is based on the assumptions listed on page 2 of this letter
- Any change in the assumptions listed on page 2 of this letter will require that pricing be re-evaluated

Please indicate Orphan's approval/acceptance of the above commercial pricing by having the appropriate individual sign and date in the space provided below.

If you have any questions or need further clarification, please do not hesitate to call.

Sincerely,

/s/ David Smithwick  
\_\_\_\_\_  
David Smithwick, Contract Manager

/s/ Randall Tlachac  
\_\_\_\_\_  
Orphan Representative, Date 12/5/00

Director, Quality Assurance  
Title

cc: Marie Mayo      Lori Thigpen      File (2)

**Proposal Valid for 60 days**  
**Confidential**

Catalytica Pharmaceuticals, Inc. • P.O. Box 1887 • Greenville, NC 27835-1887 • 252-758-3436

ASSUMPTIONS

- Volume price breaks based on [ \* ]
- 7 [ \* ] Commercial Supply Agreement
- Subject to [ \* ] specified in commercial supply agreement
- DEA Schedule CIII with ARCOS reporting
- [ \* ]
- [ \* ]
- Manufactured [ \* ]
- Minimum of [ \* ]
- [ \* ]
- Manufacturing batch size of [ \* ]
- To be ordered [ \* ]
- Batches shipped within [ \* ] of Catalytica issuing CofC/CofA
- Packaging components  
[ \* ]

**Proposal Valid for 60 days  
Confidential**

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**AMENDMENT NO. 2  
TO  
XYREM SUPPLY AGREEMENT**

THIS AMENDMENT NO. 2 dated this 19<sup>th</sup> day of **August 2002** (this "Amendment") to Xyrem Supply Agreement is made and entered into as of the 19<sup>th</sup> day of August, 2002, by and between **Orphan Medical, Inc.**, a Delaware corporation ("Orphan"), and **DSM Pharmaceuticals, Inc.** (formerly, Catalytica Pharmaceuticals, Inc.), a Delaware corporation ("DSM"):

**W I T N E S S:**

WHEREAS, Orphan and Catalytica Pharmaceuticals, Inc. have previously executed a Xyrem Supply Agreement, dated June 30, 2000, and amended by Amendment No. 1 dated November 9, 2000 (collectively, the "Agreement"); and

WHEREAS, Catalytica's interest in, and obligations under, the Agreement have been acquired and assumed by DSM; and

WHEREAS, DSM and Orphan desire to amend the Agreement as set forth in this Amendment;

NOW, THEREFORE, for and in consideration of the premises, the respective commitments and undertakings of Orphan and DSM set forth in this Amendment, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Orphan and DSM hereby agree as follows:

1. Unless otherwise defined in this Amendment, capitalized terms used in this Amendment shall have the meanings ascribed to them in the Agreement.

2. Effective as of the date of this Amendment, the Product Price shall be as set forth on Appendix D to this Amendment, which Appendix D shall supersede Appendix D to the Agreement in all respects.

3. Section 7.3 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

"7.3 Product Price Adjustments. The Product Price, as specified on Appendix D, shall be subject to adjustment from time to time as follows:

(a) The conversion component of the Product Price, as set forth on Appendix D, shall be adjusted for each Contract Year, commencing with the Contract Year beginning in [ \* ], and shall be equal to [ \* ]. [ \* ] in the conversion component Product Price pursuant to this Section 7.3(a) shall become effective as of [ \* ].

(b) The materials component of the Product Price shall also be subject to adjustment from time to time as follows:

(i) Effective as of the start of each Contract Year, commencing with the Contract Year beginning in [ \* ] the materials component may be [ \* ] by DSM by the amount of [ \* ]. DSM shall provide Orphan with written notification of any [ \* ] in the materials component of the Product Price at least [ \* ] days prior to the start of the Contract Year to which such [ \* ] applies. Orphan shall have the option, upon reasonable notice to DSM, to appoint an independent financial auditor to verify the price [ \* ]; and DSM shall make available to the auditor appropriate documentation substantiating DSM's cost [ \* ]. The auditor shall be subject to the confidentiality requirements of Article 14 and shall only disclose to Orphan the auditor's opinion as to whether or not the price [ \* ] is consistent with the [ \* ]. If there is any disagreement with respect to any price [ \* ], the dispute shall be resolved in accordance with Article 18.

ii. Notwithstanding the provisions of subpart (i), if, during any Contract Year, [ \* ] of more than [ \* ], then DSM shall be entitled to [ \* ] the Materials component of the Purchase Price during such Contract Year upon [ \* ] written notification by utilizing the protocol set forth in subpart (i)."

4. Section 15.1 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

"15.1 Unless sooner terminated pursuant to Article 16 below, the initial term of this Agreement shall commence on the Effective Date and end upon the expiration of the third (3rd) Contract Year. Unless otherwise terminated pursuant to Article 16 below, this Agreement shall be automatically renewed for additional one (1) year terms after the end of the initial term, unless either party provides written notice to the other at least twelve (12) months prior to the expiration of the initial or any extended term, as the case may be, that this Agreement shall expire at the end of the initial term or such renewal term, as the case may be. All references herein to "term of this Agreement" shall be deemed to include both the initial and any extended terms."

**Amendment No. 2: Page 2**

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5. Article 16 of the Agreement is amended by relabeling current Sections 16.2 and 16.3 as Sections 16.3 and 16.4, respectively, and by adding a new subsection 16.2, which shall read as follows:

“16.2 Termination by Orphan. In addition to any other legal or equitable remedies that it may have, Orphan may terminate this Agreement prior to the expiration of the term of this agreement upon written notice to DSM in the event that (a) DSM is cited for, or receives any warnings about, any material compliance deficiencies by the FDA that could adversely affect the manufacturing or sales of the Product, and the deficiencies noted in such FDA citation or warning are not cured by DSM to Orphan’s reasonable satisfaction within [ \* ] after receipt by DSM of such warning or citation; or (b) the FDA initiates any compliance action against DSM that directly affects the manufacturing or testing of Product by DSM under the Agreement.” During this period DSM agrees to manufacture product and fill all Purchase Orders submitted as requested by ORPHAN.

6. Section 16.3(b) of the Agreement (formerly Section 16.2(b)) shall be amended by restating the lead-in clause of section 16.3(b) to read as follows:

“Other than termination by ORPHAN pursuant to Section 16.1(a) or Section 16.2 hereof . . .”

7. As amended pursuant to this Amendment, the Agreement is hereby ratified and confirmed in all respects by each of DSM and Orphan as a legally enforceable agreement between them.

{Signatures on following page}

**Amendment No. 2: Page 3**

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IN WITNESS WHEREOF, each of DSM and Orphan has caused this Amendment No. 2 to be executed by a fully authorized corporate officer as of the date first set forth above.

**ORPHAN MEDICAL, INC.**

By: /s/ John H. Bullion  
Name/Title:

**DSM PHARMACEUTICALS, INC.**

By: /s/ Terence S. Novack  
Terence S. Novack  
Sr. Vice President of Commercial Operations

**Amendment No. 2: Page 4**

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**Appendix D**

**Product Commercial Pricing**

Product Price is based on component costs represented in Letter dated March 11, 2002, attached.

Tiered pricing for Xyrem® [ \* ]

<u>Volume Breaks [ * ]</u>	<u>Conversion</u>	<u>Materials</u>	<u>Total Unit Price</u>
[ * ]	[ * ]	[ * ]	[ * ]
<u>Volume Breaks [ * ]</u>	<u>Conversion</u>	<u>Materials</u>	<u>Total Unit Price</u>
[ * ]	[ * ]	[ * ]	[ * ]

**Amendment No. 2: Page 5**

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March 11, 2002

Mr. Randy Tlachac  
 Orphan Medical  
 13911 Ridgedale Drive, Suite 250  
 Minnetonka, Minnesota 55305

Dear Mr. Tlachac:

The purchasing department at DSM is working together with our vendors to obtain the best purchase price for components. The purchase price of the components for Xyrem<sup>®</sup> is in most cases higher than the pricing estimated by Orphan. We have listed below the actual purchase costs for the Xyrem<sup>®</sup> components paid (or to be paid) by DSM for component purchases to date as requested in your e-mail note dated 03/04/02.

<u>Component Description</u>	<u>Purchase Costs</u> <u>Unit of Measure = each</u>	<u>Extended</u> <u>Purchase Costs</u>
[ * ]	[*]	[ * ]
<b>TOTAL</b>		[ * ]
		*estimate

In the event that Orphan Medical elects to have DSM purchase from other vendors, not yet DSM qualified, Orphan Medical would accept all associated costs of changes that would be required to transition from the established vendors to new vendors for the Xyrem<sup>®</sup> components, including qualification audits, establishing new specifications and item numbers, all costs associated with machinability and line testing, and any other changes that would be required. If Orphan Medical negotiates lower prices, DSM will take every effort to negotiate these same prices with DSM suppliers.

As noted in previous correspondence, any last minute changes to components may impact the timeline for the commercial introduction of Xyrem<sup>®</sup> after FDA approval (anticipated April 9, 2002). The commercial pricing updates are due to Orphan Medical requirements as mandated by the FDA that a Medguide be included on the inside of the commercial carton and that the Medguide be referenced on the outside of the carton.

Call me if you have any questions (252-707-7322).

Sincerely,

/s/ Trudy Briley  
 Trudy Briley  
 Account Manager  
 Pharmaceutical Sales & Marketing

cc: Michel Deinum (DSM)  
 Terry Novak (DSM)  
 Lori Thigpen (DSM)  
 Bill Conway (DSM)  
 Collins Hines (DSM)  
 File (2)

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**AMENDMENT NO. 3  
TO  
XYREM SUPPLY AGREEMENT**

THIS AMENDMENT NO. 3 dated this **21st** day of **March, 2005** (this "Amendment") to Xyrem Supply Agreement dated June 30, 2000 by and between **Orphan Medical, Inc.**, a Delaware corporation ("ORPHAN"), and **DSM Pharmaceuticals, Inc.** (formerly, Catalytica Pharmaceuticals, Inc.), a Delaware corporation ("DSM"):

**WITNESS:**

WHEREAS, ORPHAN and DSM have previously executed the Xyrem Supply Agreement, dated June 30, 2000, as amended by Amendment No. 1 dated November 9, 2000, and Amendment No. 2 dated August 19, 2002 (collectively, the "Agreement"); and

WHEREAS, DSM and ORPHAN desire to amend the Agreement as set forth in this Amendment;

NOW, THEREFORE, for and in consideration of the premises, the respective commitments and undertakings of ORPHAN and DSM set forth in this Amendment, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, ORPHAN and DSM hereby agree as follows:

1. Unless otherwise defined in this Amendment, capitalized terms used in this Amendment shall have the meanings ascribed to them in the Agreement.
2. Effective as of the date of this Amendment, the Product Price and package configurations shall be as set forth in **Appendix D** to this Amendment, which Appendix D shall supersede Appendix D to the Agreement, and Appendix D to Amendment No. 2 to the Agreement, in all respects.
3. Section 4.2 of the Agreement shall be amended to read, in its entirety, as follows:

4.2 Manufacture and Supply

During each Contract Year of this Agreement, and subject to the provisions of Section 7.2 hereof as well as other provisions herein, ORPHAN agrees to purchase all of its requirements for the Product in the Territory from DSM, but no less than the minimum quantities of Product indicated below:

<u>Year</u>	<u>ORPHAN's Minimum Purchase Quantity</u>
2006	[ * ]
2007	[ * ]
2008	[ * ]

DSM shall manufacture the Product in accordance with the Specifications and applicable cGMP requirements, and shall package, label, and/or otherwise prepare the Product for bulk delivery to an ORPHAN-designated distribution site.

4. Section 5.1, "Forecasts", of the Agreement shall be amended in its entirety and shall hereafter read as follows:

5.1 Forecasts.

5.1.1 Long Term Forecast. Within thirty (30) days after the Effective Date, of this Amendment, ORPHAN shall deliver to DSM a non-binding [ \* ] forecast of Orphan's quantity requirements for each Commercial Product and for each Contract Year during the Term (the "[ \* ] Forecast"). The [ \* ] Forecast shall thereafter be updated every [ \* ] during the Term of this Agreement. If DSM is unable to accommodate any portion of the [ \* ] Forecast, it shall notify ORPHAN and the Parties shall agree on any revisions to the forecast.

5.1.2 Monthly Forecast. ORPHAN shall submit to DSM a written non-binding estimate of its [ \* ] requirements for each Product for each of the next succeeding [ \* ]. The [ \* ] Forecast shall be updated [ \* ]. If DSM is unable to accept (i) quantities stated for any new [ \* ] in the [ \* ] Forecast, or (ii) quantities in excess of previously forecasted quantities (collectively, the quantities in (i) and (ii) referred to as "Additional Quantities"), then DSM shall notify ORPHAN in writing within five (5) calendar days after receipt of the [ \* ] Forecast; otherwise such Additional Quantities shall be deemed to have been approved and accepted by DSM. The Parties shall negotiate in good faith to resolve any issues in respect of the Additional Quantities, which DSM is unable to accept for any [ \* ] stated in the [ \* ] forecast, according to DSM's available capacity.

**Amendment No. 3: Page 2**

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- 5.1.3 **Firm Purchase Commitment.** The forecast of the most current [ \* ] period from the [ \* ] Forecast required under section 5.1.2 shall always constitute a binding firm purchase commitment (the “Firm Purchase Commitment”) which shall state in detail the quantities of Products ordered and the required delivery dates, and shall be binding on the Parties regarding Products to be purchased. The forecast for the remaining [ \* ] period of the [ \* ] Forecast is for planning purposes only and shall not constitute a commitment to purchase or supply Product. In the event that ORPHAN does not ultimately purchase the forecast quantities for the Firm Purchase Commitment period[ \* ]. However, if DSM is unable for any reason [ \* ], ORPHAN shall not be obligated to pay for that portion of the Firm Purchase Commitment which DSM could not deliver. As of the end of each calendar year hereunder, if ORPHAN has failed to purchase the minimum annual quantity as set forth in Section 4.2, it shall likewise pay DSM for any deficient quantities on the basis set forth above in this Section 5.1.3.
5. Section 5.5 of the Agreement, Purchase Quantities, shall be amended to read, in its entirety, as follows:
- 5.5 Purchase Quantities. Each purchase order shall specify the quantity of units of Product being ordered. Quantities actually shipped pursuant to a given purchase order may vary from the quantities reflected in such purchase order by [ \* ] and still be deemed to be in compliance with such purchase order, *provided however*, that ORPHAN shall only be invoiced and required to pay for the quantities of Product which DSM actually ships to ORPHAN.
6. Section 6.2, Supply By DSM: This section is deleted in its entirety.
7. Section 6.3, “Manufacturing Loss”: Financial liability related to API loss shall no longer be governed by Section 6.3. Financial liability shall be governed by section 10.5, as amended by this Amendment.
8. Section 7.3, “Annual Price Adjustment Notification”, as referenced in Amendment 2 and the Agreement, shall be amended and hereafter read as follows:
- 7.3 Product Price Adjustments. The Product Price, as specified on **Appendix D**, shall be subject to adjustment from time to time as follows:
- (a) The conversion component of the Product Price, as set forth on Appendix D, shall be adjusted as of [ \* ], and shall be [ \* ]. [ \* ] in the conversion component Product Price pursuant to this Section 7.3(a) shall become effective as of [ \* ] of each calendar year for all shipment of Product during each such year.

**Amendment No. 3: Page 3**

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(b) The materials component of the Product Price shall also be subject to adjustment from time to time as follows:

(i) Effective as of [ \* ], the materials component may be [ \* ] by DSM by the amount of [ \* ]. DSM shall provide ORPHAN with written notification of any [ \* ] in the materials component of the Product Price at least [ \* ] days prior to the start of the [ \* ] to which such [ \* ] applies. ORPHAN shall have the option, upon reasonable notice to DSM, to appoint an independent financial auditor to verify the price [ \* ]; and DSM shall make available to the auditor appropriate documentation substantiating DSM's cost [ \* ]. The auditor shall be subject to the confidentiality requirements of Article 14 and shall only disclose to ORPHAN the auditor's opinion as to whether or not the price [ \* ] is consistent with the [ \* ]. If there is any disagreement with respect to any price [ \* ], the dispute shall be resolved in accordance with Article 18.

(ii) Notwithstanding the provisions of subpart (i), if, [ \* ] DSM experiences an [ \* ] in the aggregate cost of the Materials incorporated into the Product of more than [ \* ] then DSM shall be entitled to [ \* ] the Materials component of the Purchase Price [ \* ] upon [ \* ] days prior written notification by utilizing the protocol set forth in subpart (i)."

9. Section 10.5, "Limitation of Liability and Claims", is deleted in its entirety and hereafter shall read as follow:

10.5 Limitation of Liability. Notwithstanding the foregoing warranties and representations and the further obligations of the Parties hereunder, in no event shall either Party be liable to the other Party for incidental, indirect, special, consequential or punitive damages, including without limitation any claim for damages based upon lost profits or lost business opportunity. Except for the obligations of indemnity as set forth in this Article 10 [ \* ] resulting from [ \* ] Product supplied hereunder, and (ii) claims of [ \* ], which are not subject to the following limitation, [ \* ]. **The foregoing limitations shall not apply if the damages otherwise subject to limitation result from [ \* ].**

10. Section 15.1 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

15.1 Unless sooner terminated pursuant to Article 16 below, the initial term of this Agreement shall commence on the Effective Date and end on July 31, 2005. Thereafter, this Agreement shall continue in force and effect for an additional three (3) year term, ending on July 31, 2008 unless terminated earlier pursuant to Article 16 below.

#### Amendment No. 3: Page 4

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

11. Section 16.1 of the Agreement shall be amended by adding the following as a new Subsection (d):
  - (d) If either party, for any reason, elects to terminate this Agreement, in which case such party shall provide written notice thereof no less than twelve (12) months prior to the effective date of such termination.
12. Section 16.3(b) of the Agreement (formerly Section 16.2(b)) shall be amended by restating the lead-in clause of section 16.3(b) to read as follows:

“Other than termination by ORPHAN pursuant to Section 16.1(a) or Section 16.2 hereof, or termination by DSM pursuant to Section 16.1(d). . .”
13. The Agreement shall otherwise continue in force and effect according to its terms as herein amended; and the Agreement is hereby ratified and confirmed in all respects by each of DSM and ORPHAN as a legally enforceable agreement between them.

{Signatures on following page}

**Amendment No. 3: Page 5**

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IN WITNESS WHEREOF, each of DSM and ORPHAN has caused this Amendment No. 3 to be executed by a fully authorized corporate officer as of the date first set forth above.

**ORPHAN MEDICAL, INC.**

By: /s/ Dayton T. Reardan  
Dayton T. Reardan, Ph.D., RAC  
Vice President of Regulatory Affairs

**DSM PHARMACEUTICALS, INC.**

By: /s/ Terence S. Novack  
Terence S. Novack  
Chief Marketing Officer

**Amendment No. 3: Page 6**

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APPENDIX D

**Product Commercial Pricing**

**Batch Price: Domestic Bulk Packaging**

<u>Description</u>	<u>Price</u>
[ * ]	[ * ]

**Batch Price: Export Bulk Packaging**

<u>Description</u>	<u>Price</u>
[ * ]	[ * ]

Assumptions for Bulk Packaging (Domestic and Export):

[ \* ]

**Batch Price: Domestic Current Package Configuration**

[ * ]	<u>Price</u>
[ * ]	[ * ]

Assumptions:

[ \* ]

**Batch Price: Domestic New Terms**

<u>Description</u>	<u>Price</u>
[ * ]	[ * ]

Assumptions:

[ \* ]

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EXHIBIT 10.41

Execution Version

**JAZZ PHARMACEUTICALS, INC.**

**AND**

**UCB PHARMA LIMITED**

**AMENDED AND RESTATED XYREM<sup>®</sup> LICENSE AND DISTRIBUTION  
AGREEMENT**

## AMENDED AND RESTATED XYREM LICENSE AND DISTRIBUTION AGREEMENT

This AMENDED AND RESTATED LICENSE AND DISTRIBUTION AGREEMENT (this “**Agreement**”) is made and entered into as of June 30, 2006 (“**Execution Date**”), by and between Jazz Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 3180 Porter Drive, Palo Alto, California 94304, USA (together with its Affiliates, “**Jazz Pharmaceuticals**”), and UCB Pharma Limited, a company organized under the laws of England having its principal place of business at 208 Bath Road, Slough, Berkshire, SL1 3WE (together with its Affiliates, “**UCB**”).

### RECITALS

WHEREAS, Orphan Medical, Inc., a Delaware corporation (“**Orphan Medical**”) and Celltech Pharmaceuticals, Ltd., a biopharmaceutical company organized under the laws of England (“**Celltech**”) previously entered into that certain Xyrem License and Distribution Agreement (the “**Prior Agreement**”) dated October 29, 2003 (“**Effective Date**”);

WHEREAS, under the Prior Agreement, Orphan Medical granted rights to commercialize the Product in certain territories within the field of narcolepsy and associated conditions;

WHEREAS, pursuant to Section 17.7 of the Prior Agreement, Orphan Medical assigned its rights and obligations under the Prior Agreement to Jazz Pharmaceuticals and all references to “Orphan Medical” in the Prior Agreement therefore have been replaced by “Jazz Pharmaceuticals”;

WHEREAS, pursuant to Section 17.7 of the Prior Agreement, Celltech assigned its rights and obligations under the Prior Agreement to UCB and all references to “Celltech” in the Prior Agreement therefore have been replaced by “UCB”; and

WHEREAS, in accordance with Section 17.4 of the Prior Agreement, Jazz Pharmaceuticals and UCB wish to supersede and replace the Prior Agreement in its entirety with this Agreement to, amongst other things, (i) expand the Territory to include the Additional Countries (as defined below) on the terms and conditions of the Prior Agreement as amended herein and (ii) expand the Licensed Indications to include Fibromyalgia (as defined below) on the terms and conditions of the Prior Agreement as amended herein.

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NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Jazz Pharmaceuticals and UCB agree as follows:

## ARTICLE I DEFINITIONS AND INTERPRETATION

1.1 Definitions. In this Agreement:

“**Affiliate**” shall mean any corporation or non-corporate business entity controlled by, controlling or under common control with, a party to this Agreement. For the purpose of this definition, “control” shall mean the direct or indirect ownership or control of at least fifty percent (50%) of the voting stock of a corporation or a) in the absence of ownership of at least fifty percent (50%) of the voting stock of that corporation, or b) in the case of a non-corporate business entity, if it possesses, directly or indirectly, whether by virtue of an ownership interest of any kind, by contract or otherwise, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity or to elect or cause the election of a majority of the board of directors or other governing body of such corporation or non-corporate business entity. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals which are financial institutions, venture capital funds and private equity investors (other than a corporate venture fund which is an Affiliate of a publicly-traded pharmaceutical or biotechnology company) shall not be its “Affiliates” for purposes of this Agreement.

“**Adverse Event**” means the ICH guideline definition as further defined in the agreement entitled, “Agreement regarding the exchange of safety data between UCB S.A. and Jazz Pharmaceuticals, Inc. concerning Xyrem (sodium oxybate)” effective March 22, 2006 by and between the parties (a “**Pharmacovigilance Agreement**”).

“**API**” means the active pharmaceutical ingredient sodium oxybate contained in the Product, having ATC code [ \* ].

“**Claims**” shall have the meaning provided in Section 9.1.

“**Commercial Forecasts**” shall have the meaning provided in Section 7.1.

“**Commercially Reasonable Efforts**” means those efforts that are commercially reasonable under the prevailing circumstances and which are no less than those that the applicable party would undertake for [ \* ] in the Territory for [ \* ] with [ \* ] and [ \* ] (taking into account at all times the relevant [ \* ] profile of the same).

“**Competitive Product**” shall have the meaning provided in Section 2.6.

“**Components**” means the dosing cups and lids, syringe, tamper resistant seal and PIBA included in the pack issued to customers along with each Product.

“**Contract Year**” means each twelve (12) month period during the Term of this Agreement starting on 01 January and ending on 31 December.

**“Current Good Manufacturing Practices”** or **“cGMP”** means the regulations set forth in 21 C.F.R. Parts 210 - 211, 820 and 21 C.F.R. Subchapter C (Drugs), Quality System Regulations and the requirements thereunder imposed by the FDA and EU Directive 2003/94/EC and 92/25/EEC or the equivalent regulations and requirements applicable in the Territory.

**“DEA”** means the United States Drug Enforcement Administration, or any successor thereto, having the administrative authority to regulate the scheduling and distribution of certain drugs in the United States.

**“EMA”** means the European Medicines Evaluation Agency or any successor entity which coordinates the scientific review of human pharmaceutical products under the centralized licensing procedure in the European Union.

**“FDA”** means the United States Food and Drug Administration or any successor entity.

**“Fibromyalgia”** means the chronic pain syndrome (defined by widespread and longstanding pain sustained for at least three months determined by pain levels in response to the application of pressure in 11 of 18 tenderpoints) and its related symptoms (pain, stiffness, sleep disturbance, fatigue, mood disorders) diagnosed in patients as having fibromyalgia or fibromyalgia syndrome.

**“Fibromyalgia Notice”** means the written notice provided by UCB to Jazz Pharmaceuticals in accordance with Section 2.1 of this Agreement following receipt of the Final Advice Letter by UCB from Jazz Pharmaceuticals.

**“Final Advice Letter”** means a written letter provided by the Committee for Human Medicinal Products (“CHMP”) to Jazz Pharmaceuticals (based on and referring to the submission of the Request for CHMP Scientific Advice dated April 25, 2006 for the conduct of registration trials with the Product in Fibromyalgia in Europe) which letter shall contain written recommendations and guidance regarding the use of the Product for Fibromyalgia.

**“First Commercial Sale”** means the first sale of the Product by or on behalf of UCB to a wholesaler, distributor or end-user in the Territory following Registration of the Product for a particular Licensed Indication(s) in the Territory.

**“ICH”** means International Conference on Harmonization of technical requirements for registration and manufacturing of pharmaceuticals for human use as may be amended from time to time.

**“Indemnification Amounts”** shall have the meaning provided in Section 9.1.

**“Indication”** means any medical condition or set of symptoms for the treatment of which a medicinal product is or may be prescribed.

**“Improvements”** means any and all modifications, amendments, improvements, inventions or discoveries (including, without limitation, manufacturing, manufacturing processes and procedures, analytical processes, procedures or methods and analytical results), any route(s) of synthesis, new formulations and/or delivery forms of or with respect to the API and/or Product (other than the current form of the Product as defined herein), including all information and data relating thereto, whether patentable or not, whether originating from Jazz Pharmaceuticals or from UCB, including copyrights, trademarks, patents, patent applications, trade secrets, NDAs and Know How.

**“Know How”** means data and information regarding toxicology, pharmacology, clinical trials, analytical methodologies, and use of the Product that is necessary or useful for UCB to fulfill its obligations hereunder, all of which is proprietary to Jazz Pharmaceuticals.

**“LIBOR-3M”** means the quarterly London Interbank Offered Rate.

**“Licensed Indications”** means (i) Narcolepsy, (ii) Fibromyalgia (only upon receipt of a Fibromyalgia Notice pursuant to Section 2.1 and receipt by Jazz Pharmaceuticals of the milestone payment set forth in Section 4.1(h) below), and (iii) any other Indication(s) for which UCB obtains the right to develop and commercialize the Product pursuant to Section 2.3 hereof. For clarity, if UCB does not deliver the Fibromyalgia Notice to Jazz Pharmaceuticals pursuant to Section 2.1 or fails to pay Jazz Pharmaceuticals the milestone payment set forth in Section 4.1(h) below, Fibromyalgia will not be considered a Licensed Indication for the purposes of this Agreement.

**“Licensed Intellectual Property”** shall have the meaning provided in Section 2.2.

**“Major European Country(ies)”** means [ \* ].

**“Manufacturing Know How”** means all data, information and materials relating to the manufacture of the Product that is not included in the Know How.

**“Marketing Authorization”** means a Regulatory Authority approval necessary to commercially promote and distribute the Product for a Licensed Indication including, where applicable, price and reimbursement approval which must be granted for the Product to be sold in any country. Marketing Authorization as applied to any country does not include the approval of a treatment IND (or any equivalent approval outside of the United States), pre-approval human use trials under a protocol or distribution of a product under an emergency use program, e.g., distribution on a Named Patient Basis.

**“Market Sales Price”** means the price for a Product approved by the Regulatory Authority in each country of the Territory, or in countries where pricing is not regulated, the price at which UCB sells that Product.

**“Minimum Label Requirement”** means the [ \* ].

**“Named Patient Basis”** means any distribution of Product by Jazz Pharmaceuticals or UCB, as its designee, for sale prior to Registration of the Product for any Indication through approval by a Regulatory Authority in the Territory or as otherwise allowed by local law.

**“Narcolepsy”** means narcolepsy and its associated conditions, including without limitation, cataplexy and excessive daytime sleepiness.

**“Narcolepsy Trademarks”** means any trademarks for use with the Product in respect of the Narcolepsy Licensed Indication.

**“NDA”** means a New Drug Application filed by Jazz Pharmaceuticals with the FDA or any equivalent successor application for approval to commercially promote and distribute the Product in the United States.

**“Net Sales”** means for purposes of calculating the payments payable by UCB to Jazz Pharmaceuticals pursuant to Sections 4.1, 4.2, 4.3 and 4.4 of this Agreement, the gross sales prices received by UCB, its Subdistributors or Sublicensees from sales of the Product, not including Product samples, sold by or for UCB, its Subdistributors or Sublicensees to independent third parties in the Territory, after in each case, deduction of the following items allowed, given, granted, paid or borne by or for UCB, its Subdistributors or Sublicensees with respect to sales of the Product:

- (a) bona fide discounts, credits, rebates, allowances, adjustments, rejections, recalls for which the customer has been credited the original sales price and returns;
- (b) bona fide trade, quantity, or cash discounts or rebates customary to the industry and actually allowed, given or accrued (including, but not limited to, cash, governmental and managed care rebates, and hospital or other buying group chargebacks);
- (c) sales, excise, turnover, inventory, value-added, and similar taxes assessed on the sale of such Product; and
- (d) transportation, importation, insurance and other handling expenses.

For the avoidance of doubt, in order to avoid any double counting when determining Net Sales (i) Net Sales shall not include any royalties, proceeds or other amounts paid to UCB by any Sublicensee and (ii) if the gross sales price received by a Subdistributor from one or more sales has been counted, then Net Sales shall not include any royalties, proceeds or other amounts that are paid by such Subdistributor to UCB in connection with such sales.

**“Orphan Drug Designation”** means designation by the EMEA as an orphan drug, a drug for a specified rare disease or condition, or the equivalent designation by a Regulatory Authority of any country of the Territory.

**“Other Licensed Trademarks”** means any trademarks for use with the Product in relation to any Licensed Indication other than the Narcolepsy Licensed Indication.

**“Patent Rights”** means European patent [ \* ] and any other patents listed on Appendix B hereto (including the inventions described and claimed therein), and any other future patents owned by or licensed to Jazz Pharmaceuticals necessary to make, use, sell or offer for sale the Product in the Territory, and any application for letters patent relating thereto, including, without limitation a continuation application, a continued prosecution application, a continuation in part application or a divisional application, and any supplementary protection certificates, extensions, substitutions, confirmations, divisions, continuations, continuations-in-part, patents issuing thereon and reissues or re-examinations thereof (each which shall be automatically incorporated in and added to this Agreement and shall periodically be added to Appendix B attached to this Agreement and made a part hereof).

**“Person”** means any individual, general or limited partnership, corporation, limited liability company, association, business trust, joint venture, regulatory authority, business entity or other entity of any kind or nature.

**“PIBA”** means a press-in-bottle adaptor.

**“Product”** means any Jazz Pharmaceuticals’ proprietary pharmaceutical product containing the API as its active ingredient for use as a treatment for a Licensed Indication and all Components therefore (unless UCB shall elect to source such Components, at its own expense, from a Third Party as contemplated by Section 2.1(c)).

**“Product Specifications”** means specifications for the Product included in the relevant Regulatory Authority approval for a Licensed Indication, unless otherwise agreed in writing by Jazz Pharmaceuticals and UCB.

**“Proprietary Information”** shall mean the terms and provisions of this Agreement and all non-public information or data relating to the Product and the subject matter hereof first



communicated by or on behalf of one party to the other, whether in writing or orally, including without limitation, all scientific, clinical, commercial, financial and business information and data, know-how, compilations, formulae, processes, plans, technical information, new product information, compounds, formulations, methods of product-delivery, test procedures, product samples, specifications and other information or data.

**“Quality Agreement”** means the agreement effective July 6, 2004, as may be amended from time to time, by and between Orphan Medical Inc and Celltech Pharmaceuticals Ltd, or any further new quality agreement to be entered into by the parties.

**“Registration”** shall have occurred and shall continue in each country in the Territory when the Marketing Authorization required in respect of such country shall have been issued and shall continue to be effective.

**“Regulatory Authority”** means the EMEA and each other regulatory and drug scheduling or pricing authority equivalent to the FDA and DEA in the Territory or a country in the Territory, which has responsibility for scheduling or pricing drugs and/or approving Marketing Authorizations.

**“Steering Committee”** means the joint committee established pursuant to Section 3.8.

**“Subdistributors”** means any sub-distributor (exclusive of pre-wholesalers, wholesalers and Sublicensees) of the Product in the Territory appointed by UCB from and after the Effective Date pursuant to this Agreement.

**“Sublicensee”** means any Third Party who is licensed by UCB to promote, market, sell and distribute the Product in the Territory in consideration of the payment to UCB of a purchase price for the Product and royalties on sales of the Product to Third Parties.

**“Term”** shall have the meaning provided in Section 14.1 hereof.

**“Territory”** means all the countries set forth in Appendix A, as such Appendix may be amended from time by mutual written agreement of the parties.

**“Third Party”** means a Person who or which is neither a party to this Agreement nor an Affiliate thereof.

**“Trademarks”** means the Narcolepsy Trademarks and the Other Licensed Trademarks used for the Product including the trademarks set forth in Appendix B, as may be amended from time to time by Jazz Pharmaceuticals. As between Jazz Pharmaceuticals and UCB, all trademarks for the Product, including, but not limited to, the Narcolepsy Trademarks and the Other Licensed Trademarks, are owned by Jazz Pharmaceuticals.

**“Transfer Price”** means the price(s) Jazz Pharmaceuticals charges UCB for Product on a per bottle and per Component basis; provided, however, that the Transfer Price [ \* ] Jazz Pharmaceuticals’ [ \* ] for the Product, exclusive of Components plus, when Components are being purchased, [ \* ] of Components. The constituents comprising Jazz Pharmaceuticals’ standard manufacturing cost are listed on Appendix C, which also shows [ \* ] for the Product including Components as of the date hereof.

**“Weighted Average List Price”** means UCB’s total annual gross sales receipts for the Product received from UCB’s customers in the Territory calculated based on the Market Sales Price, divided by the quantity of Product sold in the Territory.

1.2 Interpretation. In this Agreement:

(a) reference to:

(i) any statute or statutory provision includes a reference:

(A) to that statute or statutory provision as from time to time consolidated, modified, re-enacted (with or without modification) or replaced by any statute or statutory provision; and

(B) any subordinate legislation made under the relevant statutory provision;

(b) the singular includes the plural and vice versa and any gender includes other genders;

(c) the table of contents and the headings to clauses and schedules are to be ignored in construing this Agreement; and

(d) the schedules form part of this Agreement as if set out in full in this Agreement and a reference to “this Agreement” includes a reference to the schedules.

## **ARTICLE II APPOINTMENT**

2.1 Appointment. Subject to the terms and conditions of this Agreement, Jazz Pharmaceuticals hereby appoints UCB, and UCB accepts such appointment, as Jazz Pharmaceuticals’ exclusive licensee and distributor of Product in the Territory; provided UCB

acknowledges that its appointment with respect to the Fibromyalgia Indication is contingent upon (i) UCB providing the Fibromyalgia Notice to Jazz Pharmaceuticals no later than the earlier of (A) the later of thirty (30) days after (x) the Execution Date and (y) receipt by UCB of a Final Advice Letter or (B) September 15, 2006 and (ii) making the milestone payment to Jazz Pharmaceuticals set forth in Section 4.1(h) below. Notwithstanding the foregoing, UCB shall only distribute, sell, market or otherwise commercialize Product [ \* ] the price of that Product shall be [ \* ] of the [ \* ] Product price [ \* ]. Furthermore, Jazz Pharmaceuticals hereby agrees to negotiate with UCB on an exclusive basis and in good faith [ \* ] an amendment to this Agreement that would contain appropriate commercial terms upon which UCB shall be appointed the exclusive licensee and distributor of Product [ \* ]. Upon any such agreement being reached, [ \* ] shall thereafter form part of the Territory; provided, however, that if the parties fail to reach such an agreement within the period set forth above, Jazz Pharmaceuticals shall be free to enter into an agreement with a Third Party with respect to the Product [ \* ]. During the Term of this Agreement, UCB shall purchase all of its requirements of the Product from Jazz Pharmaceuticals as the sole supplier subject to the following:

(a) UCB Manufacturing. Jazz Pharmaceuticals agrees to discuss with UCB the feasibility and commercial viability of transferring the manufacture of the Product to UCB's FDA approved facilities or qualifying and registering UCB as a back-up manufacturer for the Product for the Territory and/or for the rest of the world. Notwithstanding the foregoing, once aggregate Net Sales of the Product sold by or on behalf of UCB in the Territory have [ \* ] then UCB shall have the option to notify Jazz Pharmaceuticals that it intends to transfer Product manufacturing to the facilities of UCB and/or its nominated Third Party no earlier than [ \* ] from the date of UCB's initial notice to Jazz Pharmaceuticals. Following the exercise of UCB's option by notice in writing, Jazz Pharmaceuticals shall use its commercially reasonable efforts, at [ \* ] expense for all [ \* ], to provide UCB with such assistance as is reasonable to take over manufacture or to obtain and qualify a Third Party manufacturer, including without limitation, giving effect to the licensing of its Manufacturing Know-How to UCB and/or such Third Party manufacturer (as the granting of such manufacturing license rights is thereby contemplated under Section 2.2) for the purposes of manufacturing API and/or Product. Jazz Pharmaceuticals will make available to UCB and/or its nominated Third Party, on a confidential basis and for use only to make the Product, such Manufacturing Know-How of Jazz Pharmaceuticals as may be reasonably necessary to make the Product. Such Manufacturing Know-How will not be used by UCB and/or its nominated Third Party for any other purpose or provided to any other Third Party without the prior written consent of Jazz Pharmaceuticals. Jazz Pharmaceuticals will work with UCB and/or its nominated Third Party to execute all documents and to take all action reasonably requested by Jazz Pharmaceuticals to preserve the confidentiality of such Manufacturing Know-How and Jazz Pharmaceuticals' intellectual property rights therein. UCB and/or its nominated Third Party will also use commercially reasonable efforts (including allowing Jazz Pharmaceuticals to negotiate an agreement not inconsistent with this Agreement regarding the

transfer of the Manufacturing Know-How directly with UCB's nominated Third Party concurrent with the time in which UCB is negotiating its supply agreement with such Third Party), to facilitate an agreement between Jazz Pharmaceuticals and such Third Party covering any improvements to the manufacturing process, so that Jazz Pharmaceuticals either owns such improvements, or has a worldwide, paid up, irrevocable, nonexclusive license, with the right to grant sublicenses, to such improvements to make, use, sell, offer to sell and import the Product. For the sake of clarity, UCB shall be free to enter into any agreement with a Third Party for the manufacture of the Product provided that such agreement provides, in Jazz Pharmaceuticals' reasonable opinion, appropriate safeguards for the protection of the Licensed Intellectual Property and Jazz Pharmaceuticals' Confidential Information and UCB has agreed to the terms and conditions required by Section 2.1(c) below. Notwithstanding the foregoing, any agreement between UCB and its nominated Third Party will restrict such Third Party's use of Jazz Pharmaceuticals' Manufacturing Know-How and Confidential Information solely to the manufacture of the Product only.

(b) UCB/ Third Party Manufacturing in the Event of Default. If at any time after December 31, 2007, (i) more than [ \* ] percent ([ \* ]%) of the aggregate Product supplied to UCB by Jazz Pharmaceuticals in any subsequent Contract Year is found, pursuant to Section 7.12, to have failed to conform to the Product Specifications and/or the relevant purchase order(s); or (ii) Jazz Pharmaceuticals is unable to manufacture or supply the quantity of Product ordered by UCB in accordance with this Agreement for any reason whatsoever, including, without limitation, by reason of an event described in Section 16.1 (Events of Force Majeure); then UCB shall have the right at its sole election to (A) take over the manufacture of the Product or appoint a Third Party manufacturer to fulfill Jazz Pharmaceuticals' manufacturing and supply obligations under this Agreement thereafter through the remaining Term of this Agreement and/or (B) purchase the API from Jazz Pharmaceuticals and itself convert, or appoint a Third Party manufacturer to convert, the API into Product through the Term of the Agreement; provided, however, that in the case of Section 2.1(b)(ii), such right shall be exercisable only if (1) Jazz Pharmaceuticals' inability to manufacture or supply the Product could reasonably be expected to result in a period of time of at least [ \* ] during which less than [ \* ] percent ([ \* ]%) of Product ordered pursuant to UCB's last firm purchase order would be available to UCB for commercial sale, (2) UCB provides reasonable evidence of its ability to procure a Third Party manufacturer or take over the manufacture of the Product or the API more rapidly than Jazz Pharmaceuticals could restart production and supply of Product, and (3) Jazz Pharmaceuticals' inability to manufacture or supply Product did not result, wholly or in part, from a breach by UCB of its obligations hereunder. Jazz Pharmaceuticals shall, at [ \* ] expense for all [ \* ], provide UCB with all reasonable assistance as is necessary to take over or obtain and qualify a Third Party manufacturer, including without limitation, giving effect to the licensing of its Manufacturing Know-How to UCB and/or such Third Party manufacturer (as the granting of such manufacturing license rights is thereby contemplated under Section 2.2) solely for the purpose of manufacturing API and/or Product pursuant to the terms of this Agreement.

(c) Price for Manufacturing Changes. In the event that UCB shall manufacture Product or API or cause Product or API to be manufactured pursuant to this Agreement, UCB agrees to pay Jazz Pharmaceuticals the following manufacturing royalties in accordance with Section 4.5 below:

- (i) [ \* ]% of Net Sales where UCB manufactures or has manufactured API; and
- (ii) [ \* ]% of Net Sales where UCB manufactures or has manufactured the Product (other than the API).

Any other related terms shall be negotiated in good faith by UCB and Jazz Pharmaceuticals. For the avoidance of doubt, the [ \* ] royalty of [ \* ]% of Net Sales under this Section 2.1(c) shall be payable by UCB to Jazz Pharmaceuticals only where UCB manufactures or has manufactured both the API and the Product.

(d) Component Sourcing. UCB shall be permitted at any time during the Term on sixty (60) days prior written notice to Jazz Pharmaceuticals to cease purchasing some or all Components from Jazz Pharmaceuticals and purchase some or all of the Components directly from Jazz Pharmaceuticals' suppliers or qualify another Third Party(ies) to supply Components; provided that, subject to Sections 7.6 and 7.12, UCB must purchase all Components delivered by Jazz Pharmaceuticals pursuant to a firm order regardless of whether such delivery is made after UCB delivers notice to Jazz Pharmaceuticals of its intent to purchase the Components from Jazz Pharmaceuticals' suppliers or another Third Party(ies). UCB shall bear any and all costs associated with qualifying any Third Party(ies) to supply Components pursuant to this Section 2.1(c); provided that if Jazz Pharmaceuticals desires to purchase the same Components from such Third Party(ies) as UCB is purchasing, then Jazz Pharmaceuticals and UCB shall [ \* ] of any such costs.

(e) Manufacturing License. In the event that UCB assumed responsibility for the manufacture of the Product pursuant to this Section 2.1, UCB shall have a non-exclusive license under any necessary Licensed Intellectual Property during the Term, and subject to the terms of this Agreement, to make or have made the Product outside the Territory solely for sale and distribution in the Territory.

2.2 License Grant. Subject to the terms and conditions of this Agreement, Jazz Pharmaceuticals hereby grants UCB an exclusive nontransferable, royalty-bearing right and license (with the right of sublicense, as specifically set forth herein), to use the NDA, Know

How, Trademarks, Patent Rights and all Improvements and Proprietary Information of Jazz Pharmaceuticals related thereto or to the Product together with the goodwill associated therewith (the **“Licensed Intellectual Property”**) during the Term, solely in the Territory, to develop, make, have made, package, label, promote, market, sell, have sold, supply, distribute or otherwise commercialize Products in the Licensed Indications, or subject to Section 6.8 any other Indications on a Named Patient Basis, including without limitation (i) preparing applications for Marketing Authorizations and obtaining and maintaining Registrations for the Product in the Territory; and (ii) exercising its other rights under this Agreement including those provided in Articles X and XI hereof and making or having made API and/or Product but only as provided in Section 2.1. Subject to Section 2.3 and except as set forth in Section 6.8, no license is granted to UCB hereunder for any rights to market the Product for Indications other than the Licensed Indications. Except as provided in Section 14.6, the license set forth above shall terminate automatically upon termination of this Agreement. Subject only to the foregoing express license grant and its other rights as herein provided, UCB shall not have and shall not assert any claim, right, title or interest in or to the Licensed Intellectual Property.

### 2.3 Right of First Negotiation for Other Indications.

(a) Negotiation Notice. If, during the Term of this Agreement, Jazz Pharmaceuticals desires to pursue further development of the Product in the Territory for one or more Indications other than the Licensed Indications, Jazz Pharmaceuticals shall provide written notice to UCB (the **“Negotiation Notice”**) of its intent to negotiate an agreement therefore. The Negotiation Notice shall identify the relevant Indication(s). Delivery of a Negotiation Notice shall create a mutual obligation to negotiate in good faith on an exclusive basis for the grant to UCB of exclusive rights to the Product for such Indication(s). If no response (a **“Negotiation Response”**) is received by Jazz Pharmaceuticals [ \* ] after delivery of the Negotiation Notice to UCB, the offer shall be deemed declined, and Jazz Pharmaceuticals may then negotiate with any Third Party for the grant of any license for the Product for such Indication(s) subject, however, to the last sentence of Section 2.3(b). Notwithstanding the foregoing, if UCB does not deliver the Fibromyalgia Notice to Jazz Pharmaceuticals in accordance with this Agreement, the development and commercialization of a product containing the API for the Fibromyalgia Indication by Jazz Pharmaceuticals or a Third Party will not be subject to UCB’s right of first negotiation set forth in this Section 2.3.

(b) Procedure of Negotiations. UCB shall have [ \* ] from the date of its delivery to Jazz Pharmaceuticals of a Negotiation Response to send a non-binding letter of intent or term sheet to Jazz Pharmaceuticals. The parties shall then have [ \* ] from the date that UCB delivers such letter of intent or term sheet to Jazz Pharmaceuticals to negotiate in good faith (and on a confidential basis), and enter into a final agreement with regard to UCB’s distribution of the Product in the Territory for the new Indication(s). In the event that (A) UCB shall have failed to

have responded to the Negotiation Notice [ \* ] provided in Section 2.3(a) above or (B) failed to send a non-binding letter of intent or term sheet [ \* ] set out in this Section 2.3(b) or (C) Jazz Pharmaceuticals and UCB have not entered into a final agreement [ \* ] provided in this Section 2.3, Jazz Pharmaceuticals shall have no further obligation to undertake or continue negotiations with UCB for such license, and Jazz Pharmaceuticals shall be free to commence negotiations for a license to the Product for such Indication(s) with any Third Party subject to the following: (i) if a letter of intent, term sheet or final agreement with a Third Party shall not have been signed by Jazz Pharmaceuticals and such Third Party [ \* ] of the termination of UCB's right of first negotiation, then UCB's right of first negotiation shall again become effective on the terms herein provided and (ii) without UCB's prior written consent, the terms and conditions agreed by Jazz Pharmaceuticals with such Third Party [ \* ].

(c) No Trademark License. If pursuant to this Section 2.3 Jazz Pharmaceuticals licenses to a Third Party the Product in the Territory for one or more Indications other than the Licensed Indications, then such Third Party shall be obligated to market the Product under a trademark different from the Trademarks. Jazz Pharmaceuticals shall not grant, license or otherwise transfer to such Third Party any rights to the Trademarks or otherwise permit any use of the Trademarks by such Third Party for such countries.

2.4 Subdistributors/Sublicensees. UCB may appoint Subdistributors and Sublicensees with the prior written approval of Jazz Pharmaceuticals, which approval shall not be unreasonably withheld. No such appointment or delegation shall relieve UCB from any obligations hereunder, and each agreement with a Subdistributor or Sublicensee shall include terms ensuring the protection of Jazz Pharmaceuticals' rights under this Agreement. UCB shall guarantee and be responsible for the making of all payments due, and the making of reports required under this Agreement by its Subdistributors and Sublicensees, and their compliance with all applicable terms of this Agreement. All agreements between UCB and its Subdistributors and Sublicensees shall include a provision prohibiting the further appointment of Subdistributors or Sublicensees, as the case may be, and a provision terminating the Subdistributor or Sublicensee agreement to the extent such agreement relates to the Product in the Territory upon termination of this Agreement for any reason.

2.5 UCB Sales Outside the Territory; Jazz Sales Inside the Territory. Except as otherwise set forth in this Agreement, UCB shall not distribute, sell or otherwise provide the Product outside of the Territory and shall not solicit customers for the Product outside the Territory or establish any office through which orders are solicited or any depot at which inventories of the Product are stored outside the Territory. UCB shall not sell the Product to customers outside the Territory, provided that nothing herein shall preclude UCB from selling the Product to any customer, wherever located, who purchases Product with a view to its use within any country of the Territory. Except as otherwise set forth in this Agreement, Jazz

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKET BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

Pharmaceuticals shall not sell the Product inside the Territory and shall not directly solicit customers for the Product inside the Territory; provided, however, that nothing herein shall preclude Jazz Pharmaceuticals from selling the Product to any customer, wherever located, who purchases Product with a view to its use within any country outside of the Territory.

2.6 Competitive Product. Jazz Pharmaceuticals acknowledges that (i) UCB has developed and is marketing [ \* ] in certain countries within the Territory for Indications other than the Licensed Indications, but that [ \* ] is occasionally used on an [ \* ] to [ \* ]; (ii) UCB is marketing [ \* ] in the [ \* ] for the Licensed Indications; and (iii) UCB will be marketing [ \* ] in [ \* ] for the Licensed Indications. With the exception of the [ \* ] use of [ \* ] in the Territory, [ \* ] in the [ \* ], and [ \* ] in [ \* ], UCB shall not, for [ \* ] from the Execution Date of this Agreement, either directly or indirectly through subdistributors, sublicensees or otherwise, promote, market or distribute Competitive Products in the Territory; provided, however, nothing herein shall prohibit UCB from acquiring, by stock purchase, asset purchase or merger any company, or division of a company, that is developing, marketing, manufacturing, promoting or distributing a Competitive Product where the annual sales (or in the case of a product in development, the projected sales) of such Competitive Product in the Territory are [ \* ] of such company's or division's [ \* ]. For purposes of this Section 2.6, a "**Competitive Product**" shall be one that is (i) approved for prescription for a Licensed Indication in the Territory and (ii) is directly competitive with the Product as evidenced by [ \* ] of such product's annual sales in the Territory being for such Licensed Indication.

**ARTICLE III  
REGULATORY APPROVALS;  
COMPLIANCE WITH LAWS AND REGULATIONS**

3.1 Regulatory Approvals. For each Licensed Indication, UCB shall use Commercially Reasonable Efforts, at its expense, to seek Registration of the Product for each Licensed Indication in the Territory and UCB shall, in accordance with the terms of the Quality Agreement, maintain, at its own expense, the Registrations and other authorizations necessary to import, label, promote, market, sell and distribute the Product for each such Licensed Indication in the Territory. All applications for Marketing Authorizations for the Product shall be submitted in the name of UCB and all Marketing Authorizations for the Product shall be assigned to Jazz Pharmaceuticals upon termination of this Agreement for any reason. UCB shall ensure that all pages of documents submitted to Regulatory Authorities for the purpose of obtaining Registrations and Marketing Authorizations shall be coded as confidential. Notwithstanding the above, UCB shall have no obligation to use Commercially Reasonable Efforts to seek Registration of the Product for any Licensed Indication in any of the Major European Countries where a Regulatory Authority shall require of UCB any additional data or documentation or an additional action ("**Additional Step(s)**") and where any such Additional Step in a Major European Country would [ \* ] or any series of Additional Steps in any one or more of the Major European Countries would, in aggregate, [ \* ].



3.2 Regulatory Timelines; Regulatory Assistance. Jazz Pharmaceuticals shall promptly provide to UCB, at Jazz Pharmaceuticals' cost and expense, copies of all documentation, Know How and Proprietary Information in its possession, and not previously provided, relating to the Product is necessary for UCB to prepare any relevant regulatory application for the Product in a relevant Licensed Indication in a timely manner as such documentation becomes available. Jazz Pharmaceuticals shall also promptly provide, at its own cost and expense, commercially reasonable assistance to UCB in obtaining and maintaining regulatory approval for the Product in the Territory for each Licensed Indication, including without limitation, the provision of services set forth in Appendix D hereto. Each party shall keep the other party informed of any significant or material issue including contact with Regulatory Authorities, related to their respective regulatory filings, submissions and approvals which might reasonably be expected to affect or impact the other party's regulatory activities in relation to the Product. Where a Regulatory Authority requires additional data or documentation or additional action that is not within Jazz Pharmaceuticals' obligations as set out in this Section 3.2 and that neither party has or could readily produce or which cannot readily be taken by either party, the parties shall negotiate in good faith the terms upon which such data or documentation should be generated or actions taken by either party, if at all.

3.3 Other Approvals. Subject to the provisions of this Agreement and the Quality Agreement, UCB undertakes and covenants that as soon as reasonably practicable following the Execution Date it shall take all other actions to obtain and maintain during the Term all other approvals, licenses and permits necessary to import, promote, market, package, sell and distribute Products in the Licensed Indications within the Territory.

3.4 Product Changes. Jazz Pharmaceuticals shall give UCB prompt written notice of any formulation or material packaging change to the Product submitted by Jazz Pharmaceuticals to the FDA or requested or required by the FDA, or any other U.S. regulatory authority, whenever such change may affect a Registration in any country within the Territory. Jazz Pharmaceuticals may change the Product, or analytical test methods as it deems appropriate, provided Jazz Pharmaceuticals continues to supply Product conforming to the Product Specifications and in accordance with cGMP then in effect (including continuing the use of the existing analytical test methods) until such times as the Marketing Authorizations are amended to reflect such changes. In the event of such changes, UCB shall be solely responsible for additional submissions and/or regulatory updates which may be required by the Regulatory Authorities in the Territory, provided that all necessary data and information in Jazz Pharmaceuticals' possession or control shall be furnished by Jazz Pharmaceuticals at Jazz Pharmaceuticals' expense for such purposes, and provided; further that in no event shall UCB's

failure to obtain any required amendments to the Marketing Authorizations to reflect such additional submissions and/or regulatory updates, relieve Jazz Pharmaceuticals of its obligation to supply Product conforming to the Product Specifications. In the event a Regulatory Authority in any country in the Territory requires a change to the Product Specifications, Jazz Pharmaceuticals and UCB shall cooperate to develop a mutually agreeable plan to address the regulatory requirement in accordance with the change management provisions of the Quality Agreement, as applicable, and, if necessary, to include the production of separate lots, at UCB's expense, for the Territory. In the event Jazz Pharmaceuticals and UCB mutually agree it is not commercially reasonable to meet such requirements, UCB shall cease promoting, marketing, selling and/or distributing the Product in that Licensed Indication in that country in the Territory and shall promptly terminate the Registrations in such country. If the parties are in disagreement as to whether it is commercially reasonable to meet such requirements, then they shall submit the matter to arbitration in accordance with the provisions of Section 15.2 of this Agreement.

3.5 Clinical Trials. The parties shall keep one another fully and currently informed through the Steering Committee as to all tests and trials of the Product that they intend to carry out for purposes of compliance with regulatory requirements or that might affect Marketing Authorization applications or Registrations in the Territory, provided always that if (i) Jazz Pharmaceuticals itself intends to conduct, or intends to have a Third Party conduct on its behalf, a test or trial of the Product in the Territory other than the clinical trials related to obtaining Marketing Authorization for the Product in Fibromyalgia and (ii) UCB reasonably determines that such proposed activity [ \* ], UCB shall be entitled to refer such proposed activity for due consideration by the Steering Committee. The parties shall cooperate in the design of such tests and trials in order to ensure to the maximum possible extent that duplication of effort shall be avoided, and that the results shall be suitable for filing with the Regulatory Authorities in the Territory and shall otherwise be useful for purposes of meeting all applicable regulatory requirements. Without limiting the generality of the foregoing, each party shall use its Commercially Reasonable Efforts to ensure that all clinical trials sponsored by that party which is undertaken for the Product after the Execution Date, if any, shall be designed and conducted in accordance with good clinical practices and good laboratory practices as established for both the United States and the European Union.

3.6 Compliance With Applicable Laws. UCB shall comply with all applicable laws and regulations of each country in the Territory (including, without limitation, any laws or regulations in the Territory governing the distribution of a scheduled drug, as designated under regulations promulgated by the DEA). UCB shall also comply with the U.S. Export Administration Regulations, the US Foreign Corrupt Practices Act and all regulations promulgated by the DEA, in each case, as applicable to the Registration, promotion, marketing, sale and distribution of the Product in the Territory. UCB shall comply with all Marketing Authorizations issued in the Territory and Jazz Pharmaceuticals shall comply with all regulatory

approvals issued in respect of the Product outside the Territory and/or for Indications other than Licensed Indications where, in the case of Jazz Pharmaceuticals, non-compliance could have a material adverse impact on the Product in the Territory.

3.7 Approved Product Packaging and Labeling; Relevant Testing. After Product in a particular Licensed Indication receives a Marketing Authorization in any country of the Territory, UCB shall, at its own expense, package and label such Product and shall include all required labeling for such Product sold in such country(ies). For all orders submitted by UCB after Registration is received in a particular country, Jazz Pharmaceuticals shall supply to UCB in bulk (manufactured in accordance with the cGMP requirements as set out in the Quality Agreement), and final labeling and packaging of Product for such country(ies) shall be completed by UCB. After Product receives Marketing Authorization in a country in the Territory for a particular Licensed Indication, UCB shall be solely responsible for all final release testing in such country(ies) and for ensuring in such country(ies) that the Product labeling and packaging complies with the relevant Marketing Authorizations and all other applicable laws of each such country in the Territory. UCB shall provide Jazz Pharmaceuticals with approved copies of all foreign language labels. To the extent permitted by applicable laws and regulations in each country in the Territory, where that Product has been manufactured by Jazz Pharmaceuticals all labels shall identify Jazz Pharmaceuticals as the manufacturer of the Product for UCB.

3.8 Steering Committee. Under the Prior Agreement, the parties have formed a Steering Committee made up of commercial and technical employees from both companies that has certain decision-making authority, and provide oversight for the administration of this Agreement. Each party shall maintain two (2) members on the Steering Committee with other members added as needed. The parties shall each select one of its representatives to serve as a co-chairperson of the Steering Committee. The Steering Committee shall have the authority to conduct the following activities and such other activities as may be agreed to in writing by the parties: (a) review ongoing regulatory issues, (b) review the medical aspects of standards of care in the Territory, (c) review clinical developments across territories to the extent permitted by Jazz Pharmaceuticals' agreements with Third Parties, (d) review marketing campaigns and new marketing plans, (e) review sales activities and results, (f) review aspects of Product manufacturing campaigns and Product forecasts, inventory stocks and ordering, and (g) establish a manufacturing sub-committee which shall review matters relating to the manufacture of Product. In the event and to the extent that the Steering Committee is unable to come to a consensus on any matter relating to the development (except to the extent that such development involves clinical trials that would occur solely in the Territory) or manufacture of the Product, Registration (including pre-Registration activities), packaging, labeling, promoting, marketing, sale or distribution of the Product outside the Territory, the views of the Jazz Pharmaceuticals Steering Committee members shall prevail. In the event and to the extent that the Steering

Committee is unable to come to a consensus on any matter relating to clinical trial activity that would occur solely in the Territory, Registration (including pre-Registration activities), packaging, labeling, promoting, marketing, sale or distribution of the Product within the Territory, and, if UCB has exercised its manufacturing option under Section 2.2, on any matter relating to the manufacture of the Product for sale within the Territory, the views of the UCB Steering Committee members shall prevail. Notwithstanding the foregoing, in the event a particular matter for which there is no consensus of the Steering Committee could, in the good faith judgment of the party who does not have the ultimate decision making authority as to such matter (as provided in the previous two sentences), materially affect the rights or obligations under this Agreement of such party, Jazz Pharmaceuticals and UCB shall attempt to resolve the matter in a manner which will minimize the impact on such rights or obligations of such party, but in default of agreement may be referred by either party to arbitration under Section 15.2. During each Contract Year, the parties shall hold at least four (4) regular meetings of the Steering Committee. Members of the Steering Committee may participate in meetings of the Steering Committee in person or by conference telephone call. At least one (1) of the four (4) Steering Committee meetings shall be conducted in-person. Employees of each party who are not members of the Steering Committee may attend meetings of the Steering Committee as required. In-person Steering Committee meetings shall alternate between Jazz Pharmaceuticals' designated facility and a facility designated by UCB. The co-chairpersons of the Steering Committee shall alternate responsibility for the preparation of minutes setting forth discussions made at each committee meeting, with the Jazz Pharmaceuticals Chairperson preparing minutes for the first Steering Committee meeting; provided, however, that such minutes shall not become official until agreed upon by both co-chairpersons.

**ARTICLE IV  
ROYALTIES AND MILESTONE PAYMENTS**

4.1 Milestone Payments. In consideration of the rights and licenses granted hereunder, UCB has either already paid or shall pay to Jazz Pharmaceuticals non-refundable milestone payments according to the following schedule:

- (a) \$[ \* ] Dollars on the Effective Date (receipt of which is acknowledged by Jazz Pharmaceuticals).
- (b) \$5,000,000 Dollars within five (5) days of the Execution Date.
- (c) \$[ \* ] Dollars upon filing of [ \* ] application with [ \* ] (receipt of which is acknowledged by Jazz Pharmaceuticals).

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKET BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

(d) \$2,500,000 Dollars upon approval by the EMEA to commercially promote and distribute the Product for the cataplexy Licensed Indication (receipt of which is acknowledged by Jazz Pharmaceuticals).

(e) \$500,000 Dollars upon pricing approval for the cataplexy Licensed Indication in France provided the price approved [ \* ] is [ \* ] bottle.

(f) \$[ \* ] Dollars upon delivery to UCB by Jazz Pharmaceuticals of [ \* ] package for the excessive daytime sleepiness Licensed Indication (receipt of which is acknowledged by Jazz Pharmaceuticals).

(g) \$[ \* ] Dollars upon approval by [ \* ] to commercially promote and distribute the Product for the excessive daytime sleepiness Licensed Indication.

(h) \$10,000,000 Dollars upon delivery of the Fibromyalgia Notice to Jazz Pharmaceuticals by UCB.

(i) \$[ \* ] Dollars upon Jazz Pharmaceuticals' written notice to UCB of the [ \* ] in the first [ \* ] by or on behalf of Jazz Pharmaceuticals.

(j) \$[ \* ] Dollars upon Jazz Pharmaceuticals' written notice to UCB of the [ \* ] in the second [ \* ] by or on behalf of Jazz Pharmaceuticals.

(k) A one-time only payment of either (i) \$[ \* ] Dollars upon approval by [ \* ] (which would include a [ \* ]) of the Product for the Fibromyalgia Licensed Indication where such approval has achieved the Minimum Label Requirement or (ii) \$[ \* ] Dollars upon the [ \* ] Product for the Fibromyalgia Licensed Indication in a [ \* ] where such approval has not achieved the Minimum Label Requirement, whichever such milestone is achieved first.

(l) A one-time only payment of \$[ \* ] Dollars in the [ \* ] in which UCB's and its Subdistributors [ \* ] Products covered by a Narcolepsy Trademark in the Territory [ \* ].

(m) A one-time only payment of \$[ \* ] Dollars in the [ \* ] in which UCB's and its Subdistributors [ \* ] Products covered by a Narcolepsy Trademark in the Territory [ \* ].

(n) A one-time only payment of \$[ \* ] Dollars in the [ \* ] in which UCB's and its Subdistributors [ \* ] Products covered by a Narcolepsy Trademark in the Territory [ \* ].

(o) A one-time only payment of \$[ \* ] Dollars when UCB and its Subdistributors' [ \* ] Products covered by an Other Licensed Trademark in the Territory [ \* ] in [ \* ] irrespective of whether [ \* ] reach that level in any subsequent period.

(p) A one-time only payment of \$[\*] Dollars when UCB and its Subdistributors' [\*] Products covered by an Other Licensed Trademark in the Territory [\*] in [\*] irrespective of whether [\*] reach that level in any subsequent period.

(q) A one-time only payment of \$[\*] Dollars when UCB and its Subdistributors' [\*] Products covered by an Other Licensed Trademark in the Territory [\*] in [\*] irrespective of whether [\*] reach that level in any subsequent period.

(r) A one-time only payment of \$[\*] Dollars when UCB and its Subdistributors' [\*] Products covered by an Other Licensed Trademark in the Territory [\*] in [\*] irrespective of whether [\*] reach that level in any subsequent period.

4.2 Notwithstanding the milestone payments set out in Section 4.1 above, in the event that (i) the Product is sold for the Fibromyalgia Licensed Indication by UCB using the same Trademark for the Product as for the Narcolepsy Licensed Indication in the Territory or (ii) there is sales leakage in the Territory between the Products covered by a Narcolepsy Trademark and the Products covered by an Other Trademark such that a Product is sold for a Licensed Indication not approved by the applicable Regulatory Authorities, the milestone payments set forth below in Sections 4.2 (a)—(g) shall be payable in place of the milestone payments set out in Sections 4.1 (l)—(r) to the extent that and only insofar as the milestone payments set out in Sections 4.1 (l)—(r) have not previously been paid by UCB to Jazz Pharmaceuticals;

(a) A one-time only payment of \$[\*] Dollars in the [\*] in which UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] irrespective of whether [\*] in any subsequent period.

(b) A one-time only payment of \$[\*] Dollars in the [\*] in which UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] irrespective of whether [\*] in any subsequent period.

(c) A one-time only payment of \$[\*] Dollars in the [\*] in which UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] irrespective of whether [\*] in any subsequent period.

(d) A one-time only payment of \$[\*] Dollars when UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] in [\*] irrespective of whether [\*] in any subsequent period.

(e) A one-time only payment of \$[\*] Dollars when UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] in [\*] irrespective of whether [\*] in any subsequent period.

(f) A one-time only payment of \$[\*] Dollars when UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] in [\*] irrespective of whether [\*] in any subsequent period.

(g) A one-time only payment of \$[\*] Dollars when UCB's and its Subdistributors' [\*] the Product(s) in the Territory [\*] in [\*] irrespective of whether [\*] in any subsequent period.

#### 4.3 Royalty.

(a) In consideration of the licenses granted by Jazz Pharmaceuticals hereunder, UCB shall pay Jazz Pharmaceuticals quarterly royalties as follows:

(i) on each Product [\*] in the Territory, [\*]% of Net Sales of that Product by UCB and its Subdistributors in the Territory; and

(ii) on each Product [\*] in the Territory:

(A) [\*]% of Net Sales of such Products less than \$[\*] Dollars by UCB and its Subdistributors in the Territory in each Contract Year;

(B) [\*]% of Net Sales of such Products between \$[\*] Dollars and \$[\*] Dollars by UCB and its Subdistributors in the Territory in each Contract Year; and

(C) [\*]% of Net Sales of such Products equal to or greater than \$[\*] Dollars by UCB and its Subdistributors in the Territory in each Contract Year.

(b) Notwithstanding the milestone payments set out in Section 4.3(a) above, in the event that (i) the Product is sold for the Fibromyalgia Licensed Indication by UCB using the same Trademark for the Product as for the Narcolepsy Licensed Indication in the Territory or (ii) there is sales leakage in the Territory between the Products covered by a Narcolepsy Trademark and the Products covered by an Other Licensed Trademark such that a Product is sold for a Licensed Indication not approved by the applicable Regulatory Authorities, UCB shall pay Jazz Pharmaceuticals the following quarterly royalties, in place of the quarterly royalties set out in Section 4.3(a), beginning with the quarter in which such First Commercial Sale of Product for the Fibromyalgia Indication occurs:

(i) [\*]% of Net Sales of the Product(s) less than \$[\*] Dollars by UCB and its Subdistributors in the Territory in each Contract Year;

(ii) [ \* ]% of Net Sales of the Product(s) between \$[ \* ] Dollars and \$[ \* ] by UCB and its Subdistributors in the Territory in each Contract Year; and

(iii) [ \* ]% of Net Sales of the Product(s) equal to or greater than \$[ \* ] Dollars by UCB and its Subdistributors in the Territory in each Contract Year.

(c) The royalty rates set forth above shall be reduced [ \* ]% as of the date when UCB ceases to have the exclusive right in [ \* ], enforceable against Third Parties, to promote, market and sell the Product in at least one Licensed Indication because of the expiration or termination in the Territory of Patent Rights and/or regulatory exclusivity based on that Product's Orphan Drug Designation in the Territory. The royalty rate shall be further reduced [ \* ]% for a Product covered by a Trademark on a country-by-country basis, following the first calendar quarter in which the commercial sale in such country of [ \* ], approved for a Licensed Indication by the applicable Regulatory Authorities, occurs in such country in the Territory.

(d) If (i) Jazz Pharmaceuticals licenses a product containing the API in the Territory to a Third Party for one or more Indications other than the Licensed Indications pursuant to Section 2.3(b), and (ii) such product containing the API licensed in the Territory to such Third Party by Jazz Pharmaceuticals is being used [ \* ] and [ \* ] percent ([ \* ]%) of UCB's sales of the Product in a country in the Territory, and (iii) UCB can demonstrate that [ \* ] result in a [ \* ] in such countries in the Territory and/or a [ \* ] in any countries in the Territory, then [ \* ], the royalty rate in such affected countries in the Territory for the Product covered by such Licensed Indication shall be [ \* ] percent ([ \* ]%), in such affected countries, to appropriately compensate UCB for such [ \* ]. As part of its demonstration of such [ \* ], UCB shall obtain at its expense, and furnish to Jazz Pharmaceuticals, a report compiled by a recognized market research company having substantial expertise in the pharmaceutical industry, which sets forth both the [ \* ] or sets forth other relevant information demonstrating that [ \* ].

4.4 Minimum Royalty Requirement. Commencing with the Contract Year beginning [ \* ] if the royalties payable pursuant to Section 4.3 shall be less than the amounts set forth in this Section 4.4, then UCB shall pay such additional royalty amounts to Jazz Pharmaceuticals so that Jazz Pharmaceuticals shall have received aggregate royalty payments with respect to Net Sales of the Products in the Territory equal to the following minimum amounts (reducing the minimum for the Contract Year beginning [ \* ] proportionally for the days therein prior to the date of the First Commercial Sale); provided, however that the following minimum royalty amounts shall be adjusted by written agreement of the parties after the Effective Date as appropriate to take into account any royalty rate reductions determined in accordance with Section 4.3(c) and (d):

Minimum Royalty Payment (US\$)			
Year	[ * ]% or more	[ * ]%	[ * ]%
[ * ]	[ * ]	[ * ]	[ * ]

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKET BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.



4.5 Royalty and Milestone Payments. Unless otherwise agreed by Jazz Pharmaceuticals in writing, all milestone payments set forth in Sections 4.1 and 4.2 shall be payable within thirty (30) days after achievement of the relevant milestone, except for the milestone payments due on the Effective Date and the Execution Date under Sections 4.1(a) and 4.1(b), which shall be due and payable by UCB no later than ten (10) days after the Effective Date or Execution Date, as applicable. Royalty payments shall be paid within forty-five (45) days from the end of each calendar quarter and any additional royalty amounts payable as stated in Section 4.4 shall be paid within forty-five (45) days of the end of each Contract Year. All payments shall be made in United States Dollars by wire transfer to a USA bank designated by Jazz Pharmaceuticals. Any overdue payment from UCB to Jazz Pharmaceuticals under this Agreement shall accrue interest at [ \* ].

4.6 Exchange Rates. For purposes of determining the amount of Net Sales and the amount of royalties payable pursuant to Section 4.3 during any calendar quarter, the total of all sales in each currency during such quarter shall be converted into Euros or US Dollars, as applicable, at the average daily exchange rate for such calendar quarter as reported by Bloomberg. For purposes of determining the minimum royalty amount for each Contract Year as provided in Section 4.4, the amounts set forth therein shall be converted into US dollar currency at the average daily exchange rate for such Contract Year as reported Bloomberg.

4.7 Taxes. UCB shall be entitled to deduct from royalties paid hereunder the amount of any withholding taxes or other taxes, levies or charges required to be withheld by UCB, to the extent UCB pays to the appropriate governmental authority on behalf, and for the account of, Jazz Pharmaceuticals such taxes, levies or charges. UCB shall use reasonable efforts (including making, or assisting Jazz Pharmaceuticals in making, any relevant application to any tax authority) to minimize any such taxes, levies or charges which are required to be withheld by UCB from royalties paid hereunder and paid on behalf of Jazz Pharmaceuticals by UCB. UCB shall promptly deliver to Jazz Pharmaceuticals proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

4.8 Reports. Each royalty payment made by UCB hereunder shall be accompanied by a report showing all revenue generated by sales of the Product to Third Parties (including all sales by Subdistributors and Sublicensees) during the immediately preceding quarter, the computation of Net Sales, and the calculation of royalty payments due for such quarter, including

all exchange rate conversions related thereto and all on a country-by-country basis. If actual Net Sales of any Subdistributor or Sublicensee for that quarter is unavailable at the time such quarterly report is due, UCB shall include in its report for that quarter a good faith estimate of such Net Sales, and an appropriate adjustment for the difference between the actual and estimated Net Sales shall be made in the report for the following quarter, with a corresponding adjustment in the amount of royalties payable in respect of that quarter.

4.9 Books and Records; Audit. UCB shall keep for at least three (3) years or such longer period as may be required by law following the end of the calendar year to which they pertain, accurate and complete records showing all sales of the Product by UCB and its Subdistributors and Sublicensees. Such records shall include all information reasonably necessary to verify the total amount and computation of earned royalties and milestones hereunder, and shall be open to inspection and audit, during reasonable business hours, to the extent necessary to verify the amount of such royalties. Such inspection and audit shall be conducted at the request and expense of Jazz Pharmaceuticals by an independent Certified Public Accountant appointed by Jazz Pharmaceuticals. Such inspection and audit shall be made not more often than [ \* ]. Such Certified Public Accountant shall undertake a confidentiality obligation to UCB permitting it to disclose only to Jazz Pharmaceuticals the amount of the payments due hereunder, and no other information. Jazz Pharmaceuticals shall bear the costs of any such inspection and audit; provided that if any inspection and audit reveals an underpayment of more than [ \* ] percent ([ \* ]%), UCB shall reimburse Jazz Pharmaceuticals for its reasonable, documented out-of-pocket costs for such inspection and audit.

## ARTICLE V REGULATORY COMPLIANCE; PRODUCT MANUFACTURE

5.1 Regulatory Reporting. UCB shall timely file all reports relating to the Product required by the Regulatory Authorities in each country in the Territory and shall deliver a copy of each such report in hardcopy and on diskette, or electronically, to Jazz Pharmaceuticals within thirty (30) calendar days of making such report in accordance with laws in the Territory regarding transfer of data and confidentiality of patient information.

5.2 Product Recalls. (a) Each party shall promptly notify the other party in the event of any recall, market withdrawal or correction of Product ordered by any regulatory authority, whether in the Territory, the United States, or anywhere in the world. The parties shall cooperate in good faith in relation to the handling and disposal of a recall, market withdrawal or correction in the Territory. The costs of any such recall, market withdrawal or correction shall be borne by the parties in accordance with Sections 5.2 (b) and (c) below.

(b) Subject to Section 5.2(c) below, in the event of a recall, market withdrawal or correction (i) by reason of the failure of all or part of the Product supplied by Jazz

Pharmaceuticals to meet the Product Specifications, any requirement of the FDA or any Marketing Authorization or other requirement of applicable law that is not the result of any action or omission of UCB or its Subdistributors or Sublicensees as described in paragraph (c) below or (ii) because Product that meets the Product Specifications, supplied by Jazz Pharmaceuticals, is inherently defective, unsafe, dangerous or may harm users of the Product, Jazz Pharmaceuticals shall bear the costs of such recall, market withdrawal or correction (including without limitation UCB's reasonable attorneys' fees).

(c) In the event of a recall, market withdrawal or correction by reason of the failure of UCB to have obtained or properly maintained or complied with a Marketing Authorization or as a result of UCB's (or its Subdistributors', Sublicensees' or Third Party manufacturers') breach of any of their obligations under this Agreement (including without limitation Section 3.7), or the willful misconduct or negligent acts or omissions of UCB (or its Subdistributors, Sublicensees' or Third Party manufacturers'), UCB shall bear all costs of such recall, market withdrawal, or correction (including without limitation Jazz Pharmaceuticals' reasonable attorneys' fees).

5.3 Adverse Event Notifications and Reporting. The exchange of Adverse Event reports relating to the Product between the parties shall be made according to the procedures set forth in the Pharmacovigilance Agreement.

5.4 Correspondence/Complaints. (a) Each party shall promptly provide to the other party copies of any material regulatory correspondence with respect to the Product and all related documentation, information and other materials received or prepared by each party, including, in the case of UCB, copies of the proposed applications for Marketing Authorization prepared by or on behalf of UCB for Registration of Products in the Territory and any subsequent amendments, supplements, or annual updates thereto.

(b) Each party agrees to inform the other in writing of all significant complaints regarding the Product received by that party which relate to Product Specifications within fifteen (15) business days after that party's receipt thereof in all countries of the Territory. Each party shall also provide written quarterly reports of all material complaints received by it regarding the Product, regardless of significance, in English, as well as the actions taken by it to address all such complaints. Such reports shall be delivered to the other party within thirty (30) days after the end of each calendar quarter during the Term.

5.5 Translations. UCB shall provide Jazz Pharmaceuticals English translations of any material regulatory correspondence received in a language other than the English language relating to a Serious Adverse Event (as defined in the Pharmacovigilance Agreement). Furthermore, each party shall provide to the other party copies of translations of any other regulatory correspondence and reports delivered pursuant to Sections 5.1, 5.3, 5.4 or the Quality Agreement to the extent the providing party has otherwise translated such correspondence and reports for its own purposes.

5.6 Manufacture; Quality. Subject to Article VII, Jazz Pharmaceuticals agrees to manufacture UCB's requirements for Product as necessary to satisfy UCB's forecasts and purchase orders submitted by UCB pursuant to this Agreement. Products delivered to UCB pursuant to this Agreement shall be manufactured in accordance with this Agreement and the Quality Agreement.

5.7 Product Specifications. Product supplied to UCB by Jazz Pharmaceuticals shall meet the Product Specifications and shall be produced in compliance with the terms of the Quality Agreement, as applicable, provided, however, in the event that a Regulatory Authority in the Territory requires a change to the Product Specifications in effect on the Execution Date, the cost of such changes shall be borne by UCB.

5.8 Manufacturing Audits by UCB. Upon forty-five (45) days prior written notice, unless earlier if agreed to by the parties, for cause, or with one hundred twenty (120) days written notice, unless earlier if agreed to by the parties, for an annual audit, UCB or a representative thereof shall have the right, if it is within Jazz Pharmaceuticals' power to grant such right, to participate in the conduct of compliance or other inspections, audits and/or investigations of the operations and facilities where the Product and the raw materials and components used to manufacture, package, inspect, test, store and supply the Product, including, without limitation, the API and the Components, are manufactured, packaged, inspected, tested and stored. Notwithstanding the above, Jazz Pharmaceuticals shall use commercially reasonable efforts to obtain the right for UCB to participate in the conduct of such inspections, audits and/or investigations. Such inspections, audits and/or investigations shall be carried out in accordance with the procedures set out in the Quality Agreement and shall take place during normal business hours at the relevant manufacturing site(s) in the presence of UCB and Jazz Pharmaceuticals' representatives. UCB shall abide by any reasonable confidentiality requirements or security procedures of Jazz Pharmaceuticals' suppliers. Jazz Pharmaceuticals shall facilitate and lead the audit (and shall use its commercially reasonable efforts to ensure that its sub-contractors and suppliers facilitate such an audit), and it shall be Jazz Pharmaceuticals' responsibility to discuss any audit findings with its sub-contractors and suppliers. UCB and Jazz Pharmaceuticals along with any other licensing partner will agree upon a final single audit report that will be sent to the vendor by Jazz Pharmaceuticals. In the event of any disagreement among the parties relating to the audit report, Jazz Pharmaceuticals shall be the deciding entity and will finalize the audit report. Jazz Pharmaceuticals shall use its commercially reasonable efforts to require its sub-contractors and suppliers to take all reasonably necessary corrective actions identified by UCB as necessary to comply with cGMP requirements and Registrations in the Territory. [ \* ] Jazz Pharmaceuticals is generally allowed [ \* ] each year of each vendor. If additional costs are imposed due to accompaniment of UCB with Jazz Pharmaceuticals during an annual audit, UCB shall bear the burden of any reasonable additional costs.

**ARTICLE VI  
MARKETING EFFORTS**

6.1 Marketing Efforts. UCB shall have, directly or through its Subdistributors or Sublicensees, the following obligations with respect to the marketing and distribution of the Product in the Territory:

(a) To use its Commercially Reasonable Efforts to promote, market, sell and distribute Products for the Licensed Indications in the countries in the Territory where Registrations are in good standing; provided, however, that UCB shall not be required to market a Product in any country in the Territory where [ \* ] and the [ \* ];

(b) To promptly respond to all inquiries or complaints from purchasers of the Product;

(c) To maintain adequate and qualified staff to enable it to fully perform its obligations hereunder;

(d) To provide adequate and appropriate training to its staff concerning the Product; and

(e) To conduct its business in a professional manner.

6.2 Approved Product Claims. UCB shall not make and shall cause its Subdistributors and Sublicensees to not make claims to any Third Party concerning the Product except as contained in or permitted by the relevant Marketing Authorization or as approved in the Territory by the appropriate Regulatory Authority.

6.3 Development of Marketing Strategy. UCB agrees to cooperate in the development of a consistent message strategy to promote the Product in an effort to protect and strengthen branding. The global positioning of the Product for the U.S. and the Territory should be discussed before UCB launches the Product in a country in the Territory and at least once per year (or more frequently if reasonably requested by Jazz Pharmaceuticals) to ensure a message which is consistent with the local Marketing Authorizations and local treatment guidelines in such country, and, where possible, consistent with the international message. UCB and Jazz Pharmaceuticals agree to work in good faith to develop such a strategy.

6.4 Marketing Materials. UCB agrees to provide Jazz Pharmaceuticals with copies of all significant marketing and promotional materials within thirty (30) days of first use. UCB shall be solely responsible for the text, graphics, and compliance of such materials with the laws and regulations of the Territory, but may rely (without further investigation) on all Product information provided by Jazz Pharmaceuticals, except that UCB may not rely on such information to the extent UCB knows or reasonably should know that such information is inaccurate.

6.5 Sales and Technical Literature Developed by Jazz Pharmaceuticals. From time to time during the Term, Jazz Pharmaceuticals shall provide to UCB samples of such training, sales and technical literature and materials relating to the Product as Jazz Pharmaceuticals may have prepared, including, without limitation, the materials set forth on Appendix D hereto, and shall make available copies of promotional artwork it may have. The cost of printing quantities or customizing materials shall be borne by UCB. Jazz Pharmaceuticals shall provide the same to UCB in electronic format. Jazz Pharmaceuticals shall also provide UCB with copies of all post-marketing studies and updates to its regulatory filings that it provides to the FDA. UCB shall use such materials solely as provided under this Agreement. Jazz Pharmaceuticals retains all right, title and interest in and to such materials subject, however, to the terms of this Agreement.

6.6 Marketing Reports. By 31 March of each Contract Year, UCB shall provide Jazz Pharmaceuticals with a written report summarizing its sales and marketing activities across the Territory for the immediately preceding Contract Year, and sales and marketing plans for the Territory, including sales estimates, for the current Contract Year.

6.7 Cooperation. Jazz Pharmaceuticals and UCB agree to maintain open communications relating to the ongoing performance of this Agreement to ensure joint understanding of current or new issues, data, and information. Jazz Pharmaceuticals shall answer reasonable technical or marketing questions UCB may submit to Jazz Pharmaceuticals. UCB acknowledges that Jazz Pharmaceuticals does not have international marketing and regulatory staff for preparation of regulatory submissions and marketing plans. Jazz Pharmaceuticals and UCB agree to provide each other copies of market research study protocols and subsequent results therefrom, which studies are designed to generate qualitative and/or quantitative data pertaining to the Product, subject to any Third Party rights therein.

6.8 Named Patient Basis Sales. UCB will be responsible for Named Patient Basis distribution of the Product in the Territory; provided, however, that if Jazz Pharmaceuticals licenses the Product to a Third Party in the Territory for any indication other than the Licensed Indications (each, an “**Additional Indication**”), UCB will, upon Jazz Pharmaceuticals’ written request, cease all Named Patient Basis distribution activities in the Territory with respect to the Product for such Additional Indication(s). The sale of the Product on a Named Patient Basis by UCB will be subject to all of the terms and conditions of this Agreement and all such sales shall

be included in calculating the Net Sales of the Product and the payments payable to Jazz Pharmaceuticals by UCB pursuant to this Agreement. The parties acknowledge that nothing set forth in this Section 6.8 is intended to give UCB rights to the Product for any countries or Indications in addition to, or broader than, those granted pursuant to this Agreement.

## ARTICLE VII PURCHASE AND DELIVERY OF PRODUCT

7.1 Forecasts. UCB will provide Jazz Pharmaceuticals with rolling [ \* ] calendar quarter forecasts (“**Commercial Forecasts**”) of its anticipated requirements of Product to assist Jazz Pharmaceuticals to adequately plan for and meet UCB’s requirements for each country in the Territory. Each Commercial Forecast after the first (i) shall cover the [ \* ] calendar quarters commencing with the second calendar quarter of the preceding Commercial Forecast (ii) shall be delivered to Jazz Pharmaceuticals at least [ \* ] days prior to the first day of such [ \* ] calendar quarter period and (iii) without Jazz Pharmaceuticals’ written consent may not forecast an aggregate quantity of Products that is more than [ \* ] the aggregate quarterly forecast in the preceding Commercial Forecast. The quantities of Product for the first two calendar quarters of each Commercial Forecast shall be firm and UCB shall be obligated to submit purchase orders in respect thereof (“**Firm Orders**”). The quantities of Product for the remaining [ \* ] calendar quarters in each Commercial Forecast shall be non-binding estimates based on UCB’s reasonable business judgment.

7.2 Pricing. Subject to Sections 2.1(b) and 2.1(d) hereto, during the Term of this Agreement, UCB shall purchase from Jazz Pharmaceuticals all of its requirements of the Product in the Territory for the Transfer Price, plus any applicable customs duties or VAT.

7.3 Shipments. Shipments of Product shall be made ex-works (“**EXW**”) (as such term is defined in INCOTERMS 2000) Jazz Pharmaceuticals’ designated supplier unless otherwise mutually agreed to in writing by the parties. Risk of loss or of damage to Product shall remain with Jazz Pharmaceuticals until Product is loaded onto the carrier’s vehicle by Jazz Pharmaceuticals’ designated supplier for shipment at the shipping point at which time risk of loss or damage shall transfer to the UCB. Jazz Pharmaceuticals shall, in accordance with the UCB’s instructions and as agent for UCB, (i) arrange for shipping to be paid by UCB and (ii) at UCB’s risk and reasonable expense, obtain any export license or other official authorization necessary to export the Product from the United States once UCB has provided the appropriate import documentation. UCB shall arrange for insurance and shall select the freight carrier used by Jazz Pharmaceuticals to ship Product and may monitor Jazz Pharmaceuticals’ shipping and freight practices as they pertain to this Agreement. Jazz Pharmaceuticals shall deliver the Products no later than [ \* ] business days after the date(s) indicated in the applicable purchase order and no earlier than [ \* ] business days prior to such specified date(s). Jazz Pharmaceuticals shall provide prompt written notice to UCB in the event of any anticipated delays in the scheduled

delivery date and shall cooperate with UCB to reschedule delivery at the earliest possible date so as to minimize the impact on UCB, provided, however, the foregoing shall in no way modify or mitigate Jazz Pharmaceuticals' obligation to supply Product properly ordered in accordance with this Agreement or UCB's rights and remedies under this Agreement in respect of any failure to timely supply, including UCB's right to assert its remedies in respect of a breach hereof and UCB's rights to appoint a Third Party manufacturer in accordance with Section 2.1(b) or to terminate this Agreement in accordance with Section 14.2(b). Jazz Pharmaceuticals shall send UCB on the date of shipment an invoice and shipping notice, in a format to be agreed upon by the parties. All Products shall be properly packaged and shipped in accordance with the Product Specifications and instructions included in the applicable purchase order.

#### 7.4 Purchase Orders.

(a) Content. All purchase orders placed by UCB shall be in writing and shall state the quantity of Product, the delivery date, shipping information and such other similar information as may be reasonably requested by Jazz Pharmaceuticals.

(b) Lead Time. Unless otherwise agreed by Jazz Pharmaceuticals, all purchase orders must be delivered to Jazz Pharmaceuticals at least [ \* ] in advance of the requested delivery date(s).

(c) Number of Orders. UCB may submit [ \* ] per quarter for Product to be filled by Jazz Pharmaceuticals.

(d) Maximum Quantities. Jazz Pharmaceuticals may in its sole discretion reject Firm Orders that specify a quantity of Product in respect of a particular calendar quarter in excess of [ \* ]% of the most recent non-binding Commercial Forecast for such quarter; provided, however, that the maximum quantities that Jazz Pharmaceuticals shall be required to deliver in a particular calendar quarter shall be reduced by the quantity of Product Jazz Pharmaceuticals shall have delivered in the preceding calendar quarter pursuant to paragraph (e) below in excess of the maximum quantities it was required to provide in such preceding calendar quarter as determined pursuant to this paragraph (d).

(e) Miscellaneous. Jazz Pharmaceuticals shall use its Commercially Reasonable Efforts to fill purchase orders that exceed the quantity limits provided in paragraph (d) above or that are delivered to Jazz Pharmaceuticals [ \* ] days in advance of the requested delivery date(s) as required by paragraph (b) above in respect of purchase orders to be filled by Jazz Pharmaceuticals. No accepted purchase order may be modified or canceled by either party except as agreed in writing by the parties. UCB's orders (including mutually agreed change orders) shall be subject to the provisions of this Agreement, and any terms or conditions contained therein that conflict with the terms of this Agreement are excluded.



7.5 Transfer Price Variations. At least thirty (30) days prior to the end of each Contract Year or sooner if available, Jazz Pharmaceuticals shall notify UCB of the Transfer Price for the Product for the next Contract Year. Jazz Pharmaceuticals shall reserve the right to increase transfer pricing for any increases in the costs identified in Appendix C imposed on Jazz Pharmaceuticals by its suppliers. Jazz Pharmaceuticals shall reduce transfer pricing for any decreases in the costs referenced in the preceding sentence and for any other reductions in the components of Jazz Pharmaceuticals' standard manufacturing costs as listed on Appendix C (including any reductions that may result from decreases in the required fill volume resulting from improvements in the PIBA). Each such notice shall include all necessary documentation reasonably required for UCB to verify the adjusted Transfer Price; provided, however that notwithstanding Jazz Pharmaceuticals' delivery of such documentation, UCB shall be permitted to conduct inspections and audits during reasonable business hours, to the extent necessary to verify the Transfer Price and adjustments thereto. Such inspections and audits shall be conducted at the request (not to be made more than [ \* ]) and expense of UCB by an independent Certified Public Accountant appointed by UCB. Such Certified Public Accountant shall undertake a confidentiality obligation to Jazz Pharmaceuticals permitting it to disclose only to UCB the amount of the Transfer Price and adjustments and the information required to verify such Transfer Price and adjustments, and no other information.

7.6 Payment Terms.

(a) General. Unless otherwise agreed by Jazz Pharmaceuticals in writing, payments for the Product shall be paid net on the last day of the first full calendar month following the date of the invoice therefore, provided that no invoice shall be dated prior to the date of actual shipment of the Product covered by the invoice. All payments shall be made in United States Dollars by wire transfer to a U.S. bank designated by Jazz Pharmaceuticals at least five (5) days prior to the date of payment. Any overdue payment from UCB to Jazz Pharmaceuticals under this Agreement shall accrue interest at [ \* ] from time to time in force. Jazz Pharmaceuticals shall have the right to recover its reasonable collection costs and expenses (including attorneys' fees) for late payments. Notwithstanding the above, in the event UCB disputes the amount, or any portion thereof, of any invoice submitted to it by Jazz Pharmaceuticals, UCB shall promptly notify Jazz Pharmaceuticals of the amount and nature of the disagreement. Before relying on the provisions of Section 15.2 hereof, the parties first shall promptly attempt to resolve such disagreement in good faith in a manner provided in Section 7.6(b) and UCB shall make payments with respect to disputed invoices as provided in such Section.

(b) Order and Invoice Non-Conformance.

(i) In the event UCB disputes whether Product supplied by Jazz Pharmaceuticals conforms to an order placed for such Product pursuant to Section

7.4 with respect to quantity, UCB shall provide notice to Jazz Pharmaceuticals in accordance with the provisions relating to apparent non-conformities of Product set forth in Section 7.12. In the case of any such non-conformity which results from delivery of less Product than ordered, Jazz Pharmaceuticals shall supply additional Product promptly. In such case, UCB shall pay for the quantity actually received in accordance with the provisions of Section 7.6(a). In the case of any such non-conformity which results from delivery of more Product than ordered, UCB may in its sole discretion accept any Product in excess of the quantity ordered as against future orders of Product. In such latter case, UCB shall pay for the quantity actually received and accepted in accordance with the provisions of Section 7.6(a) unless otherwise agreed.

(ii) In the event that UCB disputes any invoice due to the price at which any quantity of Product is invoiced as a result of the parties being unable to reach agreement with respect to the calculation of the Transfer Price, UCB shall be obligated to pay the undisputed amount of such invoice in full in accordance with the provisions of Section 7.6(a) pending resolution of the dispute pursuant to Section 15.2.

(iii) In the event that UCB disputes any invoice due to non-conformance of the Product supplied by Jazz Pharmaceuticals with the Product Specifications, such dispute shall be resolved in accordance with Sections 7.11 and 7.12 of this Agreement. Pending resolution of such dispute, UCB shall not be obligated to pay the amount of such invoice that relates to Product alleged to be non-conforming. Upon resolution of any such dispute in favor of Jazz Pharmaceuticals, UCB shall pay the unpaid balance of such invoice within ten (10) days of such resolution.

**7.7 Short Supply Allocation.** If Jazz Pharmaceuticals is unable to supply all of UCB's orders for Product hereunder in a timely manner, Jazz Pharmaceuticals shall allocate its available sources and supplies among UCB, Jazz Pharmaceuticals and Jazz Pharmaceuticals' other partners (distributors, licensees, agents, etc.) and internal needs in accordance with the [ \* ] of each of the parties for that allocation period, provided, however, the foregoing shall in no way modify or mitigate Jazz Pharmaceuticals' obligation to supply Product properly ordered in accordance with this Agreement or UCB's rights and remedies under this Agreement in respect of any failure to timely supply, including in respect of a breach hereof and UCB's rights to appoint a Third Party manufacturer in accordance with Section 2.1(b) or to terminate this Agreement in accordance with Section 14.2(b).

## 7.8 Product Expiration.

(a) All Product supplied by Jazz Pharmaceuticals shall have a minimum expiration dating [ \* ] at the time of its delivery EXW Jazz Pharmaceuticals' designated supplier pursuant to Section 7.3.

(b) In the event the applicable Regulatory Authority grants an expiration date less than [ \* ], Jazz Pharmaceuticals and UCB shall negotiate in good faith a reasonable minimum expiration, taking into account the differing expiration dates set forth herein for Product.

(c) UCB shall not sell any Product beyond its stated expiration date.

7.9 Certificate of Analysis. With each delivery of the Product to UCB, Jazz Pharmaceuticals shall, in accordance with the terms of the Quality Agreement, provide to UCB (i) a Certificate of Analysis and Certificate of Conformity confirming that the Product has been manufactured in accordance with cGMP and the Product Specifications, (ii) a copy of all batch documentation from the Product manufacturer for the first three (3) batches of Product delivered to UCB and (iii) a copy of the annual stability test report, provided that the provision of the certificates and other documents listed in (i)—(iii) above shall not release UCB from any of its obligations hereunder, including, without limitation, its obligation to conduct all necessary release testing to ensure that the Products distributed in the Territory comply with all applicable regulatory requirements in the Territory.

7.10 Storage. Jazz shall comply with the Quality Agreement in relation to the storage of the Product prior to delivery EXW to UCB. UCB shall at its own expense maintain adequate and suitable storage facilities for the storage of Product delivered to UCB in accordance with cGMP, the Marketing Authorizations, the Quality Agreement and all applicable laws and regulations. Jazz Pharmaceuticals or its representative shall have the right no more than twice per calendar year to inspect, during normal business hours, such storage facilities upon sixty (60) days prior written notice.

7.11 Testing of Product Upon Receipt. UCB shall, as soon as practical after receipt of Product, examine the Product for any apparent non-conformance and carry out or have carried out, routine laboratory testing and other chemical analysis of the Product as required by the relevant Marketing Authorizations and/or Regulatory Authority(ies). UCB shall promptly notify Jazz Pharmaceuticals if such examination or testing establishes the basis to reject the Product for non-conformance. Any such notice shall identify the specific claims of non-conformance and include copies of relevant test results or other materials indicating such non-conformance. Upon receipt of a notification of non-conformance, Jazz Pharmaceuticals and UCB shall compare test results obtained during release testing of the Product by Jazz Pharmaceuticals to the results UCB obtained during acceptance testing to evaluate the potential cause of discrepancy. If Jazz Pharmaceuticals confirms such non-conformity, it shall promptly so notify UCB. If Jazz

Pharmaceuticals does not confirm such non-conformity, it shall promptly so notify UCB, and the parties shall submit the disputed Product shipment for testing to an independent testing laboratory or other independent Third Party expert mutually acceptable to the parties. Notwithstanding Section 15.2, the findings of the testing laboratory or Third Party expert shall be binding on the parties. The expenses of such testing shall be borne by Jazz Pharmaceuticals if the non-conformity is confirmed, and otherwise by UCB. Without limiting UCB's other remedies as herein provided, Jazz Pharmaceuticals shall promptly replace properly rejected Product. UCB shall return such Product or, if requested by Jazz Pharmaceuticals, destroy the Product and provide the certification described in Section 7.12.

7.12 Rejection of Shipments For Product Non-Conformance. If UCB rejects a shipment on the determination that such shipment of Product fails to conform to the purchase order therefore or on the grounds that it fails to conform to the Product Specifications, UCB shall give written notice of such rejection to Jazz Pharmaceuticals [ \* ] after receipt thereof, in the case of apparent non-conformance, and [ \* ] of the receipt of definitive test results obtained pursuant to Section 7.11 in the case of non-conformance established by such tests. Such notice of rejection shall specify the manner in which the Product fails to conform to the relevant purchase order, or otherwise fails to conform to the Product Specifications. If UCB fails to provide Jazz Pharmaceuticals such notice in respect of Product delivered to UCB pursuant to a purchase order within [ \* ] as the case may be, of the date of delivery, the Product shall be deemed accepted by UCB; provided, however, that such deemed acceptance shall not (i) impair UCB's right to reject shipment or recover damages in respect of any non-conformance that is not apparent and cannot be determined by such tests or (ii) reduce, diminish or alter UCB's rights to indemnification as specified in Article IX hereof or to terminate this Agreement in accordance with Section 14.2(b). If UCB expects to make a claim against Jazz Pharmaceuticals in accordance with this Section 7.12, UCB shall not dispose or allow the disposal of the Product in question without the express written authorization and instructions of Jazz Pharmaceuticals. Any such instructions from Jazz Pharmaceuticals, or UCB's compliance therewith, shall not relieve UCB of its obligation to dispose of any Product in accordance with all applicable laws and regulations in the relevant country in the Territory. UCB shall not return any rejected Product to Jazz Pharmaceuticals without a Return Material Authorization ("**RMA**") from Jazz Pharmaceuticals. Jazz Pharmaceuticals shall promptly issue a RMA for any reasonably rejected Product, provided, however, appropriate samples may be retained by UCB as evidence of the basis for such rejection by UCB. Proof of destruction or disposal shall be certified in writing to Jazz Pharmaceuticals by an officer of UCB. Within [ \* ] of receipt of a statement detailing and documenting all of UCB's costs and expenses associated with Jazz Pharmaceuticals' delivery of non-conforming Products, including without limitation, any payments made or other Indemnification Amounts arising out of Claims and the return, destruction or disposal of such Product pursuant to this Section 7.12, Jazz Pharmaceuticals shall reimburse UCB for all such amounts. Any disputes between the parties relating to such reimbursement amounts shall be resolved in accordance with the procedures set forth in Section 15.2.

**ARTICLE VIII  
REPRESENTATIONS AND WARRANTIES**

8.1 Jazz Pharmaceuticals Warranties. Jazz Pharmaceuticals represents and warrants to UCB that as of the Effective Date (unless specified otherwise):

(a) As of the Execution Date, it is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware, U.S.A. and has the corporate power to own its assets and properties and to carry on its business as now being and heretofore conducted.

(b) As of the Execution Date, it has all requisite power and authority (corporate and otherwise) to enter into this Agreement and it has duly authorized, by all necessary action, the execution and delivery hereof by the officer or individual whose name is signed on its behalf below. Jazz Pharmaceuticals' execution and delivery of this Agreement does not and will not conflict with or result in a breach of or a default under its organizational documents or any agreement, instrument, order, law or regulation applicable to it or by which it or the Product may be bound. This Agreement has been duly and validly executed and delivered by Jazz Pharmaceuticals and constitutes Jazz Pharmaceuticals' valid and legally binding obligation, enforceable against Jazz Pharmaceuticals in accordance with its terms, except as enforcement may be limited by laws of bankruptcy or insolvency or other laws of general application relating to or affecting the enforcement of creditor's rights and general equitable principles.

(c) At the time of its shipment to UCB, each order of Product shall have been manufactured, stored and shipped in accordance with cGMP, the Product Specifications and the Marketing Authorizations and other applicable laws and regulations, shall be in compliance with the Marketing Authorizations, and shall not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetics Act, as in effect at the time of shipment;

(d) At the time of its shipment to UCB, each order of the Product shall conform to the Product Specifications until the expiration of the shelf life approved by the Regulatory Authorities.

(e) Patent Rights, Trademarks and Other Intellectual Property Rights.

(i) Jazz Pharmaceuticals has good title and ownership or rights to the Licensed Intellectual Property free and clear of all liens. To Jazz

Pharmaceuticals' actual knowledge, it has all intellectual property rights necessary for (A) the manufacture of the Product by Jazz Pharmaceuticals and the distribution, marketing, promotion and sale by UCB of the Product in the Territory in accordance with the terms of this Agreement and (B) the grant by Jazz Pharmaceuticals to UCB of the rights granted under this Agreement.

(ii) Schedule 8.1(e)(ii) hereto contains a true and complete list of all Patent Rights in the Territory and all Trademarks and all other intellectual property rights of Jazz Pharmaceuticals relating to the Product in the Territory, indicating for each whether it is registered or is the subject of a pending application with any patent and/or trademark office with jurisdiction in the Territory, and all licenses and other contracts and similar rights relating thereto.

(iii) Except as set forth on Schedule 8.1(e)(iii), to Jazz Pharmaceuticals' actual knowledge, the Product as manufactured and delivered to UCB by Jazz Pharmaceuticals for distribution in the Territory pursuant to this Agreement, and UCB's use of the Licensed Intellectual Property in the Territory as contemplated hereby, [ \* ].

(f) Contracts: No Default.

(i) Except for those contracts set forth on Schedule 8.1(f)(i) and Schedule 8.1(e)(ii) and except for this Agreement, as of the date hereof, there are no material contracts, agreements, understandings, arrangements or commitments, written or oral, including without limitation, manufacturing, supply, sales agency, sales representative, distributor, dealer, license, supplier, wholesaler, or similar contracts or agreements ("**Contracts**") of Jazz Pharmaceuticals relating to the Product in the Territory.

(ii) Except as set forth on Schedule 8.1(f)(ii), Jazz Pharmaceuticals and, to Jazz Pharmaceuticals' actual knowledge, each other party to Jazz Pharmaceuticals' Contracts referenced in clause (i) above (other than UCB) has performed in all material respects, and is now performing in all material respects, its obligations under, and is not in material default (and would not by the mere lapse of time or the giving of notice or both be in default) under, or in material breach or violation of any of such Contracts; nor has Jazz Pharmaceuticals received notice of any asserted claim of a default by any other party thereto under, or a breach or violation by such other party of any of such Contracts.

(g) Actions.

(i) Except as set forth on Schedule 8.1(g)(i), there are no Claims pending or, to Jazz Pharmaceuticals' actual knowledge, threatened against Jazz Pharmaceuticals before any court or regulatory authority that (A) question or challenge the validity of this Agreement or any action taken or proposed to be taken by Jazz Pharmaceuticals pursuant hereto or in connection with the transactions contemplated hereby, or (B) relate to the Product or would if adversely determined, singly or in the aggregate, prohibit or materially impair Jazz Pharmaceuticals' or UCB's ability to perform its obligations under this Agreement.

(ii) There are no outstanding judgments, orders, decrees, writs, awards, stipulations, or injunctions of any regulatory authority against or affecting the Product or Jazz Pharmaceuticals with respect to the Product or which would if adversely determined, singly or in the aggregate, prohibit or materially impair Jazz Pharmaceuticals' or UCB's ability to perform its obligations under this Agreement.

(h) Approvals. Except as contemplated by this Agreement or set forth on Schedule 8.1(h) or as shall already have been made, obtained or given, no approval of any regulatory authority or other Person is required to be made, obtained or given by or with respect to Jazz Pharmaceuticals or the Product in connection with the execution or delivery by Jazz Pharmaceuticals of this Agreement, the performance by it of its obligations hereunder or the consummation by it of the transactions contemplated hereby.

8.2 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO THE PRODUCT OR UCB'S SALE AND DISTRIBUTION THEREOF IN THE TERRITORY. The warranties given by each party are for the sole benefit of the other party shall not extend to any Third Party. This provision does not affect the right of any patient to pursue legal remedy in the event Jazz Pharmaceuticals provides Product that is adulterated or misbranded or if Product does not meet Product Specifications. Except as provided in Section 2.1, nothing in this Agreement shall be construed as, and Jazz Pharmaceuticals expressly disclaims, any warranty or agreement to furnish any manufacturing information beyond that required to obtain Registrations for the Product in the Territory. UCB agrees that as between UCB and Jazz Pharmaceuticals, UCB alone shall be liable, to the exclusion of Jazz Pharmaceuticals, for the breach of any warranties given by UCB, its Subdistributors or its Sublicensees to customers or others regarding the Product, provided, however, nothing herein shall reduce, diminish or alter UCB's rights as herein provided including its right to assert claims against Jazz Pharmaceuticals in respect of the same facts that form or might form the basis of Claims against UCB by its Subdistributors or Sublicensees and its or their customers.

8.3 UCB Warranties. UCB represents and warrants to Jazz Pharmaceuticals that as of the Effective Date (unless specified otherwise):

(a) As of the Execution Date, it is a corporation duly organized, validly existing and in good standing under the laws of England and has the corporate power to own its assets and properties and to carry on its business as now being and heretofore conducted.

(b) As of the Execution Date, it has all requisite power and authority (corporate and otherwise) to enter into this Agreement and it has duly authorized, by all necessary action, the execution and delivery hereof by the officers or individuals whose name is signed on its behalf below. UCB's execution and delivery of this Agreement does not and will not conflict with or result in a breach of or a default under its organizational documents or any agreement, instrument, order, law or regulation applicable to it or by which it or the Product may be bound. This Agreement has been duly and validly executed and delivered by UCB and constitutes UCB's valid and legally binding obligation, enforceable against UCB in accordance with its terms, except as enforcement may be limited by laws of bankruptcy or insolvency or other laws of general application relating to or affecting the enforcement of creditor's rights and general equitable principles.

(c) During the term of this Agreement, it shall and shall require its Subdistributors, Sublicensees and Third Party manufacturers to manufacture (if applicable), store, package, label, promote, market, sell and distribute the Product in compliance with this Agreement, the Registrations and all applicable laws and regulations.

(d) Contracts; No Default.

(i) Except for those Contracts set forth on Schedule 8.1(e)(i), and except for this Agreement, as of the date hereof, there are no material Contracts of UCB relating to the Product in the Territory.

(ii) Except as set forth on Schedule 8.1(d)(ii), UCB and, to UCB's actual knowledge, each other party to UCB's Contracts referenced in clause (i) above (other than Jazz Pharmaceuticals) has performed in all material respects, and is now performing in all material respects, its obligations under, and is not in material default (and would not by the mere lapse of time or the giving of notice or both be in default) under, or in material breach or violation of any of such Contracts; nor has UCB received notice of any asserted claim of a default by any other party thereto under, or a breach or violation by such other party of any of such Contracts.



(e) Actions.

(i) Except as set forth on Schedule 8.1(e)(i), there are no Claims pending or, to UCB's actual knowledge threatened against UCB before any court or regulatory authority that (A) question or challenge the validity of this Agreement or any action taken or proposed to be taken by UCB pursuant hereto or thereto or in connection with the transactions contemplated hereby, or (B) would if adversely determined, singly or in the aggregate, prohibit or materially impair Jazz Pharmaceuticals' or UCB's ability to perform its obligations under this Agreement.

(ii) There are no outstanding judgments, orders, decrees, writs, awards, stipulations, injunctions of any regulatory authority against or affecting UCB which would if adversely determined, singly or in the aggregate, prohibit or materially impair UCB's ability to perform its obligations under this Agreement.

(f) Approvals. Except as contemplated by this Agreement or set forth on Schedule 8.1(f) or as shall already have been made, obtained or given, no approval of any regulatory authority or other Person is required to be made, obtained or given by or with respect to UCB or the Product in connection with the execution or delivery by UCB of this Agreement, the performance by it of its obligations hereunder or the consummation by it of the transactions contemplated hereby.

**ARTICLE IX  
INDEMNIFICATION**

9.1 Indemnification by Jazz Pharmaceuticals. Subject to Section 9.2, Jazz Pharmaceuticals shall indemnify and hold harmless UCB and its directors, officers, employees and agents from and against all claims, disputes, actions, arbitrations, mediations, litigations, proceedings, suits and governmental investigations brought by a Third Party and any appeal therefrom (the "**Claims**") and all liabilities, damages, losses, costs and expenses (including reasonable attorneys' fees and expenses in respect of Claims and to enforce rights to indemnification as herein provided ("**Indemnification Amounts**")) arising out of (i) a breach by Jazz Pharmaceuticals of any representation, warranty or covenant provided in this Agreement, including, without limitation, the representations and warranties set forth in Section 8.1, (ii) an allegation that bodily injury (including death) or tangible personal property damage was caused by, resulted from or arose out of the use of the Product for a Licensed Indication by whomsoever such Product was sold (including UCB, its Subdistributors and Sublicensees) and regardless of

the legal theory on which such Claim is based, except, however, where such bodily injury and/or property damage is due to (a) a circumstance described in Section 9.2(i) or 9.2(iii) hereof or (b) failure of a Third Party manufacturer appointed by UCB pursuant to Section 2.1 to manufacture, store or ship the Product in accordance with cGMP, the Marketing Authorizations and other applicable laws and regulations or due to the action or inaction of such Third Party manufacturer which causes the Product to be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as in effect at the time of shipment; and (iii) negligence, gross negligence or willful misconduct of or attributable to Jazz Pharmaceuticals, its sublicensees (other than UCB, its Subdistributors, Sublicensees or Third Party manufacturers), contractors, manufacturers and its or their directors, officers, agents, employees, consultants or clinical investigators in connection with the manufacture, storage or supply of API and/or the Product.

9.2 Indemnification by UCB. UCB agrees to indemnify, defend and hold harmless Jazz Pharmaceuticals and its directors, officers, employees and agents from and against all Claims and Indemnification Amounts arising out of (i) a breach by UCB of any representation, warranty or covenant provided in this Agreement, (ii) an allegation that bodily injury (including death) or tangible personal property damage was caused by, resulted from or arose out of the Products sold by UCB, its Subdistributors, Sublicensees or Third Party manufacturers that were used other than for a Licensed Indication, regardless of the legal theory on which such Claim is based, except, however, where such bodily injury and/or property damage is due to a circumstance described in Sections 9.1(i) and 9.1(iii) hereof, (iii) negligence, gross negligence or willful misconduct of or attributable to UCB, its Subdistributors, Sublicensees or Third Party manufacturers and its or their directors, officers, agents, employees, consultants or clinical investigators in connection with the storage, packaging, labeling, promotion, marketing, sale and distribution of the Product in the Territory; and (iv) except to the extent that Jazz Pharmaceuticals indemnifies UCB under Section 9.1, any express or implied warranty, whether oral or written, including any implied warranty or the merchantability or fitness of the Product for a particular purpose asserted by any customer of UCB, its Subdistributors or Sublicensees, if such warranty was extended by or arising from any undertaking, action or inaction of UCB, its Subdistributors or Sublicensees.

9.3 Procedure. A party seeking indemnification (an “**indemnified party**”) shall give the other party (an “**indemnifying party**”) written notice of any Claim promptly upon becoming aware thereof. The indemnifying party shall have sole and exclusive control of the defense of any Claim, including the choice and direction of legal counsel. The indemnified party shall have the right to participate in such defense through its own counsel, at its own expense. Neither party may settle or compromise any Claim for which indemnification is being sought without the written consent of the other party, which may not be unreasonably withheld.

9.4 Insurance. Both parties shall maintain during the Term of this Agreement, and for a reasonable period thereafter, general liability insurance (whether Third Party insurance or self-insurance provided through a captive insurance subsidiary), which insurance shall include product liability coverage and shall be in amounts and of a type customarily maintained by companies similarly situated. Such insurance shall provide [ \* ] (\$ [ \* ]) Dollars in coverage [ \* ]. Each party shall use commercially reasonable efforts to name the other party as an additional insured on such party's insurance policy(ies). On or prior to the Effective Date, each party shall deliver to the other evidence of its insurance.

**ARTICLE X**  
**INTELLECTUAL PROPERTY RIGHTS**  
**PERFECTION AND USE**

10.1 License Perfection. In the event that the execution and filing of any document is required in connection with the license granted in Section 2.2 to UCB for the Trademarks or Patent Rights under the laws of any country in the Territory, UCB shall promptly notify Jazz Pharmaceuticals, and Jazz Pharmaceuticals shall cause such document to be executed and filed, and UCB shall sign such document if necessary and otherwise cooperate in the filing thereof.

10.2 Quality Standards. All Products sold and marketed under the Trademarks by UCB or its Subdistributors or Sublicensees, including all related advertising, promotional materials, and all other related uses of the Trademarks shall comply with the reasonable trademark use standards adhered to by Jazz Pharmaceuticals in the manufacture, sale and promotion of the Product, which such standards are set forth in Appendix E. In particular, and without limiting the generality of the foregoing, upon reasonable request by Jazz Pharmaceuticals, UCB shall provide Jazz Pharmaceuticals with samples of Products bearing the Trademarks, as well as copies of all materials, including but not limited to brochures, professional literature, packaging and consumer instructions, which are created or intended for use by UCB, its Subdistributors and/or Sublicensees in the advertising, promotion, marketing or sale or other distribution of the Product in the Territory, for examination and testing to verify compliance with the trademark use standards set forth in Appendix E. UCB shall also permit Jazz Pharmaceuticals, not more than [ \* ] and upon thirty (30) days prior written notice and at reasonable times during normal business hours, to examine stocks of the Product held by it or its Subdistributors or Sublicensees to verify compliance with such standards. Jazz Pharmaceuticals shall notify UCB in writing of any noncompliance herewith, and UCB shall use Commercially Reasonable Efforts to correct the problem and bring such Products into compliance with applicable standards.

10.3 Use of Trademarks. UCB shall and shall cause its Subdistributors and Sublicensees to market the Product in the Narcolepsy Indication under the Narcolepsy Trademarks; provided, however that if the Narcolepsy Trademarks are unavailable or unusable in

a particular country in the Territory for the Narcolepsy Indication, the parties shall mutually agree on a suitable alternative. In addition, to the extent permitted by applicable law in each country in the Territory, where that Product has been manufactured by Jazz Pharmaceuticals, all labeling for the Product shall bear a legend, identifying Jazz Pharmaceuticals as the manufacturer of the Product for UCB.

10.4 Narcolepsy: Registration and Approvals. Attached hereto as Appendix B is a list of the registrations and pending applications for registration for the Narcolepsy Trademarks and Patent Rights in the Territory for use in relation to the Narcolepsy Indication. Jazz Pharmaceuticals shall at its sole cost file applications and maintain trademark registrations (including for the Trademarks and any alternative trademarks pursuant to Section 10.3) and patent registrations (including for the Patent Rights) in each country in the Territory including without limitation the registrations and pending applications for the Narcolepsy Trademarks and Patent Rights in each country listed in Appendix B as shall be reasonably useful or necessary to protect UCB's rights under this Agreement; provided, however, that if Jazz Pharmaceuticals shall fail to file a useful or necessary application or maintain a useful or necessary registration for any trademarks, alternative trademarks or patents in a country in the Territory, or to maintain the Trademarks and Patent Rights registrations in each country listed in Appendix B, UCB shall have the right to file such applications and maintain such registrations in each such country in the Territory for such trademarks, alternative trademarks or patents at the expense and in the name and on behalf of Jazz Pharmaceuticals (or in UCB's own name if that is not permitted in the applicable country). Such registration and use of the Trademarks and Patent Rights shall inure to the benefit of and be on behalf of Jazz Pharmaceuticals. On any termination of this Agreement pursuant to Article XIV hereof, UCB shall promptly assign to Jazz Pharmaceuticals registrations and any applications for registration of trademarks, alternative trademarks registered pursuant to Section 10.3 or patents for the Product in the Territory filed in its name pursuant to this Section 10.4.

10.5 Licensed Indications other than the Narcolepsy Indication: Registration and Approvals.

(a) Jazz Pharmaceuticals shall, at least 1 month prior to making an application, consult UCB as to the name(s) and, if applicable, form(s) of the trademark(s) it wishes to apply to register in the Territory for use with the Product in relation to the Licensed Indications other than the Narcolepsy Indication. Jazz Pharmaceuticals agrees to hold good faith discussions with UCB about such applications and to give due consideration to UCB's representations.

(b) Jazz Pharmaceuticals shall at its sole cost file applications and maintain trademark registrations (including the Other Licensed Trademarks and any alternative trademarks pursuant to Section 10.6) and patent registrations (including for the Patent Rights) in

each country in the Territory as shall be necessary to protect UCB's rights under this Agreement; provided, however, that if Jazz Pharmaceuticals shall fail to file a necessary application or maintain a necessary registration for any trademarks, alternative trademarks or patents in a country in the Territory UCB shall have the right to file such applications and maintain such registrations in each such country in the Territory for such trademarks, alternative trademarks or patents at the expense and in the name and on behalf of Jazz Pharmaceuticals (or in UCB's own name if that is not permitted in the applicable country). Such registration and use of the Other Licensed Trademarks and Patent Rights shall inure to the benefit of and be on behalf of Jazz Pharmaceuticals. Appendix B shall be updated by Jazz Pharmaceuticals at least every 12 months to list all registrations and pending applications for registration for the Other Licensed Trademarks and Patent Rights in the Territory for use in relation to the Licensed Indication other than the Narcolepsy Indication.

10.6 Use of the Other Licensed Trademarks. UCB shall and shall cause its Subdistributors and Sublicensees to market the Product in the Licensed Indications other than the Narcolepsy Indication under the Other Licensed Trademarks; provided, however that if the Other Licensed Trademarks are unavailable or unusable in a particular country in the Territory for the Licensed Indications other than the Narcolepsy Indication, the parties shall mutually agree on a suitable alternative. In addition, to the extent permitted by applicable law in each country in the Territory, where that Product has been manufactured by Jazz Pharmaceuticals, all labeling for the Product shall bear a legend, identifying Jazz Pharmaceuticals as the manufacturer of the Product for UCB.

10.7 Reservation of Rights. Except as otherwise provided herein, (i) nothing in this Agreement shall entitle UCB to any right, title or interest in or to any of the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements, and Proprietary Information of Jazz Pharmaceuticals or any associated goodwill, which is and shall remain the sole and exclusive property of Jazz Pharmaceuticals and (ii) UCB shall not take and shall cause its Subdistributors, Sublicensees and Third Party manufacturers to not take any action that might (a) impair any right, title or interest of Jazz Pharmaceuticals in and to the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements and Proprietary Information; or (b) create any right, title or interest in or to such Patent Rights, Know How, Trademarks, Improvements and Proprietary Information in UCB or any other Person. UCB acknowledges Jazz Pharmaceuticals' proprietary rights as provided in the preceding sentence, and hereby waives in favor of Jazz Pharmaceuticals any right UCB may have in and to the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements and Proprietary Information except as herein provided.

**ARTICLE XI  
INTELLECTUAL PROPERTY INFRINGEMENTS**

11.1 Protection of Intellectual Property. UCB shall cooperate with Jazz Pharmaceuticals and take all reasonable actions which Jazz Pharmaceuticals may reasonably request, at Jazz Pharmaceuticals' sole cost and expense, in order to protect and enforce Jazz Pharmaceuticals' intellectual property rights, including, but not limited to, carrying out any act Jazz Pharmaceuticals may reasonably require in connection with any registration, enforcement or protection thereof. UCB shall promptly notify Jazz Pharmaceuticals upon becoming aware of any use in the Territory by a Third Party of the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements or Proprietary Information of Jazz Pharmaceuticals related thereto, or any other Jazz Pharmaceuticals intellectual property relating to the Product which may constitute an infringement thereof. Jazz Pharmaceuticals shall have the first right, at its option, to institute proceedings against Third Party infringers in respect of such infringements occurring in the Territory. If Jazz Pharmaceuticals elects not to institute such proceedings within a period of thirty (30) days after its discovery of the infringement, UCB shall have the right at its option to do so. The party instituting proceedings in the Territory pursuant to this Article XI shall bring all such proceedings in the name of both parties. Jazz Pharmaceuticals shall have the exclusive right in its sole discretion to institute proceedings solely in its name against Third Party infringers in respect of infringements occurring outside the Territory. Each party shall cooperate fully with the other party in connection with any such proceedings against third-party infringers. All expenses of any such proceedings shall be borne by the party instituting the proceedings and damages which may be awarded or agreed upon in settlement of such action shall be allocated first to reimburse the documented costs of the proceedings incurred by the party bringing suit, with the balance of such amounts, if any, to be allocated between the parties in accordance with their relative economic loss from such infringement.

**ARTICLE XII  
IMPROVEMENTS**

12.1 Improvements by UCB. Subject to UCB's rights therein as provided elsewhere in this Agreement, including without limitation Section 2.2, UCB hereby irrevocably assigns, releases, and transfers to Jazz Pharmaceuticals its entire right, title and interest in and to any Improvement solely relating to the API and/or a Product (whether patentable or not) made or conceived solely or jointly by UCB employees or contractors.

12.2 Improvements by Jazz Pharmaceuticals. Subject to UCB's rights therein as provided elsewhere in this Agreement, including without limitation Section 2.2, Jazz Pharmaceuticals shall own all right, title and interest in and to any Improvement relating to the API and/or Product (whether patentable or not) made or conceived solely or jointly by Jazz Pharmaceuticals employees or by any Jazz Pharmaceuticals contractor, other than UCB, including, without limitation, any manufacturing or analytical process, procedure or method or any source of synthesis given to UCB.

12.3 Disclosure. UCB shall promptly disclose to Jazz Pharmaceuticals any and all Improvements relating to the API and/or Product by UCB's employees, Subdistributors, Sublicensees or contractors, either alone or together with Jazz Pharmaceuticals' employees or contractors. UCB, its Subdistributors and Sublicensees shall execute at Jazz Pharmaceuticals' expense any assignments, applications or other instruments or documents reasonably requested by Jazz Pharmaceuticals to obtain, maintain, and otherwise to perfect Jazz Pharmaceuticals' interest therein as provided by this Agreement. UCB's obligations hereunder shall survive termination of this Agreement.

### ARTICLE XIII CONFIDENTIALITY

13.1 Proprietary Information. During the Term hereof and for a period of [ \* ] years thereafter, any Proprietary Information disclosed by one party (the "**Disclosing Party**"), directly or indirectly, to the other party (the "**Receiving Party**") under this Agreement shall be deemed confidential, and trade secret information, whether so designated or not, and shall not be disclosed by the Receiving Party to any Third Party, except as set forth below. Access to such Proprietary Information shall be limited to employees, agents, consultants or contractors of the Receiving Party who reasonably require such Proprietary Information for purposes of performing the Receiving Party's obligations hereunder and who are bound to the Receiving Party by similar obligations in respect of confidentiality and use. Such employees, agents, consultants or contractors shall be advised of the nature and existence of the undertakings in respect of such Proprietary Information pursuant to this Agreement and of the applicability of such undertakings to them. The Receiving Party shall use such Proprietary Information only to carry out its obligations or to exercise its rights hereunder and shall not use such Proprietary Information for its own benefit or for the benefit of others or in any way inconsistent with this Agreement.

13.2 Exclusions. Information shall not be deemed Proprietary Information which:

- (a) at the time of disclosure, is already in the public domain or thereafter becomes part of the public domain through no act or omission of the Receiving Party;
- (b) was rightfully in the possession of the Receiving Party prior to the time of the disclosure;
- (c) is independently disclosed to the Receiving Party by a Third Party who has not violated any confidential obligation owed to the Disclosing Party;

(d) was independently developed by the Receiving Party without any use of or reliance on any Proprietary Information of the Disclosing Party;

(e) is required to be disclosed by legal process, provided that, in each case the party so disclosing information timely informs the other and uses its best efforts to limit the disclosure and maintain confidentiality to the extent possible and permits the other party to attempt by appropriate legal means to limit such disclosure;

(f) is information which is required to be included in patent applications or required to be provided to the FDA or any other Regulatory Authority in the Territory in order that Registrations for the Product can be obtained or otherwise to comply with applicable regulatory requirements; provided, however, that no Proprietary Information of UCB or Jazz Pharmaceuticals shall be disclosed in any such patent application or Registration without the prior written consent of the Disclosing Party, which consent shall not be unreasonably withheld; or

(g) is information which is required to be disclosed to customers, users, and prescribers of the Product or which is reasonably necessary to disclose in connection with the ethical marketing of the Product, if applicable.

13.3 Third Party Disclosure. Disclosure by the Receiving Party to a Third Party shall be made only to the extent necessary to enable the Receiving Party to comply with its contractual obligations to the Disclosing Party, and only if such Third Party has executed a confidentiality agreement containing terms that are at least as protective as the terms of this Agreement.

13.4 Third Party Confidentiality Agreement. Each Third Party to which Proprietary Information is disclosed other than a regulatory authority shall agree in writing prior to such disclosure to keep the Proprietary Information in strict confidence.

13.5 Confidentiality of Agreement. Except as otherwise required by law, applicable regulations or the terms of this Agreement or as mutually agreed upon by the parties hereto, each party shall treat as confidential the terms and conditions of this Agreement.

13.6 Prior Confidentiality Agreement. The Confidentiality Disclosure Agreement between Orphan Medical and Celltech hereto dated 20 November 2002 is hereby superseded and terminated. Any disclosure of Proprietary Information by either Orphan Medical or Celltech pursuant to such Confidentiality Agreement shall be deemed to have been made hereunder and shall be subject to this Article 13.



**ARTICLE XIV  
TERM AND TERMINATION**

14.1 Term. This Agreement shall become effective as of the Effective Date and, subject to earlier termination in accordance with its terms, shall remain in full force and effect until the last of Jazz Pharmaceuticals' Patent Rights to expire or ten (10) years from the date UCB receives approval from the EMEA to commercially promote and distribute Product in the relevant Licensed Indication, whichever is longer. This Agreement will be automatically extended indefinitely thereafter unless and until terminated by UCB upon not less than twelve (12) months written notice to Jazz Pharmaceuticals. All references herein to "Term" or "**Term of this Agreement**" shall be deemed to include both the initial and any extended terms.

14.2 Mutual Termination. This Agreement may be terminated prior to its normal Term as follows:

(a) Either party may terminate this Agreement immediately upon notice if the other party files a petition of any type as to its bankruptcy, is declared bankrupt, becomes insolvent, makes an assignment for the benefit of creditors, goes into liquidation or receivership, or otherwise loses legal control of its business involuntarily.

(b) Either party may terminate this Agreement if the other party materially defaults or commits a material breach of this Agreement and has failed to cure such default or breach within [ \* ] of receipt of written notice thereof from the first party.

(c) Either party may terminate this Agreement in accordance with Section 16.2.

14.3 Termination by Jazz Pharmaceuticals. In addition to its termination rights under Section 14.2, Jazz Pharmaceuticals may terminate this Agreement upon written notice to UCB if any of the following occurs otherwise than due to the default of Jazz Pharmaceuticals and continues uncured for a period of [ \* ] following receipt of written notice thereof from Jazz Pharmaceuticals:

(a) UCB shall have failed to meet the applicable minimum royalty payment requirements for the Product as provided in Article IV hereof.

(b) UCB ceases to sell the Product throughout the Territory (other than as a result of Jazz Pharmaceuticals' default and/ or where the cessation of selling arises from circumstances contemplated and separately addressed in Section 16.2 (Force Majeure)).

14.4 Termination by UCB. In addition to its termination rights under Section 14.2, UCB may terminate this Agreement upon written notice to Jazz Pharmaceuticals as follows:

(a) on 9 months' written notice, if (i) UCB is entitled to take over the manufacture of the Product or appoint a Third Party manufacturer pursuant to Section 2.1(b), (ii) UCB determines in good faith that there would be a significant impact on UCB's ability to commercialize the Product in the Territory and (iii) UCB reasonably concludes that assuming responsibility for manufacturing itself or transferring the manufacture to a Third Party manufacturer could not be achieved in sufficient time to avoid such significant impact;

(b) immediately, upon withdrawal of all of the Marketing Authorizations for the Product in [ \* ]; or

(c) on [ \* ] written notice, for any reason.

14.5 Rights and Obligations on Termination. In the event of termination of the whole of this Agreement for any reason, the parties shall have the following rights and obligations:

(i) Neither party shall be released from the obligation to make payment of all amounts then or thereafter due and payable in respect of the Term prior to such termination as otherwise herein provided.

(ii) Except as provided in Section 14.7, UCB shall cease to market, promote, sell and distribute the Product and shall return to Jazz Pharmaceuticals, at UCB's expense, all copies of promotional and technical materials and artwork provided by Jazz Pharmaceuticals; provided, however, that if this Agreement is terminated in whole by UCB pursuant to Section 14.2(b) or Section 14.4(a) or (b), Jazz Pharmaceuticals shall pay all expenses related to such return of materials and artwork;

(iii) Jazz Pharmaceuticals [ \* ], if UCB [ \* ] under Section [ \* ], [ \* ] of [ \* ] and [ \* ] at the [ \* ] by UCB [ \* ] or direct UCB to [ \* ] Third Party or parties selected by Jazz Pharmaceuticals at the [ \* ] by UCB; provided, however, that if this Agreement is terminated by UCB pursuant to Section 14.2(b) or Section 14.4(a) or (b), Jazz Pharmaceuticals [ \* ] by UCB if UCB [ \* ] under Section [ \* ];

(iv) UCB shall return or, if requested by Jazz Pharmaceuticals, destroy all of Jazz Pharmaceuticals' Proprietary Information, including, if applicable, all electronic copies thereof and shall certify in writing that it has done so;

(v) UCB shall comply with the provisions of Section 10.4 regarding the assignment to Jazz Pharmaceuticals of trademark and/or patent rights registrations filed in UCB's name; and

(vi) if UCB has contracted with a Third Party or if UCB and/or its Affiliates have taken over responsibility for the manufacturing of the Product in the Territory, UCB shall continue to manufacture or have manufactured the Product being manufactured by UCB and/or its Affiliates for supply of the Product in the Territory to Jazz Pharmaceuticals during the shorter of (i) the twelve (12) month period following termination and (ii) the period following termination and prior to Jazz Pharmaceuticals' establishment of its own manufacturing capabilities and/or Third Party manufacturing and supply arrangements with respect to the Product for the Territory, provided, however, that:

(a) if this Agreement is terminated by UCB pursuant to Section 14.2(b) or Sections 14.4(a) or 14.4(b), Jazz Pharmaceuticals shall pay UCB for the manufacture of Product [ \* ]; or

(b) if this Agreement is terminated by (i) Jazz Pharmaceuticals pursuant to Section 14.2(b) or Sections 14.3(a) or (b) or (ii) UCB pursuant to Section 14.4(b), Jazz Pharmaceuticals shall pay UCB for the manufacture of Product [ \* ]; and

(c) UCB shall during such period (i) to the extent legally permissible, assign to Jazz Pharmaceuticals all Third Party manufacturing and supply agreements relating exclusively to the Product in the Territory, (ii) transfer to Jazz Pharmaceuticals all manufacturing know-how in its possession or control, and (iii) provide Jazz Pharmaceuticals with such other assistance, at [ \* ] as to [ \* ], as Jazz Pharmaceuticals reasonably requires for the purpose of establishing its own manufacturing capabilities and/ or Third Party manufacturing and supply arrangements with respect to the Product in the Territory.

14.6 Partial Termination. In the event that a cause of termination shall relate solely to any country not subject to regulation by the EMEA, then termination of this Agreement shall be limited and applied only to such country or portion of the Territory.

14.7 Sell-Off Period. Notwithstanding anything to the contrary in Section 14.4 hereto, upon expiration or termination of this Agreement, UCB shall have the right to continue to distribute its existing inventory of non-expired Product for a period of [ \* ] after the effective

date of expiration or the effective date of termination of this Agreement as the case may be. Any such continued distribution shall be in accordance with all applicable laws and regulations and the terms of this Agreement.

14.8 Survival. The provisions of Articles I (Definitions), VIII (Representations & Warranties), IX (Indemnification), XIII (Confidentiality), XIV (Term and Termination), XV (Arbitration), and XVII (Miscellaneous), as well as the provisions of Articles III (Compliance with Laws and Regulations), XI (Intellectual Property Infringement), XII (Improvements) Article XIII (Confidentiality), Article XIV (Termination), Article XV (Arbitration), Article XVII (Miscellaneous) and the other provisions hereof which by their terms are intended to survive the expiration or termination of this Agreement (including without limitation, Section 4.9 (Books and Records)) shall survive any termination or expiration of this Agreement.

14.9 Assignment of Authorizations. As soon as possible following the expiration or earlier termination of this Agreement, UCB shall take all necessary steps to ensure expeditious assignment of all Marketing Authorizations and Orphan Drug Designations which are in UCB's name to Jazz Pharmaceuticals. If an assignment to Jazz Pharmaceuticals is prohibited under the laws of a country in the Territory, UCB agrees to and hereby grants Jazz Pharmaceuticals authorization to distribute the Product under such Marketing Authorization until Jazz Pharmaceuticals or its designee has obtained Marketing Authorizations and Orphan Drug Designations in its own name for the Product in that country; provided that Jazz Pharmaceuticals shall defend, indemnify and hold harmless UCB from and against all Claims and Indemnification Amounts of whatsoever kind or nature that result from, arise out of or relate to Jazz Pharmaceuticals' distribution of the Product under the Marketing Authorizations and Drug Designations continuing in UCB's name as contemplated by this Section 14.9.

14.10 Rights on Termination for Cause. In the event of termination of this Agreement by Jazz Pharmaceuticals pursuant to the provisions of Sections 14.2(a) or (b) or 14.3 (a) – (b), UCB shall provide to Jazz Pharmaceuticals, at no expense to Jazz Pharmaceuticals, its then current list of prospects and customers, including company name, contact, address and telephone number.

14.11 No Compensation. In the event of any expiration or termination of this Agreement for any reason, neither party shall owe any compensation to the other party for lost profits, lost opportunities, good will, or any other loss or damage in respect of future periods as a result of or arising from such termination or expiration.

**ARTICLE XV  
ARBITRATION**

15.1 Litigation Rights Reserved. If any dispute arises with respect to the unauthorized use of Proprietary Information by either Party or, Jazz Pharmaceuticals' Trademarks, Patent Rights, Know How, Manufacturing Know How, and Improvements by UCB, or with respect to acts or omissions of UCB or Jazz Pharmaceuticals relating to the Product which in the good faith discretion of Jazz Pharmaceuticals or UCB, as the case may be, negatively impact the safety of the public, Jazz Pharmaceuticals or UCB, as the case may be, may seek any available equitable remedy from a court of competent jurisdiction.

15.2 Arbitration. Except as provided in Sections 7.11, 15.1 and subject to Section 15.3, all disputes arising between the parties in connection with this Agreement shall be settled as follows:

(a) initially, through discussion between the parties;

(b) if no resolution can be reached through such discussions, then either party may request that the matter be referred to the parties' respective Chief Executive Officers for resolution by same; and

(c) if no resolution can be reached by the parties' respective Chief Executive Officers within thirty (30) days of referral to them under Section 15.2(b) then the dispute shall be submitted to arbitration for settlement. The arbitration shall take place in New York, New York, and be conducted by the American Arbitration Association in accordance with the commercial arbitration rules thereof (the "**Rules**") except as modified hereby. All necessary determinations, including the arbitration decision, shall be made by a panel of three arbitrators (the "**Panel**"). Within ten (10) days after delivery of a notice of arbitration, each of the two parties shall select one arbitrator as a member of the Panel. The two parties shall select as the third member of the Panel an independent arbitrator with no past or current business affiliations with either party, and if the parties cannot agree on such independent arbitrator within ten (10) days after delivery of a notice of arbitration, such independent arbitrator shall be selected in accordance with the Rules. The Panel shall establish a schedule of discovery and hearing such that the Panel's final written decision shall be issued within one hundred and twenty (120) days after selection of the independent arbitrator serving on the Panel. Each party must produce all relevant non-privileged documents requested by the other party within thirty (30) days after the request therefore. The Panel's decision must be in writing and shall set forth the reasons therefore. Such decision shall be conclusive determination of the matter and binding on the parties, shall have the effect of an arbitration award, and shall not (to the extent permitted by applicable law) be contested by any of them. The fees and expenses of an arbitrator selected by a party shall be borne by such party. The fees and expenses of the third independent arbitrator shall initially be borne equally by the parties, and shall be allocated between the parties in accordance with the final decision of the Panel, which decision shall allocate such fees between the parties as determined by the Panel.

15.3 Governing Law. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of New York, U.S.A., excluding (i) its choice of law rules and (ii) the United Nations Convention on the International Sale of Goods, provided that enforcement and operation of the arbitration agreement contained in Section 15.2 hereof, and the enforcement of any award rendered pursuant thereto, shall be governed by United States federal law to the exclusion of State law.

## **ARTICLE XVI FORCE MAJEURE**

16.1 Events of Force Majeure. Anything in this Agreement to the contrary notwithstanding, neither party shall be liable or responsible for any failure or delay in performance (excluding [ \* ]) due to causes affecting such party and, in the case of Jazz Pharmaceuticals, its designated suppliers, and, in the case of UCB, its Subdistributors, Sublicensees and Third Party manufacturers, beyond the reasonable control of such party, including, without limitation, any act of God; regulation or law of any government or an agency thereof, excluding, however, if a regulatory authority enjoins manufacture of the Product or otherwise closes the Product manufacturing facilities due to Jazz Pharmaceuticals' failure to comply with cGMP or any other breach by Jazz Pharmaceuticals of its obligations under this Agreement; war; terrorism; insurrection or civil commotion; earthquake, tornado, fire, flood or storm; epidemic; or failure of public utilities or common carriers. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such condition, such party shall promptly resume performance hereunder.

16.2 Notice. A party affected by an event of force majeure shall give the other party prompt written notice of the occurrence of any event of force majeure and the nature and duration thereof. An affected party shall use all Commercially Reasonable Efforts to resume performance as quickly as possible and to give the other party prompt written notice when it is again fully able to perform such obligations. If such event of force majeure continues for more than one hundred eighty (180) days, either party may terminate this Agreement by giving ten (10) days written notice to the other party. If UCB is the affected party, such notice of resumption of performance shall state the quantities of Product Jazz Pharmaceuticals needs to ship to enable UCB to resume performance of obligations.

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKET BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**ARTICLE XVII  
MISCELLANEOUS**

17.1 Notices. All notices to the parties shall be made at the following addresses (or at such other address as shall be specified by it by like notice):

To: Jazz Pharmaceuticals, Inc.  
Attention: Chief Executive Officer  
3180 Porter Drive  
Palo Alto, California 94304  
United States  
Copy: General Counsel  
Fax: +1 650 496 3781

To: UCB Pharma Limited  
Attention: Vice President, Legal Affairs  
208 Bath Road  
Slough  
Berkshire  
SL1 3WE  
Fax: +44 (0) 1753 447859

Notices permitted or required to be given hereunder shall be deemed sufficient if given by (a) overnight express mail via an internationally-recognized carrier, (b) private courier service or (c) facsimile transmission with electronic confirmation of receipt. Notices so given shall be effective (1) upon receipt by the party to whom notice is given, or (2) on the second (2nd) day following delivery to the international carrier or courier, as may be the case, whichever occurs first.

17.2 Waiver. No failure by either party to take any action or assert any right hereunder shall be deemed to be a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right.

17.3 Entire Agreement. This Agreement, the Schedules and Appendices, the Quality Agreement and the Pharmacovigilance Agreement hereto constitute the entire agreement of the parties with respect to the subject matter hereof, and supersede all previous agreements by and between the parties as well as all proposals, oral or written, and all negotiations, conversations or discussions heretofore had between the parties related to this Agreement, including (without limitation) the Prior Agreement.

17.4 Conflicts. In the event of any conflict between the terms of this Agreement, the Quality Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail.

17.5 Amendment. No modification or amendment of this Agreement shall be binding unless in writing and signed by both parties.

17.6 Headings. Article, section and paragraph headings used in this Agreement are for convenience only, have no legal significance, and in no way change the construction or meanings of the terms hereof.

17.7 Relationship of the Parties. The parties shall be deemed independent contractors of each other and, as such, they shall not be entitled to any benefits applicable to employees of the other party. Nothing contained in this Agreement shall be construed or implied to create an agency, partnership, or employer and employee relationship between Jazz Pharmaceuticals and UCB. At no time shall one party make commitments or incur any charges or expenses for or in the name of the other party except as specifically provided herein.

17.8 Assignment. Neither party may assign this Agreement without the prior written consent of the other party except that either Jazz Pharmaceuticals or UCB may assign this Agreement (a) to an Affiliate or (b) in connection with a merger, stock sale, or the sale or transfer of all or substantially all of the assets of such party or the division of such party manufacturing or marketing the Product, as the case may be, provided, however, any permitted assignee shall assume all obligations of its assignor under this Agreement and in the case of clause (a), the assigning party shall remain primarily liable for the performance of such Affiliate. Any purported assignment in violation of the foregoing sentence shall be null and void. No assignment shall relieve either party of responsibility for the performance of any accrued obligation under this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of UCB and Jazz Pharmaceuticals, respectively.

17.9 Severability. If any term or condition of this Agreement is found by a court of competent jurisdiction to violate the provisions of any applicable statute, law or regulation, the remainder of this Agreement shall remain in full force and effect. The parties shall then negotiate in good faith to modify this Agreement, to the extent necessary to make the affected term or condition of this Agreement valid and enforceable, having full regard for the original intent of the parties.

17.10 Publicity. This Agreement is confidential and neither party shall issue press releases or engage in other types of publicity of any nature (whether written or oral) dealing with the existence or details of this Agreement without the other party's prior written approval, which



approval shall not be unreasonably withheld; provided that, approval of such disclosure shall be deemed to be given to the extent such disclosure is required to comply with governmental rules, regulations or requirements. In such event, the disclosing party shall furnish a copy of such disclosure to the other party.

17.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. This Agreement may be executed and delivered via facsimile transmission with the same force and effect as if it were executed and delivered in writing. In making proof of this Agreement, it shall not be necessary to produce or account for more than one fully executed counterpart.

17.12 LIMITATION OF DAMAGES. NEITHER JAZZ PHARMACEUTICALS NOR UCB SHALL HAVE ANY LIABILITY OF ANY KIND TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES, EVEN IF JAZZ PHARMACEUTICALS OR UCB, AS THE CASE MAY BE, SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE BY THE OTHER PARTY. FOR PURPOSES OF THE LIMITATION OF LIABILITY IN THE IMMEDIATELY PRECEDING SENTENCE, (i) LEGAL FEES AND EXPENSES THAT ARE RECOVERABLE AS PROVIDED IN ARTICLE IX SHALL NOT BE CONSIDERED INDIRECT DAMAGES, (ii) INDIRECT DAMAGES PAYABLE BY AN INDEMNIFIED PARTY TO A THIRD PARTY THAT WOULD BE RECOVERABLE UNDER THE INDEMNITY PROVISIONS IN ARTICLE IX BUT FOR SUCH LIMITATION OF LIABILITY SHALL BE RECOVERABLE NOTWITHSTANDING SAID LIMITATION OF LIABILITY AND (III) [ \* ] SHALL NOT BE DEEMED TO BE SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES EXCEPT IN RESPECT OF [ \* ] IN ACCORDANCE WITH THE TERMS HEREOF.

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKET BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**IN WITNESS WHEREOF**, the parties hereto have executed this Agreement by their respective duly authorized representatives as of the Effective Date.

UCB PHARMA LIMITED

By: /s/ Robert J. Trainor  
Name: Robert J. Trainor  
Title: Executive Vice President and General Counsel

By: /s/ William J. Robinson  
Name: William J. Robinson  
Title: Executive Vice President Global Operations

JAZZ PHARMACEUTICALS, INC.

By: /s/ Robert M. Myers  
Name: Robert M. Myers  
Title: President

By: /s/ Matthew K. Fust  
Name: Matthew K. Fust  
Title: Chief Financial Officer

**[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.**

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**APPENDIX A**

**TERRITORY**

[ \* ]

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**APPENDIX B**

**TRADEMARK**

Xyrem®

[ \* ]

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N/A = Not Available

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**PATENT RIGHTS**

[\*]

[\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**APPENDIX C**

**COMPONENTS OF STANDARD MANUFACTURING COST  
AND  
TRANSFER PRICE FOR CONTRACT YEAR 2006**

<u>Direct Manufacturing Costs</u>	<u>Per Unit/Orders of One Batch</u>	
API @ \$[ * ]/ kg	\$[ * ]	
Bulk Pack and Fill	\$[ * ]	
Stability Testing	\$[ * ]	
Release Testing	\$[ * ]	
Set-up Fee @ \$[ * ] Flat Rate	\$[ * ]	Per campaign of less than [ * ] lots of bulk unlabeled/DSM
Subtotal Product	\$[ * ]	
Manufacturing Cost Markup @ [ * ]	\$[ * ]	
<b>Transfer Price</b>	<b>\$[ * ]</b>	

Assumptions:

- 1 Total Direct Manufacturing Costs above based on production of one (1) lot of approximately [ \* ] bottles.
- 2 API is manufactured per the terms of the contract between Lonza and Jazz Pharmaceuticals.
- 3 Product is manufactured per the terms of the contract between DSM and Jazz Pharmaceuticals.
- 4 Set-up fee and [ \* ] markup on the set-up fee to be deleted if [ \* ] more lots of bulk unlabeled Product are run in a campaign.

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**APPENDIX D**

**REGULATORY ASSISTANCE**

1. Marketing Authorizations and Registrations

In connection with UCB's acquisition of the Marketing Authorizations and Registrations and in addition to Jazz Pharmaceuticals' obligations set forth elsewhere in this Agreement, Jazz Pharmaceuticals will, [ \* ] (but subject to the limitations set forth in Section 3.2), take the following actions:

[ \* ]

2. Training, Sales and Technical Literature.

In addition to the materials that Jazz Pharmaceuticals is to provide UCB pursuant to Section 6.5 of this Agreement, Jazz Pharmaceuticals shall also provide to UCB in accordance with Section 6.5, the following materials:

[ \* ]

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**APPENDIX E**

**TRADEMARK USE STANDARDS**

See attached.

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The trademark use standards below are minimum requirements to ensure consistent and appropriate use of the Xyrem® trademark. The consistent application of the Xyrem® trademark standards are essential to conveying a common image to reinforce consumer awareness and recognition of the Xyrem® trademark.

**Use Requirements:**

The Xyrem® trademark should always be displayed in its entirety with the word and design elements used together. To maintain a consistent presentation of the Xyrem® trademark, the word elements should never be separated from the design portion or otherwise manipulated. Such prohibited manipulation includes, but is not limited to, changes in the stylization, font, proportions, and spacing of the word elements.

In order to help preserve the visual impact of the Xyrem® trademark, a minimum amount of clear space should surround the Xyrem® trademark to separate the trademark from other elements such as headlines, text, and other imagery. In addition, the ® symbol should always be displayed with the Xyrem® trademark in its proper position following the last letter within the Xyrem® trademark in those countries in which the mark is registered. Otherwise, the TM symbol should be used.

**Color Requirements:**

**Two color Xyrem logo:** The Xyrem® trademark should be presented in Pantone Match System Blue PMS 287 and Orange PMS 144 and black.



**Four color print to match Xyrem logo:** The Xyrem® trademark is made up of print to match orange PMS 144, yellow PMS 123, blue PMS 287 and Black.



**Black and White Xyrem logo:** The Xyrem® trademark is made up of Black and White.



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**Schedule 8.1(e)(ii)**  
**Patent Rights, Trademarks and Other Intellectual Property**  
**Relating to the Product in the Territory**

[ \* ]

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**Schedule 8.1(e)(iii)**  
**Infringement or Conflict**

None

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**Schedule 8.1(f)(i)**  
**Contracts**

[ \* ]

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**Schedule 8.1(f)(ii)**  
**Default, Breach or Violation**

None

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**Schedule 8.1(g)(i)**  
**Claims**

None

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**Schedule 8.1(h)**  
**Required Approvals**

None

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**LICENSE AGREEMENT**

**by and between**

**SOLVAY PHARMACEUTICALS, INC.**

**and**

**JAZZ PHARMACEUTICALS, INC.**

**relating to**

**LUVOX®-IR (fluvoxamine) and LUVOX®-ER (fluvoxamine extended release)**

**Dated January 31, 2007**



## LICENSE AGREEMENT

This License Agreement (the "Agreement") is made and entered into as of the 31<sup>st</sup> day of January, 2007 ("Effective Date"), by and between SOLVAY PHARMACEUTICALS, INC., a Georgia corporation having its principal office at 901 Sawyer Road, Marietta, Georgia 30062 ("Solvay") and JAZZ PHARMACEUTICALS, INC., a Delaware corporation, having its principal offices at 3180 Porter Drive, Palo Alto, California 94304 ("Jazz Pharmaceuticals"). Solvay and Jazz Pharmaceuticals are referred to herein on occasion separately as a "Party" or together as the "Parties".

WHEREAS, each of Solvay and Jazz Pharmaceuticals is engaged in the business of developing, manufacturing, distributing and selling pharmaceuticals; and

WHEREAS, Solvay is the owner or exclusive licensee of certain assets related to the Products (as hereinafter defined); and

WHEREAS, Solvay has developed and currently has filed an NDA (as hereinafter defined) for each of the Products;

WHEREAS, Solvay has agreed to transfer, assign and/or license to Jazz Pharmaceuticals, as hereinafter set forth, certain rights and interests relating to the Products, and Jazz Pharmaceuticals has agreed to acquire such rights and interests, all as set forth in this Agreement; and

WHEREAS, the Parties will enter into the following agreements related to the Products at the Time of Closing (as hereinafter defined) under this Agreement, the Trademark License and the Supply Agreement (each, as hereinafter defined).

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth in this Agreement, the Parties agree as follows:

### **1. Definitions**

The capitalized terms used in this Agreement shall have the meanings specified below or as otherwise set forth in this Agreement.

1.1 "Affiliate" of an entity means any person or entity controlling, controlled by or under common control with such entity for so long as such control exists. As used herein, "control" means ownership, directly or indirectly, of at least fifty (50%) percent of the common stock or voting ownership interests of the entity in question. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals, such as financial institutions, venture capital funds and private equity investors, will not be "Affiliates" of Jazz Pharmaceuticals for purposes of this Agreement.

1.2 "API" means fluvoxamine maleate, the active pharmaceutical ingredient in the Products.

1.3 “API Information” means the [ \* ] the API.

1.4 “Closing Date” means January 31, 2007 or such other time as Solvay and Jazz Pharmaceuticals shall mutually agree.

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

1.6 “IND” means any Investigational New Drug Applications relating to the Products.

1.7 “Elan” means Elan Pharma International Limited, a company incorporated in Ireland, and its affiliates.

1.8 “Elan Agreement” means the License Agreement by and between Solvay and Elan dated December 22, 1997, as amended up to and including the Closing Date. A copy of the Elan Agreement, as amended up to and including the Effective Date, is attached hereto as Exhibit A.

1.9 “First Commercial Sale” of a Product means the first invoiced commercial sale by Jazz Pharmaceuticals or its Affiliates or sublicensees (excluding, however, sales made by one such entity to another such entity) to a Third Party for commercial purposes in the Territory after receipt of appropriate NDA approval for such Product.

1.10 “Laws and Regulations” means all applicable laws, statutes, licensing requirements, rules, regulations and judicial or administrative decisions applicable to the Products in the Territory and the development, use, sale, import, marketing, promotion, distribution or manufacture thereof in the Territory.

1.11 “Milestones” means the events identified in Sections 3.1 (b) through (k).

1.12 “Milestone Payments” means the payments to be made by Jazz Pharmaceuticals to Solvay pursuant to Sections 3.1 (b) through (k).

1.13 “NDAs” means the New Drug Applications for approval to market the Products submitted to the FDA, as amended or supplemented from time to time, as listed on Schedule 1.13. The NDA currently filed with the FDA relating to LUVOX-IR [ \* ] will be referred to individually as the “LUVOX-IR NDA” and the NDA currently filed with the FDA relating to LUVOX-ER [ \* ] will be referred to individually as the “LUVOX-ER NDA”. The LUVOX-IR NDA and the LUVOX-ER NDA will be referred to collectively as the “Current NDAs.”

1.14 “Net Sales” means the gross amounts invoiced by Jazz Pharmaceuticals and its Affiliates and sublicensees on all sales of the Products to independent unrelated Third Parties in bona fide arms’ length transactions (including, but not limited to, hospital sales, mail orders, retail sales, and sales to federal or state governments, wholesalers, medical institutions, etc.) in the Territory, less (a) transportation and freight charges, including insurance and handling, to the extent that such charges are included in the gross amounts invoiced in connection with the transport of the Products; (b) sales, use and excise taxes, value added taxes, and duties which fall

due and are paid as a consequence of such sales by Jazz Pharmaceuticals or its Affiliates or sublicensees and any other governmental charges imposed upon the importation, use or sale of the; and (c) the following deductions actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to Jazz Pharmaceuticals or its Affiliates:

- (i) trade, quantity and cash discounts;
- (ii) allowances or credits on account of rejection, defects, recall or return of the Products or on account of retroactive price reductions or wholesaler chargebacks affecting such Products; and
- (iii) rebates, refunds, reductions and charge backs specifically related to Products including those granted to insurers, buying groups, government agencies or similar bodies.

“Net Sales” shall not include any sales among Jazz Pharmaceuticals and its Affiliates and sublicensees.

1.15 “Products” means the pharmaceutical preparations owned or controlled by Solvay and/or developed on behalf of Solvay under the Elan Agreement containing the API, referred to and defined below as LUVOX-IR (fluvoxamine maleate) and LUVOX-ER (fluvoxamine maleate extended release), which are the subject of, and are further described in, the Current NDAs. LUVOX<sup>®</sup>-IR (fluvoxamine maleate) will be referred to individually as “LUVOX-IR” and LUVOX<sup>®</sup>-ER (fluvoxamine maleate extended release) will be referred to individually as “LUVOX-ER”.

1.16 “Product Experience Data” means all adverse event information and all product complaints, both technical and medical, concerning the Products in Solvay’s possession or control.

1.17 “Regulatory Materials” means all regulatory submissions and filings or registrations, including any INDs, NDAs, certifications or approvals, made with or received from the FDA and all correspondence and material communications related thereto, together with all other reports or correspondence provided to or received from the FDA, in each case which primarily relate to the API or any Product.

1.18 “Solvay Know-How” means all data (including all clinical, adverse event and product complaint data), information, specifications, methods, processes, techniques, compositions, technology, discoveries, inventions, assays, designs for and results of experiments, tests and studies, study materials, information contained in submissions to and information from the FDA, and statistical and other analyses, in each case related to one or both of the Products or otherwise required for or useful to the development, manufacture, use or sale of one or both Products in the Territory, whether patented or unpatented, which are, at the Time of Closing, owned or controlled by Solvay, including, without limitation, pharmacology, toxicology, clinical and non-clinical safety and efficacy data and quality control and quality assurance data, expressly excluding, however, API Information.

1.19 “**Territory**” means, in the case of LUVOX-IR, the United States of America, its territories and possessions, including Puerto Rico and the U.S Virgin Islands (collectively, the “United States”) and, in the case of LUVOX-ER, the United States and any country(ies) for which Jazz Pharmaceuticals exercises its right of first offer described in Section 2.8 below.

1.20 “**Third Party**” means any person or entity other than Solvay or Jazz Pharmaceuticals or each of their respective Affiliates or, in the case of Jazz Pharmaceuticals, its sublicensees.

1.21 “**Time of Closing**” means 11:00 A.M. (Pacific Daylight Time) on the Closing Date or such other time and date as the Parties mutually agree in writing at which time the Parties are to deliver the closing documents and other deliverables described in Article 8.

1.22 “**Trademark**” means LUVOX® and all trademarks, service marks, logos, slogans, and trade names (whether or not registered), including all variations, derivations, combinations, registrations and applications for registration or renewals of the foregoing and all goodwill associated therewith to the extent of any interest owned, controlled or licensed by Solvay.

## **2. Assignment and License Grants**

2.1 **License to Solvay Know-How.** Solvay hereby grants to Jazz Pharmaceuticals, and Jazz Pharmaceuticals hereby accepts, an exclusive, royalty bearing license, with the right to sublicense, to use Solvay Know-How to use, sell, have sold, offer to sell, import, market, promote and distribute the Products solely in the Territory, and to make or have made the Products inside or outside the Territory (subject to the terms of the Supply Agreement) solely for use, sale, marketing, promotion or distribution in the Territory, and for no other purpose whatsoever, in accordance with and subject to the terms and conditions of this Agreement, the Supply Agreement and the Elan Agreement.

2.2 **Assignment of Elan Agreement.** Pursuant to the terms and conditions of the assignment and assumption agreement attached hereto as Exhibit D (“Assignment and Assumption Agreement”), Solvay shall assign to Jazz Pharmaceuticals, and Jazz Pharmaceuticals shall assume, in each case as of Time of Closing, all of Solvay’s rights and obligations under the Elan Agreement. Solvay will not enter into any amendment to, or otherwise agree to any modification of, the Elan Agreement in the form attached hereto as Exhibit A between the Effective Date and the Closing Date without the prior written consent of Jazz Pharmaceuticals.

2.3 **Trademark License.** The Parties agree to enter into, at the Time of Closing, a Trademark License Agreement dated as of the Closing Date in the form attached as Exhibit B hereto (the “Trademark License”) whereby Solvay grants to Jazz Pharmaceuticals an exclusive license to use the Trademark in the Territory in connection with the Products. In addition, Solvay agrees to apply for any additional trademarks in the Territory containing the term LUVOX® (the “Additional Trademarks”) as may be requested by Jazz Pharmaceuticals [ \* ] and such Additional Trademarks will be included in the definition of (i) Trademark for purposes of this Agreement and (ii) Licensed Mark (as defined in the Trademark License) for purposes of the Trademark License without any further action required by either Party. For the avoidance of doubt, any Additional Trademark shall be the [ \* ].

2.4 Supply Agreement. The Parties agree to enter into, at the Time of Closing, a supply agreement dated as of the Closing Date for supply of API in the form attached hereto as Exhibit C (the "Supply Agreement"), pursuant to which Solvay will manufacture Jazz Pharmaceuticals' requests of API for Jazz Pharmaceuticals during the term thereof. The Parties further agree to enter into a Quality Agreement promptly after the Closing Date defining each Party's responsibilities with respect to quality matters in connection with the Supply Agreement.

2.5 Sublicense to Solvay. Jazz Pharmaceuticals agrees to grant to Solvay an exclusive royalty-free sublicense, outside the LUVOX-ER Territory, under all of the rights assigned and licenses granted hereunder, to use, sell, have sold, offer to sell, import, market, promote and distribute LUVOX-ER outside the LUVOX-ER Territory subject to the Parties negotiating and entering into an agreement within [ \* ] days after the Time of Closing providing for (a) the grant of such royalty-free sublicense rights as described above (and no additional payments will be due to Jazz Pharmaceuticals from Solvay for such sublicense rights); (b) an appropriate apportionment of any payments due to Elan under the Elan Agreement with respect to sales outside the LUVOX-ER Territory; (c) arrangements whereby Solvay will provide Jazz Pharmaceuticals with reports and other information regarding its activities as a sublicensee sufficient to allow Jazz Pharmaceuticals to satisfy its obligations to Elan under the Elan Agreement; (d) Solvay to be bound by terms required to be passed through to a sublicense under the Elan Agreement; (e) Jazz Pharmaceuticals to supply LUVOX-ER to Solvay for sale outside the LUVOX-ER Territory for a price equal to the price that Jazz Pharmaceuticals pays to Elan for LUVOX-ER [ \* ] ([ \* ]%) percent of such price to cover administrative costs; (f) arrangements whereby Jazz Pharmaceuticals will provide Solvay with all necessary access to the NDA dossier for use outside of the Territory; and (g) such other provisions as the Parties deem appropriate. The Parties will negotiate and execute such an agreement promptly and in good faith within [ \* ] days after the Time of Closing.

2.6 No Sales By Solvay Inside the Territory. Solvay, its Affiliates and any successors or assigns of Solvay or its Affiliates shall not, and shall not at any time during the term of this Agreement enter into an agreement whereby it will: (a) sell, market, promote or distribute, directly or indirectly, LUVOX-ER in the Territory; (b) sell, market, promote or distribute, directly or indirectly, a fluvoxamine product in the United States; or (c) sell or distribute the Products to any person outside the Territory if Solvay has knowledge that such person intends to sell such Products in the United States. To the extent permitted by law, such agreement shall secure from such Third Party its obligation to abide by the restrictions relating to inside the Territory contained in this Agreement, including refraining from knowingly engaging, directly or indirectly, in parallel importation or dealing in "grey market" products in connection with its sale and distribution of the Products.

2.7 No Sales By Jazz Pharmaceuticals Outside the Territory. Jazz Pharmaceuticals, its Affiliates and any successors or assigns of Jazz Pharmaceuticals or its Affiliates shall not at any time during the term of this Agreement enter into an agreement whereby it will: (a) sell, market, promote or distribute, directly or indirectly, LUVOX-ER outside the Territory; or (b) sell or distribute LUVOX-ER to any person inside the Territory if Jazz Pharmaceuticals has knowledge that such person intends to sell such LUVOX-ER outside the Territory. To the extent permitted by law, such agreement shall secure from such Third Party its obligation to abide by the restrictions

relating to sales outside the Territory contained in this Agreement, including refraining from knowingly engaging, directly or indirectly, in parallel importation or dealing in “grey market” products in connection with its sale and distribution of LUVOX-ER.

2.8 Right of First Offer. In the event (a), (b) or (c) below occurs, Solvay hereby grants to Jazz Pharmaceuticals a right of first offer to acquire the exclusive license or right to commercialize LUVOX-ER in the applicable country outside the Territory:

(a) Within [ \* ] months following the [ \* ] in a country, Solvay has not [ \* ] LUVOX-ER;

(b) Within [ \* ] months following the [ \* ] in a country, Solvay has not [ \* ] LUVOX-ER; or

(c) Solvay wishes to sublicense, assign or otherwise transfer the rights to LUVOX-ER in a country outside the Territory to any Third Party during the term of this Agreement.

If Solvay (i) fails to [ \* ] stated in (a) or (b) above or (ii) wishes to transfer the rights to LUVOX-ER as set forth in (c) above, Solvay will provide prompt written notice of the same to Jazz Pharmaceuticals. Jazz Pharmaceuticals shall have [ \* ] following the date of Solvay’s written notice within which to deliver written notice to Solvay of its election to acquire the exclusive license or right to commercialize LUVOX-ER in such country. In the event Solvay does not receive such notice within this [ \* ] period, the failure shall be deemed to be Jazz Pharmaceuticals’ election not to acquire the exclusive license or right for such country. In the event Solvay receives such notice within this [ \* ] period, the parties will negotiate in good faith the terms upon which Jazz Pharmaceuticals will acquire this right in such country.

### 3. Compensation

3.1 Upfront Payment and Milestone Payments. As consideration for the license granted by Solvay to Jazz Pharmaceuticals hereunder, Jazz Pharmaceuticals will make the following upfront and milestone payments to Solvay:

(a) Two million (\$2,000,000.00) dollars to be paid as a non-refundable payment at the Time of Closing (the “Upfront Payment”);

(b) Two million (\$2,000,000.00) dollars within [ \* ] days of the First Commercial Sale of LUVOX-IR, supplied by or on behalf of Solvay, by Jazz Pharmaceuticals;

(c) [ \* ] dollars within [ \* ] (which is either an [ \* ] for the [ \* ] of [ \* ] or an [ \* ] for the [ \* ] of [ \* ] );

(d) [ \* ] dollars within [ \* ] (which is either an [ \* ] for the [ \* ] of [ \* ] or an [ \* ] for the [ \* ] of [ \* ] );

(e) [ \* ] dollars within [ \* ] ;

(f) [ \* ] dollars [ \* ] of the [ \* ] of [ \* ] by [ \* ] of the [ \* ] (which is either an [ \* ] for the [ \* ] of [ \* ] or an [ \* ] for the [ \* ] ); provided, however, if the [ \* ] occurs more than [ \* ] following [ \* ] due to [ \* ], the milestone payment payable pursuant to this Section 3.1(f) shall be reduced to [ \* ] (\$[ \* ]) dollars;

(g) [ \* ] dollars within [ \* ] (which is either an [ \* ] for the [ \* ] of [ \* ] or an [ \* ] for the [ \* ]); provided, however, if the [ \* ] (which is either an [ \* ] for the [ \* ] of [ \* ] or an [ \* ] for the [ \* ]) occurs more than [ \* ] following [ \* ], the milestone payment payable pursuant to this Section 3.1(g) shall be reduced to [ \* ] (\$[ \* ]) dollars;

(h) [ \* ] dollars payable as set forth in Section 3.5 after [ \* ] in accordance with the terms and conditions of the [ \* ];

(i) [ \* ] dollars payable as set forth in Section 3.5 when [ \* ];

(j) [ \* ] dollars payable as set forth in Section 3.5 when [ \* ]; and

(k) [ \* ] dollars payable as set forth in Section 3.5 when [ \* ].

Each Milestone Payment shall be made only once, regardless of how many times each related Milestone is achieved. No payment shall be owed for a Milestone which is not reached. In the event that more than one Milestone is achieved at one time, then all applicable payments under Section 3.1 shall be made.

For the sake of clarity, it is acknowledged and understood that in the event [ \* ], the payments in 3.1(c) and 3.1(d) will be due and payable at the same time and the payments in 3.1(f) and 3.1(g) will be due and payable at the same time.

3.2 Reimbursement by Solvay. Solvay will reimburse Jazz Pharmaceuticals for any amounts paid by Jazz Pharmaceuticals to Elan under Sections [ \* ] of the Elan Agreement within thirty (30) days of Jazz Pharmaceuticals' written notice to Solvay that such amounts have been paid.

3.3 Royalty Payments. In addition to the Upfront Payment and Milestone Payments set forth in Section 3.1 above, as further consideration for the transactions contemplated hereunder, including without limitation the license granted by Solvay to Jazz Pharmaceuticals hereunder, Jazz Pharmaceuticals shall pay to Solvay the following royalty payments on Net Sales of LUVOX-ER in each calendar year during the term of the Agreement until such time as [ \* ], excluding [ \* ] (a) [ \* ] percent of LUVOX-ER Net Sales up to and including [ \* ] dollars in such calendar year, and (b) [ \* ] percent of LUVOX-ER Net Sales in excess of [ \* ] dollars in such calendar year. If Jazz Pharmaceuticals (i) is required, by a final court order from which no appeal can be taken, to obtain a royalty-bearing license from a Third Party under any patent which would be infringed by the manufacture, use, offer for sale, sale or import of LUVOX-ER by Jazz Pharmaceuticals or its Affiliates or sublicensees in the Territory or by the manufacture of LUVOX-ER outside the Territory solely for use, sale, marketing, promotion or distribution in the Territory, or (ii) in the exercise of its reasonable judgment, Jazz Pharmaceuticals believes that a license from such Third Party is necessary, then royalty payments due to Solvay under this Section 3.3 will be reduced by an amount equal to [ \* ] by Jazz Pharmaceuticals to such Third Party under such license, provided, however, that in no event will the royalty payments otherwise due under this Section 3.3 be so reduced by more than [ \* ] percent of the amount that would otherwise be calculated under this Section 3.3.

3.4 Records. Jazz Pharmaceuticals shall keep complete and accurate records of all sales of LUVOX-ER in the applicable Territory and the calculation of Net Sales of LUVOX-ER. Solvay shall have the right, at Solvay's expense and after thirty (30) days' prior written notice to Jazz Pharmaceuticals, through an independent certified public accountant, on a mutually agreeable date, to examine such records at any time within [ \* ] after the due date of the royalty payments to which such records relate (but no more than [ \* ]) during regular business hours, during the life of this Agreement and for [ \* ] after its expiration or termination, in order to verify the accuracy of the reports to be made under Section 3.5 hereunder. The results of such examination will be made available to Jazz Pharmaceuticals. If, thereafter, Jazz Pharmaceuticals disputes in good faith the accuracy of the results of such examination, the parties will retain a second independent certified public accountant whose examination will be binding upon both parties. [ \* ].

3.5 Reports. Within forty-five (45) days after the end of each calendar quarter during the term of this Agreement, Jazz Pharmaceuticals shall provide Solvay with a written report of Net Sales of LUVOX-ER during such quarter. Simultaneously with the submission of such report, Jazz Pharmaceuticals shall pay to Solvay all royalty payments due to Solvay under Section 3.3 hereof and the milestone payments due under Sections 3.1(h), (i), (j) and (k), if applicable. Interest, at a rate of [ \* ] percent ([ \* ]%) per annum, or at the highest legal rate if less than [ \* ]%, shall be payable for any late payments.

3.6 Payment Mechanics, Taxes. All payments will be made by wire transfer to an account designated by Solvay to Jazz Pharmaceuticals in writing. All undisputed payments not made when due hereunder will bear interest at the rate stated in Section 3.5 on the date the payment became due. Jazz Pharmaceuticals shall be responsible for the payment of, and shall promptly pay, all federal, state, and local transfer, sales, and other taxes, if any, levied or imposed on Jazz Pharmaceuticals as a result of the transactions contemplated by this Agreement, including without limitation sales and use taxes but excluding any tax payable on any income or gain of Solvay or related to any Upfront Payment, Milestone Payment or royalty payable to Solvay hereunder, for which Solvay shall be responsible and shall pay. All sums payable to Solvay hereunder shall be paid net of any required withholding taxes. Jazz Pharmaceuticals shall submit to Solvay proof of payment of any taxes withheld in accordance with the preceding sentence.

**4. Representations and Warranties of Solvay.** The only representations and warranties of Solvay are those contained in this Article 4. Solvay hereby represents and warrants to Jazz Pharmaceuticals as follows as of the Effective Date and again as of the Time of Closing:

4.1 Organization; Standing. Solvay is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation, and has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, including the performing of all the obligations set forth in this Agreement.

4.2 Authorization; Binding Effect. The execution and delivery by Solvay of this Agreement, the performance by Solvay of its obligations hereunder and the consummation by



Solvay of the transactions contemplated hereby have been duly authorized by all necessary action on the part of Solvay. This Agreement has been duly executed and delivered by a duly authorized representative of Solvay and constitutes the valid and legally binding obligation of Solvay enforceable against Solvay in accordance with its terms.

4.3 No Conflict; No Consents Required. The execution, delivery and performance of this Agreement by Solvay will not (a) violate or result in the breach of, constitute a default under, or accelerate the performance required by, any term of any covenant, agreement or understanding to which Solvay is a party, or any judgment, order, decree, law, rule or regulation to which Solvay entities or is subject, or (b) violate or constitute a breach of or default under the articles of incorporation or bylaws of Solvay. Except as provided in Article 7 and other than any consent required from Elan under the terms of the Elan Agreement as well as any standard corporate proceedings required to be taken by Solvay in connection with the transactions contemplated hereby, no authorization, consent, approval, license, exemption of or filing or registration with any Third Party is or will be necessary for, or in connection with, the execution of this Agreement, the Trademark License or the Supply Agreement by Solvay or the performance of Solvay's obligations thereunder.

4.4 Title; Liens and Encumbrances. Solvay has good and marketable title, free of any mortgage, charge, lien, security interest, restriction, encumbrance or pledge of any nature, to the rights being transferred or licensed to Jazz Pharmaceuticals hereunder. Solvay has the lawful right to grant the licenses as described herein and to assign the Elan Agreement as assigned herein.

4.5 Claims; Litigation. Except as described in Schedule 4.5 attached hereto, there is no action, claim, suit, arbitration, or other legal or administrative proceeding, pending, or, to the knowledge of Solvay or its Affiliates, threatened against, Solvay or its Affiliates pertaining to the API or either or both Products or the development, use, sale, import, marketing, promotion, distribution or manufacture of any thereof, the NDAs or the Elan Agreement and, to Solvay's or its Affiliates' knowledge, no governmental investigation pertaining to any of the foregoing is pending or threatened. There is no judgment, decree, injunction, rule or order of any court, governmental department, commission, agency, instrumentality or arbitrator or other similar ruling outstanding against Solvay or its Affiliates relating to the API or the Products or the development, use, sale, import, marketing, promotion, distribution or manufacture thereof, the NDAs or the Elan Agreement.

4.6 No Broker. Solvay has not engaged any corporation, firm or other person who is entitled to any fee or commission as a finder or broker as a result of the negotiation or consummation of the transactions contemplated by this Agreement.

4.7 Disclosure. Solvay has, to the best of its knowledge, provided or made available to Jazz Pharmaceuticals all relevant and material documents in Solvay's and its Affiliates' possession or control, in each case relating to the Solvay Know-How, the API and the Products and the development, use, sale, import, marketing, promotion, distribution or manufacture thereof in the Territory, the NDAs and the Elan Agreement, including without limitation all agreements with Third Parties set forth on Schedule 4.7 attached hereto related to the development, use, sale, import, marketing, promotion, distribution or manufacture of the API or Products in the Territory

(collectively, the “Third Party Agreements”), and all Product Experience Data and Regulatory Materials. No representations or warranties of Solvay in this Agreement, and no statement contained in any document, certificate or other writing furnished, or to be furnished, to Jazz Pharmaceuticals pursuant hereto contains any untrue statement of a material fact, or omits to state any material fact, which would, in light of the circumstances under which it was made, make such representations, warranties or statements not misleading.

4.8 Compliance with Laws and Regulations. To Solvay’s knowledge, Solvay and its Affiliates have complied and are in compliance with all Laws and Regulations and all laws, statutes, licensing requirements, rules, regulations, and judicial or administrative decisions applicable to the API, the Current NDAs and the Elan Agreement. Without limiting the foregoing, in Solvay’s good faith belief without further investigation (a) no statement contained in any IND, Current NDA or other Regulatory Materials related to the API and the Products contains any untrue statement of a material fact, or omits to state any material fact, which would, in light of the circumstances under which it was made, make any statement of a material fact misleading, and (b) there is no relevant material clinical trial data, CMC information, Product Experience Data or other data or information that should have been disclosed to the FDA in connection with the filing of any IND, Current NDA or Regulatory Materials which has not been so disclosed to the FDA.

4.9 Other Fluvoxamine Products. Solvay and its Affiliates do not [ \* ], including any combination product, [ \* ].

4.10 Contracts. Solvay is not in material breach of or default under the Elan Agreement or any other Third Party Agreements and, to Solvay’s knowledge, no event has occurred which with the passage of time or giving of notice or both would constitute such a default. To Solvay’s knowledge, there is no existing material breach or default by Elan under the Elan Agreement or by any Third Party under any Third Party Agreement and, in each case, no event has occurred which with the passage of time or giving of notice or both would constitute such a default. Solvay has not received any notice from Elan that it intends to terminate or is threatening to terminate or to breach the Elan Agreement or that Solvay is in breach of the Elan Agreement. Solvay has not received any notice from any Third Party that it intends to terminate or is threatening to terminate or to breach any Third Party Agreement or that Solvay is in breach of any Third Party Agreement.

4.11 Patents. The patents and patent applications listed on Schedule 4.11 are the only patents or patents applications owned, controlled or licensed by Solvay or its Affiliates or, to Solvay’s knowledge, owned, controlled or licensed by Elan relating to the Products in the applicable Territory.

4.12 Claims of Infringement. Neither Solvay nor any of its Affiliates has received any notice of any claims by any Third Party asserting that the API or the Products, or the development, use, sale, import, marketing, promotion, distribution or manufacture thereof as contemplated herein, infringes or will infringe or misappropriates or will misappropriate any patent rights or other intellectual property rights of any Third Party or require any payments to any Third Party; [ \* ] with regard to [ \* ].

4.13 Third Party Intellectual Property Rights. To the best of Solvay's and its Affiliates' knowledge after reasonable inquiry, no Third Party patent rights or other intellectual property rights are necessary for the development, use, sale, import, marketing, promotion, distribution or manufacture of the Products as contemplated herein, except those rights assigned to Jazz Pharmaceuticals hereunder under Elan Agreement.

4.14 No Conflicting Rights. Solvay has not granted, and will not grant during the term of this Agreement, any right to any Affiliate or Third Party which would conflict with the rights granted to Jazz Pharmaceuticals hereunder. Solvay will not take, or cause or permit any Affiliate or Third Party to take, any action that will conflict with, contravene or otherwise limit or restrict the rights of Jazz Pharmaceuticals hereunder or the right of Jazz Pharmaceuticals to enjoy the benefits of this Agreement.

4.15 Elan Agreement. The copy of the Elan Agreement attached hereto as Exhibit A is a true, correct and complete copy of the Elan Agreement as in effect as of the Effective Date.

**5. Representations and Warranties of Jazz Pharmaceuticals.** The only representations and warranties of Jazz Pharmaceuticals are those contained in this Article 5. Jazz Pharmaceuticals hereby represents and warrants to Solvay as follows as of the Effective Date and again as of the Time of Closing:

5.1 Organization; Standing. Jazz Pharmaceuticals is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation, and has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, including the performing of all the obligations set forth in this Agreement.

5.2 Authorization; Binding Effect. The execution and delivery by Jazz Pharmaceuticals of this Agreement, the performance by Jazz Pharmaceuticals of its obligations hereunder and the consummation by Jazz Pharmaceuticals of the transactions contemplated hereby have been duly authorized by all necessary action on the part of Jazz Pharmaceuticals. This Agreement has been duly executed and delivered by a duly authorized officer of Jazz Pharmaceuticals and constitutes the valid and legally binding obligation of Jazz Pharmaceuticals enforceable against Jazz Pharmaceuticals in accordance with its terms.

5.3 No Conflict; Consents. The execution, delivery and performance of this Agreement by Jazz Pharmaceuticals will not (a) violate or result in the breach of, constitute a default under, or accelerate the performance required by, any term of any covenant, agreement or understanding to which Jazz Pharmaceuticals is a party, or any judgment, order, decree, law, rule or regulation to which Jazz Pharmaceuticals is subject and (b) violate or constitute a breach of or default under the certificate of incorporation or bylaws of Jazz Pharmaceuticals. Except as provided in Article 7 as well as any standard corporate proceedings required to be taken by Jazz Pharmaceuticals in connection with the transactions contemplated hereby, no authorization, consent, approval, license, exemption of or filing or registration with any Third Party is or will be necessary for, or in connection with, the execution of this Agreement, the Trademark License or the Supply Agreement by Jazz Pharmaceuticals or the performance of Jazz Pharmaceuticals' obligations thereunder.

5.4 No Broker. Jazz Pharmaceuticals has not engaged any corporation, firm or other person who is entitled to any fee or commission as a finder or broker as a result of the negotiation or consummation of the transactions contemplated by this Agreement.

5.5 Disclosure. No representations or warranties of Jazz Pharmaceuticals in this Agreement, and no statement contained in any document, certificate or other writing furnished, or to be furnished, to Solvay pursuant hereto contains any untrue statement of a material fact, or omits to state any material fact, which would, in light of the circumstances under which it was made, make such representations, warranties or statements not misleading.

## **6. Regulatory Matters.**

6.1 Transfer of Current NDAs. Within [ \* ] business days of Solvay's receipt of notification of FDA approval of the LUVOX-IR NDA, Solvay shall transfer and assign ownership and responsibility of such NDA and corresponding INDs to Jazz Pharmaceuticals. Within [ \* ] business days of Solvay's receipt of notification of FDA approval of the LUVOX-ER NDA, Solvay shall transfer and assign ownership and responsibility of the LUVOR-ER NDA and corresponding INDs to Jazz Pharmaceuticals.

6.2 Transfer of Regulatory Responsibilities. Until the transfer of each respective Current NDA (and corresponding INDs) to Jazz Pharmaceuticals, Solvay shall remain responsible, at its sole expense, for all regulatory responsibilities as holder of such NDA and corresponding INDs and all other responsibilities under applicable Laws and Regulations. Subject to Solvay's indemnification obligations hereunder and any other obligations and/or rights of Solvay contained in this Agreement and the Supply Agreement, effective upon the transfer and assignment of each respective Current NDA, all of Solvay's obligations and responsibilities as the holder of such Current NDAs shall be assumed in their entirety by Jazz Pharmaceuticals; provided, however, that Solvay will remain responsible for any liability incurred or obligation breached under each NDA which is not a Current NDA and corresponding INDs; provided further that Solvay will remain responsible for any liability incurred or obligation breached under each Current NDA and corresponding INDs prior to the effective date of the transfer and assignment to Jazz Pharmaceuticals of such Current NDA and corresponding INDs. Upon transfer of each respective Current NDA (and the corresponding INDs) to Jazz Pharmaceuticals, Jazz Pharmaceuticals shall assume, at its sole expense, all regulatory responsibilities as holder of such Current NDA and corresponding INDs and all other responsibilities under applicable Laws and Regulations in the applicable Territory, reporting and otherwise, in connection with each of the Products in the applicable Territory. These responsibilities shall include, without limitation, those responsibilities related to (i) the marketing and promotion by Jazz Pharmaceuticals and its Affiliates and sublicensees of the Product in the Territory; (ii) reporting Product Experience Data relating to the Products to the FDA; (iii) if applicable, the filing of additional new drug applications and/ supplements to NDAs for product line extensions, extensions of the expiry date and additional product claims or additions to the labeling of the Products; and (iv) any ongoing and future commitments to the FDA applicable to the holder of the Current NDAs.

6.3 Regulatory Materials. Solvay has provided Jazz Pharmaceuticals and will continue to provide Jazz Pharmaceuticals with full access to all Regulatory Materials and

Product Experience Data. Upon the transfer and assignment of each respective Current NDA and corresponding INDs, Solvay will provide Jazz Pharmaceuticals with all Regulatory Materials and copies of Product Experience Data related thereto (including without limitation any and all electronic databases related thereto); provided that Solvay may retain an archival copy of the Regulatory Materials, including supplements and records that are required to be kept under 21 C.F.R. §314.81.

6.4 Communications with Regulatory Agencies. Prior to the transfer of the Current NDAs to Jazz Pharmaceuticals, Solvay shall have primary responsibility for communications with the FDA; provided, however, that (a) Solvay will promptly provide Jazz Pharmaceuticals with copies of all correspondence (and summaries of all communications) from or to the FDA with respect to the API and the Products and the Current NDAs, (b) Jazz Pharmaceuticals will have the right to review and comment upon any filings and correspondence from Solvay to the FDA with respect to the API, the Products and the Current NDAs prior to filing and Solvay will include any changes reasonably requested by Jazz Pharmaceuticals; (c) Jazz Pharmaceuticals will have the right to participate in all meetings and significant telephone calls with the FDA with respect to the API, the Products and the Current NDAs and (d) Solvay will not make any agreements with, or commitments to, the FDA or otherwise in connection with the API, the Products or the Current NDAs between the Effective Date and the Closing Date, and thereafter until the effective date of the transfers of the Current NDAs, without the prior written consent of Jazz Pharmaceuticals, which consent shall not be unreasonably delayed or withheld. After the transfer of the each Current NDA (and the corresponding INDs), Jazz Pharmaceuticals shall have responsibility for all communications with the FDA with respect matters relating to the Products and the Current NDAs and corresponding INDs. To the extent reasonably requested by Jazz Pharmaceuticals, Solvay will cooperate with and assist Jazz Pharmaceuticals in its communications with the FDA relating to the Products and the Current NDAs and corresponding INDs for a reasonable transition period after the effective date of the transfers of the Current NDAs.

6.5 Post-Transfer Activities. The Parties agree to enter into a Pharmacovigilance Agreement promptly after the Closing Date, defining each Party's responsibilities with respect to drug safety and communications relating thereto after the transfer of each Current NDA and the corresponding INDs to Jazz Pharmaceuticals.

6.6 Additional Regulatory Commitments. In the event that, in connection with or as a condition of the approval of either of the Current NDAs, the FDA requires the conduct of additional post-approval studies or activities, Solvay will reimburse Jazz Pharmaceuticals for [ \* ] percent ([ \* ]%) of all amounts expended by Jazz Pharmaceuticals and submitted to Solvay prior to the [ \* ] anniversary of the date upon which such NDA approval or conditional approval is granted on the preparation for and conduct of such studies or other activities and related filings with regulatory authorities[ \* ].

## 7. HSR Filing

7.1 Filing. Solvay and Jazz Pharmaceuticals shall file, prior to, on or promptly after the Effective Date of this Agreement, with the Federal Trade Commission ("FTC") and the Antitrust Division of the United States Department of Justice ("Antitrust Division"), the notification and

report form (the "Report") required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act"), with respect to the transactions contemplated under this Agreement. The Parties shall cooperate with each other to proceed to obtain any necessary approvals under the HSR Act, including, without limitation, the expiration or, if requested by Jazz Pharmaceuticals, the earlier termination of any and all applicable waiting period required by the HSR Act. Each Party will be responsible for its own costs and expenses associated with any filing under the HSR Act and the Parties will share equally the filing fee due to the FTC for filing of the Report.

7.2 HSR Cooperation. Solvay and Jazz Pharmaceuticals shall each use diligent efforts to eliminate any concern on the part of any court or government authority regarding the legality of the proposed transaction, including, if required by federal or state antitrust authorities, promptly taking steps to secure government antitrust clearance, including, without limitation, cooperating in good faith with any government investigation.

7.3 HSR Termination. In the event that the FTC, the Antitrust Division or any U.S. court or government authority of competent jurisdiction shall issue a final determination to the Parties that the transactions contemplated under this Agreement are illegal and/or violative of U.S. federal antitrust laws, then either Party shall at any time thereafter have the right to terminate and rescind this Agreement by notifying the other Party to that effect. Upon mutual agreement, the Parties may also elect to contest such determination and shall coordinate such efforts with each Party bearing its own expenses in connection therewith. Upon receipt of notice of termination and rescission by a Party pursuant to this Section 7.3, this Agreement shall be rescinded and of no further force or effect and the Parties shall fully cooperate to return all rights, assignments and other interests and/or property exchanged or transferred by one Party to the other pursuant to this Agreement or otherwise in connection with the completion of the transactions contemplated hereunder, including all amounts paid by Jazz Pharmaceuticals hereunder.

## **8. Closing.**

8.1 Conditions Precedent to Jazz Pharmaceuticals' Obligations. Each and every obligation of Jazz Pharmaceuticals to be performed on the Closing Date shall be subject to the satisfaction prior to or on the Closing Date of each of the following conditions, any or all of which may be waived by Jazz Pharmaceuticals in writing:

(a) Representations and Warranties True on the Closing Date. Each of the representations and warranties made by Solvay in this Agreement shall be true and correct in all material respects when made and shall be true, complete and correct in all material respects at and as of the Closing Date as though such representations and warranties were made or given on and as of the Closing Date.

(b) Compliance with Agreement. Solvay shall have in all material respects performed and complied with all of its agreements and obligations under this Agreement which are to be performed or complied with by Solvay prior to or on the Closing Date.

(c) Consents and Approvals. Solvay has received all approvals, consents and waivers that are required to effect the transactions contemplated hereby and copies of such documents

which are in Solvay's possession shall have been received by Jazz Pharmaceuticals on or prior to the Closing Date. Any necessary approvals under the HSR Act shall have been received, including, without limitation, the expiration or, if requested by Jazz Pharmaceuticals (or Solvay, at Jazz Pharmaceuticals' request), the earlier termination of any and all applicable waiting period required by the HSR Act.

8.2 Conditions Precedent to Solvay's Obligations. Each and every obligation of Solvay to be performed on the Closing Date shall be subject to the satisfaction prior to or on the Closing Date of each of the following conditions, any or all of which may be waived by Solvay in writing:

(a) Representations and Warranties True on the Closing Date. Each of the representations and warranties made by Jazz Pharmaceuticals in this Agreement shall be true, complete and correct in all material respects when made and shall be true and correct in all material respects at and as of the Closing Date as though such representations and warranties were made or given on and as of the Closing Date.

(b) Compliance with Agreement. Jazz Pharmaceuticals shall have in all material respects performed and complied with all of its agreements and obligations under this Agreement which are to be performed or complied with by Jazz Pharmaceuticals prior to or on the Closing Date.

(c) Consents and Approvals. Jazz Pharmaceuticals has received all approvals, consents and waivers that are required to effect the transactions contemplated hereby and copies of such documents which are in Jazz Pharmaceuticals' possession shall have been received by Solvay on or prior to the Closing Date. Any necessary approvals under the HSR Act shall have been received, including, without limitation, the expiration or, if requested by Jazz Pharmaceuticals, the earlier termination of any and all applicable waiting period required by the HSR Act.

### 8.3 Deliveries at Closing.

(a) Solvay Deliveries. At or prior to the Time of Closing, Solvay shall have delivered or caused to be delivered to Jazz Pharmaceuticals, any or all of which may be waived by Jazz Pharmaceuticals in writing:

(i) physical possession (or the implementation of arrangements reasonably satisfactory to both Parties of transfer and delivery of physical possession) of all tangible personal property (or copies thereof) concerning the Products, including all tangible personal property included in the Solvay Know-How, with as much as possible in electronic form;

(ii) a certificate, dated the Closing Date and signed by its President or any Vice President, to the effect that all corporate proceedings required to be taken by Solvay in connection with the transactions contemplated hereby have been taken and that all representations and warranties are true, complete and correct as of the Closing Date;

(iii) a duly executed Trademark License;

(iv) a duly executed Supply Agreement;

(v) a true, correct and complete copy of the Elan Agreement as in effect as of the Closing Date, accompanied by a certificate, dated the Closing Date and signed by Solvay's President or any Vice President, to that effect;

(vi) a written consent of Elan, in a form acceptable to Jazz Pharmaceuticals, to Solvay's assignment of the Elan Agreement hereunder;

(vii) a duly executed Assignment and Assumption Agreement relating to the Elan Agreement; and

(viii) such other documents, instruments and certificates as Jazz Pharmaceuticals and Solvay may mutually agree upon.

(b) Deliveries by Jazz Pharmaceuticals. At or prior to the Time of Closing, Jazz Pharmaceuticals shall deliver or cause to be delivered to Solvay, any or all of which may be waived by Solvay in writing:

(i) the Upfront Payment;

(ii) a duly executed Trademark License;

(iii) duly executed Supply Agreement;

(iv) a certificate, dated the Closing Date and signed by its Chief Executive Officer, to the effect that all corporate proceedings required to be taken by Jazz Pharmaceuticals in connection with the transactions contemplated hereby have been taken and that all representations and warranties are true, complete and correct as of the Closing Date;

(v) a duly executed Assignment and Assumption Agreement relating to the Elan Agreement; and

(vi) such other documents, instruments and certificates as Jazz Pharmaceuticals and Solvay may mutually agree upon.

## **9. Cooperation; Further Assurances.**

9.1 Proceedings Relating to the Products. Each Party covenants and agrees as to any suit, action, arbitration or judicial proceeding or any governmental investigation or inquiry, relating to the API, either of the Products or the NDAs, being prosecuted or defended by the other Party, to cooperate in making records available to such other Party and to provide such access to, and use of, such information and data as reasonably requested by such other Party in connection therewith. Each Party will reimburse the Party providing such cooperation for its reasonable out-of-pocket expenses incurred in connection with its obligations hereunder.

9.2 Information. From time to time after the Closing Date, the Parties hereto shall deliver to each other such information and data concerning the transactions contemplated hereby as either Party may reasonably request including that required in order to enable such Party to complete and file all national, state and local forms which may be required to be filed by it and to complete all customary tax and accounting procedures and otherwise to enable such Party to satisfy its internal accounting, tax and other requirements.



9.3 Further Assurances. From time to time after the Closing Date, without further consideration, Solvay shall perform all such other actions and shall execute, acknowledge and deliver all such assignments, transfers, consents and other documents as Jazz Pharmaceuticals or its counsel may reasonably request with respect to, and for the purpose of carrying out or evidencing, any of the transactions contemplated hereby.

## 10. Indemnification; Insurance.

10.1 Survival. All representations and warranties of Solvay and Jazz Pharmaceuticals contained herein will survive for a period of [ \* ]. The covenants and agreements of the parties hereto contained in this Agreement will survive and remain in full force for the applicable periods described therein or, if no such period is specified, [ \* ]. Any right of indemnification pursuant to this Article 10 with respect to a claimed breach of a representation, warranty or covenant will expire at the date of termination of the representation, warranty or covenant claimed to be breached, unless on or prior to such date the party from whom indemnification is sought will have received notice in accordance with the provisions of Section 10.5 hereof.

10.2 Indemnification by Solvay. Solvay hereby agrees to indemnify Jazz Pharmaceuticals and its Affiliates and their respective officers, directors and employees (the "Jazz Pharmaceuticals Indemnified Parties") from and against all claims, disputes, actions, arbitrations, mediations, litigations, proceedings, suits and governmental investigations brought by a Third Party and any appeal therefrom (the "Claims"), and agrees to hold them harmless from, any costs, expenses, damages, and loss, including reasonable attorneys fees in respect of such Claims and to enforce rights to indemnification as herein provided ("Losses") to the extent such Losses arise from or in connection with the following:

- (i) any breach by Solvay of any representation or warranty made by it contained in this Agreement, provided Solvay receives notice of the same within [ \* ] after the Time of Closing;
- (ii) any breach by Solvay of any of its covenants contained in this Agreement;
- (iii) any and all liabilities and obligations of Solvay to Elan, any Affiliates of Elan or any other Third Party which liabilities or obligations either (A) accrued to Solvay prior to the Time of Closing, (B) relate to events occurring prior to the Time of Closing or (C) accrue to or from Solvay under any sublicense rights granted to Solvay by Jazz Pharmaceuticals under Section 2.5 of this Agreement;
- (iv) the manufacture, sale, marketing or distribution of the API or Products outside the Territory by Solvay or its Affiliates or sublicensees, and the operation of the business of Solvay or its Affiliates or sublicensees related to the API or the Products at any time after the Closing Date;

(v) the negligence or willful misconduct of any of the Solvay Indemnified Parties (as defined below);

provided, however, that in each case Solvay will not be obligated to indemnify any Jazz Pharmaceuticals Indemnified Parties with respect to, and to the extent of, any Losses for which Jazz Pharmaceuticals is obligated to indemnify Solvay pursuant to Section 10.3.

Notwithstanding anything to the contrary, the indemnifications in favor of the Jazz Indemnified Parties contained in this Section 10.2: (a) [ \* ]; (b) and [ \* ].

Jazz Pharmaceuticals acknowledges and agrees that the indemnification provided in this Section 10.2 [ \* ].

10.3 Indemnification by Jazz Pharmaceuticals. Jazz Pharmaceuticals hereby agrees to indemnify Solvay and its officers, directors and employees (the “Solvay Indemnified Parties”) against, and agrees to hold them harmless from, any Claims and Losses to the extent such Losses arise from or in connection with the following:

- (i) any breach by Jazz Pharmaceuticals of any representation or warranty made by it contained in this Agreement;
- (ii) any breach by Jazz Pharmaceuticals of any of its covenants contained in this Agreement;
- (iii) the manufacture, sale, marketing or distribution of the Products in the Territory by Jazz Pharmaceuticals or its Affiliates or sublicensees after the Closing Date, and the operation of the business of Jazz Pharmaceuticals or its Affiliates or sublicensees related to the Products at any time after the Closing Date; or
- (iv) the negligence or willful misconduct of any of the Jazz Pharmaceuticals Indemnified Parties;

provided, however, that in each case Jazz Pharmaceuticals will not be obligated to indemnify any Solvay Indemnified Parties with respect to, and to the extent of, any Losses for which Solvay is obligated to indemnify Jazz Pharmaceuticals pursuant to Section 10.2.

Solvay acknowledges and agrees that the indemnification provided in this Section 10.3 will [ \* ].

10.4 No Incidental Damages. In no event will either Party be liable to the other Party for incidental, indirect, punitive, exemplary, special or consequential damages, such as losses of revenues or profits, whether based upon a claim or action of contract, warranty, negligence, strict liability or other tort, a product claim, or otherwise arising out of or related to this Agreement; provided, however, that the foregoing limitation shall not apply to damages due to a third party which are the subject of a valid claim for indemnification hereunder.

10.5 Procedure. In order for an indemnified party under this Article 10 (an “Indemnified Party”) to be entitled to any indemnification provided for under this Agreement, such Indemnified Party will, promptly following the discovery of the matters giving rise to any

Loss, notify the indemnifying party under this Article 10 (the “Indemnifying Party”) in writing of its claim for indemnification for such Loss, specifying in reasonable detail the nature of such Loss and the amount of the liability estimated to accrue therefrom, if known; provided, however, that failure to give such prompt notification will not affect the indemnification provided hereunder except to the extent the Indemnifying Party will have been actually prejudiced as a result of such failure (except that the Indemnifying Party will not be liable for any expenses incurred during the period in which the Indemnified Party failed to give such notice). Thereafter, the Indemnified Party will deliver to the Indemnifying Party, within ten (10) business days after the Indemnified Party’s receipt of such request, all information and documentation reasonably requested by the Indemnifying Party with respect to such Loss.

10.6 Third Party Claims. If the indemnification sought pursuant hereto involves a claim made by a third party against the Indemnified Party (a “Third Party Claim”), the Indemnifying Party will be entitled to participate in the defense of such Third Party Claim and, if it so chooses, to assume the defense of such Third Party Claim with counsel selected by the Indemnifying Party; provided, however, that the Indemnifying Party shall not be entitled to assume control of such defense and shall pay the reasonable fees and expenses of counsel retained by the Indemnified Party if the Third Party Claim relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation. Should the Indemnifying Party be permitted and so elect to assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof unless and to the extent that a conflict arises between the interests of the Parties. If the Indemnifying Party assumes such defense, the Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof (other than during any period in which the Indemnified Party will have failed to give notice of the Third Party Claim as provided above) or in the event of a conflict of interest between the Parties. If the Indemnifying Party chooses to defend or prosecute a Third Party Claim, each of the Parties hereto will cooperate in the defense or prosecution thereof. Such cooperation will include the retention and (upon the Indemnifying Party’s request) the provision to the Indemnifying Party of records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will agree to any settlement, compromise or discharge of such Third Party Claim which the Indemnifying Party may recommend and which by its terms obligates the Indemnifying Party to pay the full amount of the liability in connection with such Third Party Claim; provided, however, that the Indemnified Party shall have the right to consent to any such settlement, compromise or discharge that (x) would materially adversely affect the rights granted to the Indemnified Party hereunder, (y) would materially conflict with the terms of this Agreement or (z) would materially adversely affect the Products outside the Territory. Whether or not the Indemnifying Party will have assumed the defense of a Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnifying Party’s prior written consent.

## 11. Term and Termination.

11.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in effect until terminated in accordance with the terms hereof.

11.2 Termination for Breach. This Agreement may be terminated by either Party in the event the other Party breaches its obligation(s) under this Agreement and does not cure the same within [ \* ] following written notice of such breach; provided, however, that if the breach is of such a nature that it can not be cured within [ \* ], then the time to cure shall be extended until such breach can reasonably be cured.

11.3 Termination by Either Party. If the FTC and/or the Antitrust Division has not made a determination regarding the validity or legality of the transactions contemplated herein within [ \* ] following the Effective Date, then either of the Parties may terminate this Agreement, in which case the Parties shall fully cooperate to return all rights, assignments and other interests and/or property exchanged or transferred by one Party to the other pursuant to this Agreement, including all amounts paid by Jazz Pharmaceuticals hereunder; provided, however, that a Party shall not be permitted to terminate this Agreement in the event that the failure of the FTC and/or the Antitrust Division to make a determination regarding the validity or legality of the transactions contemplated herein within [ \* ] following the Effective Date is a result of such Party's failure to cooperate with respect to the Report in accordance with the terms of Article 7. In addition, this Agreement may be terminated by either Party in accordance with the terms of Section 7.3 and/or Section 13.9.

11.4 Termination by Jazz Pharmaceuticals. If either (a) the FDA has not approved the LUVOX-IR NDA by [ \* ] or (b) the FDA has not approved the LUVOX-ER NDA by [ \* ], then Jazz Pharmaceuticals shall have the right to terminate this Agreement with written notice to Solvay, in which case the Parties shall fully cooperate to return all rights, assignments and other interests and/or property exchanged or transferred by one Party to the other pursuant to this Agreement, including all amounts paid by Jazz Pharmaceuticals hereunder (expressly excluding the Upfront Payment).

## 12. Confidentiality.

12.1 "Confidential Information" means the existence of this Agreement, information relating to the terms of this Agreement, the products, services, business, personnel, research, development, manufacturing or commercial activities of a Party, including, but not restricted to, unpublished patent applications, formulae, compilations, programs, devices, concepts, tests, results, inventions, designs, methods, techniques, marketing and commercial strategy and information, processes, data concepts, and unique combinations of separate items which individually may or may not be confidential, which information is not generally known to the public and either derives economic value, actual or potential, from not being generally known or has a character such that the Party has a legitimate interest in maintaining its secrecy. Confidential Information will not include information which, as demonstrated by competent evidence: (i) was known to the receiving Party prior to the disclosure; (ii) was generally available to the public at the time of disclosure or becomes available to the public after disclosure other than through any act or omission of the receiving Party in breach of this Agreement; or (iii) becomes known to the receiving Party as the result of disclosure

from a third party under no obligation of secrecy to the disclosing Party. If Confidential Information is required to be disclosed by law or pursuant to the disclosure requirements of a governmental agency, the Party ordered to disclose the Confidential Information shall notify the disclosing Party which owns or supplied the Confidential Information sought to be disclosed pursuant to such request, requirement or order in sufficient time to allow such disclosing Party to oppose such request, requirement or order.

12.2 Confidentiality Obligation. The Parties shall each keep in strictest confidence all Confidential Information and shall not disclose such Confidential Information to any third person except employees, consultants or other agents who need to receive such Confidential Information for the purpose of achieving an objective of this Agreement and who are bound by obligations of confidentiality with respect thereto, as necessary in connection with the transactions provided for or contemplated hereby, or as may otherwise be required by law and to the extent related to the exploitation of the Products, including such disclosures to licensees, sublicensees or assigns as may be reasonably required to permit the exploitation of the Products. Each such licensee, sublicensee or assignee shall be obligated to by an agreement of confidentiality binding such licensee, sublicensee or assignee to the same extent to which the Party from which it received the Confidential Information is bound. The Parties shall exercise all necessary precautions to safeguard the secrecy of Confidential Information and to prevent the unauthorized disclosure thereof. Except as otherwise provided herein, the obligations of this Article 12 shall survive for a period of [ \* ] years from the [ \* ].

### 13. Miscellaneous.

13.1 Force Majeure. If any Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement, by reason of force majeure, including, but not limited to fire, flood, earthquake, explosion, storm, strike, lockout or other labor trouble, riot, war, rebellion, accidents, acts of God and/or any other cause or externally induced casualty beyond its reasonable control, whether similar to the foregoing matters or not, then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability; provided that the Party asserting force majeure shall bear the burden of establishing the existence of such force majeure by clear and convincing evidence; and provided further, that the Party prevented from complying shall use its best efforts to remove such disability within thirty (30) days, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the force majeure event not more than five (5) working days from the time of the event. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

13.2 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

13.3 Headings. Section headings are inserted for convenience of reference only and do not form a part of this Agreement, and no construction or inference shall be derived from them.

13.4 Counterparts. This Agreement may be executed simultaneously in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.5 Entire Agreement. This Agreement and the Exhibits attached hereto, together with the Trademark License, Assignment and Assumption Agreement and the Supply Agreement, set forth the entire agreement and understanding of the Parties regarding the subject matter.

13.6 Amendment; Waiver, Etc. This Agreement may be amended, modified, superseded or canceled, and any of its terms may be waived, only by a written instrument executed by both Parties or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provision shall in no manner affect the rights of such Party at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such breach or the breach of any other term of this Agreement.

13.7 No Third Party Beneficiaries. No person or entity not a Party to this Agreement, including any employee of any Party to this Agreement, shall have or acquire any rights by reason of this Agreement, nor shall either Party have any obligations or liabilities to such other person or entity by reason of this Agreement.

13.8 Assignment and Successors. This Agreement may not be assigned by either Party to any Third Party without the prior written consent of the other Party; except that either Party may assign this Agreement, without the prior written consent of the other Party, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation with or into such corporation. In the event of any such assignment, the assignee shall expressly assume in writing the performance of all the terms and conditions of this Agreement and all of the obligations to be performed by the assignor. Any assignment not in accordance with this Agreement will be void.

13.9 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance will, to any extent, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, will not be affected thereby and each term, covenant or condition of this Agreement will be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated; provided, however, that if a provision is stricken so as to significantly alter the economic arrangements of this Agreement, the Party adversely affected may terminate this Agreement upon sixty (60) days' prior written notice to the other Party.

13.10 Notices. All notices shall be mailed via certified mail, return receipt requested, by nationally recognized overnight courier or by facsimile transmission (receipt verified), addressed as follows, or to such other addresses as may be designated from time to time by notice given in the manner provided in this Section 13.10:

If to Solvay: SOLVAY PHARMACEUTICALS, Inc.  
901 Sawyer Road  
Marietta, Georgia 30062  
ATTN: Office of the President  
CC: General Counsel  
Facsimile: 770-578-5749

If to Jazz Pharmaceuticals: JAZZ PHARMACEUTICALS, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
Attn: General Counsel  
Facsimile: 650-496-3781

13.11 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with the laws of the State of New York, without regard to principles of conflicts of law.

13.12 Publicity. The Parties will agree upon the contents of a joint press release or a Jazz Pharmaceuticals press release to be made promptly after the Closing Date or, if requested by Jazz Pharmaceuticals, at a later date chosen by Jazz Pharmaceuticals. Except for information in such press release, neither Party will make any public announcement concerning, or otherwise publicly disclose, the existence of this Agreement, any information with respect to the transactions contemplated by this Agreement, the performance under it or any of the terms and conditions hereof without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may make any public disclosure concerning the transactions contemplated hereby that in the opinion of such Party's counsel may be required by law or the rules of any stock exchange on which such Party's or its Affiliates' securities trade; provided, however, the Party making such disclosure will provide the non-disclosing Party with a copy of the intended disclosure reasonably, and to the extent practicable, prior to public dissemination, and the Parties hereto will coordinate with one another regarding the timing, form and content of such disclosure.

13.13 Consent/Approval. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval will not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval will not unreasonably be exercised.

13.14 Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Except as otherwise expressly provided in this Agreement, neither Party assumes or will assume, either directly or indirectly, any liability or obligations of or for the other Party, whether past, present or future. Neither Party will have the authority to bind or obligate the other Party and neither Party will represent that it has such authority.

13.15 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing Party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such Party may be entitled.

13.16 Specific Performance. The Parties hereto agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof and that the Parties shall be entitled to seek specific performance of the terms hereof in addition to any other remedy at law or in equity.

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.



IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

**JAZZ PHARMACEUTICALS, INC.**

By: /s/ Samuel R. Saks, M.D.  
Print Name: Samuel R. Saks, M.D.  
Title: Chief Executive Officer  
Date: January 22, 2007

**SOLVAY PHARMACEUTICALS, INC.**

By: /s/ Laurence J. Downey, M.D.  
Print Name: Laurence J. Downey, M.D.  
Title: President and Chief Executive Officer  
Date: January 26, 2007

**[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.**

**Exhibit A**  
**Elan Agreement**

{This Exhibit A has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**Exhibit B**  
**Form of Trademark License Agreement**

{This Exhibit B has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**Exhibit C**  
**Form of Supply Agreement**

{This Exhibit C has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

28

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**Exhibit D**  
**Assignment and Assumption Agreement**

{This Exhibit D has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

29

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**Schedule 1.13**

There have been three NDAs filed related to LUVOX-IR or its predecessor products:

- [ \* ] (withdrawn in September 1994)
- [ \* ] (withdrawn in May 2002)
- [ \* ] (pending with the FDA)

There have been two NDAs filed related to LUVOX-ER or its predecessor products:

- [ \* ] (withdrawn in June 2001)
- [ \* ] (pending with the FDA)

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**Schedule 4.5**

Solvay has been contacted regarding a [ \* ] resulting from [ \* ] To Solvay's knowledge and belief, [ \* ]

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**Schedule 4.7**

None.

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**Schedule 4.11**

Elan has the following patents and patent applications:

[ \* ]

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SUPPLY AGREEMENT

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Between  
Jazz Pharmaceuticals, Inc.  
and  
Solvay Pharmaceuticals, Inc.  
for  
Fluvoxamine Maleate

## SUPPLY AGREEMENT

This Supply Agreement (the "Agreement") is entered into as of the 31<sup>st</sup> day of January, 2007 (the "Effective Date"), by and between Jazz Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, "Jazz Pharmaceuticals"), and Solvay Pharmaceuticals, Inc., a Georgia corporation ("Solvay").

### RECITALS

WHEREAS, Solvay is engaged in the manufacture of the active pharmaceutical ingredient fluvoxamine maleate;

WHEREAS, Jazz Pharmaceuticals and Solvay have entered into a License Agreement (the "License Agreement"), dated as of January 31, 2007, whereby Solvay transferred, assigned and licensed to Jazz Pharmaceuticals certain rights and interests in the pharmaceutical products referred to as LUVOX<sup>®</sup>-IR and LUVOX<sup>®</sup>-ER, as more fully described in the Assignment and License Agreement;

WHEREAS, in connection with the License Agreement, Jazz Pharmaceuticals wishes to have Solvay manufacture and supply API (as defined below) for use in the manufacture of LUVOX-IR and LUVOX-ER during the Term of this Agreement; and

WHEREAS, Solvay wishes to manufacture and supply Jazz Pharmaceuticals with the API on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

### ARTICLE 1

#### DEFINITIONS

Capitalized terms used in this Agreement shall have the meanings ascribed to them in this Article 1 or as otherwise set forth herein. Unless the context indicates otherwise, the singular shall include the plural and the plural shall include the singular.

1.1 "Act" means the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

1.2 "Affiliates" means a corporation or any other entity that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the designated party, but only for so long as the relationship exists. "Control" shall mean ownership of shares of stock having at least 50% of the voting power entitled to vote for the election of directors in the case of a corporation. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals such as financial institutions, venture capital funds and private equity investors shall not be its "Affiliates" for purposes of this Agreement.

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1.3 "API" means fluvoxamine maleate conforming to cGMP, all applicable Laws and the API Specifications, as they may be updated from time to time in accordance with this Agreement or as required by applicable Regulatory Approvals.

1.4 "API Specifications" means the written specifications for the API as set forth in [ \* ] as well as the corresponding Regulatory Approvals in the Territory.

1.5 "Batch" means a specific quantity of API that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

1.6 "Bulk API" means the API packaged in drums for delivery to a common carrier.

1.7 "Certificate of Analysis" means a certificate issued by the manufacturer of a lot or batch of a drug, which certificate contains such information as provided in the Quality Agreement (as defined below).

1.8 "cGMP" means current good manufacturing practices, as applicable, as described in:

- (i) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;
- (ii) Division 2 of Part C of the Food and Drug Regulations (Canada);
- (iii) EC Directive 91/356/EEC; and
- (iv) the latest Health Canada, FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, as updated, amended and revised from time to time and as applicable under the particular circumstances.

1.9 "EMA" means the European Medicine Evaluation Agency or any successor European governmental agency performing similar functions with respect to pharmaceutical products.

1.10 "FDA" means the United States Food and Drug Administration or any successor United States governmental agency performing similar functions with respect to pharmaceutical products.

1.11 "Health Canada" means a section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and Health Products and Food Branch Inspectorate, or any successor Canadian governmental agency performing similar functions with respect to pharmaceutical products.

1.12 "Laws" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of the United States, Canada and the European Union or any domestic or other state, province, county, city or other political subdivision or any regulatory authority.

1.13 "NDA" means a New Drug Application pursuant to Section 505 of the Act (21 U.S.C. Section 355) submitted to the FDA or any successor application or procedure or any foreign counterpart of a United States New Drug Application for approval to market, including where applicable, applications for pricing and reimbursement approval.

1.14 "Quality Agreement" means the agreement to be entered into by the parties hereto, promptly after the date hereof, setting out the quality assurance standards to be applicable to the manufacturing services provided by Solvay.

1.15 "Regulatory Approval" means any and all approvals (including supplements, amendments, label expansions, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a product in a regulatory jurisdiction.

1.16 "Territory" means the entire world.

1.17 "United States" means the United States of America and its states, territories, possessions and protectorates thereof, the District of Columbia and the Commonwealth of Puerto Rico.

## ARTICLE 2

### MANUFACTURE, PURCHASE AND SUPPLY OF API

2.1 Supply. Pursuant to the terms and conditions of this Agreement, during the Term, Solvay agrees to supply or have supplied Jazz Pharmaceuticals' requirements of API (including any API to be used for manufacturing clinical trial supplies). Subject to the provisions of Section 2.7, Jazz Pharmaceuticals agrees to purchase from Solvay, or its permitted designee, during the Term, certain quantities of API ordered pursuant to this Agreement. API supplied hereunder shall be supplied as Bulk API and shall meet the API Specifications. Each shipment shall be accompanied by a Certificate of Analysis in English. API shall be manufactured in accordance with cGMP and all other applicable Laws and any procedures set forth in the API Specifications, and such additional procedures as may be agreed upon by the parties. Notwithstanding the requirements for the purchase and delivery of API set forth in this Article 2, Solvay agrees to sell, and Jazz Pharmaceuticals agrees to purchase, up to [ \* ] kilograms of API for \$[ \* ] per kilogram and on the payment terms set forth in Section 3.3 of this Agreement.

#### 2.2 Firm Orders.

(a) From time to time and subject to the other provisions of this Agreement, Jazz Pharmaceuticals shall place its firm orders for API, specifying requested delivery dates. The delivery dates specified in any such orders shall not be less than [ \* ] from the date of such orders.

(b) To the extent that firm orders requested for shipment in any quarter exceed the most recent Jazz Pharmaceuticals forecast for such quarter provided under Section 2.4 by more than [ \* ] percent ([ \* ]%) (any excess of [ \* ] percent ([ \* ]%) or less shall, for this purpose, be deemed not to exceed forecast), Solvay shall use its commercially reasonable efforts to accommodate any such excess contained in Jazz Pharmaceuticals' firm orders, but Solvay shall not be liable to Jazz Pharmaceuticals for any inability, despite its reasonable efforts, to fill orders in excess of such forecast.

(c) Solvay shall use commercially reasonable efforts to accommodate any Jazz Pharmaceuticals' request for the API in excess of the quantities described in any previously-submitted purchase order, or for delivery of the API sooner than as otherwise provided in such purchase order. Should Jazz Pharmaceuticals business conditions necessitate reduction or delay in purchase order requirements, then Solvay shall use commercially reasonable efforts to implement such requested changes; provided that [ \* ]. Notwithstanding the foregoing, Solvay shall not take any action in response to any such requests which would result in charges to Jazz Pharmaceuticals in addition to those set forth in the respective purchase order without Jazz Pharmaceuticals' prior written consent.

2.3 Acceptance. Orders placed with Solvay by Jazz Pharmaceuticals pursuant to the provisions of Section 2.2 shall be acknowledged by Solvay in writing. Solvay shall use [ \* ] efforts to ensure that the API ordered by Jazz Pharmaceuticals in accordance with this Agreement is shipped in accordance with the delivery dates specified in Jazz Pharmaceuticals' purchase order accepted by Solvay, and Solvay shall notify Jazz Pharmaceuticals promptly of any significant anticipated delay.

#### 2.4 Forecasts and Production Planning.

(a) On or before the [ \* ] working day of each month, Jazz Pharmaceuticals shall provide Solvay with an [ \* ] month rolling forecast of the quantity of API required by Jazz Pharmaceuticals, by month, for the following [ \* ] months (each, a "Forecast"). It is understood that such Forecasts, after the [ \* ] month, are intended to be good faith estimates only, and shall not be binding upon Jazz Pharmaceuticals. Solvay's inability to supply amounts in excess of the foregoing amounts shall not constitute a breach of this Agreement by Solvay.

(b) Solvay shall base its production planning on the forecasts provided to Solvay by Jazz Pharmaceuticals pursuant to Section 2.4(a). Solvay shall have the right, at any time, to order materials and supplies to manufacture [ \* ] percent ([ \* ]%) of those amounts of API ordered by Jazz Pharmaceuticals under Section 2.2 and forecast by Jazz Pharmaceuticals under Section 2.4(a) for the then current and [ \* ]. In addition, to the extent any materials necessary to the manufacture of the API require a longer lead time, Solvay shall be entitled to order such materials as it deems appropriate to fulfill its obligations hereunder and consistent with normal production practices in the pharmaceutical industry, and considering the term of this Agreement. If any such materials or any work in process become unusable due to a change in the API Specifications or orders lower than forecasts, Solvay shall have the right to [ \* ] and Jazz Pharmaceuticals shall promptly [ \* ]. Jazz Pharmaceuticals shall have full rights and title to [ \* ]. At Jazz Pharmaceuticals' election, such [ \* ] shall be (i) destroyed by Solvay or (ii) transferred by Solvay to Jazz Pharmaceuticals.

(c) Notwithstanding the foregoing, Solvay agrees to use its commercially reasonable efforts to cooperate with Jazz Pharmaceuticals in connection with Jazz Pharmaceuticals' commercial launch of any pharmaceutical product containing the API. Such cooperation shall include, but not be limited to, joint review and revision of forecasts and firm orders during the period prior to FDA approval and during the [ \* ] months immediately

following the commercial launch of such pharmaceutical product in the United States (and covering similar periods for other applicable countries). Solvay shall use its commercially reasonable best efforts to accommodate any changes requested by Jazz Pharmaceuticals during such period, [ \* ] such changes [ \* ] such changes.

2.5 Delivery. Shipments of API shall be made [ \* ] (as such term is defined in INCOTERMS 2000) [ \* ] unless otherwise mutually agreed to in writing by the parties. Risk of loss or of damage to the API [ \* ] until such API is loaded onto the carrier's vehicle by Solvay for shipment at the shipping point at which time risk of loss or damage shall transfer to Jazz Pharmaceuticals. Solvay shall, in accordance with Jazz Pharmaceuticals' instructions and as agent for Jazz Pharmaceuticals, (i) arrange for shipping to be paid by Jazz Pharmaceuticals and (ii) at the Jazz Pharmaceuticals' risk and expense, obtain any export licence or other official documentation necessary to export the API from the United States. Jazz Pharmaceuticals shall arrange for insurance and shall select the freight carrier used by Solvay to ship the API and may monitor Solvay's shipping and freight practices as they pertain to this Agreement. API shall be transported in accordance with the API Specifications and other applicable Laws.

#### 2.6 Manufacturing Changes.

(a) For changes to the API Specifications or manufacturing processes that are required by applicable Laws (collectively "Required Manufacturing Changes"), Solvay and Jazz Pharmaceuticals shall cooperate in making such changes and use commercially reasonable efforts to implement such changes promptly in a manner that minimizes any effect on the supply hereunder to Jazz Pharmaceuticals of API meeting the API Specifications.

(b) For changes to the API Specifications or manufacturing process that are not Required Manufacturing Changes (collectively "Discretionary Manufacturing Changes"), [ \* ] must [ \* ] to any Discretionary Manufacturing Changes for them to be made and [ \* ], each party shall, to the extent commercially reasonable under the circumstances, cooperate in making such changes, and each agrees that it shall not [ \* ] to such Discretionary Manufacturing Changes.

(c) Notwithstanding the foregoing, all external costs, including, without limitation, obsolete raw materials, regulatory filings, work-in-process, equipment and API (i) associated with Required Manufacturing Changes that are caused by, or result from, the acts or omissions of a single party shall be borne by such party, (ii) associated with all Required Manufacturing Changes for use of the API in the United States shall be borne by [ \* ], (iii) associated with all Required Manufacturing Changes for use of the API in any country other than the United States shall be borne by [ \* ] and (iv) all costs associated with Discretionary Manufacturing Changes shall be borne by [ \* ].

## 2.7 Shortages.

(a) During the Term of this Agreement, if Solvay is not able to meet firm orders submitted by Jazz Pharmaceuticals pursuant to Section 2.2 due to a shortage of API, Solvay shall promptly notify Jazz Pharmaceuticals of such shortage of such API, and, if possible, the date such shortage of API is expected to end. In such event, [ \* ] in such [ \* ]. In addition, [ \* ], Jazz Pharmaceuticals [ \* ].

(b) In the event an interruption described in Section 2.7(a) continues for more than [ \* ] days, then upon Jazz Pharmaceuticals' written request, Solvay will provide all necessary information, licenses and technical assistance required to reasonably assist Jazz Pharmaceuticals in (i) the qualification of an alternate API manufacturer and (ii) obtaining all authorizations of the appropriate authorities for the approval of the alternate manufacturer of API for the Territory. Notwithstanding the foregoing, Solvay shall not incur [ \* ] costs as a result of providing this assistance, and Solvay shall only be responsible for assuming [ \* ] incurred as a result of providing this assistance.

## ARTICLE 3

### PRICING AND PAYMENT

3.1 Price. Subject to the remainder of this Article 3, the price to be paid by Jazz Pharmaceuticals for API shipped in any calendar year shall be as set forth on Exhibit A.

3.2 Price Adjustment. The price for API under Section 3.1 may be increased or decreased by Solvay under this Section 3.2, by written notice to Jazz Pharmaceuticals, no more than [ \* ]. Any such increase shall not exceed [ \* ] under this Section 3.2 (the "[ \* ] Increase"). In addition to the [ \* ] Increase permitted in the previous sentence, Solvay will also be entitled to an additional price increase for API under this Section 3.2 if the [ \* ] of the [ \* ] increases by more than [ \* ] percent ([ \* ]%) over [ \* ] for such [ \* ] during the previous calendar year, such additional price increase to be no greater than [ \* ]. Solvay shall submit evidence of material cost increases to Jazz Pharmaceuticals or a mutually agreed Third Party auditor for increase verification. Solvay must provide written notice prior to execution of any price adjustment made pursuant to this Section 3.2 and such price increase shall be effective as to any new orders placed thereafter.

3.3 Payment. Payment by Jazz Pharmaceuticals for API supplied by Solvay hereunder meeting API Specifications shall be in United States dollars and made within [ \* ] after the date of Solvay's invoice by check or wire transfer to such bank as Solvay may designate in writing, and shall be made without set-off and free and clear of, and without any deduction or withholding for or on account of any taxes, duties, levies, fees or charges. API shall be invoiced no sooner than the date of shipment by Solvay. Notwithstanding the foregoing, Jazz Pharmaceuticals may withhold any amounts invoiced by Solvay that it disputes. If Jazz Pharmaceuticals disputes any invoice, Jazz Pharmaceuticals, within [ \* ] after such invoice is furnished to it, notify Solvay that it disputes the accuracy or appropriateness of such invoice and specify the particular respects in which such invoice is inaccurate or inappropriate. Jazz Pharmaceuticals and Solvay shall make good faith efforts to resolve any disputes within [ \* ] thereafter. Any amounts that are disputed by Jazz Pharmaceuticals shall not be due until [ \* ] following the resolution of such dispute.



3.4 Foreign Exchange. Conversion to U.S. dollars of any amounts recorded in local currencies shall be made using the spot foreign exchange rate, noon buying rated certified by the Federal Reserve Bank of New York for customs purposes in New York City for cable transfers payable in foreign currencies on the date of the calculation.

3.5 Late Payments. All payments not made when due hereunder shall bear interest at an annual rate equal to [ \* ] as published by [ \* ] on the date the payment became due.

#### ARTICLE 4

##### QUALITY AND REGULATORY MATTERS

4.1 Quality Control. Solvay shall produce API in accordance with the API Specifications, cGMP, the Laws and any procedures agreed upon by the parties in writing, and shall permit quality assurance representatives of Jazz Pharmaceuticals or its designee to audit and inspect Solvay's manufacturing facilities and testing procedures for API and the related batch records, upon [ \* ] written notice, [ \* ] in each calendar year (and additional times, if deficiencies are noted, to monitor correction thereof), during normal business hours and on a confidential basis. If deficiencies are found during any audits or inspections, the parties shall meet promptly to discuss and resolve them, and Jazz Pharmaceuticals or its designee shall be entitled to make reasonable follow-up inspections to monitor the correction of the deficiencies. Solvay shall use commercially reasonable efforts to obtain the right for Jazz Pharmaceuticals or its designee to have similar inspection, audit and follow-up rights with respect to all third-party suppliers used by Solvay to provide key materials for API. Solvay agrees to allow the FDA or any other applicable regulatory authority to inspect its facilities and all records required under cGMP and all other applicable regulations in connection with such production. Solvay shall furnish to Jazz Pharmaceuticals all material information supplied to, or supplied by, such regulatory authority or third party supplier to the extent that such report relates to API, or the ability of Solvay to supply such API, within [ \* ] business days of their receipt of such information or delivery of such information, as the case may be.

##### 4.2 Testing.

(a) Solvay agrees to permit Jazz Pharmaceuticals or its designee to review Solvay's standard operating procedures for the manufacture of the API. Solvay shall test or cause to be tested each Batch of API to be supplied pursuant to this Agreement, in accordance with the approved testing methods, before delivery of such API to Jazz Pharmaceuticals or its designee. Each time Solvay ships API to Jazz Pharmaceuticals or its designee, it shall provide Jazz Pharmaceuticals or its designee with the Certificate of Analysis that sets out the test results for each Batch of API and that certifies that such Batch of the API complies with the API Specifications and was manufactured in accordance with cGMP. Solvay shall retain a sample of each Batch of API shipped for at least the shelf life of such Batch plus [ \* ], or such longer period as may be required by cGMP. Nothing contained herein, however, shall be deemed or construed to require Solvay to turn over the DMF relative to the API.

(b) Solvay shall conduct stability testing on the API in accordance with the Quality Agreement and API Specifications. Solvay shall not make any changes to the API Specifications or testing protocols without prior written approval from Jazz Pharmaceuticals. Solvay shall promptly provide any and all data and results relating to the stability testing of the API upon request by Jazz Pharmaceuticals. In the event that any Batch of the API fails, or is suspected to fail, stability testing, Solvay shall notify Jazz Pharmaceuticals within [ \* ] business days and Solvay and Jazz Pharmaceuticals shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure.

4.3 Notice of Failure to Meet API Specifications. Upon Solvay's discovery that any Batch of API fails to conform to the API Specifications, Solvay shall notify Jazz Pharmaceuticals within [ \* ] business days of discovery of such failure to meet the API Specifications and of the nature thereof. Solvay shall investigate all such failures and promptly and cooperate with Jazz Pharmaceuticals in determining the cause for the failure and a corrective action to prevent future failures.

4.4 Records. Solvay shall keep records of the manufacture, testing and shipping of the API, and retain samples of such API as are necessary to comply with the API Specifications and all manufacturing regulatory requirements and Laws applicable to Solvay, as well as to assist with resolving API complaints and other similar investigations. Copies of such records and samples shall be retained for a period of [ \* ] following the date of API expiry or longer if required by Law, after which Solvay may destroy such records or samples; provided, however, Solvay shall notify Jazz Pharmaceuticals in writing at least [ \* ] prior to such destruction and shall retain or deliver such records or samples to Jazz Pharmaceuticals, at Jazz Pharmaceuticals' option and expense, if Jazz Pharmaceuticals so requests.

4.5 Notice; Replacement. Jazz Pharmaceuticals or its designee shall notify Solvay in writing of (i) any claim relating to any API that fails to meet the API Specifications or (ii) any shortage in quantity of any shipment of API as soon as reasonably practical, but not later than [ \* ] days of receipt of such API except where such failure to meet the API Specifications could not be reasonably known at such time, in which case such [ \* ] day period commences when Jazz Pharmaceuticals could reasonably have known of such failure. Jazz Pharmaceuticals or its designee shall be deemed to have accepted the API if it does not provide Solvay written notice of such shortfall or failure to meet specification within such [ \* ] day period. If the parties agree that such API is defective or that there is a shortage, Solvay shall replace the defective API or use [ \* ] efforts to make up the shortage at the next practical delivery date, [ \* ]. Jazz Pharmaceuticals shall make arrangements with Solvay for the return or disposal of any rejected API; the costs of such return or disposal shall be paid by [ \* ]. In the event that only a limited supply of API is available to replace or supply such rejection or shortage, then Solvay shall ship to Jazz Pharmaceuticals such amount of API as is available and [ \* ] for the remaining quantity of rejected API.

4.6 Disputes. If, for any reason (i) Jazz Pharmaceuticals disagrees with Solvay's certification that any API meets the API Specifications or that any API was manufactured in accordance with cGMP or both, or (ii) Jazz Pharmaceuticals rejects any shipment in accordance with Section 4.5 and Solvay disagrees, the relevant party shall assert any such disagreement or rejection in writing, setting forth the specifics of its disagreement or rejection within forty-five (45) days after Solvay's certification with respect to the API in question. The parties shall attempt in good faith, within the forty-five (45) day period following the other party's receipt of

such written notice, to resolve the dispute. If the parties fail to agree during such time period, they shall retest jointly, in a laboratory agreed upon by the parties, in each case using the test methodology set forth in the API Specifications. If the joint tests substantiate Jazz Pharmaceuticals' disagreement or rejection, the API in question shall, [ \* ], be destroyed or be returned to Solvay. Jazz Pharmaceuticals shall not be obligated to pay for justifiably rejected API and Solvay or Jazz Pharmaceuticals shall notify, if required by Law, the relevant government agencies regarding any affected API. If the joint test does not substantiate Jazz Pharmaceuticals' claim, Jazz Pharmaceuticals shall accept the API in question and pay the purchase price with respect to such API. The results of the joint testing shall be binding on the parties, and the costs of the joint testing shall be borne by the party whose results were not substantiated by the joint testing.

4.7 Recalls. In the event (i) the FDA or any other regulatory authority issues a request, directive or order that a product containing the API manufactured by Solvay pursuant to this Agreement be recalled, (ii) a court of competent jurisdiction orders such a recall, or (iii) Jazz Pharmaceuticals shall reasonably determine that the a product containing the API manufactured by Solvay pursuant to this Agreement should be recalled, all costs of such API recall shall be borne by [ \* ], except to the extent that any recall results from [ \* ], which costs shall be governed by the provisions of [ \* ].

4.8 Technical Complaints. Jazz Pharmaceuticals shall promptly submit to Solvay all API quality or manufacturing inquiries and technical API quality complaints, together with all available evidence and other information relating thereto, in accordance with procedures to be agreed upon by the parties. Except as otherwise required by Law, Solvay shall be responsible for investigating all such technical inquiries and complaints regarding the API and the outcome of such investigation shall be promptly reported by Solvay to Jazz Pharmaceuticals in writing. Where complaints or matters result from acts or omissions of [ \* ], investigation and correction shall be at [ \* ] expense; otherwise investigation and correction shall be at [ \* ] expense.

4.9 Response to Complaints and/or Adverse Drug Events. In the event of a reported complaint and/or adverse drug event, if the nature of the reported complaint and/or adverse drug event requires testing, Solvay shall, at [ \* ] (unless the event was the result of [ \* ], in which case [ \* ]), investigate and perform all requested testing including without limitation, analytical testing of corresponding retention samples, and provide the results thereto to Jazz Pharmaceuticals as soon as reasonably practicable. Such testing shall be performed using the approved testing procedures as set forth in the API Specifications.

4.10 Reports. For so long as Solvay is manufacturing and/or supplying API pursuant to this Agreement, Solvay shall furnish to Jazz Pharmaceuticals manufacturing reports reasonably requested by Jazz Pharmaceuticals, but in no event more than [ \* ], including such information that is agreed upon by the parties.

4.11 Quality Agreement. Within three (3) months following the execution of this Agreement, the parties shall execute a Quality Agreement.

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## ARTICLE 5

### WARRANTIES

5.1 Compliance with cGMP. Solvay warrants that any API supplied by it hereunder shall be manufactured in accordance with cGMP.

5.2 Conformity with Specifications. Solvay warrants that, at the time of shipment and for its shelf life, any API supplied by it hereunder shall meet the API Specifications except for any failure to meet API Specifications arising due to the handling, packaging or other act or omission of Jazz Pharmaceuticals.

5.3 Compliance with Laws. Solvay warrants that, during the [ \* ] year period prior to the Effective Date, Solvay has materially complied with all Laws applicable to the manufacture of the API. During the term of this Agreement, Solvay shall comply with all Laws applicable to the conduct of its business in the performance of this Agreement.

5.4 Exclusion of Other Warranties. EXCEPT WHERE OTHERWISE SET FORTH IN THIS AGREEMENT, SOLVAY'S WARRANTIES SET FORTH IN SECTIONS 5.1, 5.2 AND 5.3 ARE ITS EXCLUSIVE WARRANTIES TO JAZZ PHARMACEUTICALS WITH RESPECT TO THE API, AND ARE GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, GUARANTEES, CONDITIONS AND REPRESENTATIONS, EXPRESS OR IMPLIED, CONCERNING THE PRODUCT, AND INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

## ARTICLE 6

### INDEMNIFICATION AND INSURANCE

6.1 Solvay Indemnity. Subject to Sections 6.2 and 6.4, Solvay shall indemnify and hold harmless Jazz Pharmaceuticals and its Affiliates against all third party claims, actions, costs, expenses, including court costs and legal fees or other third party liabilities ("Third Party Liabilities") whatsoever in respect of:

(a) Solvay's and/or its Affiliates', subcontractors' or suppliers' failure to comply with the API Specifications, cGMP or applicable Laws;

(b) any breach of a representation or warranty made by Solvay in Article 5;

(c) the use, marketing, storage, distribution, handling or sale of the API prior to the Effective Date by Solvay or any third party; and

(d) any negligence, omission or willful misconduct by Solvay and/or its Affiliates, subcontractors and suppliers in the manufacture, testing and handling of the API.

6.2 Jazz Pharmaceuticals Indemnity. Subject to Sections 6.1 and 6.4, Jazz Pharmaceuticals shall indemnify and hold harmless Solvay and its Affiliates against all Third Party Liabilities whatsoever in respect of (i) the use, marketing, storage, distribution, handling or sale of the API after the Effective Date by Jazz Pharmaceuticals or any third party, other than a third party acting on behalf of Solvay or its Affiliates and/or (ii) any breach by Jazz Pharmaceuticals hereunder.

6.3 Procedures for Indemnification. In the event that a party (the “Indemnified Party”) is seeking indemnification under Sections 6.1 or 6.2, the Indemnified Party shall inform the other party (the “Indemnifying Party”) of a claim as soon as reasonably practicable after the Indemnified Party receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested by the Indemnifying Party (at the expense of the Indemnifying Party) in the defense of the claim.

6.4 Mitigation. In the event of any occurrence which may result in either party becoming liable under Section 6.1 or Section 6.2, each party shall use its best efforts to take such actions as may be reasonably necessary to mitigate the damages payable by the other party under Section 6.1 or Section 6.2, as the case may be.

6.5 Limitation of Liability. EXCEPT AS SPECIFICALLY PROVIDED IN SECTIONS 6.1 AND 6.2, IN NO EVENT SHALL ANY PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES BE LIABLE TO THE OTHER PARTIES FOR ANY INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT.

6.6 Insurance. Each party shall maintain commercial general liability insurance, through the term of this Agreement, which insurance shall afford limits of not less than \$[ \* ] for each occurrence for personal injury or property damage liability. Furthermore, each party shall maintain products liability insurance, through the term of this Agreement and for a period of [ \* ] years thereafter, which insurance shall afford limits of not less than \$[ \* ] in the aggregate per annum with respect to product and completed operations liability. This insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement. If requested, each party shall provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of thirty (30) days’ written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

## ARTICLE 7

### TERM AND TERMINATION

7.1 Term. This Agreement shall remain in effect until the termination of the Assignment and License Agreement pursuant to Article 11 thereof (the “Term”) or until this Agreement is terminated earlier in accordance with Sections 7.2, 7.3 or 7.4 hereof.

7.2 Termination by Jazz Pharmaceuticals. Jazz Pharmaceuticals may terminate this Agreement at any time upon [ \* ] days’ written notice to Solvay.

7.3 Termination for Breach. If either Jazz Pharmaceuticals or Solvay breaches or defaults in the performance or observance of any material provisions of this Agreement and such breach or default is not cured within thirty (30) days after written notice by the other party specifying such breach or default (or if such breach or default is not of a type which can reasonably be cured in thirty (30) days, then such longer period as is reasonable), such party shall have the right to terminate this Agreement upon a further thirty (30) days' written notice.

7.4 Termination for Insolvency. This Agreement may be terminated upon thirty (30) days' advance written notice by either party at any time during the Term upon the declaration by a court of competent jurisdiction that the other party is bankrupt and, pursuant to the U.S. Bankruptcy Code such other party's assets are to be liquidated; upon the filing or institution of bankruptcy, liquidation or receivership proceedings (other than reorganization proceedings under Chapter 11 of the U.S. Bankruptcy Code); or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party; or in the event a receiver or custodian is appointed for such party's business; provided, however, that in the case of any involuntary proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within sixty (60) days after the filing thereof.

7.5 Rights on Termination. Termination of this Agreement for any reason shall not affect the accrued rights and obligations of either Jazz Pharmaceuticals or Solvay arising under or out of this Agreement. Upon early termination of this Agreement by Jazz Pharmaceuticals pursuant to Sections 7.3 or 7.4 above, Solvay shall transfer to Jazz Pharmaceuticals all regulatory information and other information and materials reasonably necessary for Jazz Pharmaceuticals to assume responsibility for performance of the manufacturing activities undertaken by Solvay under this Agreement, and the parties shall establish such operational procedures as are reasonably necessary for Jazz Pharmaceuticals to assume such responsibility as quickly as possible.

7.6 No Liability. Neither party shall incur any liability to the other by reason of the expiration or termination of this Agreement as provided herein for loss of goodwill, anticipated profits or otherwise, and the parties shall accept all rights granted and all obligations assumed hereunder, including those in connection with such expiration or termination, in full satisfaction of any claims resulting from such expiration or termination.

## ARTICLE 8

### CONFIDENTIALITY

8.1 Nondisclosure. During the Term of this Agreement and for a period of [ \* ] years after expiration or termination of this Agreement, the parties, their Affiliates and their respective employees, directors, officers, consultants and contractors shall keep and maintain as confidential any Confidential Information (as defined below) supplied by the other party during the Term of this Agreement. For purposes of this Agreement, "Confidential Information" means all information disclosed by a party in connection with this Agreement other than: (i) information that at the time of disclosure by one party to the other is in the public domain or otherwise publicly known; (ii) information which after disclosure by one party to the other becomes part of the public domain, other than by breach of this Agreement by the receiving party; (iii) information which the receiving party can establish by documentary evidence was already in its possession without restriction at the time of receipt; or (iv) information received from a third party without restriction who was lawfully entitled to disclose such information without restriction.

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

8.2 Permitted Disclosure. Notwithstanding Section 8.1, the party receiving Confidential Information may disclose such Confidential Information to the extent such disclosure is reasonably necessary in the following instances: (i) to governmental or other regulatory agencies in order to file patent applications or prosecute such applications to grant or to gain approval to conduct clinical trials in relation to the API, provided that the disclosure is limited to the extent reasonably necessary to obtain such patents or authorizations and the disclosing party is notified of the proposed disclosure of its Confidential Information and consents to such disclosure, with such consent not to be unreasonably withheld; (ii) as required by this Agreement; (iii) to Affiliates, employees, consultants, vendors or agents who need to know and agree to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 8; or (iv) to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, the disclosing party shall give the party that owns the Confidential Information prompt written notice, in advance, to enable it to seek protection or confidential treatment of such Confidential Information.

8.3 Injunctive Relief. The parties hereto understand and agree that remedies at law may be inadequate to protect against any breach of any of the provisions of this Article 8 by either party or their employees, agents, officers or directors or any other person acting in concert with it or on its behalf. Accordingly, each party may be entitled to seek injunctive relief from a court of competent jurisdiction against any action that constitutes any such breach of this Article 8.

## ARTICLE 9

### MISCELLANEOUS

9.1 Force Majeure. If any party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement, by reason of force majeure, including, but not limited to fire, flood, earthquake, explosion, storm, strike, lockout or other labor trouble, riot, war, rebellion, accidents, acts of God and/or any other cause or externally induced casualty beyond its reasonable control, whether similar to the foregoing matters or not, then, upon written notice by the party liable to perform to the other party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability; provided that the party asserting force majeure shall bear the burden of establishing the existence of such force majeure by clear and convincing evidence; and provided further, that the party prevented from complying shall use its best efforts to remove such disability within thirty (30) days, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other party of the force majeure event not more than five (5) working days from the time of the event. When such circumstances arise, the parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

9.2 Trademarks. Each party agrees and acknowledges that it shall not acquire by virtue of this Agreement any interest in or to any trademarks or trade names of the other party; provided, however, that Jazz Pharmaceuticals shall have the right to identify Solvay as the manufacturer of the API.

9.3 Notices. Except as otherwise specifically provided, any notice or other documents to be given under this Agreement shall be in writing and shall be deemed to have been duly given if sent by registered mail, nationally recognized overnight delivery service or facsimile transmission to a party or delivered in person to a party at the address or facsimile number set out below for such party or such other address as the party may from time to time designate by written notice to the other:

If to Solvay: Solvay Pharmaceuticals, Inc.  
901 Sawyer Road  
Marietta, Georgia 30062  
Attention: Senior Vice President, Law,  
Government and Public Affairs  
Facsimile: (770) 578-5749

If to Jazz Pharmaceuticals:  
  
Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
Attention: General Counsel  
Facsimile: (650) 496-3781

Any such notice provided pursuant to this Section 9.3 shall be deemed to have been received by the addressee five business days following the date of dispatch of the notice or other document by mail or, where the notice or other document is sent by overnight delivery service, by hand or is given by facsimile, simultaneously with the transmission or delivery. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched. Either party may change its address at which notice is to be received by written notice provided pursuant to this Section 9.3.

9.4 Waiver and Amendment. A waiver by either party of any term or condition of this Agreement in any one instance shall not be deemed or construed to be a waiver of such term or condition for any other time. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement of either party. This Agreement may not be amended or modified, except in a writing signed by an officer of each party hereto.

9.5 Severability. If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable in any respect, the validity, legality or enforceability of the remaining provisions hereof shall not in any way be affected or impaired thereby. In the event any provisions shall be held invalid, illegal or unenforceable, the parties shall use their best efforts to substitute a valid, legal and enforceable provision which, insofar as practical, implements the purposes hereof.

9.6 Headings. The headings contained in this Agreement are included herein for reference and convenience and shall not affect the meaning of the provisions of this Agreement.

9.7 Assignment and Successors. This Agreement may not be assigned by either party to any third party without the prior written consent of the other party; except that either party



may assign this Agreement, without the prior written consent of the other party, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation with or into such corporation. In the event of any such assignment, the assignee shall expressly assume in writing the performance of all the terms and conditions of this Agreement and all of the obligations to be performed by the assignor. Any assignment not in accordance with this Agreement shall be void.

9.8 Governing Law. This Agreement shall be construed, and the rights of the parties determined, in accordance with the laws of the State of New York, excluding any choice of law rules which may direct the application of the laws of another jurisdiction.

9.9 Independent Parties. This Agreement shall not be deemed to create any partnership, joint venture, amalgamation or agency relationship between the parties. Each party shall act hereunder as an independent contractor. Neither party shall at any time enter into, incur, or hold itself out to third parties as having authority to enter into or incur, on behalf of the other party, any commitment, expense, or liability whatsoever.

9.10 Survival of Provisions. The provisions of Articles, 1, 5, 6 and 8 and Sections 3.3, 3.4, 3.5, 4.2(a), 4.3, 4.4, 4.6, 4.7, 4.8, 4.9, 7.5, 7.6, 9.3, 9.5, 9.8, 9.10, 9.12 and 9.14 shall survive the termination for any reason of this Agreement.

9.11 Publicity. Neither party shall make any public announcement concerning, or otherwise publicly disclose, any information with respect to the transactions contemplated by this Agreement or any of the terms and conditions hereof without the prior written consent of the other party hereto. Notwithstanding the foregoing, either party may make any public disclosure concerning the transactions contemplated hereby that in the opinion of such party's counsel may be required by law or the rules of any stock exchange on which such party's or its Affiliates' securities trade; provided, however, the party making such disclosure shall provide the non-disclosing party with a copy of the intended disclosure reasonably, and to the extent practicable, prior to public dissemination, and the parties hereto shall coordinate with one another regarding the timing, form and content of such disclosure.

9.12 Entire Agreement. This Agreement, together with the Quality Agreement and the License Agreement, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of a conflict between the agreements, the License Agreement shall prevail.

9.13 No Third Party Beneficiaries. No person or entity not a party to this Agreement, including any employee of any party to this Agreement, shall have or acquire any rights by reason of this Agreement, nor shall either party have any obligations or liabilities to such other person or entity by reason of this Agreement.

9.14 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one remedy shall not preclude the exercise of any other remedy. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

9.15 Further Assurances. Each party shall execute and deliver such additional instruments and other documents and use commercially reasonable efforts to take or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable law to consummate the transactions contemplated hereby.

9.16 Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute a single agreement. This Agreement may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, as of the date first above written, by their duly authorized representatives.

Solvay Pharmaceuticals, Inc.

Jazz Pharmaceuticals, Inc.

By: /s/ Laurence J. Downey, M.D.

By: /s/ Samuel R. Saks, M.D.

Title: President and CEO

Title: Chief Executive Officer

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**Exhibit A**

**API Price**

[ \* ] per kilogram of API.

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#### TRADEMARK LICENSE AGREEMENT

THIS TRADEMARK LICENSE AGREEMENT (the "Trademark License Agreement") is entered into as of the 31<sup>st</sup> day of January, 2007, by and between Solvay Pharmaceuticals, Inc. ("Licensor") and Jazz Pharmaceuticals, Inc. ("Licensee").

WHEREAS, Licensor and Licensee are parties to a License Agreement dated as of January 31, 2007 ("License Agreement");

WHEREAS, Licensor or its affiliates is the owner of the trademark Luvox<sup>®</sup> for use with pharmaceutical products, (hereinafter referred to as the "Licensed Mark");

WHEREAS, Licensee desires to utilize the Licensed Mark in connection with the Products (as defined in the License Agreement); and

WHEREAS, Licensor is willing to grant to Licensee the right to use the Licensed Mark on the Products and has the ability to do so, on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual promises and undertakings herein contained, and for other good and valuable consideration, the parties agree as follows:

#### I

#### GRANT OF LICENSE

Licensor hereby grants to Licensee, and Licensee hereby accepts, an exclusive license to use the Licensed Mark in the Territory (as defined below) in connection with the Products (including the right to sublicense), including but not limited to making, offering, advertising, marketing, providing, selling, and distributing the Products, subject to the terms and conditions set forth herein. Licensor, at its own cost, shall be responsible for maintaining and renewing trademark registrations for the Licensed Mark, subject to Section IX(c) below.

II

TERRITORY AND TERM

The Territory shall be as defined in the License Agreement. The term of this Trademark License Agreement shall be the same as the term set forth in Article 11 of the License Agreement unless terminated earlier pursuant to Section VI(a) below.

III

OWNERSHIP AND USE OF THE TRADEMARK

Licensee acknowledges that Licensor, or its affiliate, is the exclusive owner of all right title and interest in the Licensed Mark and any registration thereof in the Territory, and that all use of the Licensed Mark by Licensee inures to the benefit of Licensor. Licensee further acknowledges that the Licensed Mark embodies substantial goodwill and enjoys favorable public recognition, and that Licensor's rights therein constitute valuable assets of Licensor. Licensee will [ \* ] to assist Licensor to protect and enforce the Licensed Mark, and Licensee agrees that it will not at any time knowingly do, or cause to be done, anything that would, [ \* ], be detrimental to, injure or impair the Licensed Mark or their registration or goodwill, or any of Licensor's common law or other rights in the Licensed Mark, or the validity of or Licensor's exclusive ownership of all right, title and interest in and to the Licensed Mark.

IV

REPRESENTATIONS AND WARRANTIES OF LICENSOR

Licensor represents and warrants that (i) Licensor or its affiliates are the sole owners of the Licensed Mark in the Territory and the Licensor possesses sufficient powers and rights to grant the rights and license granted to the Licensee herein; (ii) to the best of Licensor's knowledge, there are not any adverse or concurrent rights of any third party with respect to the use of the Licensed Mark in the Territory; (iii) to the best of Licensor's knowledge, Licensee may use the Licensed Mark in accordance with this Trademark License Agreement and the License Agreement in the Territory, without breaching any rights of any third party; (iv) Licensee may advertise the Licensed Mark on the Products in the Territory without thereby infringing any rights of any third party; (v) Licensor is duly authorized to execute and deliver this Trademark License Agreement and to perform its obligations hereunder, and the person or persons executing this Trademark License Agreement on its behalf has been duly authorized to do so by all requisite

corporate action; (vi) Licensor is aware of no action, suit or inquiry or investigation instituted by or before any court or governmental agency which questions or threatens the validity of this Trademark License Agreement or the Licensed Mark; and (vii) Licensor shall not take (or cause any other person to take) any action which will conflict with, contravene or otherwise limit or restrict the rights of the Licensee hereunder or the right of the Licensee to enjoy the benefits of this Trademark License Agreement (other than as expressly provided herein).

## V

### QUALITY CONTROL

In order to protect the goodwill and reputation associated with the Licensed Mark, Licensee covenants and agrees that:

(a) Quality of Product:

(i) Licensee shall provide Licensor with representative specimens of the packaging, labeling, advertising, and promotional material showing Licensee's use of the Licensed Mark.

(ii) the Products shall be manufactured, sold and distributed in compliance with GMPs and with all applicable Federal, state and local laws and regulations in the Territory, including but not limited to, the laws and regulations of the Food and Drug Administration.

(iii) Within [ \* ] days from receipt of a written request by Licensor, Licensee will supply Licensor with representative samples of the Products bearing the Licensed Mark.

(b) Requirements of Trademark Use: In all publicly disseminated packaging, labeling, advertising, and promotional material referencing the Licensed Mark, Licensee shall use the Licensed Mark in the manner set forth in the Requirements of Trademark Use set forth as Exhibit A hereto. Any deviation from the Requirements of Trademark Use must be approved in writing by Licensor, such approval not to be unreasonably withheld.

## VI

### TERMINATION AND RENEWAL

(a) Licensor may terminate this Trademark License Agreement if Licensee has breached a material obligation under this Trademark License Agreement and has not cured the breach within [ \* ] days after notice by Licensor of such breach or, if such breach is not amenable to cure within such [ \* ] day period, Licensee has not commenced a cure within such period.

## 3

[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

(b) Upon proper termination of this Trademark License Agreement by either party, or at the expiration of the term under Article II hereof, Licensee shall discontinue using the Licensed Mark. Licensee may, continue to use any signs, advertising and marketing materials, purchase orders, and the like that bear the Licensed Mark and sell any Product bearing the Licensed Mark in its inventory as of the date of termination until the supplies have been exhausted. Thereafter, Licensee may not use the Licensed Mark.

## VII

### THIRD PARTY INFRINGEMENTS

If either party learns of any use by any person of any product or material bearing any name, mark, or designation that infringes or is likely to infringe the Licensed Mark in the Territory, it shall promptly notify the other party. Whether to take action shall be in Licensee's sole, reasonable discretion, subject to the remainder of this Article VII. If requested by Licensee, Licensor shall join with Licensee [ \* ] in such action as Licensee in its reasonable discretion may deem advisable for the protection of its rights[ \* ]. In connection therewith, Licensor shall cooperate to the extent reasonably required by Licensee to stop such infringement or act, and, if so requested by Licensee, shall join with Licensor as a party to any action brought by Licensee for such purpose. Licensee shall have full control over any action taken, including, without limitation, the right to select counsel, to settle on any terms it deems advisable in its discretion, to appeal any adverse decision rendered in any court, to discontinue any action taken by it, and otherwise to make any decision in respect thereto as it in its discretion deems advisable; provided, however, that any settlement of such action that would (i) include any admission of liability on the part of the Licensor or (ii) not include an unconditional release of the Licensor from all liability for claims that are the subject matter of such action, will require Licensor's prior written consent. [ \* ] shall bear all expenses connected with the foregoing. Any recovery as a result of such action shall belong [ \* ]. In addition, if either party receives any written notice or claim that the use by Licensee of the Licensed Mark infringes the intellectual property rights of a third party, then such party will promptly so notify the other party in writing, and in such event: (i) if Licensee's use of the Licensed Mark was and/or is in accordance with the express terms and/or conditions of use provided for herein, Licensor will agree in writing, within ten days after Licensee's notice, to indemnify Licensee against all costs, losses and expenses resulting from the third party's claim, or, in the alternative, Licensee will have the right to immediately stop using the Licensed Mark as otherwise required pursuant to the License Agreement; or (ii) if Licensee's use of the Licensed Mark was and/or is contrary to the express terms and/or conditions of use provided for herein, Licensee will indemnify Licensor against all costs, losses and expenses resulting from the third party's claim.

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VIII

TRADEMARK REGISTRATIONS

(a) If registration of Licensee as a registered user of the Licensed Mark is required, [ \* ] shall bear all expenses, including government fees and reasonable trademark agents' fees, relating to such registration.

(b) Licensor shall notify Licensee of any decision not to maintain any trademark registration for the Licensed Mark in the Territory at least 30 days prior to abandonment thereof, in which event Licensee shall have the right, but not the obligation, to continue to maintain the registration of such licensed mark at [ \* ].

IX

MISCELLANEOUS PROVISIONS

(a) No Joint Venture: Nothing herein contained shall be construed to constitute the parties joint venturers, nor shall any similar relationship be deemed to exist between them.

(b) Waiver; Modification: No waiver or modification of any of the terms of this Trademark License Agreement shall be valid unless in writing and signed by both parties. No waiver by either party of a breach hereof or a default hereunder shall be deemed a waiver by such party of a subsequent breach or default of like or similar nature.

(c) Assignment and Transfer: Either party may assign or transfer this Trademark License Agreement pursuant to Section 13.8 of the License Agreement.

(d) Notices: Any communication to be given hereunder by either party to the other party shall be in writing and delivered by messenger, sent by air mail (postage prepaid), or transmitted by facsimile, to the address or designation of such party set forth below or as changed by such party by notice given hereunder. A communication transmitted by facsimile shall be deemed effective when received; a communication sent by mail shall be deemed effective ten days after posting; and a communication delivered by messenger shall be deemed effective when delivered.

Licensor: Solvay Pharmaceuticals, Inc.  
901 Sawyer Road  
Marietta, Georgia 30062  
Facsimile: 770-578-5749  
Attention: Senior Vice President, Law, Government and Public Affairs

Licensee: Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
Facsimile: 650-496-3781  
Attention: General Counsel



The foregoing is not intended to be exclusive; any written communication actually received shall be effective when received.

(e) Captions: The section captions used in this Trademark License Agreement are for reference and cross-reference purposes only and shall not otherwise affect the meaning or interpretation of this Trademark License Agreement.

(f) Counterparts and Attachments: This Trademark License Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original and all of which shall be deemed to constitute the same Trademark License Agreement.

(g) Entire Agreement: This Trademark License Agreement, together with the License Agreement, expresses the entire understanding of the parties hereto with respect to the Licensed Mark. Neither this Trademark License Agreement nor any provision hereof may be changed, waived, discharged, or terminated orally, but only by an agreement in writing signed by the party against whom or which the enforcement of such change, waiver, discharge, or termination is sought.

(h) Conflict with License Agreement: If any provision of this Trademark License Agreement is deemed to conflict with or contradict the terms of the License Agreement, the terms of the License Agreement shall govern and be controlling.

(i) Injunctive Relief: It is further understood and agreed that money damages would not be a sufficient remedy for any breach of this Trademark License Agreement by either party. In the event of any breach or threatened breach of this Trademark License Agreement, the non-breaching party, in addition to any other remedies it may have at law or in equity, shall be entitled to equitable relief, including injunctive relief and specific performance, without proof of actual damages. Further, the breaching party shall reimburse the non-breaching party for all costs and expenses (including attorney fees) the non-breaching party may incur in connection with the enforcement of this Trademark License Agreement.

IN WITNESS WHEREOF, Licensor and Licensee have each caused this Trademark License Agreement to be duly executed in its corporate name by a duly authorized representative as of the date first above written.

LICENSEE:  
Jazz Pharmaceuticals, Inc.

By: /s/ Samuel R. Saks, M.D.  
Name: Samuel R. Saks, M.D.  
Title: Chief Executive Officer

LICENSOR:  
Solvay Pharmaceuticals, Inc.

By: /s/ Laurence J. Downey, M.D.  
Name: Laurence J. Downey, M.D.  
Title: President and CEO

EXHIBIT A  
REQUIREMENTS OF TRADEMARK USE

1. The first or most prominent reference to the Licensed Mark shall be marked with a ® symbol.
2. The Licensed Mark shall be followed by the appropriate generic term at least once in each package or promotional piece.
3. The Licensed Mark shall not be used in possessive form.
4. The Licensed Mark shall not be used in the plural form.

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**ASSIGNMENT, ASSUMPTION AND CONSENT**

THIS ASSIGNMENT, ASSUMPTION AND CONSENT (this “**Agreement**”) is dated as of January 31, 2007 (the “**Effective Date**”), by and among Jazz Pharmaceuticals, Inc., a Delaware corporation (“**Assignee**”), Solvay Pharmaceuticals, Inc., a Georgia corporation (“**Assignor**”) and Elan Pharma International Limited, a company incorporated in Ireland (“**Elan**”).

**WITNESSETH**

(A) **WHEREAS**, Assignor and Elan Corporation, plc entered into a license agreement dated December 22, 1997 as amended by Amendment No. 1 to the License Agreement dated March 1, 1999, Amendment No. 2 to the License Agreement dated April 13, 2000 and Amendment No. 3 to the License Agreement dated November 7, 2006 (collectively, the “**Elan Agreement**”);

(B) **WHEREAS**, Solvay and Solvay Pharmaceuticals Marketing & Licensing AG of Binningerstrasse 94, 4123 Allschwil, Switzerland (“**SPML**”) entered into an Assignment and Assumption Agreement of the Elan Agreement dated 4 August 2000 (the “**Assignment Agreement**”) which was subsequently re-assigned back by SPML to Solvay through a letter agreement for reassignment and re-assumption dated 13 December 2001, (the “**Re-assignment Agreement**”), and said Assignment Agreement and Re-assignment Agreement were consented to by Elan Corporation plc.;

(C) **WHEREAS**, on December 31, 2006, Elan Corporation, plc assigned all of its rights and obligations under the Elan Agreement to its Affiliate, Elan, and Elan has assumed said rights and obligations, as Assignor and Assignee hereby acknowledge;

(D) **WHEREAS**, Assignor desires to assign all of its right, title and interest in and to the Elan Agreement to Assignee, and Assignee desires to assume all of Assignors’ right, title and interest in and to the Elan Agreement;

(E) **WHEREAS**, in accordance with Article XII, Section 2 of the Elan Agreement, Elan is willing to consent to such assignment and assumption on the terms set out below;

(F) **WHEREAS** all parties have agreed to the terms of this Agreement setting out how their respective future contractual relationship shall be governed; and

(G) **WHEREAS** the parties also wish to clarify that monies currently held on account by Elan for Assignor as of the date of this Agreement may be applied by Elan to cover the costs of on-going engineering and other work that is conducted by Elan under the Agreement before, on or after the Effective Date.

**NOW, THEREFORE**, the parties agree as follows:

1. Assignment. Subject to Paragraph 2 below, Assignor hereby assigns and conveys unto Assignee, its successors and assigns, as of the Effective Date all of Assignor’s right, title and interest in and to the Elan Agreement.

2. Assumption. Assignee hereby accepts the Assignment as of the Effective Date and agrees to assume all the obligations, covenants and agreements of Assignor under the Elan Agreement as of the Effective Date.
3. Consent. Elan hereby consents to such assignment and assumption of the Elan Agreement by Assignee.
4. Acknowledgement. Elan, Assignor and Assignee hereby each acknowledge to each other as of the Effective Date that it is not aware, after due enquiry, of any breach of the Elan Agreement by Assignor (in the case of Elan) or Elan (in the case of Assignor and Assignee).
5. Outstanding Amounts and Responsibilities. The parties acknowledge that as of the Effective Date Assignee shall be responsible for compensating Elan for all future milestone payments and for the cost of all on-going and future activities that may be conducted by Elan under the Elan Agreement. The parties also acknowledge and agree that Elan currently holds certain monies on account on behalf of Assignor as of the Effective Date and said monies may be used by Elan and Assignee to off-set Assignee's financial responsibilities for the cost of on-going activities conducted by Elan before, on or after the Effective Date.
6. Confidentiality.
  - a. Nothing in this Agreement diminishes the obligation of any party under Article XII, Section 1 of the Elan Agreement.
  - b. The parties agree that, prior to the transfer of any Elan confidential information from Assignor to Assignee, the Assignor and Elan shall meet and identify the Elan confidential information currently in Assignor's possession as a result of the Elan Agreement. The parties shall then convene the Transition Committee to determine the Elan confidential information currently held by Assignor that shall be transferred by the Assignor to the Assignee (to enable Assignee to fulfill its obligations under the Elan Agreement) and the Elan confidential information held by Assignor in relation to the Elan Agreement that shall be destroyed or returned to Elan. The parties further agree that, for any documents that are destroyed, Assignor shall provide Elan with a written list of said materials and acknowledgement of their destruction; provided, however, Assignor shall be permitted to retain one (1) copy of such confidential information in its legal files solely for the purposes of verifying compliance with the terms of the Elan Agreement.
  - c. Assignor covenants that it shall continue to maintain the confidentiality of any Elan confidential information that it is unable to destroy or return or that may be provided in the future to the Assignor as an

agent, subcontractor or sub-licensee of Assignee or as the holder of INDs, NDA filings and NDAs in accordance with Article XII, Section 1 of the Elan Agreement.

- d. Assignee covenants that it shall obtain additional Elan confidential information under the Elan Agreement (with the exception of that Elan confidential information that is contained in and forms part of any NDA regulatory filings that are provided directly to Assignee by Assignor) directly from Elan in accordance with the Elan Agreement.
- e. Elan and Assignee covenant that they shall maintain confidential information provided by one to the other after the Effective Date in accordance with the Article XII, Section 1 of the Elan Agreement.

7. Cooperation. Assignor, Assignee and Elan shall reasonably cooperate with one another in transferring to Assignee the rights and obligations assigned by Assignor hereunder.

8. Coordination. Until the US NDA is fully transferred to Assignee, the parties agree that they shall oversee the management of all activities conducted under the Elan Agreement that are associated with the INDs, the NDA filings, and the US NDA and the transfer of same from the Assignor to the Assignee through a transition committee ("**Transition Committee**").

Unless otherwise mutually agreed in writing by the parties:

- a. The Transition Committee shall be composed of four (4) Elan representatives and four (4) representatives in total for the Assignee and Assignor, one of which must, in every instance, represent Assignee.
- b. The Transition Committee shall meet within fourteen (14) days of the Effective Date to discuss and determine how the parties shall interact with one another while the Assignor continues to own and maintain the INDs, NDA filings and the US NDA. Specific issues to be discussed include, but are not limited to, the transfer and return of Elan confidential information, how the parties shall coordinate and respond to FDA enquiries, the new COMPOUND qualification, on-going activities prior to process validation, the use of process validation batches, and PRODUCT launch activities;
- c. Thereafter, the Transition Committee shall meet as often as may be reasonably necessary to resolve any management issues that may arise between the parties while Assignor continues to own and be responsible for the INDs, the NDA filings and the US NDA. The meetings may take place by telephone or, if necessary, in person;
- d. Transition Committee meetings shall be co-chaired by a representative from Elan and a representative from Assignee.

All decisions made shall be mutually agreed by the Elan and Assignee, and Assignor shall be bound by such decisions. Any dispute that cannot be resolved by the Transition Committee shall be submitted for resolution to the President and Chief Operating Officer of Elan and the Chief Executive Officer of Assignee.

- e. The Transition Committee shall be promptly disbanded following the transfer of the INDs, the NDA filings and the US NDA to Assignee.

9. Notices. Any notice, request, consent or communication under this Agreement shall be provided in accordance with the terms of Article XII, Section 13 of the License Agreement and shall be addressed as follows:

If to Assignor to:

Solvay Pharmaceuticals, Inc.  
901 Sawyer Road  
Marietta, Georgia 30062  
Attention: Office of the President  
cc: General Counsel  
Facsimile: 770-578-5749

If to Assignee to:

Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, California 94304  
United States of America  
Fax: 650-496-3781  
Attention: General Counsel

With a copy to:

Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, California 94304  
United States of America  
Fax: 650-496-3781  
Attention: Executive Vice President, Chief Business Officer

If to Elan:

Elan Pharma International Limited  
Monksland  
Athlone  
Co Westmeath  
Ireland  
Fax: +353 90 649 5402  
Attention: Vice President and Legal Counsel

With a copy to:

Elan Pharma International Limited  
Treasury Building  
Lower Grand Canal Street  
Dublin 2  
Ireland  
Fax: +353 1 709 4700  
Attention: Vice President, Commercial Management

10. Definitions.

- a. Further Definitions: In this agreement, the following expressions have the following meanings:
  - “**IND**” means Investigational New Drug Application as set forth in the 21 C.F.R. Section 312 in the United States and/or its equivalent in the other countries of the Territory.
  - “**NDA**” means a New Drug Application in the United States made in accordance with applicable regulations and requirements of the FDA as from time to time in effect and/or its equivalent in the other countries of the Territory.
- b. Capitalized Terms. Capitalised expressions not expressly defined in this Agreement shall have the same meaning as in the Elan Agreement.
- c. Interpretation. In this Agreement:
  - i. Unless the context otherwise requires, reference to a recital, article, paragraph, provision, clause or schedule is to a recital, article, paragraph, provision, clause or schedule of or to this Agreement.
  - ii. The headings in this Agreement are inserted for convenience only and do not affect its construction.
  - iii. The expressions “include”, “includes”, “including”, “in particular” and similar expressions shall be construed without limitation.

11. Entire Agreement.

- a. Assignee and Assignor have entered into separate agreements and intend in the future to enter into further separate agreements which make certain financial and other provisions as between themselves and which have not been fully disclosed to Elan.



- b. All of the parties hereby expressly acknowledge that Elan shall not be bound or otherwise prejudiced by these agreements, and in the event of any conflict between such agreements and this Agreement, this Agreement shall prevail.
  - c. Subject to the foregoing, this Agreement constitutes the entire agreement and understanding between the parties with respect to its subject matter, and except as expressly provided, supersedes all prior representations, writings, negotiations or understandings with respect to that subject matter.
12. Modifications and Amendments. This Agreement shall not be amended, modified, varied or supplemented except in writing signed by a duly authorized representative of each of the parties hereto.
  13. Successors and Assigns. The terms and conditions of this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, personal representatives, successors and assigns.
  14. Relationship of the Parties. In this Agreement, nothing shall be deemed to constitute a partnership between the parties, or any of them, or make any party an agent for any other party, for any purpose whatsoever.
  15. Costs. Each party shall bear its own legal and professional advisers's costs and expenses incurred in connection with the negotiation and entering into this Agreement.
  16. Severability. If any provision of this Agreement is deemed to be, or becomes invalid, illegal, void or unenforceable under applicable laws, such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable, or if it cannot be so amended without materially altering the intention of the parties, it will be deluged, but the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.
  17. Further Assurance. Each party shall do and execute, or arrange for the doing and executing of, each necessary act, document and thing reasonably within its power to implement this Agreement.
  18. Waivers. A failure to exercise or delay in exercising a right or remedy provided by this Agreement or by law does not constitute a waiver of the right or remedy or a waiver of other rights or remedies. No single or partial exercise of a right or remedy provided by this Agreement or by law prevents further exercise of the right or remedy or the exercise of another right or remedy.
  19. Variations. No variation of this Agreement shall be effective unless it is made in writing and signed by each of the parties.
  20. Governing Law. This Assignment and any dispute arising from the performance or breach hereof shall be governed by and construed in

accordance with the laws of the State of Georgia, without regard to principles of conflicts of law. Any dispute arising under this Agreement that cannot be resolved between the parties shall be resolved through binding arbitration in accordance with Article XII, Section 12 of the Elan Agreement.

21. Counterparts. This Assignment may be executed in several counterparts, each of which will be deemed an original document, but all of which will constitute a single document.

**{Reminder of Page Intentionally Left Blank; Signature Page Follows}**

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be duly executed as of the Effective Date.

**ASSIGNOR:**

**SOLVAY PHARMACEUTICALS, INC.**

By: /s/ Laurence J. Downey, M.D.

Name: Laurence J. Downey, M.D.

Its President and CEO

**ASSIGNEE:**

**JAZZ PHARMACEUTICALS, INC.**

By: /s/ Bob Myers

Name: Bob Myers

Its EVP and Chief Business Officer

**ELAN:**

**ELAN PHARMA INTERNATIONAL LTD.**

By: /s/ Shane Cooke

Name: Shane Cooke

Its Director

.As executed

**This Agreement is made the 22nd day of December 1997**

**BY AND BETWEEN**

**ELAN CORPORATION, plc**

An Irish company, of Lincoln House, Lincoln Place, Dublin 2, Ireland.

AND

**SOLVAY PHARMACEUTICALS, INC.**

An American company, of 901 Sawyer Road, Marietta, Georgia, United States of America.

## **RECITALS**

### **WHEREAS**

- ELAN is beneficially entitled to the use of various patents, including the ELAN PATENT RIGHTS, which have been granted or are pending under the International Convention in relation to the development and production of drug specific dosage forms for pharmaceutical products and process, and
- ELAN is knowledgeable in the development of drug specific dosage forms and has developed a unique range of delivery systems designed to provide newer and better formulations of medicaments, and
- COMPANY wishes to have ELAN develop a new, improved dosage form or forms of the COMPOUND and ELAN is willing to use its technology to develop an improved dosage form or dosage forms of the COMPOUND.
- COMPANY is desirous of entering into a licensing agreement with ELAN by virtue of which COMPANY will be free to have manufactured the PRODUCT in accordance with the terms of this Agreement and COMPANY will be granted an exclusive world-wide licence to market the PRODUCT in the TERRITORY without infringing any of the ELAN PATENT RIGHTS or ELAN KNOW-HOW rights held by ELAN, and
- ELAN is prepared to develop and license the marketing and sales rights, including the ELAN PATENT RIGHTS and ELAN KNOW-HOW for the PRODUCT in the TERRITORY to COMPANY and ELAN is prepared to supply the PRODUCT to COMPANY.

### **NOW IT IS HEREBY AGREED AS FOLLOWS:**

#### **ARTICLE I: DEFINITIONS**

1.1. In the present Agreement and any further agreements based thereon between the parties hereto, the following definitions shall prevail:

1. AFFILIATE shall mean any corporation or entity controlling, controlled by or under the common control of ELAN or COMPANY as the case may be.
2. cGCP, cGMP, cGLP shall mean current Good Clinical Practice, current Good Manufacturing Practice and current Good Laboratory Practices as defined in the Code of Federal Regulations 21 as issued by the FDA, as amended from time to time.

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3. CMC SECTION shall mean the chemistry, manufacturing, and controls section of an NDA as defined in 21 CFR Section 314.50 (D)(1) & (E) and its equivalent in other registration applications.
4. COMPANY shall mean Solvay Pharmaceuticals, Inc. and any of its AFFILIATES.
5. COMPANY KNOW-HOW shall mean all knowledge, information trade secrets, data and expertise owned or licensed by COMPANY or to be developed by COMPANY during the term of this Agreement relating to the COMPOUND which is not generally known to the public, whether or not covered by any patent, copyright, design or other industrial or intellectual property rights and all clinical data relevant to the COMPOUND (excluding any such data which is relevant solely to [ \* ]) generated by [ \* ] during the PROJECT.
6. COMPANY PATENT RIGHTS shall mean all patents and patent applications listed in Appendix A, Part II. COMPANY PATENT RIGHTS shall also include all continuations, continuations-in-part, divisionals and re-issues of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder. Extensions of patents shall include: a) extensions under the U.S. Patent Term Restoration Act, b) extension of patents under the Japanese Patent Law, and c) Supplementary Protection Certificates for members of the European Patent Convention and other countries in the European Economic Area.
7. COMPOUND shall mean the active substance Fluvoxamine maleate, hereafter called Fluvoxamine.
8. COMPOUND SPECIFICATIONS shall mean the specifications for the COMPOUND as approved by the FDA under COMPANY's Drug Master File or equivalent licence in the United States of America and any further specifications which may be agreed by the parties in writing.
9. ELAN shall mean Elan Corporation, plc and any of its AFFILIATES.
10. ELAN KNOW-HOW shall mean all knowledge, information, trade secrets, data and expertise owned or licensed by ELAN or to be developed by ELAN whether before or during the term of this Agreement relating to the PRODUCT, whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

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11. ELAN PATENT RIGHTS shall mean all patents and patent applications listed in Appendix A, Part I. ELAN PATENT RIGHTS shall also include all continuations, continuations-in-part, divisionals and re-issues of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder. Extensions of patents shall include: a) extensions under the U.S. Patent Term Restoration Act, b) extension of patents under the Japanese Patent Law, and c) Supplementary Protection Certificates for members of the European Patent Convention and other countries in the European Economic Area.  
  
ELAN PATENT RIGHTS shall further include any patents or patent applications covering any improved methods of making or using the PRODUCT acquired by ELAN, whether before or during the term of this Agreement, and under which ELAN has a right to grant a licence to COMPANY hereunder; provided that ELAN is not obliged to pay a royalty or any other consideration to a third party in connection with such licence. In the event that ELAN acquires or merges with a third party entity, ELAN PATENT RIGHTS shall not include any patent rights to the extent that such patent rights relate to a product containing the COMPOUND which has been approved for marketing or is in development by the said third party entity.
12. EX WORKS shall have the meaning as such term is defined in the ICC Incoterms, 1990, International Rules for the Interpretation of Trade Terms, ICC Publication No. 460.
13. FCA shall have the meaning as such term is defined in the ICC Incoterms, 1990, International Rules for the Interpretation of Trade Terms, ICC Publication No. 460.
14. FDA shall mean the United States Food and Drug Administration or any other successor agency whose approval is necessary to market the PRODUCT in the United States of America and/or its foreign equivalents in the other countries of the TERRITORY.
15. IN MARKET shall mean the sale of the PRODUCT by COMPANY or its AFFILIATE (or where applicable by a permitted sub-licensee) to an unaffiliated third party such as a wholesaler, distributor, managed care organisation, hospital or pharmacy and shall exclude the transfer pricing of the PRODUCT by COMPANY to an AFFILIATE or a permitted sub-licensee.
16. MANUFACTURING COST shall mean the cost to ELAN for the manufacture of the PRODUCT which is calculated by the method described in Appendix D hereto.
17. NDA shall mean the New Drug Application or any other application for regulatory approval which COMPANY intends to file, including any supplements or amendments thereto which COMPANY may file, for the PRODUCT in the United States of America and the other countries of the TERRITORY.

18. NDA APPROVAL shall mean the final approval to market the PRODUCT in the relevant country of the TERRITORY.
19. NSP shall, subject to the provisions of Article V paragraphs 3.5., mean in the case of any PRODUCT sold by COMPANY or AFFILIATE or a permitted sub-licensee, that sum determined by deducting from the aggregate gross IN MARKET sales proceeds billed for the PRODUCT the following deductions:
  - (a) any sales or other taxes (excluding income or corporation taxes), assessments, charges or fees, including customs tax, imposed by any government authority which are paid, directly or indirectly, by COMPANY or its AFFILIATES or permitted sub-licensees as applicable, as directly relates to the sale of the PRODUCT;
  - (b) a discount from the gross sales proceeds to cover such normal costs as are imposed on COMPANY or its AFFILIATES or permitted sub-licensees as applicable, in respect of freight, postage, and shipping insurance;
  - (c) a discount from the gross sales proceeds to cover such costs as are imposed on COMPANY or its AFFILIATES or permitted sub-licensees as the case may be, in respect of quantity or cash discounts actually taken or allowed, including Medicaid rebates, said discounts being consistent with normal practices applied by COMPANY in relation to its other branded products;
  - (d) a maximum deduction of [ \* ] to cover amounts repaid or credited by COMPANY or its AFFILIATES or its permitted sub-licensees as the case may be, by reason of rejections, return of goods and retroactive price reductions directly relating to the PRODUCT;
  - (e) a [ \* ] discount from the gross sales proceeds in each country of the TERRITORY to cover [ \* ] price reductions initiated by COMPANY in response to the [ \* ].
20. PRODUCT shall depending upon the context mean one or more of the oral controlled release dosage forms being developed by ELAN during the course of the PROJECT containing the COMPOUND as its sole active ingredient.
21. PRODUCT SPECIFICATIONS shall mean the specifications for the PRODUCT to be agreed by the parties hereto, which shall be consistent with the specifications to be determined by FDA in the NDA APPROVAL, and which shall be attached as Appendix C, as well as such other specifications such as interim specifications which may be required during the PROJECT and which may be agreed upon by the parties in writing.

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22. PROJECT shall mean all activity in order to develop the PRODUCT(S) in accordance with the plan shown in Appendix B.
23. PROJECT TEAM shall mean the group to be established pursuant to Article IX.
24. QUALITY PROCEDURES shall mean the technical and quality procedures specified in Appendix E hereto and which may be amended by agreement of the parties from time to time
25. STAGE I, STAGE II, STAGE III and STAGE IV shall mean the stages as set out in Appendix B.
26. TERRITORY shall mean all of the countries of the world.
27. \$ shall mean United States Dollars.

1.2 In this Agreement

- 1.2.1. the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa.
- 1.2.2. any reference to an Article or Appendix shall, unless otherwise specifically provided, be to an Article or Appendix of this Agreement.
- 1.2.3. the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.
- 1.2.4. all references to "days" in this Agreement shall mean calendar days.

**ARTICLE II : THE LICENCE**

**Licence to COMPANY**

1. ELAN shall remain proprietor of all ELAN PATENT RIGHTS and ELAN KNOW-HOW and all other intellectual property relating thereto, as well as products derived therefrom, but shall grant to COMPANY for the term of the Agreement an exclusive licence pursuant to the ELAN PATENT RIGHTS and ELAN KNOW-HOW, to have manufactured, package, use and sell the PRODUCT as a prescription medicine in the TERRITORY under the terms and conditions set out herein.

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2. Subject to the provisions of the following sentence, COMPANY hereby accepts such licence and confirms that COMPANY and its AFFILIATES [ \* ] during the Initial Period and for one year thereafter. Should COMPANY [ \* ] in the countries of the European Union and/or in the European Economic Area, ELAN reserves the right to [ \* ].
3. COMPANY shall remain the sole owner of all COMPANY PATENT RIGHTS and COMPANY KNOW-HOW. ELAN shall remain the sole owner of all ELAN PATENT RIGHTS and ELAN KNOW-HOW.
4. ELAN shall be entitled to use the ELAN PATENT RIGHTS and ELAN KNOW-HOW, including all improvements and other intellectual property thereto, generated by ELAN pursuant to this Agreement in connection with [ \* ], and in connection with [ \* ] or following termination of this Agreement.
5. COMPANY shall market the PRODUCT in the TERRITORY under COMPANY's trademark.
6. COMPANY shall submit copies of all trade package cartons and labels and other printed materials to ELAN once commercial sale of the PRODUCT commences. When packaged, and to the extent permitted by law, a product label shall include an acknowledgement that the PRODUCT is made under licence from ELAN. Such acknowledgement shall take into consideration regulatory requirements and COMPANY's commercial requirements. COMPANY shall wherever possible give due acknowledgement and recognition to ELAN in all printed promotional and other material regarding the PRODUCT such as stating that the PRODUCT is manufactured by, ELAN.
7. Where appropriate, COMPANY shall mark or have marked the patent number on all PRODUCT labelling, or otherwise reasonably communicate to the trade concerning the existence of any ELAN PATENT RIGHTS for the countries within the TERRITORY in such a manner as to ensure compliance with, and enforceability under, applicable laws.
8. For the avoidance of doubt, ELAN acknowledges that it has exclusively licensed the ELAN PATENT RIGHTS and ELAN KNOW-HOW to COMPANY to have manufactured, package, use and sell the PRODUCT as a prescription medicine in the TERRITORY. This exclusivity shall not restrict ELAN from licensing any other product containing the COMPOUND which is not a [ \* ] solid oral dosage form of the COMPOUND or any [ \* ]. In the event that ELAN subsequently develops a product containing the COMPOUND ("Developed Product") in accordance with this paragraph and intends to licence the Developed Product to a third party, then subject to any pre-existing contractual obligations, ELAN shall

grant to COMPANY a right of first refusal to licence such Developed Product for a licence royalty to be negotiated. Said right of first refusal shall expire [ \* ] days after the Developed Product has been offered to COMPANY. Subject to any confidentiality restraints, ELAN shall notify COMPANY in the event that ELAN commences development of any other product containing the COMPOUND during the term of this Agreement. In the event that ELAN acquires or merges with a third party entity, this provision [ \* ] by the said third party entity. ELAN shall not use the ELAN PATENT RIGHTS, ELAN KNOW-HOW, COMPANY PATENT RIGHTS or COMPANY KNOW-HOW to [ \* ].

#### **Sub-licence**

9. COMPANY may grant a sub-licence to use and sell the PRODUCT in one or more countries of the TERRITORY, provided that COMPANY not grant a sub-licence to [ \* ]. Sub-licenses hereunder shall be in the same terms mutatis mutandis as the terms of this Agreement insofar as they are applicable, but excluding the right to grant a sub-licence or a production licence. COMPANY shall remain responsible for all acts and omissions of such sub-licensees as though such acts and omissions were by COMPANY.
10. Any sub-licence permitted by Article II, paragraph 9 shall automatically and immediately terminate if the country or countries for which the sub- licensee has rights are terminated in accordance with this Agreement (so that a sub-licence shall only terminate for such country or countries if the Agreement has been terminated for the country or countries concerned). For the avoidance of doubt, the parties agree that any such sub-licence agreement shall not be capable of surviving the termination of this Agreement and that [ \* ] by the sub- licensee shall be included [ \* ], whether under paragraph [ \* ] of this Agreement. COMPANY shall use its reasonable endeavours to ensure that ELAN shall have the same rights of audit and inspection vis a vis a sub- licensee, as ELAN has pursuant to this Agreement concerning COMPANY.

#### **Licence to ELAN**

11. In the event that COMPANY
  - 11.1. exercises its right to terminate the PROJECT in accordance with Article III, paragraph 4 or Article XII, paragraph 5.3.; or
  - 11.2. fails to [ \* ] within [ \* ] from the conclusion of the [ \* ] and the [ \* ] as are appropriate for the [ \* ]; or
  - 11.3. fails to [ \* ] within [ \* ] from the date of [ \* ], including [ \* ] where applicable, [ \* ]; or

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11.4. notifies ELAN that it does not wish to commercialise the PRODUCT in any country of the TERRITORY;

then, ELAN shall have the right to terminate the licence granted to COMPANY pursuant to Article II, paragraph 1 for the whole of the TERRITORY (pursuant to paragraph 11.1.) or for any such country or countries of the TERRITORY (pursuant to paragraphs 11.2., 11.3. and 11.4.), as appropriate. Thereafter, ELAN shall be entitled to research, develop and commercialise the PRODUCT in the countries of the TERRITORY in which the license has been so terminated. If ELAN should require a licence to the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in order to research, develop and/or commercialise the PRODUCT in the TERRITORY, COMPANY shall grant ELAN a licence to such COMPANY PATENT RIGHTS and COMPANY KNOW-HOW for a term of [ \* ] starting from the date of the launch of the PRODUCT by ELAN or up to the expiration of the life of the last to expire patent included in the COMPANY PATENT RIGHTS, whichever is longer, in consideration of the payment of a royalty by ELAN in accordance with Article V, paragraph 3.7.

12. ELAN may grant a sub-licence to such COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in one or more countries of the TERRITORY mutatis mutandis with the terms of Article II, paragraphs 9 and 10. In consideration for the royalty which may be payable under Article V, paragraph 3.8., COMPANY shall transfer to ELAN or ELAN's designee without charge any and all pending or granted NDA APPROVALS for the PRODUCT for such country or countries of the TERRITORY

### **ARTICLE III: DEVELOPMENT OF THE PRODUCT**

1. ELAN shall develop the PRODUCT in accordance with the PROJECT.
2. ELAN shall apply its technical skill and expertise, including the ELAN PATENTS and ELAN KNOW-HOW, in the development of the PRODUCT on behalf of COMPANY. However, it is acknowledged that pharmaceutical research and development incorporates inherent risk in terms of outcomes and, save for acts of negligence or omission by ELAN, ELAN shall have no liability to COMPANY as a result of any failure or delay of the PRODUCT to achieve one or more of the milestones set out in the PROJECT and/or to obtain the NDA APPROVAL in one or more of the other countries of the TERRITORY.
3. ELAN and COMPANY hereby confirm that each shall undertake its respective part of the PROJECT as a collaborative effort and that the provisions of this Agreement requires that each party diligently carries out those tasks assigned to it under the PROJECT and as otherwise agreed during the course of the PROJECT. Each party

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shall co-operate with the other in good faith particularly with respect to unknown problems or contingencies and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner.

4. COMPANY may evaluate the reports furnished by ELAN at the end of STAGES I, II and III of the PROJECT for the PRODUCT for the purpose, inter alia, of deciding whether or not to proceed further with the PROJECT for the PRODUCT. COMPANY shall use its reasonable efforts to review the content of the said reports in a timely fashion and shall promptly undertake such discussions it requires with ELAN on the future conduct and direction of subsequent stages of the PROJECT.
5. Within thirty (30) days of the execution of this Agreement, COMPANY shall impart to ELAN a full package of physicochemical, pharmacokinetic and clinical data regarding the COMPOUND, including the COMPOUND SPECIFICATIONS, and current marketed versions thereof as it might be reasonably expected shall be required by ELAN to successfully undertake the PROJECT. The foregoing data shall include, but shall not be limited to, [ \* ]. ELAN shall not be required to commence the PROJECT until it has received such data and information. For the avoidance of doubt, all confidential information disclosed by COMPANY in accordance with this paragraph shall be considered COMPANY KNOW-HOW for the purposes of this Agreement.
6. For so long as this Agreement is in effect and COMPANY is participating in the PROJECT, COMPANY will supply ELAN with all of ELAN's requirements of COMPOUND [ \* ] to enable ELAN to carry out the PROJECT. For the avoidance of doubt, ELAN shall not be required to commence or to continue with any STAGE of the PROJECT in the event that ELAN is not in receipt of appropriate quantities of the COMPOUND. In such an event, appropriate adjustment will be made by ELAN and COMPANY to extend the time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V for the achievement by ELAN of the tasks set out therein.
7. With reference to the strict time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V for the achievement of the tasks set out therein by ELAN and the potential financial implications for ELAN in the event that any of such tasks are not achieved within the time period set out in paragraphs 2.1.2. and 2.1.3. of Article V, the parties recognise that the timely supply by COMPANY to ELAN of the information, data, materials and COMPOUND in accordance with Article III on an ongoing basis throughout the PROJECT is fundamental to the successful completion of the PROJECT and to ELAN's successful attainment of the tasks within the time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V. Accordingly, in addition to the other provisions of Article II, COMPANY shall:-
  - 7.1. ensure that all information and data, materials and COMPOUND, which are required by ELAN from COMPANY are supplied to ELAN within the timeframe so requested by ELAN and agreed with COMPANY;

- 7.2. in the event that there are delays in the supply of any information, data, materials or COMPOUND by COMPANY to ELAN, or delays by any government agency or authority (which delays by any such agency or authority are not attributable to any act or omission of ELAN) which will materially affect ELAN's ability to achieve the tasks and/or successfully complete the PROJECT within the time schedules set out in paragraphs 2.1.2. and 2.1.3. of Article V, the parties shall agree in good faith an appropriate mechanism to remedy any such delays by COMPANY or any government agency or authority and amend paragraphs 2.1.2. and 2.1.3. of Article V, in particular to extend the dates set out therein for the achievement of the tasks by ELAN to ensure that any such delays by COMPANY or any government agency or authority will not adversely affect the payment of the full amount of any licence royalty to ELAN under paragraphs 2.1.2. and 2.1.3. of Article V.
8. COMPANY shall inform ELAN as to its choice of initial developmental dosage strengths within thirty (30) days of the execution of this Agreement and ELAN shall promptly inform COMPANY as to the suitability of such dosage strengths for development. Pursuant to the PROJECT, ELAN shall then develop up to [ \* ] unit dosage strengths of the PRODUCT after the preferred dosage form (SODAS or HYDAS) has been chosen by COMPANY. In the event that ELAN informs COMPANY that one or more of the dosage strengths is unsuitable for development, the parties shall agree on a suitable alternative dosage strength(s).
9. In the event that COMPANY wishes to have more than [ \* ] dosage strengths developed pursuant to this Agreement, the parties shall negotiate in good faith as to the additional costs to be paid to ELAN for such development and such amendments as are required to the PROJECT and the timeframe for the PROJECT, including the time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V. The parties agree that ELAN's charges to COMPANY for any such work shall be as set out in Article V, paragraph 4 of the Agreement.
10. ELAN shall conduct the pilot and pivotal Phase I pharmacokinetic studies and associated bio- and statistical analysis in human volunteers in accordance with the PROJECT [ \* ]. The design [ \* ] of such studies and associated analytical testing shall be as set out in the PROJECT, provided however, that the [ \* ] of such studies shall [ \* ], as appropriate, in the event of a [ \* ] of the studies. The design [ \* ] of such studies shall be finalised with COMPANY prior to commencement of each such study. The parties agree that [ \* ] shall be as set out in [ \* ] of the Agreement. ELAN shall furnish a full and detailed report to COMPANY on the results of all such pharmacokinetic studies. [ \* ]. ELAN undertakes that it shall carry out all such pharmacokinetic studies to prevailing cGCP and cGLP and most specifically in accordance with FDA standards and guidelines.

11. COMPANY shall be responsible for carrying out [ \* ] the efficacy clinical studies programme in human patients. The objective of the programme so conducted shall be to assist in obtaining NDA APPROVAL. COMPANY agrees to carry out and complete the clinical efficacy programme to an FDA approvable standard and to a standard and timeframe that COMPANY would otherwise find acceptable for one of its major branded products. COMPANY shall keep ELAN informed as to the progress of the studies and on completion, shall impart summary reports on the studies. COMPANY undertakes that it shall carry out all such clinical studies to prevailing cGCP and cGLP and most specifically in accordance with FDA standards and guidelines.
12. During the PROJECT, the parties shall review and agree on interim specifications for the PRODUCT and shall also agree on the final PRODUCT SPECIFICATIONS following the filing of the NDA in the United States of America, which shall at that time be attached to this Agreement as Appendix C. The PRODUCT SPECIFICATIONS may thereafter be amended as agreed by the parties or as may otherwise be requested or mandated by the regulatory authorities in the TERRITORY, most specifically the FDA.
13. For the avoidance of doubt, the parties hereby confirm that the primary objective of the PROJECT is to generate the NDA and secure NDA APPROVAL for the PRODUCT in the United States of America. As of the date of this Agreement, it is the parties' expectation that the body of data so generated in the PROJECT will also be used to support such applications for regulatory approval that COMPANY, its AFFILIATES or permitted sub-licensees shall make in the other countries of the TERRITORY.
14. In the event however that such expectation proves unfounded or incorrect and further data is required to obtain such other NDA APPROVAL as are pursued by COMPANY in the other countries of the TERRITORY, COMPANY shall determine the viability of proceeding further with the regulatory application and generation of the further data requirements. In the event that COMPANY elects to continue, the parties shall agree on the programme of work to be undertaken to generate such additional data and the apportioning of tasks and costs therefor. COMPANY shall reimburse ELAN for all such additional work which it requires ELAN to carry out in accordance with ELAN's charges as set out in Article V, paragraph 4 of the Agreement.

**ARTICLE IV : SUPPLY OF THE PRODUCT**

1. Except as otherwise herein provided, ELAN shall produce and supply to COMPANY its entire requirements of the PRODUCT. ELAN shall be the sole

and exclusive supplier of the PRODUCT to COMPANY in the TERRITORY and COMPANY will purchase the PRODUCT exclusively from ELAN in the TERRITORY. COMPANY may qualify a second site for the manufacture of PRODUCT for the purposes of Article IV paragraphs 14 and 15.

2. The PRODUCT to be supplied to COMPANY by ELAN shall be in the form of bulk capsules or tablets (as will be agreed by the parties during the PROJECT) complying with the PRODUCT SPECIFICATIONS. ELAN shall deliver the PRODUCT to COMPANY and/or any party designated by COMPANY in proper packaging so as to permit safe storage and transport. COMPANY shall be responsible for the packaging of the PRODUCT into final market packaging, whether such packaging is conducted by COMPANY or by a sub-contractor which it may nominate, but whose final selection will be subject to ELAN's prior written agreement, which agreement will not be unreasonably withheld or delayed.
3. In the event that ELAN appoints a third party manufacturer, then ELAN shall be solely responsible and liable to COMPANY for the performance of the said manufacturer and ELAN shall ensure that the said manufacturer's facility is an FDA approved facility and that such facility complies with all relevant FDA and other relevant governmental and regulatory requirements and that all accepted practises of cGMP are adhered to. For the avoidance of doubt, the parties agree that in the event ELAN does not itself wish to manufacture the PRODUCT, then it shall offer to COMPANY a production licence as outlined in paragraph 14.1 below first before appointing a third party manufacturer. Should COMPANY decline such production license, then ELAN shall be free to appoint a third party manufacturer for the PRODUCT. The parties confirm that the provisions of Article V paragraph 3.1 shall apply to the sale of PRODUCT manufactured by COMPANY or by a third party manufacturer, whether appointed by ELAN or COMPANY in accordance with this paragraph.
4. No later than sixty (60) days after the date of filing of the NDA, COMPANY will provide ELAN with a forecast of COMPANY's requirements for the PRODUCT for the twelve (12) month period following NDA APPROVAL. The said forecast will be updated quarterly until NDA APPROVAL of the PRODUCT. Except as otherwise provided herein, all forecasts made hereunder shall be made to assist ELAN in planning its production and COMPANY in planning marketing and sales. Such forecasts shall not be binding purchase orders, and shall be without prejudice to COMPANY's subsequent firm orders for the PRODUCT in accordance with the terms of this Agreement.
5. The parties acknowledge that it is in their mutual interest that launch of the PRODUCT shall be effected in the United States of America and in the remainder of the TERRITORY on a country by country basis as soon as possible following



NDA APPROVAL, for which purpose the parties shall in advance of the NDA APPROVAL discuss and agree upon the manufacture and purchase of specific quantities of launch stocks of the PRODUCT for commercial sale and promotional sampling (“Launch Stocks”). For the avoidance of doubt, the parties hereby confirm that ELAN’s manufacturing obligations shall only arise on receipt of firm purchase orders. ELAN shall deliver the PRODUCT to COMPANY within [ \* ] days of the receipt of a firm purchase order. During the period in which ELAN is manufacturing Launch Stocks, the foregoing period of [ \* ] days shall be increased to [ \* ] days. In any event and notwithstanding any firm purchase orders for such Launch Stocks which COMPANY has already placed with ELAN, COMPANY will notify ELAN within five (5) working days of its receipt from the FDA of an approvable letter, or a pre-approval letter, for the NDA from the FDA. COMPANY will within fifteen (15) days of such notification place a firm purchase order with ELAN for Launch Stocks, unless such a purchase order has already been submitted to ELAN prior to that date. COMPANY will use its reasonable efforts to provide forecasts for deliveries for the balance of the year in which the NDA is approved which it requires in addition to the Launch Stocks.

6. Within fifteen (15) days of NDA APPROVAL and at the beginning of each calendar month thereafter, COMPANY will provide a rolling month by month forecast for the [ \* ] month period beginning on the first day of the calendar month following the calendar month in which the forecast is made and the [ \* ] of such forecast shall be a binding purchase commitment of COMPANY.
7. Subject to the agreement of ELAN, the forecasts (other than for Launch Stocks ) shall not vary from [ \* ] by more than [ \* ] per cent ([ \* ]%) in terms of volume of PRODUCT ordered. Notwithstanding the foregoing provision, ELAN will use its reasonable efforts to fulfil COMPANY’s requirements in excess of forecasted amounts, but shall not be obliged to meet such requirements if it is not reasonably practicable to do so provided that ELAN shall supply the PRODUCT so ordered but not immediately available as soon thereafter as reasonably practicable.
8. The parties shall agree upon a minimum batch and order size for the manufacture and supply of the PRODUCT.
9. ELAN [ \* ].
10. All quantities of the PRODUCT delivered by ELAN hereunder shall conform to the PRODUCT SPECIFICATIONS and all prevailing legislative and regulatory requirements of the TERRITORY and the country where the PRODUCT is manufactured. ELAN shall furnish the appropriate certificate of analysis with each delivery of PRODUCT. Furthermore, ELAN shall manufacture and supply the PRODUCT and shall provide supporting and accompanying documentation and information in compliance with the QUALITY PROCEDURES.

11. All claims for failure of any shipment of the PRODUCT to conform to PRODUCT SPECIFICATIONS must be made by COMPANY to ELAN in writing within [ \* ] following delivery. Failure to make timely claims in the manner prescribed shall constitute acceptance of the shipment except in the case of latent defects. Claims for latent defects, not discovered during the routine testing protocol to be agreed upon by COMPANY and ELAN, shall be made by COMPANY to ELAN in writing within [ \* ] days of discovery. PRODUCT which has been delivered and which has been shown within the designated period not to conform to PRODUCT SPECIFICATIONS shall be replaced at ELAN's cost within [ \* ] days of the receipt by ELAN of the failed PRODUCT except where such non-conformance is as the result of the supply of defective COMPOUND by COMPANY to ELAN. COMPANY shall bear sole responsibility for all costs associated with the supply of defective COMPOUND to ELAN.
12. In the event of an unresolved dispute as to conformity of PRODUCT supplied with PRODUCT SPECIFICATIONS, the parties shall nominate an independent first class laboratory to undertake the relevant testing. Its findings shall be conclusive and binding upon the parties. All costs relating to this process shall be borne exclusively by the unsuccessful party. Should the parties fail to agree upon a mutually acceptable independent laboratory then the [ \* ] shall be entrusted with appointing such an independent laboratory.
13. Save as otherwise agreed between the parties, delivery of consignments of PRODUCT shall be effected by ELAN EX WORKS the manufacturing facility designated by ELAN and all risks therein shall pass to COMPANY when each such consignment of the PRODUCT is loaded onto the vehicle of COMPANY's agent on which it is to be dispatched from ELAN's designated facility. COMPANY shall fully insure or procure the insurance of all consignments of the PRODUCT when risk passes as aforesaid and shall produce such insurance documentation supporting same as and when requested by ELAN.
14. In the event that (i) ELAN fails to supply PRODUCT which has been ordered by COMPANY for a period exceeding [ \* ] days from the receipt of a firm purchase order or (ii) there are delays in filling [ \* ] successive orders which delays cumulatively exceed [ \* ] days when each delay is measured beginning on the [ \* ] day from receipt of the corresponding firm purchase order or (iii) there is a shortfall [ \* ] successive orders delivered by ELAN which on a cumulative basis, exceeds [ \* ] of the total amount of said [ \* ] orders; and unless such failure, delay or shortfall is caused by the COMPANY [ \* ], then ELAN shall, upon written notice from COMPANY remedy the failure, delay or shortfall within a further period of [ \* ] days from said notice and in the event of ELAN's failure to do so, ELAN shall immediately, upon written request from COMPANY, for so long as such conditions exist:

- 14.1. grant to COMPANY a production licence in the TERRITORY so that COMPANY may manufacture the relevant PRODUCT without infringing any of ELAN's patent and/or any other industrial property rights (including the ELAN PATENT RIGHTS and ELAN KNOW-HOW). Any such licence shall apply only in regard to the relevant PRODUCT as well as to the applications of technology derived from the ELAN PATENT RIGHTS related to its use with such PRODUCT. In the event that COMPANY is unable or unwilling to itself undertake manufacture of the PRODUCT under any of the circumstances envisaged here, and ELAN is itself unable to offer a third party sub-contractor to manufacture and supply PRODUCT to COMPANY, then COMPANY may assign this production license to a third party sub-contractor which it may nominate, but whose final selection will be subject to ELAN's prior written agreement, which agreement will not be unreasonably withheld or delayed. For the avoidance of doubt, the provisions of Article V paragraph 3.5 shall apply to the sale of PRODUCT manufactured by COMPANY or its sub-contractor appointed in accordance with this paragraph.
- 14.2. unless already provided under Article IV paragraph 19, provide COMPANY with any technical data necessary for the carrying of this into effect. To this end, ELAN shall impart to COMPANY the documentation constituting the required material support, more particularly practical performance advice, shop practice, specifications as to materials to be used and control methods.
- 14.3. unless already carried out under Article IV paragraph 19., assist COMPANY for the working up and use of the technology necessary to manufacture the relevant PRODUCT as well as for the training of COMPANY's personnel. For this purpose, ELAN shall receive COMPANY's scientific staff in its premises for periods the term of which shall be decided by common consent.
15. In the event of such a transfer of manufacture the parties shall, if appropriate, agree on a reasonable period of time within which said transfer is to be made and ELAN shall continue to supply COMPANY with the PRODUCT until such transfer is fully effected so that COMPANY's supply of the PRODUCT shall be continuous and uninterrupted until COMPANY receives all necessary regulatory approvals.
16. When ELAN has remedied the situation that prevented ELAN from satisfying COMPANY's requirements and is once again able to fulfil its obligations to

supply the PRODUCT as provided for in this Agreement, COMPANY shall cease manufacturing the PRODUCT and shall resume purchasing the PRODUCT from ELAN pursuant to the terms of this Agreement; provided that COMPANY shall be entitled to manufacture the PRODUCT for the period necessary so as to enable COMPANY to recoup those fixed and unrecoverable commercial costs expended by COMPANY in establishing its manufacturing capability for the PRODUCT prior to commercial production of the PRODUCT. If ELAN wishes COMPANY to cease manufacturing the PRODUCT prior to the expiration of this period but in no event within [ \* ] months from the grant of the production licence to COMPANY, ELAN shall be entitled to re-commence manufacturing the PRODUCT and reimburse COMPANY in respect of such costs by means of a cash payment or a deduction from royalty payments, or by means of a combination of the foregoing (not to exceed [ \* ] percent ([ \* ]%) of royalty payments payable by COMPANY to ELAN) or otherwise howsoever at the discretion of ELAN provided that:

- 16.1. prior to discharge of any such costs by ELAN by whatever means, COMPANY shall provide ELAN with a detailed breakdown of such costs, together with a detailed explanation of the bases upon which the breakdown has been calculated and
  - 16.2. to the extent that such costs include the cost of fixed capital items which can be transferred to ELAN, and provided that COMPANY agrees to sell the assets, ELAN shall have an option to take delivery of such fixed capital item(s), the costs of such delivery to be for the account of ELAN.
17. For so long as ELAN or its appointed sub-contractor is manufacturing the PRODUCT, ELAN, its AFFILIATES or subcontractors shall be responsible for all process and equipment validation required by the FDA and other relevant regulatory agency and the regulations thereunder and shall take all steps reasonably necessary to pass government inspection by the FDA or other regulatory agency. In the event that COMPANY or its appointed sub-contractor commences manufacture of the PRODUCT in accordance with the terms of this Agreement, COMPANY shall be responsible for all process and equipment validation required by the FDA and other relevant regulatory agency and the regulations thereunder and shall take all steps reasonably necessary to pass government inspection by the FDA or other regulatory agency. ELAN shall have no liability to COMPANY for any PRODUCT which is manufactured by COMPANY or any sub-contractor appointed by COMPANY.
18. At any time during the term of this Agreement, ELAN shall be entitled to notify COMPANY of [ \* ]. In such an event, ELAN shall grant COMPANY a production licence in accordance with Article IV paragraphs 14 and 15, which license shall be assignable in the manner provided for in Article IV, paragraph 14.1. In such an event the parties confirm that the provisions of [ \* ] shall apply to the sale of PRODUCT manufactured by COMPANY or its permitted sub-contractor.

19. Upon acceptance of the filing of the NDA by the FDA in the United States of America, COMPANY may, at its option, request ELAN to assist it in the working up and use of the technology necessary to manufacture the PRODUCT so as to qualify COMPANY as a second supporting site of manufacture. [ \* ] involved in the set-up and qualification of manufacture at its designated site in the United States of America, [ \* ]. [ \* ]. For the avoidance of doubt, the qualification of COMPANY as a second supporting site of manufacture as envisaged herein shall not constitute or be interpreted as the granting to COMPANY of a production license.
20. In the event that COMPANY is at any stage the manufacturer of the PRODUCT in accordance with Article IV, paragraphs 3, 14 or 18 or Article XII, paragraph 5.1, then COMPANY shall supply PRODUCT to ELAN for sale in any country of the TERRITORY which ceases to be a part of the TERRITORY in accordance with Article II, paragraph 11 or where ELAN has a non-exclusive licence in accordance with [ \* ]. Subject to the following sentence, the terms of this Agreement shall apply mutatis mutandis to the manufacture and supply of PRODUCT by COMPANY to ELAN. The price of the PRODUCT for commercial sale and free-of-charge promotional samples to be charged to ELAN shall be negotiated by the parties at terms substantially similar to Article V, paragraph 5 of the Agreement and ELAN shall pay COMPANY a royalty equal to [ \* ].

#### **Supply of the COMPOUND**

21. COMPANY shall supply to ELAN such quantities of COMPOUND [ \* ] as ELAN requires for the manufacture and supply of PRODUCT to COMPANY for commercial sale or promotional samples. COMPANY shall be responsible for ensuring that ELAN receives delivery of COMPOUND in such quantities and at such times so as to ensure that ELAN has sufficient stocks of the COMPOUND to meet COMPANY's firm purchase orders and supply the PRODUCT to COMPANY. COMPANY shall furnish the appropriate certificate of analysis with each delivery of COMPOUND. The parties agree that adequate quantities of COMPOUND shall be delivered by COMPANY to ELAN in accordance with orders submitted by ELAN and at least [ \* ] days in advance of the date on which the delivery of PRODUCT is scheduled to be made to COMPANY. During the period in which ELAN is manufacturing Launch Stocks, the foregoing period of [ \* ] days shall be increased to [ \* ] days. For the avoidance of doubt, COMPANY shall not be obligated to supply COMPOUND [ \* ] to ELAN for the manufacture of PRODUCT which shall not be sold by COMPANY, its AFFILIATES or permitted sub-licensees, in the TERRITORY. Where ELAN, its AFFILIATES or

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

permitted sub-licensees are selling PRODUCT in the TERRITORY in consideration for the payment of a royalty to COMPANY in accordance Article V, paragraph 3.7. of the Agreement, then COMPANY shall supply COMPOUND to ELAN at a price to be negotiated in good faith. The terms of this paragraph regarding appropriate certificates of analysis and a [ \* ] day delivery period shall also apply to the delivery of such COMPOUND to ELAN.

22. Prior to the end of STAGE III the parties shall negotiate in good faith to conclude a technical agreement regulating the parties' respective obligations from a technical and quality perspective for the supply of the COMPOUND by COMPANY to ELAN and the supply of PRODUCT by ELAN to COMPANY. In no event shall the terms of said technical agreements overrule the terms of this Agreement.
23. All quantities of the COMPOUND delivered by COMPANY hereunder shall conform to the COMPOUND SPECIFICATIONS and all prevailing legislative and regulatory requirements of the country where the COMPOUND is manufactured.
24. Save as otherwise agreed between the parties, delivery of consignments of COMPOUND shall be effected by COMPANY, FCA the manufacturing facility designated by ELAN, and all risks therein shall pass to ELAN when each such consignment of the COMPOUND is delivered to ELAN's designated facility. ELAN shall fully insure or procure the insurance of all consignments of the COMPOUND when risk passes as aforesaid and shall produce such insurance documentation supporting same as and when requested by COMPANY. For purposes of inventory control and/or reconciliation, ELAN will provide an accurate account of inventory levels of COMPOUND to COMPANY on a monthly basis, at the end of each calendar month.
25. Title to the COMPOUND supplied to ELAN by COMPANY shall at all times remain in COMPANY. ELAN shall clearly mark such COMPOUND as the property of COMPANY and keep such COMPOUND separate and apart from other raw materials. ELAN shall not at any time sell or offer for sale, assign, mortgage, pledge, or allow any lien to be created upon the COMPOUND provided by COMPANY, or any portion thereof. At the termination of this Agreement, ELAN shall surrender to COMPANY all useable COMPOUND in ELAN's possession. In the alternative and at the option of ELAN, ELAN may purchase such useable COMPOUND at the cost incurred by COMPANY for the manufacture and delivery of such COMPOUND.
26. All claims for failure of any shipment of the COMPOUND to conform to the COMPOUND SPECIFICATIONS must be made by ELAN to COMPANY in writing within [ \* ] following delivery except in the case of latent defects. Claims

for latent defects, not discovered during the routine testing protocol to be agreed upon by COMPANY and ELAN, shall be made by ELAN to COMPANY in writing within [ \* ] days of discovery. Failure to make timely claims in the manner prescribed shall constitute acceptance of the shipment. COMPOUND which has been delivered and which has been shown within the designated period not to conform to COMPOUND SPECIFICATIONS shall be replaced at COMPANY's cost within [ \* ] days of the receipt by COMPANY of the failed COMPOUND.

27. In the event that the COMPOUND supplied by COMPANY is not in compliance with the COMPOUND SPECIFICATIONS, or is otherwise adulterated, misbranded or defective, ELAN shall immediately notify COMPANY and shall follow all reasonable instructions of COMPANY regarding, and be responsible, at the [ \* ], for re-analysis, sampling, processing, return, disposal or destruction, including certification of destruction, of such non-conforming bulk COMPOUND. In addition, [ \* ] shall be responsible for all costs borne by ELAN in the processing of the COMPOUND.
28. In the event of an unresolved dispute as to conformity of the COMPOUND with the COMPOUND SPECIFICATIONS, the parties shall nominate an independent first class laboratory to undertake the relevant testing. Its findings shall be conclusive and binding upon the parties. All costs relating to this process shall be borne exclusively by the unsuccessful party. Should the parties fail to agree upon a mutually acceptable independent laboratory then the [ \* ] shall be entrusted with appointing such an independent laboratory.

#### **ARTICLE V : FINANCIAL PROVISIONS**

##### **1. Development Royalties**

- 1.1. In consideration for the development of the PRODUCT by ELAN under this Agreement, as further described in the PROJECT plan in Appendix B hereto, but specifically excluding the [ \* ] envisaged therein, COMPANY shall pay to ELAN amounts as are set out below :
  - 1.1.1. \$[ \* ] on commencement of STAGE I;
  - 1.1.2. \$[ \* ] on commencement of STAGE II;
  - 1.1.3. \$[ \* ] on commencement of STAGE III; and
  - 1.1.4. \$[ \* ] on commencement of STAGE IV.

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

- 1.2. The programme of [ \* ] which the parties envisage will be necessary for the development and registration of the PRODUCT is also described in the PROJECT plan in Appendix B, along with projected study designs and budgeted costs and schedules, which costs include bioanalysis, statistical analysis and report generation. However, the final design and corresponding cost for each [ \* ] to be carried out by ELAN in the PROJECT shall be agreed with COMPANY in advance of carrying out the study [ \* ] (to a standard agreed in advance of the commencement of the study by the PROJECT TEAM) for said study.
- 1.3. Additional development royalty payments agreed to in advance by the parties in writing shall be payable if COMPANY requires ELAN to carry out work or tasks relating to the development and registration of the PRODUCT which are not included in the PROJECT, including but not limited to, [ \* ]. ELAN's charges for such work shall be as set out in Article V, paragraph 4 of the Agreement.

## 2. **Licence Royalties**

- 2.1. In consideration of the licence of the ELAN PATENT RIGHTS granted to COMPANY by virtue of this Agreement, COMPANY shall pay to ELAN the following amounts **SUBJECT ALWAYS** to the provisions of Article III, paragraph 7 (which outlines the effect of any delays by COMPANY, or delays of government agencies which are not attributable to acts or omissions of ELAN, which materially affect ELAN's ability to achieve the tasks within the time periods set out in paragraphs 2.1.2. and 2.1.3.):
  - 2.1.1. \$[ \* ] upon the execution of this Agreement;
  - 2.1.2. \$[ \* ] due upon the [ \* ] day inclusive following the designated start date being the receipt by ELAN of the written confirmation by COMPANY to ELAN as to COMPANY's agreement to [ \* ].

In the event that [ \* ], then the licence royalty to be paid to ELAN under this paragraph 2.1.2. shall [ \* ]. Thus for example, if [ \* ].

However, in the event that such [ \* ] day, then the \$[ \* ] license royalty payable here shall [ \* ]. Thus, for example, if [ \* ]. COMPANY's obligation to pay a license fee to ELAN under this 2.1.2. shall expire on the [ \* ] day of the specified period if no such [ \* ] as envisaged here is effected by that date.
  - 2.1.3. \$[ \* ] due upon [ \* ] day inclusive following the designated start date, being the date of [ \* ].



In the event that [ \* ] as envisaged herein in this 2.1.3. prior to the specified [ \* ] day, then the royalty to be paid to ELAN under this paragraph 2.1.2. shall [ \* ]. Thus for example, if [ \* ].

However, in the event that such [ \* ] day, then the \$[ \* ] license royalty payable here shall [ \* ]. Thus, for example, if [ \* ]. COMPANY's obligation to pay a license fee to ELAN under this 2.1.3. shall expire on the [ \* ] day of the specified period if no such [ \* ] as envisaged here is effected by that date.

2.1.4. \$[ \* ] upon either the [ \* ] or the [ \* ];

2.1.5. \$[ \* ] due upon [ \* ]; and

2.1.6. \$[ \* ] due upon [ \* ].

- 2.2. COMPANY shall be entitled to recover [ \* ] percent ([ \* ]%) of the licence royalties payable in accordance with paragraphs [ \* ] against the royalty payable by COMPANY to ELAN in accordance with either [ \* ], whichever is applicable, following the [ \* ]. COMPANY shall be entitled to withhold [ \* ] percent ([ \* ]%) of the royalty calculated as payable on NSP to ELAN in each quarter following first launch of PRODUCT until such time as total royalty withholdings reach said [ \* ] percent ([ \* ]%) of such licence royalties, at which point this recovery provision shall cease.

### **3. Royalty on Sales**

- 3.1. Subject to paragraph 3.6 below, in consideration of the license of the ELAN PATENT RIGHTS to COMPANY, the royalty payable by COMPANY to ELAN on NSP of the PRODUCT by COMPANY, its AFFILIATES or its permitted sub-licensees shall be:

(i) [ \* ] percent ([ \* ]%) on the first \$[ \* ] sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(ii) [ \* ] percent ([ \* ]%) on sales of PRODUCT, calculated as NSP value, in excess of \$[ \* ] in any one calendar year.

The parties agree that for the purposes of the interpretation of this paragraph 3.1, the parties' intention as regards the operation of this paragraph 3.1 should be clearly stated in this Agreement and the parties further agree that this will best be achieved by way of a hypothetical example set out below.

**EXAMPLE:** If in any one year period following the first launch of the PRODUCT, the annual NSP were \$[ \* ], the royalty payable to ELAN shall be calculated as follows:

[ \* ]

- 3.2. Within thirty days of the end of each quarter, COMPANY shall notify ELAN of the NSP of PRODUCT for that preceding quarter. Payments shown by each calendar quarter report to have accrued but which have not yet been paid shall be due on the date such report is due.
- 3.3. Payment of royalties shall be made quarterly within thirty (30) days after the expiry of the quarter.
- 3.4. All payments due hereunder shall be made in U.S. Dollars (\$).
- 3.5. In the event that COMPANY or any AFFILIATE or a permitted sub-licensee shall sell the PRODUCT together with other products of COMPANY to third parties in any country of the TERRITORY by the tying of a discount on the gross selling price of the PRODUCT to a volume commitment of another product to the same customer in such country, and the price attributable to the PRODUCT is less than [ \* ] percent ([ \* ]%) of the average price of "arms length" sales for the reporting period in which sales occur in such country (such sales to be excluded from the calculation of the average price of "arms length" sales), the NSP for any such sales shall be [ \* ] during the reporting period in which such sales occur in such country of the TERRITORY.
- 3.6. In the event that a production licence is granted to COMPANY in accordance with Article IV, paragraph 14 or ELAN exercises its option to cease manufacturing the PRODUCT in accordance with Article IV, paragraph 18, then in consideration of the license of the ELAN PATENT RIGHTS to COMPANY, the royalty payable by COMPANY to ELAN in accordance with paragraph 3.1. above, on PRODUCT manufactured by COMPANY or its permitted sub-contractor on sales of the PRODUCT by COMPANY, its AFFILIATES or its permitted sub-licensees shall be reduced to:
  - (i) [ \* ] percent ([ \* ]%) on the first \$[ \* ] sales of PRODUCT, calculated as NSP value, in any one calendar year; and
  - (ii) [ \* ] percent ([ \* ]%) on sales of PRODUCT, calculated as NSP value, in excess of \$[ \* ] in any one calendar year.

Any royalty payable by COMPANY to ELAN under this paragraph shall replace the royalty payable by COMPANY in accordance with paragraph 3.1 above on sales of PRODUCT manufactured by COMPANY or its permitted sub-contractor. Any such royalty shall be calculated and paid mutatis mutandis as the terms of this Agreement.

- 3.7. In consideration of the licence to the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in accordance with Article II, paragraph 11, ELAN shall pay a royalty by COMPANY on NSP of the PRODUCT on sales by ELAN, its AFFILIATES or its permitted sub-licensees as follows :
- (i) [ \* ] percent ([ \* ]%) on the first \$[ \* ] sales of PRODUCT, calculated as NSP value, in any one calendar year; and
  - (ii) [ \* ] percent ([ \* ]%) on sales of PRODUCT, calculated as NSP value, in excess of \$[ \* ] in any one calendar year.
- Any such royalty payable by ELAN to COMPANY shall be calculated and paid mutatis mutandis as the terms of this Agreement.
4. **Additional Expenses**
- 4.1. COMPANY shall reimburse ELAN for cost of any [ \* ] or any other type of work requested by COMPANY which is not included in the PROJECT at the following charges:
- 4.1.1. any such work which is necessary in order to obtain NDA APPROVAL in [ \* ] shall be charged at [ \* ];
  - 4.1.2. any such work which is necessary in order to [ \* ]; and
  - 4.1.3. all other such work, [ \* ], shall be charged at terms to be negotiated in good faith by ELAN and COMPANY.
5. **Price of PRODUCT**
- 5.1. The price of the PRODUCT to be charged to COMPANY shall be [ \* ] percent ([ \* ]%) of MANUFACTURING COST which price shall apply to bulk capsules or tablets (as determined during the PROJECT) of PRODUCT supplied EX WORKS ELAN's manufacturing facility to COMPANY. For the avoidance of doubt, the price of the PRODUCT shall not include the cost of any COMPOUND used in the manufacture of the PRODUCT provided that such COMPOUND was supplied [ \* ] by COMPANY to ELAN.
- 5.2. The price of the PRODUCT to be charged to COMPANY for supplies for

distribution as free-of-charge promotional samples in its marketing of the PRODUCT shall be [ \* ] percent ([ \* ]%) of MANUFACTURING COST which price shall apply to bulk capsules or tablets (as determined during the PROJECT) of PRODUCT supplied EX WORKS ELAN's manufacturing facility to COMPANY. COMPANY shall inform ELAN when placing an order for PRODUCT that the PRODUCT is for distribution as free-of-charge promotional samples in its marketing of the PRODUCT.

- 5.3. The price of the PRODUCT shall be reviewed on an annual basis and shall be fixed for the following twelve (12) month period. Notwithstanding the foregoing, at the end of each such twelve (12) month period, ELAN shall retrospectively determine the exact amount of MANUFACTURING COST for the preceding twelve (12) month period. In the event that the sums payable to ELAN pursuant to paragraph 5.1. and 5.2. above are less than [ \* ] percent ([ \* ]%) and [ \* ] percent ([ \* ]%) of MANUFACTURING COST respectively, COMPANY shall pay the difference to ELAN.
- 5.4. Payment for all PRODUCT supplied to COMPANY shall be effected in U.S. Dollars (\$) within thirty (30) days of the date of the relevant invoice.

6. **Performance by COMPANY**

- 6.1. Within [ \* ] of the filing of the NDA the COMPANY will determine the preliminary structure of the promotional activities to be carried out by COMPANY for the period up to launch of the PRODUCT in the United States of America and for a period of one year after launch of the PRODUCT in that market. COMPANY shall both prior to and subsequent to the launch of the PRODUCT communicate with ELAN regarding its objectives for and performance of the PRODUCT in the TERRITORY.
- 6.2. COMPANY shall effect the first full scale commercial launch of the PRODUCT in the United States of America within [ \* ] of NDA APPROVAL, provided that COMPANY shall have received the agreed quantities of Launch Stocks at least [ \* ] in advance of the launch date (provided that such Launch Stocks have been ordered pursuant to firm purchase orders placed in accordance with the terms of this Agreement). It is agreed that with respect to each of the other countries of the TERRITORY, COMPANY will effect a national commercial launch of the PRODUCT within [ \* ] after the necessary regulatory approvals and provided that COMPANY shall also have received the agreed quantities of Launch Stocks for each country of the TERRITORY at least [ \* ] in advance of the launch date (provided that such Launch Stocks have been ordered by COMPANY pursuant to firm purchase orders placed in accordance with the terms of this Agreement). In the event that COMPANY does not make a national commercial launch within

the [ \* ] period, or such longer period as may be agreed between the parties, the licences granted to COMPANY hereunder for such country or countries of the TERRITORY shall become non-exclusive and ELAN shall have the right to commercialise the PRODUCT in such country or countries.

- 6.3. Should COMPANY fail to effect a national commercial launch of the PRODUCT in the said non-exclusive country or countries within a further [ \* ] of the license becoming non-exclusive], then ELAN may, at its option, terminate the non-exclusive licenses granted to COMPANY for such country or countries. In such events none of the monies paid by COMPANY to ELAN shall be repayable.
- 6.4. COMPANY shall control the format of the promotional campaign to be submitted to the FDA. COMPANY shall use reasonable efforts to obtain approval by the FDA of the promotional campaign for the PRODUCT.
- 6.5. The parties intend that the PRODUCT will be marketed and promoted by the COMPANY as the flagship brand under COMPANY's prevailing trademark(s) for the COMPOUND in the United States of America. Wherever regulatory and commercially feasible, the parties also intend that the PRODUCT will be marketed and promoted as the flagship brand by the COMPANY, its AFFILIATES and permitted sub-licensees, under COMPANY's prevailing trademark(s) for the COMPOUND in all other countries of the TERRITORY. However, COMPANY may continue to sell the existing formulation(s) of the COMPOUND, including the formulation marketed and promoted in the United States of America as Luvox<sup>®</sup>, in each country of the TERRITORY following the launch of the PRODUCT PROVIDED ALWAYS that any such sale of such products by COMPANY shall at all times be subject to the parties' agreement hereunder that the PRODUCT will be the flagship brand and in addition to the parties' intention to maximise the sales potential of the PRODUCT.
- 6.6. Subject to paragraph 6.5. above, COMPANY shall use reasonable efforts consistent with its normal business practices to market and promote the PRODUCT throughout the TERRITORY. In doing so COMPANY will use the same level of effort as with its other similar products of similar sales potential.

#### **ARTICLE VI: REGISTRATION OF THE PRODUCT**

1. In respect of the PRODUCT, COMPANY shall be responsible for the filing of the NDA with the FDA and all other relevant regulatory agencies in the TERRITORY and shall consult with ELAN in this regard. COMPANY shall use its commercially reasonable efforts to obtain and maintain NDA APPROVAL for the PRODUCT in each country of the TERRITORY.

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2. COMPANY shall notify ELAN of the date of submission of any NDA for the PRODUCT in the TERRITORY and shall also notify ELAN of the NDA APPROVAL of any registration application as soon as is reasonably possible following said approval. COMPANY shall allow ELAN access to the NDA for the United States of America and other registration applications as may be required. COMPANY shall also furnish ELAN with a copy of any further regulatory filings and submissions and its correspondence with the FDA relevant to the PRODUCT.
3. Each party shall notify the other as soon as possible of any notification received by that party from the FDA, or any other regulatory authority to conduct an inspection of its manufacturing or other facilities used in the manufacturing, packaging, storage or handling of the PRODUCT. Copies of all correspondence relevant to the PRODUCT with the regulatory authority will be provided to the other party.
4. COMPANY and ELAN shall discuss on an ongoing basis the regulatory status of the PRODUCT in the TERRITORY whether at meetings of the PROJECT TEAM or otherwise.
5. COMPANY shall be responsible for obtaining all FDA, and other approvals necessary for COMPANY to package the PRODUCT into final marketing packaging and for obtaining all applicable state and local regulatory approvals for the distribution of the PRODUCT in the TERRITORY. ELAN shall co-operate with COMPANY in obtaining such approvals.
6. ELAN shall provide to COMPANY scientific data from the works performed during its development of the PRODUCT which comprises the CMC SECTION and the biopharmaceutics package corresponding to the data as specified in Appendix B. COMPANY shall undertake to protect the confidentiality of ELAN's formulation, engineering and manufacturing processes for the PRODUCT in its dealings with permitted sub-licensees or approved sub-contractor and shall where possible refrain from transmitting such information within the CMC SECTION to permitted sub-licensees.
7. Save as otherwise outlined in this Agreement, the costs and expenses of any filings and proceedings made by ELAN at the request of COMPANY to the FDA, or any other governmental authority in respect of the PRODUCT hereunder shall be paid by [ \* ].
8. COMPANY shall indemnify and hold harmless ELAN, its agents and employees from and against all claims, damages, losses, liabilities and expenses to which ELAN, its agents, and employees may become subject related to or arising out of COMPANY's bad faith, negligence or intentional misconduct in connection with the filing or maintenance of the NDA in the TERRITORY.

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9. It is hereby acknowledged that there are inherent uncertainties involved in the research, development and registration of pharmaceutical products with the FDA and other regulatory agencies insofar as obtaining approval is concerned and such uncertainties form part of the business risk involved in undertaking the form of commercial collaboration as set forth in this Agreement. Therefore, save for using their reasonable efforts, ELAN and COMPANY shall have no liability to the other solely as a result of any failure of the PRODUCT to successfully achieve approval of the FDA or any other regulatory body in the TERRITORY.
10. Notwithstanding the foregoing provisions of Article VI, COMPANY may call upon ELAN to carry out all or part of the work necessary to obtain regulatory approval in the TERRITORY. [ \* ].
11. COMPANY may conduct any pharmacokinetic, clinical, non-clinical safety studies, pharmacoeconomic, or any other market analysis, study or test on the PRODUCT without first informing ELAN. In the event that COMPANY does conduct such analysis, study or test, COMPANY shall own said data and information which shall thereafter form part of the COMPANY KNOW-HOW. COMPANY shall provide ELAN with a copy of any such analysis, study or test performed by COMPANY.
12. Subject to Article II, paragraph 11, ELAN shall be entitled to file for NDA APPROVAL for the PRODUCT in any country which ceases to be a part of the TERRITORY, or in the TERRITORY in the event of termination of this Agreement or in any country where COMPANY has a non-exclusive licence in accordance with Article V paragraph 6.2. Where a royalty is payable by ELAN to COMPANY in accordance with Article V. paragraph 3.7 of the Agreement, COMPANY shall permit ELAN or ELAN's designee without charge to conduct sufficient cross-referencing to, any and all pending NDAs or NDA APPROVALS for the PRODUCT for the relevant country or countries of the TERRITORY.

**ARTICLE VII: WARRANTY AND INDEMNITY.**

1. ELAN represents and warrants that it has the sole, exclusive and unencumbered right to grant the licences and rights herein granted to COMPANY, and that it has not granted any option, licence, right or interest in or to the ELAN PATENT RIGHTS or ELAN KNOW-HOW to any third party which would conflict with the rights granted by this Agreement. ELAN agrees to hold COMPANY harmless from any and all costs, expenses and damages (including reasonable attorneys' fees) incurred or sustained by COMPANY as the result of any third party's challenges to ELAN's right to grant the rights and licences herein granted to COMPANY.
2. ELAN represents and warrants that the execution of this Agreement and the full

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performance and enjoyment of the rights of COMPANY under this Agreement will not breach or in any way be inconsistent with the terms and conditions of any licence, contract, understanding or agreement, whether express, implied, written or oral between ELAN and any third party.

3. ELAN represents and warrants that, once successfully developed, the PRODUCT supplied to COMPANY by ELAN under this Agreement shall conform to the PRODUCT SPECIFICATIONS and in accordance with all regulations and requirements of the FDA and other relevant regulatory agencies including the then cGMP regulations which apply to the manufacture and supply of the PRODUCT. Except as expressly stated in this Article VI, all other warranties, conditions and representations, express or implied, statutory or otherwise, including a warranty as to the quality or fitness for any particular purpose of the PRODUCT are hereby excluded and ELAN shall not be liable in contract, tort or otherwise for any loss, damage, expense or injury of any kind whatsoever, consequential or otherwise, arising out of or in connection with the PRODUCT or any defect in the PRODUCT or from any other cause.
4. ELAN is or will become fully cognisant of all applicable statutes, ordinances and regulations of the TERRITORY with respect to the manufacture of the PRODUCT including, but not limited to, the U.S. Federal Food, Drug and Cosmetic Act and regulations thereunder, cGLP and cGMP. ELAN shall manufacture or procure the manufacture of the PRODUCT in conformity with the PRODUCT SPECIFICATIONS and the relevant NDA or Drug Master File in the countries where such activities takes place or have effect and in a manner which fully complies with such statutes, ordinances, regulations and practices.
5. COMPANY is or will become fully cognisant of all applicable statutes, ordinances and regulations of the TERRITORY with respect to the promotion, marketing and sale of the PRODUCT and COMPANY shall comply with all such statutes, ordinances and regulations of the countries where such activities take place or have effect.
6. ELAN certifies to the best of its knowledge that as of the date of this Agreement neither ELAN or any person employed by ELAN has been debarred under Section 306 (a) or 306 (b) of the Federal Food, Drug and Cosmetic Act and that no debarred person will in the future be employed by ELAN to perform any services in connection with any application for approval of the PRODUCT by the FDA. ELAN certifies to the best of its knowledge that neither ELAN nor any person employed by ELAN has a conviction on their record for which a person can be debarred as described in Section 306 (a) or 306 (b) of the Federal Food, Drug and Cosmetic Act. ELAN further certifies that should ELAN or any person employed by ELAN be convicted in the future, of any act for which a person can be debarred as described in Section 306 (a) or 306 (b) of the Federal Food Drug and Cosmetic Act, ELAN shall immediately notify COMPANY of such conviction.



7. ELAN shall assume the sole and entire responsibility and shall indemnify and save harmless COMPANY from any and all claims, liabilities, expenses, including reasonable attorney's fees, responsibilities and damages by reason of any claim, proceedings, action, liability or injury arising out of any faults of the PRODUCT resulting from the preparation, manufacture, packaging, storage, or handling of the PRODUCT by ELAN, (including the distribution, marketing or sale of the PRODUCT if ELAN or any sub-licensee appointed by ELAN is marketing the PRODUCT) to the extent that it was caused by the negligence or wrongful acts or omissions on the part of ELAN or any sub-contractor appointed by ELAN.
8. COMPANY shall assume the sole and entire responsibility and shall indemnify and save harmless ELAN from any and all claims, liabilities, expenses, including reasonable attorney's fees, responsibilities and damages by reason of any claim, proceedings, action, liability or injury arising out of any faults of the PRODUCT resulting from the transport, packaging, storage, handling, distribution, regulatory filing, marketing or sale of the PRODUCT by COMPANY (including the preparation or manufacture of the PRODUCT if COMPANY or any sub-contractor appointed by COMPANY is manufacturing the PRODUCT), to the extent that it was caused by the negligence or wrongful acts or omissions on the part of COMPANY or any sub-contractor appointed by COMPANY.
9. As a condition of obtaining an indemnity in the circumstances set out in this Agreement, the party seeking an indemnity shall:
  - 9.1. fully and promptly notify the other party of any claim or proceeding, or threatened claim or proceeding;
  - 9.2. permit the indemnifying party to take full care and control of such claim or proceeding;
  - 9.3. assist in the investigation and defence of such claim or proceeding;
  - 9.4. not compromise or otherwise settle any such claim or proceeding without the prior written consent of the other party, which consent shall not be unreasonably withheld; and
  - 9.5. take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceeding.
10. Notwithstanding anything to the contrary in this Agreement, ELAN and COMPANY shall not be liable to the other by reason of any representation or warranty, condition or other term or any duty of common law, or under the express

terms of this Agreement, for any consequential or incidental loss or damage (whether for loss of profit or otherwise) and whether occasioned by the negligence of the respective parties, their employees or agents or otherwise.

11. ELAN represents and warrants that Elan Corporation plc will provide Elan Pharma Limited, Elan Pharma Inc. or any other subsidiaries with a licence and the rights to manufacture the PRODUCT in accordance with the terms of this Agreement.

#### **ARTICLE VIII: CUSTOMER COMPLAINTS; PRODUCT RECALL**

1. COMPANY shall notify ELAN promptly of any complaints from third parties reported to COMPANY involving any serious adverse reactions resulting from the use of the PRODUCT. COMPANY and ELAN shall establish a procedure for formal adverse event handling and reporting. It is envisaged that COMPANY shall be responsible for furnishing spontaneous post marketing reports to the FDA and other relevant regulatory agencies and ELAN will be responsible for furnishing COMPANY with periodic reports which are required by the FDA concerning manufacturing and GMP compliance. COMPANY and ELAN shall keep each other informed and shall copy the other party with all communications with the FDA and other relevant regulatory agencies with respect to the PRODUCT.
2. In the event of any recall of the PRODUCT, as suggested or requested by any governmental authority, COMPANY shall perform the recall of the PRODUCT in the TERRITORY. If the recall arises from ELAN's acts or omissions in the manufacturing or delivery of the PRODUCT, all reasonable trade notifications of the recall of PRODUCT, COMPANY's manufacturing cost of COMPOUND contained in the recalled PRODUCT, the price of the recalled PRODUCT charged to COMPANY by ELAN, and all freight charges associated with the recall of the PRODUCT (collectively referred to as "Recall Costs") shall be borne by [ \* ] provided that [ \* ]. In all other events the Recall Costs shall be borne by [ \* ] in accordance with [ \* ]. No royalty shall be payable by COMPANY on any recalled PRODUCT, whether due to the default of ELAN or COMPANY. Neither party shall be liable to the other or to any third party for consequential or incidental damages which may arise as a result of the recall of the PRODUCT.

#### **ARTICLE IX: PROJECT TEAM**

1. It is recognised by the parties hereto that a significant resource shall be required from each party to accomplish a successful NDA APPROVAL and launch of the PRODUCT, particularly in the co-ordination of logistics, finalisation of various specifications, methodologies transfer, supply and packaging configurations,

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shipping and handling procedures etc., and for this purpose, the parties agree to the establishment of a PROJECT TEAM. The PROJECT TEAM shall meet from time to time as deemed necessary by the parties during the PROJECT, such meetings to continue until the time of launch or some such later time thereafter as may be agreed. The PROJECT TEAM shall review the clinical and regulatory strategy for the PRODUCT on an ongoing basis. Meetings shall be chaired by the chief representative of the COMPANY. At and between meetings of the PROJECT TEAM, each party shall keep the other fully and regularly informed as to its progress with its respective obligations.

2. The PROJECT TEAM shall also monitor the progress of the PROJECT against the time period set out in paragraphs 2.1.2. and 2.1.3. of Article V and shall report on delays in the conduct of the PROJECT which would materially affect ELAN's ability to achieve the tasks set out paragraphs 2.1.2. and 2.1.3. of Article V and recommend whether corrective action is required under the provisions of Article II, paragraph 7.
3. The PROJECT TEAM shall not be empowered to alter the terms of this Agreement.
4. Following the first launch of the PRODUCT, the parties shall meet on a semi-annual basis for the first, second and third year and on an annual basis thereafter. At such meetings, COMPANY shall report on the ongoing sales performance of the PRODUCT in the TERRITORY. ELAN shall report on matters such as manufacturing, quality and resource planning.

#### **ARTICLE X: PAYMENTS, REPORTS AND AUDITS**

1. COMPANY shall keep true and accurate records of gross sales of the PRODUCT by COMPANY, its AFFILIATES or permitted sub-licensees, the items deducted from the gross amount in calculating the NSP, the NSP and the royalties payable to ELAN under Article V hereof. COMPANY shall deliver to ELAN a written statement thereof within sixty (60) days following the end of each calendar quarter (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The said written statements shall set forth on a country-by-country basis, the calculation of the NSP from gross revenues during that calendar quarter, the applicable percentage rate, and a computation of the sums due to ELAN ("the Statement"). The parties' financial officers shall agree upon the precise format of the Statement.
2. Payments due on NSP of the PRODUCT based on sales amounts in a currency other than United States Dollars shall first be calculated in the foreign currency and then converted to United States Dollars on the basis of the exchange rate in

effect for the purchase of United States Dollars with such foreign currency quoted in the Wall Street Journal (or comparable publication if not quoted in the Wall Street Journal) with respect to the sale of currency of the country of origin of such payment for the day prior to the date on which the payment by COMPANY is being made.

3. Any income or other taxes which COMPANY and ELAN, if applicable, is required by law to pay or withhold on behalf of the receiving party with respect to royalties and any other monies payable to such party under this Agreement shall be deducted from the amount of such NSP payments, royalties and other monies due. COMPANY and ELAN, if applicable, shall furnish the receiving party with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by the receiving party. COMPANY and ELAN, if applicable, shall promptly provide the receiving party with a certificate or other documentary evidence to enable the receiving party to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by the paying party. Both parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable the paying party to make such payments to the receiving party without any deduction or withholding.
4. All payments due hereunder shall be made to the designated bank account of ELAN in accordance with such timely written instructions as ELAN shall from time to time provide.
5. COMPANY shall pay interest to ELAN at the rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office at its prime or best rate plus [ \* ] on all late payments under this Agreement (applicable as of the date on which payment should have been made pursuant to the applicable provisions of this Agreement) from the date on which payment should have been made pursuant to the applicable provision until the date of payment.
6. COMPANY shall provide ELAN with quarterly sales reports outlining the status of the PRODUCT in the TERRITORY, [ \* ]. .
7. For the one hundred and eighty (180) day period following the close of each calendar year during the term of the Agreement, ELAN and COMPANY will provide each others independent certified accountants (reasonably acceptable to the other party) with access, during regular business hours and upon reasonable prior request and subject to the confidentiality provisions as contained in this Agreement, to such party's books and records relating to the PRODUCT, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended.

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8. In the event of a discovery of a discrepancy which exceeds [ \* ] percent ([ \* ]%) of the amount due or charged by a party for any period, the cost of such accountants shall be borne by the audited party; otherwise, such cost shall be borne by the auditing party.
9. ELAN shall make (and where relevant shall procure that ELAN's subcontractor shall make) that portion of its manufacturing facility where PRODUCT is manufactured, including all record and reference samples relating to the PRODUCT available for inspection by COMPANY's duly qualified person or by the relevant governmental or regulatory authority. The investigation shall be limited to determining whether there is compliance with cGMP and other requirements of applicable law.

#### **ARTICLE XI PATENTS**

1. ELAN shall make a good faith effort to secure the grant of all of the ELAN PATENT RIGHTS in the appropriate countries of the TERRITORY at its own expense and shall be the title holder thereof. ELAN shall keep COMPANY apprised of all significant activities in connection therewith in timely manner. ELAN agrees to defend and pay all governmental charges and maintenance fees thereon and extend the term of any resulting patent at COMPANY's request with COMPANY's assistance.
2. COMPANY and ELAN shall promptly inform the other in writing of any alleged infringement of which it shall become aware by a third party of any patents within the ELAN PATENT RIGHTS or COMPANY PATENT RIGHTS and provide such other with any available evidence of infringement.
3. Both ELAN and COMPANY recognise that it is most desirable that patent protection be secured for the PRODUCT. The parties will in good faith jointly decide how ELAN shall file and prosecute all patent applications regarding the PRODUCT and how to share the costs.
4. The following provisions shall apply to any proceedings ("Enforcement Proceedings") taken by the parties during the term of this Agreement in respect of infringements which relate to the enforcement of the ELAN PATENT RIGHTS, ELAN KNOW-HOW, COMPANY PATENT RIGHTS, AND COMPANY KNOW-HOW relating to the PRODUCT:
  - 4.1. The parties may agree to institute Enforcement Proceedings in their joint names and shall reach agreement as to the proportion in which they will share the proceeds of any such Enforcement Proceedings, and the expense

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of any costs not recovered, or the costs or damages payable to the third party. The parties will share the proceeds of any Enforcement Proceedings in proportions equivalent to the proportions of each party's respective costs directly associated with the Enforcement Proceedings.

- 4.2. In the event that COMPANY does not wish to institute Enforcement Proceedings under paragraph 4.1, ELAN shall have the right to institute Enforcement Proceedings at its own expense and for its own benefit and COMPANY shall co-operate with any such Enforcement Proceedings. Any expenses borne by COMPANY shall be reimbursed by ELAN, provided that COMPANY shall bear the costs incurred by it if it elects to retain an independent firm of attorneys to advise it in relation to the Enforcement Proceedings.
- 4.3. In the event that ELAN does not wish to institute Enforcement Proceedings under paragraph 4.1., COMPANY shall have the right to institute Enforcement Proceedings at its own expense and for its own benefit and ELAN will co-operate with any such Enforcement Proceedings. Any expenses borne by ELAN shall be reimbursed by COMPANY provided that ELAN shall bear the costs incurred by it if it elects to retain an independent firm of attorneys to advise it in relation to the Enforcement Proceedings.

## **ARTICLE XII: SUNDRY CLAUSES**

### **1. Secrecy**

1.1. Any information, whether written or oral (oral information shall be reduced to writing within one month by the party giving the oral information and the written form shall be furnished to the other party) pertaining to the PRODUCT that has been or will be communicated or delivered by ELAN to COMPANY, and any information from time to time communicated or delivered by COMPANY to ELAN, including, without limitation, trade secrets, business methods, and cost, supplier, manufacturing and customer information, shall be treated by COMPANY and ELAN, respectively, as confidential information, and shall not be disclosed or revealed to any third party whatsoever or used in any manner except as expressly provided for herein; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this section to the extent that such confidential information:

- 1.1.1. is available to the public in public literature or otherwise, or after disclosure by one party to the other becomes public knowledge through no default of the party receiving such confidential information; or

- 1.1.2. was known to the party receiving such confidential information prior to the receipt of such confidential information by such party, whether received before or after the date of this Agreement; or
  - 1.1.3. is obtained by the party receiving such confidential information from a third party not subject to a requirement of confidentiality with respect to such confidential information; or
  - 1.1.4. is required to be disclosed pursuant to: (A) any order of a court having jurisdiction and power to order such information to be released or made public; or (B) any lawful action of a governmental or regulatory agency. In such event, the party receiving such confidential information shall notify the disclosing party of the required disclosure in advance to enable the disclosing party to have an opportunity to object to such governmental entity or court of law regarding the required disclosure. The receiving party shall use all reasonable efforts to obtain confidential treatment of such confidential information required to be disclosed; or
  - 1.1.5. is independently discovered by the receiving party after the date of this Agreement without the aid, application or use of the confidential information of the disclosing party.
- 1.2. Each party shall take all such precautions as it normally takes with its own confidential information to prevent any improper disclosure of such confidential information to any third party; provided, however, that such confidential information may be disclosed within the limits required to obtain any authorisation from the FDA or any governmental or regulatory agency or, with the prior written consent of the other party, which shall not be unreasonably withheld, or as may otherwise be required in connection with the purposes of this Agreement.
  - 1.3. COMPANY agrees that it will not use, directly or indirectly, any ELAN KNOW-HOW, or otherwise confidential information disclosed to COMPANY or obtained from ELAN pursuant to this Agreement, other than as expressly provided herein. ELAN agrees that it will not use, directly or indirectly, any COMPANY KNOW-HOW, or otherwise confidential information disclosed to ELAN or obtained from COMPANY pursuant to this Agreement, other than as expressly provided herein.
  - 1.4. COMPANY and ELAN will not publicise the existence of this Agreement in any way without the prior written consent of the other subject to the disclosure requirements of applicable laws and regulations. In the event that either party wishes to make a public disclosure concerning this Agreement and such disclosure mentions the other party by name or description, such other party will

be provided with an advance copy of the disclosure and will have three (3) business days within which to approve or disapprove such use of its name or description. Approval shall not be unreasonably withheld by either party. Failure to respond within such three (3) business days shall be deemed to be approval. Absent approval, no public disclosure shall use the name or otherwise describe such party except to the extent required by law. Notwithstanding the foregoing, it is understood and agreed that no approval shall be required in the event that the information to be disclosed has previously been the subject of a prior disclosure.

2. **Assignments/ Sub-contracting**

This Agreement may not be assigned by COMPANY without the prior written consent of ELAN, such consent not being unreasonably withheld or delayed, save that COMPANY may assign this Agreement to its AFFILIATE or AFFILIATES without such consent provided that such assignment has no adverse tax implications for ELAN. ELAN may assign this Agreement to an AFFILIATE. ELAN shall also have the right to subcontract all or any portion of the PRODUCT to a third party with the prior written consent of COMPANY, such consent not being unreasonably withheld or delayed.

3. **Parties bound**

This Agreement shall be binding upon and enure for the benefit of parties hereto, their successors and permitted assigns.

4. **Severability**

If any provision in this Agreement is agreed by the parties to be, or is deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto, (i) such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the parties, it will be deleted, with effect from the date of such agreement or such earlier date as the parties may agree, and (ii) the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

5. **Duration and Termination**

- 5.1. This Agreement is concluded for a period commencing as of the date of this Agreement and shall expire on a country by country basis after ten (10) years starting from the date of the launch of the PRODUCT, or for the life of the last to expire patent included in the ELAN PATENT RIGHTS whichever is longer (“the



Initial Period"). After the expiry of the Initial Period, the parties shall negotiate in good faith the terms of a new agreement, including an appropriate royalty, taking into account the then prevailing market conditions. Pending the execution of any new agreement, the terms of this Agreement shall continue.

If such a new agreement is not concluded, subject to giving two (2) years' written notice to commence after the expiry of the Initial Period, COMPANY may commence manufacturing the PRODUCT, or after any longer period in which ELAN continues to supply PRODUCT under a new agreement concluded between the parties, ELAN shall grant to COMPANY a production licence to the ELAN KNOW-HOW in terms similar to Article III paragraph 14 of the Agreement. In consideration of such a production licence to the ELAN KNOW-HOW, COMPANY shall pay an ongoing royalty of [ \* ] percent ( [ \* ]%) on NSP of the PRODUCT to ELAN.

In the event that [ \* ] (as the term is defined and accepted by the FDA or [ \* ] by other regulatory authorities) generic competitor is approved and marketed for commercial sale in any country of the TERRITORY after the expiry of the Initial Period, [ \* ]. However, the ongoing royalty of [ \* ] percent ( [ \* ]%) on NSP of the PRODUCT shall be paid to ELAN in all other countries of the TERRITORY.

5.2. In addition to the rights of early or premature termination provided for elsewhere in this Agreement, it is hereby acknowledged that in the event that any of the terms or provisions hereof are incurably breached by either party, the non-breaching party may immediately terminate this Agreement by written notice. An incurable breach shall be committed:

5.2.1. when either party is dissolved, liquidated, discontinued, becomes insolvent, or when any proceeding is filed or commenced by or against either party under bankruptcy, insolvency or debtor relief laws and is not dismissed within ninety (90) days of filing, or

5.2.2. where there is a [ \* ], or

5.2.3. where a [ \* ], or

5.2.4. where a [ \* ]; provided however that this paragraph shall only apply in the event that [ \* ].

Subject to the other provision of this Agreement, in the event of any other breach, the non-breaching party may terminate this Agreement by the giving of written notice to the breaching party that this Agreement will terminate on the sixtieth (60th) day from notice unless cure is sooner effected.

- 5.3. COMPANY may elect to terminate this Agreement in accordance with Article III, paragraph 4 and otherwise up to the [ \* ]. In addition to these and any other rights of termination specified in this Agreement, COMPANY may also terminate this Agreement for economic or strategic reasons at any time after [ \* ]. In the event that COMPANY so elects to terminate this Agreement at any time after [ \* ] up to the [ \* ], COMPANY shall pay to ELAN, [ \* ] in recognition of the utilisation by COMPANY of the ELAN PATENT RIGHTS up to the date of such termination. In such an event and should [ \* ], COMPANY shall be entitled to recover the \$[ \* ] payable to ELAN in accordance with [ \* ]. ELAN shall pay COMPANY such [ \* ] in each quarter following first launch of PRODUCT until such time as total additional royalty payments reach \$[ \* ], at which point this additional royalty shall cease.
- 5.4. Upon exercise of those rights of termination as specified in Article XII, paragraphs 5.1., 5.2 and 5.3., or elsewhere within the Agreement, this Agreement shall, subject to the other provisions of the Agreement and Article XII paragraph 5.5., automatically terminate forthwith and be of no further legal force or effect.
- 5.5. Upon termination of the Agreement by either party, or upon termination by ELAN of a licence for a particular country in accordance with Article II, paragraph 11 or any other the terms of the Agreement, the following shall be the consequences relating to the TERRITORY or the particular country, as applicable:
- 5.5.1. any sums that were due from COMPANY to ELAN prior to the exercise of the right to terminate this agreement as set forth herein shall be paid in full within sixty (60) days of termination of this Agreement and ELAN shall not be liable to repay to COMPANY any amount of money paid or payable by COMPANY to ELAN up to the date of termination of this Agreement;
  - 5.5.2. all confidentiality provisions set out herein shall remain in full force and effect for a period of [ \* ] from the date of termination of the Agreement;
  - 5.5.3. all responsibilities and warranties shall insofar are appropriate remain in full force and effect;
  - 5.5.4. the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement;
  - 5.5.5. depending on the scope of termination as provided for in this Agreement, ELAN shall be entitled to commercialise the PRODUCT for its own benefit in the TERRITORY or in the relevant country or countries of the TERRITORY;
  - 5.5.6. Where a royalty is payable by ELAN to COMPANY in accordance with

Article V., paragraph 3.7 of the Agreement, COMPANY shall transfer to ELAN or ELAN's designee without charge, and/or permit ELAN or ELAN's designee without charge to conduct sufficient cross-referencing to, any and all pending or granted NDA APPROVALS for the PRODUCT for the relevant country or countries of the TERRITORY; and

- 5.5.7. COMPANY shall have an ongoing right for a period of six (6) months to sell or otherwise dispose of the stock of any PRODUCT on hand as of the date of termination of the AGREEMENT, which such sale shall be subject to Article V and the other applicable terms of this AGREEMENT.
- 5.6. In the event that this Agreement is terminated and should ELAN require a licence of the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in order to research, develop and commercialise the PRODUCT in accordance with Article II, paragraph 11:-
- 5.6.1. COMPANY shall grant ELAN a licence in respect of the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW subject to the payment of a royalty mutatis mutandis with Article V, paragraph 3.7 of this Agreement for a term of [ \* ] starting from the date of the launch of the PRODUCT by ELAN or up to the expiration of the life of the last to expire patent included in the COMPANY PATENT RIGHTS, whichever is longer;
- 5.6.2. the parties shall enter into a further written licence and supply agreement which shall incorporate the foregoing provisions of this paragraph 5.6. and which shall include customary and reasonable terms relating to, inter alia, the supply of COMPOUND by COMPANY to ELAN, the timing of royalty payments to COMPANY, reporting obligations regarding net sales, audit rights of COMPANY with respect to books and records relating to net sales, and indemnity provisions, which obligations shall, unless otherwise agreed by the parties, be substantially similar to those in this Agreement with respect to commercialisation of the PRODUCT by COMPANY;

6. **Force Majeure**

Neither party to this Agreement shall be liable for delay in the performance of any of its obligations hereunder if such delay results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, or intervention of a government authority, non availability of raw materials, but any such delay or failure shall be remedied by such party as soon as practicable.

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7. **Relationship of the Parties**

Nothing contained in this Agreement is intended or is to be construed to constitute ELAN and COMPANY as partners or joint venturers or either party as an employee of the other. Neither party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other party or to bind the other party to any contract, agreement or undertaking with any third party.

8. **Amendments**

No amendment, modification or addition hereto shall be effective or binding on either party unless set forth in writing and executed by a duly authorised representative of both parties.

9. **Waiver**

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

10. **Headings**

The section headings contained in this Agreement are included for convenience only and form no part of the agreement between the parties. Save as otherwise provided herein, references to articles, paragraphs, clauses and appendices are to those contained in this Agreement.

11. **No effect on other agreements**

No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the parties unless specifically referred to, and solely to the extent provided, in any such other agreement.

12. **Applicable Law**

12.1. This Agreement is construed under and ruled by the internal laws of the State of Georgia, without regard to conflicts of laws principles. For the purpose of this Agreement the parties submit to the exclusive jurisdiction of the courts of the State of Georgia.

12.2. Any controversy or claim arising out of or in relation to the Agreement, or the breach thereof, shall be settled by binding arbitration, which will be the parties exclusive remedy, and judgement on the award rendered by the arbitrators may be

entered in any court having jurisdiction thereof. Any such arbitration shall be conducted in the English language in Atlanta, Georgia and shall proceed pursuant to the then-existing Commercial Arbitration Rules of The American Arbitration Association (“Rules”) but only to the extent the Rules do not conflict with the provisions of this Agreement.

- 12.3. Within fifteen (15) days after the demand for arbitration is sent to the other party, each party shall select one person to act as arbitrator and the two selected arbitrators shall select a third arbitrator within ten (10) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be selected by The American Arbitration Association. A majority of the arbitrators shall be required to rule in favour of any final award.
- 12.4. The parties shall allow and participate in discovery in accordance with the Federal Rules of Civil Procedure for a period of ninety (90) days after the demand for arbitration is sent to the other party. Unresolved discovery disputes may be brought to the attention of the arbitrators and may be disposed of by the arbitrators.
- 12.5. All fees and expenses of the arbitration shall be borne by the parties equally. The prevailing party shall be entitled to an award of reasonable attorney fees, including disbursements.

13. **Notice**

- 13.1. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or telecopied to:

- ELAN at

Elan Corporation plc.  
Lincoln House,  
Lincoln Place  
Dublin 2  
Ireland.

Attention: Vice-President & General Counsel,  
Elan Pharmaceutical Technologies

Telephone: 353 1 7094301

Telefax : 353 1 6624960

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- COMPANY at

Solvay Pharmaceuticals, Inc.  
901 Sawyer Road,  
Marietta, Georgia 30062,  
United States of America.

Attention: Vice President, Law, Government & Public Affairs  
Telephone: 770 578 5736  
Telefax: 770 578 5749

or to such other address(es) and telecopier numbers as may from time to time be notified by either party to the other hereunder.

- 13.2. Any notice sent by mail shall be deemed to have been delivered within seven (7) working days after despatch and any notice sent by telex or telecopy shall be deemed to have been delivered within twenty four (24) hours of the time of the despatch. Notice of change of address shall be effective upon receipt.

**IN WITNESS THEREOF** the parties hereto have executed this Agreement in duplicate.

Executed by **COMPANY** on 22 December, 1997

By : /s/ David A. Dodd  
Name: David A. Dodd  
Title: President and CEO

Executed by **ELAN** 23 December, 1997

By: /s/ Seamus Mulligan  
Name: Seamus Mulligan  
Title: President – EPT

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**APPENDIX A**

**PART I**

**ELAN PATENT RIGHTS**

**United States of America Patent Numbers**

[ \* ]

**PART II**

**COMPANY PATENT RIGHTS**

**Not filed with the executed document.**

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**APPENDIX B**

**THE PROJECT**

For the consideration outlined in this Agreement, ELAN will undertake the PROJECT as described hereunder, consistent with the objectives of this Agreement and specifically with the provisions of Article III. The PROJECT will consist of four distinct stages of activities which are outlined below;

STAGE I [ \* ]  
STAGE II [ \* ]  
STAGE III [ \* ]  
STAGE IV [ \* ]

[ \* ]

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**APPENDIX C**

**PRODUCT SPECIFICATIONS**

**None.**

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**APPENDIX D**

**MANUFACTURING COST**

The following expenses are manufacturing expenses which are prepared in accordance with generally accepted accounting principles consistently applied.

**The following expenses are included in manufacturing costs:**

[ \* ]

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QUALITY PROCEDURES

QUALITY PROCEDURES APPENDIX

**1. SPECIFICATIONS AND MASTER DOCUMENTATION**

- 1.1. COMPANY will hold on file copies of all regulatory applications, submissions and approvals for the PRODUCT and shall allow ELAN access to the NDA for the United States of America and other registration applications as may be required, including all supplements, amendments, and related correspondence which provide the necessary documentation and information to ensure the PRODUCT is manufactured and tested in accordance with the relevant regulatory requirements.
- 1.2. ELAN will be responsible for preparing manufacturing and quality control documentation for the PRODUCT to reflect the formulation, method, manufacture and control parameters leading to bulk supply of finished PRODUCT (in capsule or tablet form) as detailed in the regulatory documents and in conformance with cGMP. COMPANY and ELAN shall designate primary contacts at each company for the dissemination of all necessary documentation to relevant internal personnel at each site.
- 1.3. COMPANY and ELAN shall agree and formalize a change control procedure to be in place on NDA APPROVAL which will allow for communication and authorization of proposed changes in the relevant manufacturing documentation of the COMPOUND and PRODUCT.

**2. SUPPLY AND CONTROL OF MATERIAL**

- 2.1. COMPANY will procure the COMPOUND. ELAN will procure all other materials for the PRODUCT.
- 2.2. ELAN will test and approve all raw materials in accordance with the requirements of the regulatory approval as set out in the relevant approved analytical protocols for the PRODUCT and in conformance with operating procedures.
- 2.3. ELAN will not change the source or grade of material used in the manufacture of the PRODUCT post NDA APPROVAL without prior change control communication. In the event such a change warrants it, COMPANY will be responsible for obtaining all required regulatory approvals.

- 2.4. COMPANY will ensure COMPOUND is manufactured and tested in accordance with the agreed specifications, relevant regulatory requirements, and in conformance with cGMP and operating procedures. This will be confirmed by certificates of analysis to accompany each lot of COMPOUND provided to ELAN.
- 2.5. COMPANY will ensure no revision in manufacturing and controls of COMPOUND without prior change control communication. In the event such a change warrants it, COMPANY will be responsible for obtaining all required regulatory approvals.
- 2.6. COMPANY will permit the appropriate ELAN personnel to periodically assess the COMPANY quality system in terms of its relevance to the manufacture and quality of the COMPOUND and will make available batch and related documentation for review at the COMPANY manufacturing site.

### **3. PROCESSING**

- 3.1. ELAN will manufacture the PRODUCT in accordance with the NDA requirements and in conformance with cGMP and will supply the PRODUCT to COMPANY in the form of bulk capsules or tablets, as determined in the PROJECT. COMPANY will be responsible for the packaging of the PRODUCT into final market packaging in accordance with the NDA requirements and in conformance with cGMP.
- 3.2. ELAN will be responsible for validation of the current processes and equipment (and of any changes made to same) used by ELAN in the manufacture of the PRODUCT. Details of such validation work will be made available to COMPANY for review at ELAN's manufacturing site.
- 3.3. ELAN will permit the appropriate COMPANY personnel to periodically assess the ELAN quality system in terms of its relevance to the manufacture and quality control of the PRODUCT and will make available batch and related documentation for review at the ELAN manufacturing site.

### **4. PACKAGING, LABELLING AND TRANSPORTATION**

- 4.1. COMPANY will pack, label and ship the COMPOUND to ELAN so as to permit safe storage and transport, to retain COMPOUND security, and to enable swift identification of package contents.
- 4.2. ELAN will pack, label and ship the PRODUCT in bulk capsules or tablets (as determined in the PROJECT) so as to permit safe storage and transport, to retain PRODUCT security and to enable swift identification of package contents.
- 4.3. Shipping containers will be appropriately labeled with PRODUCT labels detailing PRODUCT description, storage information, lot reference, manufacture date, quantity, and container number. An address label for the appropriate COMPANY destination will be attached to each shipping container. Any revisions to labeling requirements can be agreed in advance of NDA submission.

## 5. QUALITY CONTROL AND RELEASE FOR SHIPMENT

- 5.1. ELAN will test each batch of the PRODUCT as detailed in the approved analytical protocol and will review all relevant batch documentation prior to approval for shipment to COMPANY. ELAN will provide copies of confirmed out-of-specification investigations to COMPANY on commercial distributed PRODUCT.
- 5.2. On an exceptional basis and by prior arrangement with COMPANY, ELAN may authorize shipment of PRODUCT after testing but before final QA review. Such PRODUCT will not be released by COMPANY prior to receipt of certification from ELAN that the results of testing are satisfactory.
- 5.3. Final release of packaged PRODUCT to the market place is the responsibility of COMPANY's Quality Unit.

## 6. BATCH DOCUMENTATION

- 6.1. ELAN will retain batch records and related documents in accordance with regulatory and corporate retention requirements.
- 6.2. ELAN will, by issuing a certificate of analysis to the COMPANY, confirm that each batch of PRODUCT supplied to COMPANY complies with the relevant analytical specifications and that it has been manufactured in accordance with cGMP.

## 7. CUSTOMER COMPLAINTS

### 7.1. Clinical Complaints

- 7.1.1. For clinical complaints arising from the field (patient/practitioner), it will be the responsibility of COMPANY to log, investigate, follow up and respond to each complaint. In the event of COMPANY requiring ELAN to contribute to the investigation of such complaints, ELAN will respond to COMPANY within fourteen (14) working days or earlier, depending on the nature of the clinical complaint.
- 7.1.2. Field complaints received directly by ELAN, will be forwarded to COMPANY for processing.
- 7.1.3. Any field complaints which, upon review are adverse events by definition, will also be the responsibility of COMPANY.

### 7.2. Complaint Handling Non-Clinical

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7.2.1. COMPANY will forward copies of complaints and related correspondence to ELAN for investigation if associated with any aspect of manufacture/handling carried out at ELAN.

7.2.2. On receipt of a complaint from COMPANY, ELAN will log and evaluate the incident. Within thirty (30) days, ELAN will provide a written response to COMPANY.

7.3 Complaint Reports

7.3.1 COMPANY will provide ELAN with a summary of all non-clinical complaints relating to the PRODUCT on a quarterly basis.

**8. FIELD ALERT/RECALL**

8.1. In the event of a field alert or recall of PRODUCT in the TERRITORY and subject to the provisions of Article VIII of this Agreement, as deemed appropriate or agreed with the relevant regulatory agency, COMPANY will be responsible for all communications with the regulatory authority and will perform the said recall.

8.2. ELAN will be provided with copies of all correspondence with the regulatory authority if related to manufacture/handling activities by ELAN.

**9. RETAIN SAMPLES**

9.1. ELAN will hold sufficient retains of the PRODUCT in bulk, to enable complete re-analysis to be performed twice. COMPANY will hold sufficient retains of the packaged PRODUCT to meet their own retest requirements. The results of any such analysis on retains of PRODUCT will be provided to COMPANY.

**10. STABILITY**

10.1. COMPANY will carry out all post marketing stability studies to meet NDA or other relevant regulatory commitments. COMPANY will provide ELAN with all stability reports, for informational purposes only. Any communication to the FDA or other relevant agencies will be made through COMPANY. In the event of a stability failure, COMPANY will notify ELAN immediately of the failure and will provide a written stability report within five (5) working days.

**11. ADVERSE EVENTS**

11.1. COMPANY will be responsible for meeting all regulatory obligations with regard to adverse event receipt, evaluation, and reporting.

## 12. ANNUAL PRODUCT REPORTS/REVIEWS

- 12.1. COMPANY is responsible for Annual Reports and similar regulatory obligations in support of regulatory applications (i.e., IND, NDA) for the PRODUCT. COMPANY will provide ELAN with their requirements and the defined review period in support of said applications.
- 12.2. ELAN will conduct an Annual Product Review in accordance with cGMP for the PRODUCT following NDA APPROVAL. COMPANY will provide the required documentation (e.g. complaint history, stability data, etc.) as requested by ELAN for completion of the report. Access to the Review will be made available to COMPANY for review at ELAN's manufacturing site.

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AMENDMENT TO LICENSE AGREEMENT

This Amendment to the Licence Agreement (the "Amendment") is effective as of the 1<sup>st</sup> day of March 1999 between Elan Corporation, plc and Solvay Pharmaceutical, Inc.

Introduction

A. ELAN and COMPANY entered into a Licence Agreement dated 22<sup>nd</sup> December, 1997 (the "Agreement").

B. COMPANY requested and ELAN agreed, to conduct Additional Development Work (as defined below) to that specified in the PROJECT. Such Additional Development Work was conducted by ELAN in accordance with the terms of the Agreement. As a result of such Additional Development Work having been performed, ELAN and COMPANY have agreed to amend STAGE III of the PROJECT.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, and for other good and valuable consideration, it is agreed as follows:

1. Definitions and Incorporation. Unless otherwise defined, all terms used herein shall have the meaning ascribed to them in the Agreement, and the terms and provisions of the Agreement are incorporated herein by reference as though set forth in full.

2. Financial Provisions.

2.1. At the COMPANY's request, ELAN conducted the additional development work set out in Schedule A ("Additional Development Work") during STAGE II of the PROJECT. The COMPANY is responsible for the cost of such Additional Development Work in accordance with [ \* ] of the Agreement. The parties have agreed that \$[ \* ] is presently owing and due to ELAN by COMPANY in respect of such Additional Development Work.

2.2. As a result of the Additional Development Work conducted during STAGE II of the PROJECT, ELAN and COMPANY have agreed to reduce the work programme outlined for STAGE III of the PROJECT in Appendix B in the Agreement. The parties have agreed to a reduction in the work requirements relating to the [ \* ] originally envisaged and included in the STAGE III programme and costing. As a result of such agreed reductions, the cost of STAGE III of the PROJECT, unless modified by further agreement of



the parties, to be paid by COMPANY to ELAN under [ \* ] of the Agreement shall be reduced from \$[ \* ] to \$[ \* ]. For the avoidance of doubt, the STAGE III development fee shall be paid upon COMPANY's election and notification in writing to ELAN to commence with STAGE III.

2.3. ELAN and COMPANY shall review in good faith whether ELAN's ability to complete STAGE III within the strict time periods set out in [ \* ] shall be impinged as a result of the COMPANY's modifications to the work programme for STAGE HI of the PROJECT as outlined in Clause 2.2 of this Amendment or any delay in the commencement of such work programme due to COMPANY's modifications. For the avoidance of doubt, in the event that there is any delay in the completion of STAGE III as a result of such modifications of the aforementioned work programme, the parties shall agree in good faith an appropriate mechanism to remedy any such delay and extend the time periods set out in [ \* ]. In the event that the parties fail to reach agreement on such appropriate mechanism, the dispute may be referred to arbitration pursuant to Clause 12.2 of the Agreement.

3. Reaffirmation of the Agreement and Other Documents. Except as modified herein, all of the covenants, terms and conditions of the Agreement, and all documents, instruments and agreements executed in conjunction therewith remain in full force and effect and are hereby ratified and reaffirmed in all respects. In the event of any conflict, inconsistency or incongruity between the terms and conditions of this Amendment and the covenants, terms and conditions of the Agreement or any documents, instruments or agreements executed in conjunction therewith, the terms and conditions of this Amendment shall govern and control.

4. Counterparts. This Amendment may be executed in two or more counterparts, each of which together shall constitute an original but which, when taken together, shall constitute but one instrument.

IN WITNESS WHEREOF, this Amendment is executed as of the day and year first above written.

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SOLVAY PHARMACEUTICALS, INC.

ELAN CORPORATION, PLC

By: /s/ Harold Shlevin  
Name: Harold H. Shlevin, Ph.D.  
Title: Sr. Vice President Business Development and Scientific Affairs  
Date: 6/1/99

By: /s/ Larry A. Sternson  
Name: Larry Sternson  
Title: President, EPT (A Division of Elan Corporation , PLC)  
Date: 10 June 1999

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**Schedule A**

**ADDITIONAL DEVELOPMENT WORK**

[ \* ]

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April 13, 2000

Larry Sternson  
President  
Elan Pharmaceutical Technologies  
a division of Elan Corporation, plc

**Licence Agreement between Elan Corporation, plc and Solvay Pharmaceuticals Inc. dated 22<sup>nd</sup> December, 1997 as amended by Amendment dated 1<sup>st</sup> March, 1999 (the "Agreement")**

Dear Sir,

We refer to the above Agreement for the development of a once daily fluvoxamine product.

Defined texts used in this letter shall have the meanings assigned to them in the Agreement unless such terms are expressly defined in this letter. All other provisions of the Agreement not amended herein shall remain unchanged and in full force and effect.

Whereby it is agreed by ELAN and the COMPANY that Article V, Paragraph 2.1.3 of the Agreement shall be deleted and replaced with the following:

*"2.1.3. \$[\*] due upon [\*].*

*In the event that [\*] as envisaged herein in this 2.1.3. prior to the specified [\*] day, then the royalty to be paid to ELAN under this paragraph 2.1.2. shall be [\*]. Thus for example, if [\*].*

*However, in the event that such [\*] day, then the \$[\*] license royalty payable here shall [\*]. Thus, for example, if [\*]. COMPANY's obligation to pay a license fee to ELAN under this 2.1.3. shall expire on the [\*] day of the specified period if no such [\*] as envisaged here is effected by that date."*

Kindly confirm your agreement to the above amendments by signing this letter which is hereby furnished in duplicate and returning one (1) fully executed original to Solvay.

Yours sincerely

/s/ Harold H. Shlevin

Harold Shlevin, Ph.D.  
Senior Vice President  
Solvay Pharmaceuticals, Inc.

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Accepted and agreed on behalf of  
Elan Pharmaceutical Technologies

By: /s/ Larry A. Sternson  
Name: Larry Sternson  
Title: President, EPT  
Date: 3 May 2000

cc: P. Ashe (Elan)  
J. Benesh  
V. Harrison  
M. Kelleher (Elan)  
J. Nolan

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7 November 2006

ELAN CORPORATION, PLC.

AND

SOLVAY PHARMACEUTICALS INC.

AMENDMENT AGREEMENT NO. 3  
TO THE LICENCE AGREEMENT OF 22 DECEMBER 1997

*Luvox (fluvoxamine) CR*  
*Worldwide*

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**BETWEEN:**

- (1) **Elan Corporation, plc.**, a public limited company incorporated under the laws of Ireland, and having its registered office at Treasury Building, Grand Canal Street Lower, Dublin 2, Ireland; and
- (2) **Solvay Pharmaceuticals Inc.**, a company organised under the laws of the State of Georgia and having its principal place of business at 901 Sawyer Road, Marietta, Georgia, 30062 United States of America (“**Solvay**”)

**RECITALS:**

- (A) Elan and Solvay entered into an agreement dated 22 December 1997 whereby, inter alia, Elan licensed to Solvay certain patents and know how to have manufactured oral controlled release dosage forms of fluvoxamine maleate (the “**First Agreement**”).
- (B) Elan and Solvay entered into (i) an Amendment Agreement dated 1 March 1999 whereby STAGE III of the PROJECT (as each of those terms was defined in the First Agreement) was amended (the “**Amendment Agreement No. 1**”); and (ii) a letter of amendment dated 13 April 2000 and countersigned 3 May 2000, whereby Article V, Section 2.1.3 was amended (the “**Amendment Agreement No. 2**”).
- (C) Solvay and Solvay Pharmaceuticals Marketing & Licensing AG of Binningerstrasse 94, 4123 Allschwil, Switzerland (“**SPML**”) entered into an Assignment and Assumption Agreement dated 4 August 2000 (the “**Assignment Agreement**”) whereby Solvay assigned to SPML its rights and obligations under the First Agreement as amended. Elan agreed to that assignment. Subsequently Solvay and SPML entered into a letter agreement for reassignment and re-assumption dated 13 December 2001, (the “**Re-assignment Agreement**”) whereby SPML re-assigned to Solvay its rights and obligations under the First Agreement as amended. Elan also agreed to that assignment, as Elan hereby acknowledges and confirms.
- (D) Elan and Solvay now wish to amend certain of the financial and other provisions of the **Original Agreement**, as hereinafter defined, with effect from the Amendment No. 3 Date.
- (E) Elan and Solvay are desirous of entering into this Amendment No.3 Agreement to give effect to the arrangements described at Recital (D).



**NOW IT IS HEREBY AGREED AS FOLLOWS:**

**1. Preliminary**

1.1. In this Amendment Agreement No. 3

“**Original Agreement**” shall mean the First Agreement as amended by the Amendment Agreement No. 1, Amendment Agreement No. 2, the Assignment Agreement and the Reassignment Agreement.

“**this Amendment**” shall mean this Amendment No 3 Agreement, including its recitals and schedules.

1.2. Except where expressly provided to the contrary in this Amendment Agreement No. 3:

1.2.1 all capitalised terms used in this Amendment Agreement No. 3 shall have the same meanings as are assigned thereto in the Original Agreement, as amended by this Amendment; and

1.2.2 this Amendment Agreement No. 3 shall be interpreted in the same manner as the Original Agreement.

**2. Amendment of Definitions**

2.1. ELAN and COMPANY hereby agree that the Original Agreement is hereby amended with effect from the Amendment No. 3 Date by the insertion of the following definitions:

“**Amendment Agreement No. 3**” shall mean the Amendment Agreement No. 3 between ELAN and COMPANY dated the 7<sup>th</sup> November 2006

“**Amendment No. 3 Date**” shall mean 7 November 2006.

**3. Refund of Milestone and Re-Filing of Drug Master File “DMF”**

3.1. ELAN and COMPANY acknowledge that COMPANY paid to ELAN the sum of \$[ \* ] pursuant to Article V Section 2.1.3 of the Original Agreement. The filing referred to in that Section subsequently having been withdrawn, ELAN and COMPANY agree that within five (5) business days of the signature of this Amendment Agreement No. 3 and upon receipt by ELAN of an appropriate invoice from the COMPANY, ELAN shall repay to COMPANY the sum of \$[ \* ]

3.2. The parties hereby agree that each party shall bear all costs and expenses incurred by it, pursuant to any development or other activities carried out by it in connection with the PRODUCT, from the date of the withdrawal referred to at Section 3.1 to the Amendment No. 3 Date. For the avoidance of doubt, insofar as either party has taken steps to discharge its responsibilities as listed in the attached Schedule A prior to the execution of this Amendment Agreement No. 3, that party shall be responsible for the reasonable costs and expenses associated with same except as expressly stated therein to be the responsibility of the other party.

- 3.3. Subject to Article III, Section 2 of the Original Agreement, the parties further agree that Schedule A hereto sets out the agreed allocation of responsibility including responsibility for costs and expenses for re-filing the DMF.
- 3.4. COMPANY acknowledges that the foregoing repayment and assumption of costs and expenses by ELAN is in complete substitution for any other remedy COMPANY may have or may have had against ELAN in respect of such withdrawal. COMPANY hereby waives and releases all such claims against ELAN.
- 3.5. COMPANY further acknowledges that such repayment and assumption of costs and expenses by ELAN is without prejudice to ELAN's right to the payment set out in Article V Section 2.1.3 as amended by this Amendment Agreement No. 3.

#### **4. Amendment of Financial Provisions**

ELAN and COMPANY hereby agree that Article V of the Original Agreement is hereby amended with effect from the Amendment No. 3 Date as follows:

- 4.1. by the deletion of the entirety of Section 2.1.3 and the substitution therefor of the following:  
"2.1.3. \$[\* ] due upon [\* ].";
- 4.2. by the deletion of the amount "\$[\* ]" in Section 2.1.4 and the substitution therefor of the amount "\$[\* ]"; and by the addition at the end of that section of the word "and";
- 4.3. by the deletion of the amount "\$[\* ]" in Section 2.1.5 and the substitution therefor of the amount "\$[\* ]"; and by the deletion at the end of that section of the word "and";
- 4.4. by the deletion of Section 2.1.6 in its entirety;
- 4.5. by the deletion of paragraphs (i) and (ii) of Section 3.1 and the substitution therefor of the following paragraphs:
  - (i) [\* ] percent ([\* ]%) on the first \$[\* ] sales of PRODUCT, calculated as NSP value, in any one calendar year;
  - (ii) [\* ] percent ([\* ]%) on the next \$[\* ] sales of PRODUCT, calculated as NSP value, in any one calendar year; and
  - (iii) [\* ] percent ([\* ]%) on sales of PRODUCT, calculated as NSP value, in excess of \$[\* ] in any one calendar year.";

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4.6. by the deletion in Section 3.1 of the hypothetical example (beginning with the words “EXAMPLE: If in any one year ...” until the end of the Section) and the substitution therefor of the following:

“EXAMPLE: If in any one year period following the first launch of the PRODUCT, the annual NSP were \$[ \* ], the royalty payable to ELAN shall be calculated as follows:

[ \* ]

4.7. by the deletion of Section 3.7 in its entirety and the substitution therefor of the following:

“3.7 In consideration of the licence to the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in accordance with Article II, paragraph 11, ELAN shall pay to COMPANY:

(a) [ \* ]% of net revenues achieved by ELAN in relation to the PRODUCT, “net revenues” meaning for this purpose [ \* ]; and

(b) a royalty on NSP of the PRODUCT on sales by ELAN, its AFFILIATES or its permitted sub-licensees as follows:

(i) [ \* ] percent ([ \* ]%) on the first \$[ \* ] sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(ii) [ \* ] percent ([ \* ]%) on sales of PRODUCT, calculated as NSP value, in excess of \$[ \* ] in any one calendar year.

Any such royalty payable by ELAN to COMPANY shall be calculated and paid mutatis mutandis as the terms of this Agreement.”

4.8. by the deletion of Section 5 and the substitution therefor of the following paragraphs:

“5.1 The price of bulk capsules of the PRODUCT to be charged to COMPANY shall be as follows EX WORKS:

<u>Dosage Strength</u>	<u>Price per 1,000 capsules</u>
[ * ]	\$[ * ]
[ * ]	\$[ * ]

5.2 Payment for all such PRODUCT supplied to COMPANY shall be effected in U.S. Dollars (\$) within thirty (30) days of the date of the relevant invoice.

- 5.3 COMPANY shall [ \* ] manufactured by ELAN which [ \* ] as laid out in its standard operating procedures then in force, at the following rates: [ \* ]
- 5.4 ELAN shall provide COMPANY with a written statement of the amount of [ \* ] following the end of each calendar quarter and a summary of the [ \* ], and COMPANY shall make a payment to ELAN in respect thereof not later than thirty (30) days of the end of the calendar quarter in question (or if later, fifteen (15) days from the date of such statement), subject to receipt of a proper invoice from ELAN in respect thereof.
- 5.5 The prices and [ \* ] rates set forth in paragraphs 5.1 and 5.3 may each be increased not more than [ \* ] by a percentage equal to [ \* ] since the previous increase (or, as applicable, the Amendment No. 3 Date), by written notice from ELAN to COMPANY.
- 5.6 In the event that COMPANY places orders for delivery in any calendar year in excess of [ \* ]mg equivalents (as referred to in Article IV Section 19), the price for all orders in excess of that number shall be reduced by [ \* ]% ([ \* ] per cent.).”
- 4.9. by the deletion of Article I Section 16 and Appendix D in their entirety.

#### **5. Amendments to Supply Terms**

ELAN and COMPANY hereby agree that Article IV of the Original Agreement is hereby amended with effect from the Amendment No. 3 Date as follows:

- 5.1. by the deletion from Article IV, Section 6 in its entirety and its replacement with the following:
- “6. Within fifteen (15) days of NDA APPROVAL and at the beginning of each calendar month thereafter, COMPANY will provide a rolling month by month forecast for the [ \* ] month period beginning on the first day of the calendar month following the calendar month in which the forecast is made and the [ \* ] of such forecast shall be a binding purchase commitment of COMPANY. Additionally, prior to NDA APPROVAL and in August of each calendar year, COMPANY will provide a non-binding [ \* ] forecast.”
- 5.2 by the deletion of Article IV, Section 14 in its entirety and its replacement with the following:
- “14. The Parties agree as follows:-
- 14.1 COMPANY shall be entitled to qualify an alternate facility as a second source of PRODUCT (“Second Source”). In the event COMPANY wishes to qualify a Second Source, it shall so notify

ELAN in writing at any time up to 30 (thirty) days after ELAN's notice to cease manufacturing under Section 18. If the operator of COMPANY's desired facility is not COMPANY or an affiliate of COMPANY, [ \* ]. The operator of any such third party facility shall undertake to ELAN, in terms reasonably satisfactory to ELAN, to protect the confidentiality of ELAN's patents, manufacturing processes and/or any other industrial property rights (including the ELAN PATENT RIGHTS and ELAN KNOW-HOW). Thereafter, the parties shall negotiate in good faith a technology transfer program ("Program") consistent with this Agreement. Such program shall have due regard to the commercial interests of both parties in relation to the manufacture of PRODUCT and shall be such that the Program will be completed with due dispatch but without undue disruption to ELAN's other commercial activities, provided further that such program shall last not longer than [ \* ] from its commencement.

- 14.2** At COMPANY's request, it shall be part of the Program that ELAN shall assist in qualifying the Second Source as an alternative site of manufacture of PRODUCT. Pursuant to this obligation ELAN shall:
- 14.2.1** Provide COMPANY with any technical data necessary to qualify the Second Source. To this end, ELAN shall impart to COMPANY the documentation constituting the required material support, more particularly practical performance advice, shop practice and specifications as to materials to be used and control methods;
  - 14.2.2** Assist COMPANY with the working up and use of the technology and with the training of personnel which may reasonably be necessary in relation to the manufacture of PRODUCT by or on behalf of COMPANY.
- 14.3** In the event that personnel from COMPANY or from an approved third party manufacturer visit ELAN's premises, or personnel from ELAN, visit the premises of COMPANY or of an approved third part manufacturer, for the purpose of enabling COMPANY or such approved third party to manufacture PRODUCT, then:
- (a) the party whose premises are visited shall take such steps to protect those personnel from physical injury in the course of the visit as it takes with its own personnel (but not less than the standard required by law); but;
  - (b) the visiting party shall ensure that those personnel are adequately trained in safety relating to pharmaceutical manufacturing generally, and that those personnel conduct themselves lawfully and in compliance with this Agreement.

**14.4** COMPANY may acquire the following quantities of PRODUCT from the Second Source and accordingly, if so purchased, COMPANY shall have no obligation to purchase such quantities from ELAN and ELAN shall have no obligation to supply such quantities to COMPANY:

**14.4.1** Such quantities of PRODUCT as are required to be produced in order to maintain any registration with the FDA or other relevant regulatory agency so as to permit PRODUCT to be manufactured at the Second Source;

**14.4.2** Such further quantities of PRODUCT to make up any portion of a valid purchase order where, and for so long as the following conditions exist:

- (i) ELAN fails to supply PRODUCT which has been ordered by COMPANY for a period exceeding [ \* ] days from the receipt of a firm purchase order; or
- (ii) There are delays in filling each of [ \* ] successive orders which delays cumulatively exceed [ \* ] when each delay is measured beginning on the [ \* ] day from receipt of the corresponding firm purchase order; or
- (iii) There is a shortfall in [ \* ] successive orders delivered by ELAN which on a cumulative basis, exceeds [ \* ] percent ([ \* ]%) of the total amount of said [ \* ] orders;

PROVIDED such failure, delay or shortfall is not caused by COMPANY or any other supplier of the Compound or other raw materials and PROVIDED FURTHER that ELAN, having received written notice from COMPANY, has not remedied the failure, delay or shortfall within a further period of [ \* ] days from said notice.

**14.5** In respect, of the establishment, qualification and operation of the Second Source, COMPANY shall be solely responsible for:

**14.5.1** COMPANY's own costs and expenses;

**14.5.2** All third party costs and expenses including reasonable out of pocket expenses incurred by ELAN; and

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14.5.3 Work contracted by ELAN, its Affiliates and their employees and consultants under the Program in accordance with ELAN's [ \* ].

14.6 The provisions, of the Article IV, Section 14 [ \* ].

14.7 The parties acknowledge and confirm that to the extent that COMPANY is permitted hereunder to purchase PRODUCT from the Second Source, such right is by virtue of COMPANY's right under this Agreement to "have manufactured" PRODUCT. Nothing herein shall be deemed to permit COMPANY to sub-license the right to manufacture or have manufactured PRODUCT. "

5.3 By the deletion of Article IV Sections 18 and 19 and their replacement with the following:

"18. At any time during term of this Agreement, ELAN shall be entitled to notify COMPANY of [ \* ]. If it notifies COMPANY, ELAN's [ \* ]:

- (i) the Second Source received the necessary governmental approvals to manufacture PRODUCT, and demonstrated its capability to manufacture the quantities of PRODUCT necessary to meet current forecasts in effect at that time, or
- (ii) if earlier, [ \* ] from the [ \* ], or
- (iii) if earlier, [ \* ] from the [ \* ].

In such an event, the parties confirm that the provisions of Article V, paragraph 3.6 shall apply to the sale of PRODUCT manufactured by COMPANY or a permitted third party manufacture.

"19. In the event that ELAN gives notice [ \* ] after the [ \* ], then:

19.1 As from [ \* ] after the [ \* ] until such [ \* ], COMPANY shall pay to ELAN [ \* ] in that calendar quarter.

19.2 For this purpose, [ \* ] means the [ \* ].

19.3 The "applicable price" of such [ \* ] shall be the price of [ \* ]mg capsules as set out in Article V, Section 5.1, as adjusted.

19.4 In respect of the first and last calendar quarters in respect of which the [ \* ] is payable, the [ \* ] shall be reduced proportionately by reference to the period before or after the applicability of the [ \* ], as appropriate.

19.5 In respect of the final calendar quarter of each calendar year or the final calendar quarter in which the [ \* ] is payable, the parties

shall conduct a reconciliation such that the aggregate of [ \* ] in that calendar year shall be the applicable price of the [ \* ] for the whole calendar year.

19.6 For the avoidance of doubt, ELAN shall not be obliged to give any credit or make any payment in respect of any [ \* ], except as set out in paragraph 19.5, nor shall COMPANY be entitled to set any such [ \* ] in a given year against [ \* ].

19.7 The [ \* ] may be invoiced at the end of a calendar quarter and shall be payable within thirty (30) days.”

5.4 By the deletion of Article IV, Section 20 in its entirety.

5.5 By replacing each occurrence in Article IV, Section 21 of the words “[ \* ] days” with the words “[ \* ] days”, and the words “[ \* ] days” with the words “[ \* ] days”.

## **6. Miscellaneous and Consequential Amendments**

ELAN and COMPANY hereby agree that the Original Agreement is hereby further amended with effect from the Amendment No. 3 Date as follows:

6.1 By amending Article XII as follows:

6.1.1 by insertion in Article XII Section 5.2.1 after the word filing of a full stop and a new sentence: “Notwithstanding the bankruptcy of ELAN, or the impairment of performance by ELAN of its obligations under this Agreement as a result of bankruptcy or insolvency of ELAN, COMPANY shall be entitled to retain the licenses granted herein, subject to ELAN’s rights to terminate this Agreement for reasons other than bankruptcy or insolvency as expressly provided for.”

6.1.2 by deletion of Section 5.2.2; 5.2.3 and 5.2.4 of Article XII in their entirety.

6.1.3 by the insertion in Article XII Section 5.3 after the words “terminate this Agreement” of the words “in whole or with respect to one or more countries of the TERRITORY”;

6.1.4 by the deletion from Article XII Section 5.3 of the third, fourth and fifth sentences, which is to say the passage beginning “In the event that COMPANY so elects to terminate ...” through the end of that Section;

6.1.5 by the deletion in Article XII of Sections 5.5.5.; 5.5.6 and 5.5.7 and 5.6 in their entirety.

6.1.6 by the deletion of Article XII Section 13.1 and the substitution therefor of the following:

“13.1. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or fax to:

- ELAN at

Elan Corporation plc.  
Treasury Building  
Lower Grand Canal Street  
Dublin 2  
Ireland.

Attention: Vice President, Commercial Management  
Fax: 353 1 709 4700



with a courtesy copy (receipt of which shall not constitute notice) to:

Elan Corporation plc.  
Monksland  
Athlone  
County Westmeath  
Ireland

Attention: Vice President & Legal Counsel, Elan Drug Technologies  
Fax: +353 90 64 95350

COMPANY at

Solvay Pharmaceuticals, Inc.  
901 Sawyer Road,  
Marietta, Georgia 30062,  
United States of America.

Attention: Senior Vice President, Law, Government & Public Affairs  
Fax: +1 770 578 5749

or to such other address(es) and fax numbers as may from time to time be notified by either party to the other hereunder.

“13.2 Any notice sent by mail shall be deemed to have been delivered within seven (7) working days after despatch and any notice sent by fax shall be deemed to have been delivered within twenty four (24) hours of the time of the despatch. Notice of change of address shall be effective upon receipt.”

6.2 Amending Article II:

6.2.1 By deleting from Article II Section 6.2.1 the words “once commercial sale of PRODUCT commences” and replacing them with the words “a reasonable time prior to the commencement of commercial sale in any given country of the TERRITORY”; and

- 6.2.2 By deleting from Article II, Section 12 the words “In consideration for the royalty which may be payable under Article V, paragraph 3.8.” and replacing them with the words “In consideration for the fees and royalty which may be payable under Article V, paragraph 3.7”.
- 6.3 By inserting the following new Article III, Sections 15 to 17:
- “15. In the event that [ \* ], ELAN and COMPANY shall meet to discuss how to proceed, and any appropriate amendments to this Agreement, in good faith.
16. ELAN agrees to manufacture [ \* ] commercial batches of each dosage strength of the PRODUCT for the purposes of process validation, and to conduct validation sampling and testing in respect thereof in accordance with the protocol to be agreed. In respect thereof, COMPANY shall pay to ELAN US\$[ \* ], payable upon delivery. Subject to applicable law, COMPANY may use such process validation batches for commercial purposes, and for the avoidance of doubt if it does so, no further amount shall be payable under Article V, Section 5 (but without prejudice to any royalties). The parties shall additionally discuss in good faith stability requirements, and payment for work conducted by ELAN in respect thereof.
17. For the avoidance of doubt, [ \* ] shall be [ \* ] responsible for all costs associated with the proposed change in the manufacturer and manufacturing process for the COMPOUND in progress or to be progressed following the Amendment No. 3 Date, including any work conducted by ELAN on the basis set out in [ \* ].
18. As of the Amendment No. 3 Date, it is the parties’ expectation that the [ \* ]mg dosage strength of the PRODUCT will not be developed or produced. In the event that FDA requests the development of the [ \* ]mg dosage strength, the parties shall consult to agree an appropriate response to FDA in respect thereof. If, following such response, FDA still requires the development of the [ \* ]mg dosage strength, the parties shall negotiate a development plan therefor in good faith. Such development shall be [ \* ].”
- 6.4 By deleting from Article IV, Section 25 the words “and keep such COMPOUND separate and apart from other raw materials”.
- 6.5 By deleting Article VI, Section 3 and replacing it with the following:
- “3. Each party shall notify the other as soon as possible of any notification received by that party from the FDA, or any other regulatory authority to conduct an inspection of its manufacturing or other facilities used in the manufacturing, packaging, storage or handling of the COMPOUND or the PRODUCT.”

---

**7. Other Provisions**

Notwithstanding anything to the contrary in the Original Agreement and any Amendment thereof, subject to the allocation of responsibilities in Schedule A, COMPANY shall bear all cost and expenses of [ \* ] required under the Original Agreement or any Amendment thereto.

**8. No Other Amendment to Original Agreement**

Except as modified herein, all of the covenants, terms and conditions of the Original Agreement remain in full force and effect and are hereby ratified and reaffirmed in all respects. In the event of any conflict, inconsistency or incongruity between the terms and conditions of this Amendment and the covenants, terms and conditions of the Original Agreement, the terms and conditions of this Amendment shall govern and control.

**9. Counterparts**

This Amendment may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Amendment.

**10. Governing Law and Jurisdiction**

This Amendment shall be governed by the laws of the State of Georgia. Any dispute arising in relation to it shall be resolved in the same manner as a dispute under the Original Agreement.

**IN WITNESS WHEREOF** the parties hereto have executed this Agreement

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**SIGNED**

/s/ William F. Daniel

for and on behalf of

**ELAN CORPORATION, PLC.**

**SIGNED**

/s/ Laurence J. Downey, M.D.

for and on behalf of

**SOLVAY PHARMACEUTICALS INC.**

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**Schedule A**  
**Fluvoxamine CR Activities to NDA refiling /approval**

**I ELAN RESPONSIBILITIES**

Preparation for Stability Batches including ordering, testing & release of raw materials, updating batch manufacturing records, relevant SOPs, protocols.  
Manufacture, Test, Release batches of [ \* ]mg & [ \* ]mg with the proposed commercial manufacturing process. (Note: [ \* ] batches of each strength to be manufactured. Solvay to bear costs of [ \* ])  
Stability of bulk product: components and finished product for both [ \* ]mg  
Stability of Packaged Product in [ \* ] of both [ \* ]mg and [ \* ]mg strengths. (Note: [ \* ] to bear the costs of [ \* ])  
[ \* ] for Proposed Commercial manufacturing process, should the FDA insist on it  
Update US DMF, including revisiting current NDA filing requirements, specifications justification, updating analytical protocols, stability reports, development report and MBRs  
[ \* ] prior to process validation  
Process Validation for proposed commercial manufacture (at [ \* ] expense as set out in Article III, Section 16 of the Agreement as amended)  
Pre Approval Inspection preparation  
Responses to FDA on CMC aspects of the filing

**II SOLVAY RESPONSIBILITIES**

Provide API for pre-validation / engineering, stability and validation batches  
Carry out any [ \* ] required under current NDA filing requirements e.g. [ \* ]  
[ \* ]  
Refiling the NDA

---

**III EXCLUDED FROM ACTIVITIES TO REFILING / APPROVAL OF NDA**

1. Qualification of an alternate source of API
2. Any additional activities requested by [ \* ]

For the avoidance of doubt, [ \* ] will bear all costs and expenses relating to activities at III, 1 to 2 above in the event they occur.

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**XYREM®**

**Manufacturing Services and Supply Agreement**

**Between**

**Patheon Pharmaceuticals Inc.**

**and**

**Jazz Pharmaceuticals, Inc.**

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**MANUFACTURING SERVICES AND SUPPLY AGREEMENT**

THIS MANUFACTURING SERVICES AND SUPPLY AGREEMENT (the "Agreement") made as of the 13th day of March, 2007, and with an Effective Date and a Manufacturing Commencement Date as set forth below.

B E T W E E N:

**PATHEON PHARMACEUTICALS INC.**,  
a corporation existing under the laws of the  
State of Delaware,  
(hereinafter referred to as "**Patheon**"),

- and -

**JAZZ PHARMACEUTICALS, INC.**,  
a corporation existing under the laws of the State of Delaware,  
(hereinafter referred to as the "**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

**ARTICLE 1**

**INTERPRETATION**

**1.1 Definitions.**

The following terms shall have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

"**Act**" means the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

"**Active Material**" means the active pharmaceutical ingredient listed on Schedule D hereto;

"**Active Material Reimbursement Value**" means the actual cost to Client of the Active Materials for the purposes of Section 10.2(b) of this Agreement as set forth in Schedule D hereto and as may be amended from time to time by the Client to reflect the actual cost of such Active Materials paid by the Client;

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"**Affiliate**" means:

- (a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or
- (b) a business entity which is controlled by a party to this Agreement either directly or indirectly, by stock ownership or otherwise.

For the purposes of this definition, "control" means the ownership of shares carrying at least a majority of the votes in respect of the election of the directors of a corporation. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of the Client such as financial institutions, venture capital funds and private equity investors will not be its "Affiliates" for purposes of this Agreement;

"**Annual Volume**" means the volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B hereto.

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"**Batch**" means a specific quantity of Active Material and Components that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"**Bulk Product**" means unlabeled bottled and capped Product packaged in accordance with the applicable packaging configurations as set forth in the Specifications and Schedule M hereto which, prior to the Manufacturing Commencement Date, will be packaged in shippers by current supplier of Product and then delivered to Patheon for secondary packaging only;

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the State of Ohio which have been provided in writing to the Client by Patheon;

"**cGMPs**" means current good manufacturing practices, as applicable, as described in:

- (a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;
- (b) Division 2 of Part C of the Food and Drug Regulations (Canada);
- (c) EC Directive 91/356/EEC; and

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(d) the latest Health Canada, FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, as updated, amended and revised from time to time and as applicable under the particular circumstances;

"**Components**" means, collectively, all packaging components, raw materials and ingredients, required to be used in order to produce the Product in accordance with the Specifications, other than the Active Material;

"**Deficiency Notice**" shall have the meaning ascribed thereto in Section 6.1(a);

"**DEA**" means the United States Drug Enforcement Administration or its international counterparts.

"**Effective Date**" means March 13, 2007 unless revised by mutual written agreement of the parties in accordance with this Agreement.

"**EMA**" means the European Medicines Agency or any successor European governmental agency performing similar functions with respect to pharmaceutical products;

"**FDA**" means the United States government department known as the Food and Drug Administration or any successor United States governmental agency performing similar functions with respect to pharmaceutical products;

"**Firm Orders**" has the meaning specified in Section 5.1(b);

"**Fully Packaged Product**" means the Product packaged in accordance with the applicable packaging configurations as set forth in the Specifications and Schedule L hereto.

"**Health Canada**" means a section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and Health Products and Food Branch Inspectorate or any successor Canadian governmental agency performing similar functions with respect to pharmaceutical products;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyright and industrial designs;

"**Invention**" means information relating to any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon in connection with the manufacture of the Product but, for greater certainty, does not include the Active Material;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority applicable to the activities hereunder;

"**Manufacturing Commencement Date**" means a date certain, specified in a written notice from Client to Patheon delivered at least sixty (60) days prior to such date, when Patheon will commence Manufacturing Services to manufacture and package Product hereunder.

"**Manufacturing Services**" means (i) during the period commencing on the Effective Date and ending on the day immediately preceding the Manufacturing Commencement Date, the Packaging Services only; and (ii) during the period commencing on the Manufacturing Commencement Date and throughout the term of this Agreement, all of the manufacturing, quality control, quality assurance and stability testing, packaging and related services, as contemplated in this Agreement, required to produce Product from the Active Material and Components;

"**Manufacturing Site**" means the US facility owned and operated by Patheon that is located at [ \* ];

"**Minimum Run Quantity**" means the minimum number and size of Batches of Product to be produced during the same cycle of manufacturing as set forth in Schedule B hereto;

"**NDA**" means a New Drug Application for the Product made in accordance with applicable regulations and requirements of the FDA as from time to time in effect;

"**Packaging Services**" means the packaging and related services performed or to be performed by Patheon hereunder to accept Bulk Product and package it into Fully Packaged Product after the Effective Date and prior to the Manufacturing Commencement Date.

"**Patheon Manufacturing Responsibilities**" means Patheon's responsibilities and obligations with respect to the provision of Manufacturing Services as set forth in Sections 2.1 and 2.2;

"**Product**" means the product listed on Schedule A hereto;

"**Quality Agreement**" means the agreement entered into between the parties hereto setting out the quality assurance standards to be applicable to the Manufacturing Services provided by Patheon, which agreement shall be in the form attached hereto as Schedule E;

"**Quota**" means the procurement quota quantity of Active Material allotted by the DEA to Patheon in order for Patheon to perform the Manufacturing Services.

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**“Regulatory Filings”** means the NDA and any other filing under the United States Federal Food, Drug and Cosmetic Act and rules and regulations thereunder, and any corresponding filing required in other countries and jurisdictions (including, without limitation, the EMEA), in connection with the registration, manufacturing, sale and use of the Product, other than local or federal permits required to be obtained by Patheon in connection with performance of the Manufacturing Services.

**“Specifications”** means the file, for the Product, which is provided by the Client to Patheon in accordance with the procedures listed in Schedule A hereto and which contains documents relating to such Product, including, without limitation:

- (a) specifications for the Active Material and Components;
  - (b) manufacturing specifications, vendors, directions and processes;
  - (c) storage requirements;
  - (d) environmental, health and safety information relating to the Product including material safety data sheets; and,
  - (e) the finished Product specifications, applicable packaging specifications and shipping requirements for each Product;
- all as updated, amended and revised from time to time by the Client in accordance with the terms of this Agreement;

**“Technical Dispute”** has the meaning specified in Section 12.2;

**“Territory”** means the entire world;

**“United States”** means the United States of America, its territories and possessions, including Puerto Rico and the U.S Virgin Islands; and

**“Year”** means in the first year of this Agreement, the period from the Commencement Date up to and including December 31 of the same calendar year, and thereafter shall mean a calendar year.

## **1.2 Currency.**

Unless otherwise specifically provided herein, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

### **1.3 Sections and Headings.**

The division of this Agreement into Articles, sections, subsections and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise specifically provided herein, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement and not to any particular part, Section, Schedule or the provision hereof.

### **1.4 Singular Terms.**

Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa.

### **1.5 Schedules.**

The following Schedules are attached to, incorporated in and form part of this Agreement:

Schedule A	Product Specifications
Schedule B	- Minimum Run Quantity, Annual Volume, Fees & Price Adjustments
Schedule C	- Stability Testing
Schedule D	- Active Material & Active Material Reimbursement Value
Schedule E	- Batch Numbering & Expiration Dates
Schedule F	- Technical Dispute Resolution
Schedule G	- Quality Agreement
Schedule H	- Quarterly Active Materials Inventory Report
Schedule I	- Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Schedule J	- Form of Exclusive Components Purchasing Summary
Schedule K	- Bill-Back Items
Schedule L	- Packaging Configurations for Full Packaged Product
Schedule M	- Packaging Configurations for Bulk Package Product

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ARTICLE 2

MANUFACTURING SERVICES

**2.1 Manufacturing Services.**

Patheon shall provide the Manufacturing Services for the fees specified in Schedules B and C. Patheon may change the Manufacturing Site for the Product only with the prior written consent of Client. None of the Manufacturing Services may be subcontracted by Patheon without the Client's prior written consent.

Client shall specify the Manufacturing Commencement Date by [ \* ] days' written notice to Patheon. For clarity, the parties acknowledge that the Manufacturing Commencement Date is conditioned upon (i) the approval of Patheon as a manufacturer of the Product, including approval of Patheon's facility by the FDA and any other applicable regulatory Authority, (ii) receipt of appropriate Quota and (iii) [ \* ] of Client's [ \* ],

During the period from the Effective Date through the day immediately preceding the Manufacturing Commencement Date, Patheon shall perform Packaging Services for Bulk Product on a non-exclusive basis in accordance with the description of services below as applicable to Packaging Services.

From and after the Manufacturing Commencement Date, Patheon shall perform the Manufacturing Services set forth below. The Client shall purchase (A) its entire requirements of [ \* ] and [ \* ] for distribution in [ \* ]; provided, however, that the Client may establish other third party suppliers as additional manufacturers of the Product for [ \* ], and may purchase Product from such manufacturers, if [ \* ] pursuant to the terms and conditions of this Agreement and (B) [ \* ] for distribution in [ \* ], in each case, from Patheon pursuant to the terms of this Agreement. In providing the Manufacturing Services, Patheon shall perform the following services:

- (a) Conversion of Active Materials and Components. Patheon shall convert Active Material and Components into Product.
- (b) Quality Control and Quality Assurance of Product manufactured by Patheon. Patheon shall perform the quality control and quality assurance testing specified in the Quality Agreement. Each time Patheon ships Product to the Client, it shall provide the Client with a certificate of analysis that sets out the test results for each Batch of Product, and that certifies that such Batch has been evaluated by Patheon's Quality Control/Quality Assurance department and that the Product complies with the Specifications and was manufactured in accordance with cGMPs. Patheon shall test or cause to be tested each Batch of Product to be supplied pursuant to this Agreement, in accordance with the testing

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methods for the Product set forth in the Specifications, before delivery of such Batch to the Client. Notwithstanding the foregoing, the Client reserves the right to test or have tested all Product supplied by Patheon and pursuant to Section 6.1 hereof to reject any Product that fails to comply with the Specifications or Product that is not made in accordance with cGMPs.

(c) Testing of Components and Active Material.

- (i) Components. Patheon shall purchase and test all Components at Patheon's expense and as specified by the Specifications. The Client will have the right to specify the suppliers for the Components. Patheon shall not change any Specifications or supplier of such Components without the prior written consent of the Client.
- (ii) Active Material. Promptly following receipt of the Active Material to be supplied by Client, Patheon will test (pursuant to test methods and drug specifications to be provided by the Client) and approve such Active Material as acceptable for performing Manufacturing Services under this Agreement. Patheon will notify the Client in writing within [ \* ] days of receipt of any failure of Active Material unless earlier notice is required by Law; absent any such notice Active Material will be deemed to be accepted and approved by Patheon.

(d) Stability Testing. Patheon shall conduct stability testing on the Product in accordance with agreed upon protocols and Specifications in Schedule C. Patheon shall not make any changes to these Specifications or testing protocols without prior written approval from the Client. Patheon will promptly provide any and all data and results relating to the stability testing upon request by the Client. In the event that any Batch of the Product fails, or is suspected to fail, stability testing, Patheon will notify the Client within one Business Day and Patheon and the Client shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure.

(e) Packaging. During the period between the Effective Date and the Manufacturing Commencement Date, Patheon shall convert Bulk Product into Fully Packaged Product for the Client in accordance with the applicable Specifications from time to time as requested by Client. From and after the Manufacturing Commencement Date, Patheon shall package Bulk Product and Fully Packaged Product, as specified by Client in its purchase orders, each in accordance with the applicable Specifications. In addition, Patheon shall assign Batch numbers and expiration dates for all Product shipped, if applicable. Such Batch numbers and expiration dates shall be affixed on the Product and on the shipping cartons, as applicable, of each Product as outlined in the Specifications and as required by cGMPs. The system used by Patheon for Batch numbering and expiration dates of Product manufactured by Patheon is detailed in the Quality Agreement attached hereto as Schedule G. The Client may, in its sole discretion, make changes to labels, product inserts and other

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packaging for the Product. Patheon's name shall not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) [ \* ] expressly consents to such use of its name in writing.

- (f) Active Materials and Client Supplied Components Importing. The Client will deliver all Active Materials and Components which Client is responsible for supplying (if any) to Patheon [ \* ] (INCOTERMS 2000).
- (g) Bill-Back Items. The expenses in respect of all third party supplier fees for the purchase of columns, standards, tooling, and other project specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components, shall be set forth on Schedule K hereto, as may be amended from time to time by the written consent of both parties, and charged to the Client at [ \* ].

## **2.2 Standard of Performance.**

Patheon shall provide the Manufacturing Services in accordance with the Specifications, all applicable Laws and cGMPs.

## **2.3 Active Material Reports and Quota.**

(a) Reporting. Patheon shall provide the Client with a quarterly inventory report of the Active Materials held by Patheon in accordance with the inventory report form annexed hereto as Schedule H, which shall contain the following information for such quarter:

**Quantity Received:** The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

**Quantity Dispensed:** The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications and is held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications and is held at the end of such period. The Quantity Dispensed shall only include Active Materials received and dispensed in connection with commercial manufacturing of Product and, for certainty, shall not include any Active Materials received or dispensed in connection with technical transfer activities or development activities during the applicable period, including, without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

**Quantity Converted:** The total amount of Active Materials contained in the Product produced with the [ \* ] (including any [ \* ] in accordance with [ \* ]), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 as a result of a failure by Patheon to provide Manufacturing Services in accordance with Specifications, cGMPs and all applicable Laws.

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(b) Quota. The parties acknowledge that the Active Material is scheduled under the Federal Controlled Substances Act. Patheon is required to obtain a Quota from the DEA before producing Product. In that regard, throughout the term hereof, Patheon will submit to DEA in a timely manner all necessary documents to obtain a Quota sufficient to meet Client's forecasts made pursuant to Section 5.1(a). Additional request(s) will be submitted by Patheon to DEA in a timely manner as necessary to reflect changes in Client's forecast requirements of Active Material and Product. Patheon further agrees to [ \* ] obtain a Quota from the DEA that allows Patheon to manufacture all of Client's forecasted requirements for Product including cooperating with the Client in connection with any discussions with the DEA regarding a Quota. PATHEON ACKNOWLEDGES THAT TIME IS OF THE ESSENCE IN PERFORMING ITS OBLIGATIONS UNDER THIS PROVISION.

(c) Unused Active Material; Reports. Patheon will use [ \* ] to avoid any loss of Active Material. If and to the extent that Active Material is spilled, lost, scrapped or otherwise unusable hereunder, Patheon will dispose of such Active Material in accordance with applicable regulations and will prepare all necessary disposal reporting documents and furnish such to DEA in accordance with applicable regulations and take such steps as are necessary to reclaim such lost amounts of Active Material for the Quota in the same Quota year any such loss occurs. In the event of any diversion of Active Material, Patheon will prepare all required diversion reports and will, contemporaneously with the filing thereof with DEA in accordance with applicable regulations, provide a copy to Client.

(d) Registrations. Patheon will acquire and maintain current DEA registrations required to manufacture, hold, import and export Product

(e) Volumes Constrained by Quota. Notwithstanding any other provision of this Agreement, in the event of any inconsistency or conflict between this Agreement and any terms or provisions hereof relating to quantity of Product to be ordered, manufactured, purchased or sold under this Agreement, applicable law and regulations relating to Quota shall control.

### ARTICLE 3

#### CLIENT'S OBLIGATIONS

##### 3.1 Payment

Pursuant to the terms of this Agreement, the Client shall pay Patheon for the provision of the Manufacturing Services according to the fees specified in Schedules B and C hereto (such fees being subject to adjustment in accordance with the terms hereof).

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### **3.2 Active Materials.**

The Client shall [ \* ], deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) in sufficient quantities and at such times to facilitate the provision of the Manufacturing Services by Patheon. The Active Materials shall be [ \* ] by Patheon [ \* ] on the terms and subject to the conditions herein contained. [ \* ] shall pay [ \* ] \$[ \* ] per [ \* ] (each [ \* ] to hold [ \* ]), per [ \* ] for [ \* ] Active Materials in [ \* ] plus a [ \* ]. The parties acknowledge and agree that title to the Active Materials shall [ \* ] the property of [ \* ]. Any Active Materials received by it shall only be used by Patheon to provide the Manufacturing Services. Patheon's liability with respect to any lost or damaged Active Materials shall be as set forth in Section 10.2(b).

## **ARTICLE 4**

### **CONVERSION FEES AND COMPONENT COSTS**

#### **4.1 Pricing.**

The fees for the Manufacturing Services (which fees include [ \* ]) shall be as set forth in Schedules B and C and are subject to the adjustments set forth therein and in Section 4.2 hereof. Subsequent Year's pricing, and adjustments to pricing, are set forth in Schedule B hereof.

#### **4.2 Adjustments Due to Technical Changes.**

For changes to the Specifications or manufacturing processes that are required by applicable Laws ("**Required Manufacturing Changes**"), Patheon and the Client shall cooperate in making such changes and use commercially reasonable efforts to implement such changes promptly in a manner that minimizes any effect on the supply hereunder to the Client of Product meeting Specifications. All costs associated with Required Manufacturing Changes directly related to the [ \* ] shall be borne by [ \* ]. All other costs associated with Required Manufacturing Changes under this Agreement, including, without limitation, obsolete Components, Regulatory Filings, work in process, equipment and Product shall be borne by [ \* ]. Amendments to the Specifications or the Quality Agreement requested by the Client that are not Required Manufacturing Changes ("**Client Requested Changes**") will only be implemented following [ \* ] necessitated by any such amendment. Amendments to the Specifications, the Quality Agreement or the Manufacturing Site requested by Patheon that are not Required Manufacturing Changes ("**Patheon Requested Changes**") will only be implemented following the approval of Client, [ \* ], and the costs of the Patheon Requested Changes will be borne by [ \* ]. If the Client accepts a proposed fee change, the proposed change in the Specifications shall be implemented, and the fee change shall become effective only with respect to those orders of the Product that are manufactured in accordance with the revised Specifications. In addition, with respect to the [ \* ] Requested Changes, the [ \* ] agrees to purchase, at [ \* ] (including all costs incurred by [ \* ] in connection with the purchase and handling of such [ \* ]), all [ \* ] utilized under the [ \* ] Specifications and purchased or maintained by Patheon in order to fill Firm Orders or in accordance with Section 5.2, to the extent that such [ \* ] can [ \* ] under the revised Specifications. Open purchase orders for

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Components no longer required under any revised Specifications that were placed by Patheon in accordance with this Agreement with suppliers in order to fill Firm Orders or in accordance with Section 5.2 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be [ \* ].

## ARTICLE 5

### ORDERS, SHIPMENT, INVOICING, PAYMENT

#### **5.1 Orders and Forecasts.**

(a) Rolling Forecasts. The Client shall provide Patheon with a written non-binding [ \* ] forecast of the volume of each Product that the Client then anticipates will be required to be produced and delivered to the Client during each [ \* ] of that [ \* ] period. Such forecast will be updated by the Client [ \* ] on or before the [ \* ] day of each [ \* ] on a rolling [ \* ] basis. The most recent [ \* ] forecast shall prevail.

(b) Firm Orders. On or before the [ \* ] day of each [ \* ] the Client shall issue firm written orders ("**Firm Orders**") for the Product from time to time at Client's discretion to be produced and delivered to the Client on a date not less than [ \* ] from the [ \* ] the date that the Firm Order is submitted. Such Firm Orders submitted to Patheon shall specify the Client's purchase order number, quantities by Product, type of packaging, delivery schedule and any other elements necessary to ensure the timely production and shipment of the Product. The quantities of Product ordered in such written orders shall be firm and binding on the Client. Notwithstanding the foregoing, and subject to the availability of required Components, Patheon will permit amendments and substitutions to Firm Orders issued by the Client upon prior written notice to Patheon in respect of Product packaging; provided, however no amendments or substitutions will be accepted by Patheon once [ \* ], as the case may be, has commenced.

(c) Acceptance. Firm Orders placed with Patheon by the Client pursuant to the provisions of Section 5.1(b) shall be acknowledged by Patheon in writing within [ \* ] days of receipt thereof. Patheon will [ \* ] ensure that all Product ordered by the Client in accordance with this Agreement will be shipped in accordance with the delivery dates specified in the Client's purchase order but in no event shall the [ \* ] delivery date be [ \* ] from the [ \* ], and Patheon will notify the Client promptly of any significant anticipated delay no later than [ \* ] prior to such delivery date.

#### **5.2 Reliance by Patheon.**

The Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted pursuant to Sections 5.1(a) and (b) in ordering the Components required to meet such Firm Orders. In addition, the Client understands that to ensure an orderly supply of such Components, it may be desirable for Patheon to purchase such Components in sufficient volumes to meet the production requirements for Product during [ \* ] of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed in writing to by Patheon and the

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Client. Accordingly, the Client authorizes Patheon to purchase Components in order to satisfy the production requirements for Product for the first [ \* ] contemplated in the most recent forecast provided by the Client pursuant to Section 5.1(a) and agrees that Patheon may make such other purchases of Components to meet production requirements during such longer periods as may be agreed to in writing from time to time by the Client at the request of Patheon or the Client. If Components ordered by Patheon pursuant to Firm Orders under this Section 5.2 are not included in finished Product purchased by the Client within [ \* ] after the date of the Firm Order in respect of which such purchases have been made (or such longer period as the parties may agree) or if such Components have expired during such period, then [ \* ]; provided, however, that in the event such Components are incorporated into Product subsequently purchased by the Client or into third party products manufactured by Patheon and subsequently purchased by a third party, the [ \* ] of such Components [ \* ].

Patheon shall provide Client, initially upon execution of this Agreement and thereafter on an annual basis, with a listing of all Components which Patheon anticipates purchasing pursuant to the terms of this Agreement in the form set out in Schedule J (the "**Components Purchasing Summary**"). Patheon will advise the Client in writing which Components have a limited shelf-life and which are subject to minimum order quantities specified by the supplier. [ \* ] for the [ \* ] Components [ \* ] purchased by Patheon in accordance with the terms of this Agreement but not used to perform the Manufacturing Services prior to the expiry of the Component's shelf life, so long as such Components have expiration dating of at least [ \* ] from the date of purchase by Patheon. If Patheon is able to use such Components in activities other than the Manufacturing Services, Patheon will [ \* ] the Client any [ \* ] for such Components.

### **5.3 Minimum Orders.**

The Client may only order Product in multiples of the Minimum Run Quantities set out in Schedule B.

### **5.4 Shipments.**

Shipments of Product shall be made [ \* ] (as such term is defined in INCOTERMS 2000) Patheon's shipping point unless otherwise mutually agreed to in writing by the parties. Risk of loss or of damage to Product shall remain with Patheon until [ \* ] at which time risk of loss or damage shall transfer to the Client. Patheon shall, in accordance with the Client's instructions and as agent for the Client, (i) arrange for shipping to be paid by the Client and (ii) at the Client's risk and expense, obtain any export licence or other official authorization necessary to export the Product from the US. The Client shall arrange for insurance and shall select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Product shall be transported in accordance with the Specifications and other applicable Laws.

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## **5.5 Invoices and Payment.**

Invoices shall be sent by fax or e-mail to such fax number or e-mail address as may be provided by the Client in writing from time to time but no earlier than [ \* ]; provided, however, that if Client requests Patheon to hold or store Bulk Product or Fully Packaged Product for more than [ \* ] after completion of the applicable Manufacturing Services, Patheon may invoice Client for any such Product [ \* ]. Patheon shall also submit to the Client, with each shipment of Product, a duplicate copy of the invoice covering such shipment. Patheon shall also provide the Client with an invoice covering [ \* ] pursuant to the terms and conditions of this Agreement and, in accordance with Section [ \* ]. Each such invoice shall, to the extent applicable, identify the Client purchase order number, Product numbers, names and quantities, unit price, freight charges and the total amount to be remitted by the Client. The Client shall pay all such invoices within thirty (30) days of the date thereof. Notwithstanding the foregoing, the Client may withhold any amounts invoiced by Patheon that it disputes. If the Client disputes any invoice, the Client shall within [ \* ] after such invoice is furnished to it notify Patheon that it disputes the accuracy or appropriateness of such invoice and specify the particular respects in which such invoice is inaccurate or inappropriate. The Client and Patheon will make good faith efforts to resolve any disputes within [ \* ] thereafter. Any amounts that are disputed by the Client shall not be due until [ \* ] following the resolution of such dispute.

## **ARTICLE 6**

### **PRODUCT CLAIMS AND RECALLS**

#### **6.1 Product Claims.**

(a) **Product Claims.** The Client has the right to reject any portion of any shipment of Product that deviates from the Specifications or cGMPs, without invalidating any remainder of such shipment. The Client or its designee shall inspect the Product manufactured by Patheon upon receipt thereof and shall use its commercially reasonable efforts to give Patheon written notice (a "**Deficiency Notice**") of all claims for Product that deviate from the Specifications or cGMPs within [ \* ] after the Client's or its designee's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [ \* ] after discovery thereof by the Client, but in no event after the expiration date of the Product). Should the Client fail to provide Patheon with the Deficiency Notice within the applicable period described above, then the delivery shall be deemed to have been accepted by the Client on the day after the end of the period described above.

(b) **Determination of Deficiency.** Upon receipt of a Deficiency Notice, Patheon shall have [ \* ] to advise the Client by notice in writing that it disagrees with the contents of such Deficiency Notice. If the Client and Patheon fail to agree within [ \* ] after Patheon's notice to the Client as to whether any Product identified in the Deficiency Notice deviates from the Specifications or cGMPs, then the parties shall mutually select a laboratory to evaluate if the Product deviates from the Specifications or cGMPs. Such evaluation shall be binding on the parties, and if such evaluation certifies that any Product deviates

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from the Specifications or cGMPs, the Client may reject such Product in the manner contemplated in this Section 6.1. If such evaluation does not so certify in respect of any such Product, then the Client shall be deemed to have accepted delivery of such Product on the [ \* ] day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [ \* ] day after discovery thereof by the Client, but in no event after the expiration date of the Product).

(c) Patheon Responsibility. In the event the Client rejects Product in accordance with this Section 6.1, and the deviation is determined to arise from Patheon's failure to provide the Manufacturing Services in accordance with Specifications or cGMPs, Patheon will credit the Client's account for Patheon's invoice price to the Client for such defective Product. If the Client shall have previously paid for such defective Product, Patheon shall promptly, at the Client's election, either: (i) refund the invoice price for such defective Product; (ii) offset such amount against other amounts due to Patheon hereunder; or (iii) replace such Product with conforming Product without the Client being liable for payment therefor under Section 3.1, contingent upon the receipt from the Client of all Active Material required for the manufacture of such replacement Product. Subject to the conditions and limitations set out in Section 10.2, Patheon shall be responsible for paying for any Active Material used for the rejected Product under this Section 6.1(c).

(d) Shortages. In the event of a shortage of Product in any shipment by Patheon, at the Client's election, Patheon shall [ \* ] to make up the shortage [ \* ]; provided, however, that if the shortage is more than [ \* ]% of the quantity ordered [ \* ], Patheon will [ \* ] to make up the shortage [ \* ] after the shortage is reported to Patheon, but no later than [ \* ] thereafter, if so requested by the Client, on the following terms: (i) Patheon will manufacture Product in increments of any Minimum Run Quantity listed on Schedule B as determined by the Client and (ii) the [ \* ] such Product will equal the [ \* ] set forth on [ \* ] without regard to [ \* ].

**6.2 Product Recalls and Returns.**

(a) Records and Notice. Patheon and the Client shall each maintain such records as may be necessary to permit a Recall of any Product delivered to the Client or customers of the Client. Each party shall promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Product and/or which might result in the Recall or seizure of the Product. Upon receiving any such notice or upon any such discovery, each party shall cease and desist from further shipments of such Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, shall be made and implemented by the Client. For purposes of this Agreement, "**Recall**" shall mean any action (i) by the Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); or (ii) by any regulatory authorities to detain or destroy any of the Product. Recall shall also include any action by either party to refrain from selling or shipping quantities of the Product to third parties which would have been subject to a Recall if sold or shipped.

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(b) Recalls. In the event (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert with respect to a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders such a Recall, or (iii) the Client determines that any Product should be Recalled or that a “dear doctor” letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by the Client, having regard to all applicable Laws.

(c) Product Returns. The Client shall have the responsibility for coordinating customer returns of the Product. Patheon shall provide the Client with such assistance as the Client may reasonably require to coordinate Product returns.

(d) Patheon's Responsibility. To the extent that a Recall or return results from, or arises out of, a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications and cGMPs, Patheon shall be responsible for the documented out-of-pocket expenses of such Recall or return and shall [ \* ] to replace the Recalled or returned Product with new Product, contingent upon the receipt of all Active Materials required for the manufacture of such replacement Product. In the event that Patheon is unable to replace the Recalled or returned Product (except where such inability results from a failure to receive the required Active Materials due to the fault of Client), then at Client's request, Patheon will reimburse the Client for the price that the Client paid to Patheon for manufacturing the affected Product. In either case, subject to the conditions and limitations set out in Section 10.2, Patheon shall pay all costs related to the Active Materials required for the manufacture of replacement Product. In all other circumstances, Recalls, returns or other corrective actions shall be made at the Client's cost and expense.

(e) Patheon will be responsible for investigating all Recalls and returns (other than as a result of the expiration of such Product) resulting from Patheon's failure to manufacture the Product in accordance with the Specifications and cGMPs, at its own expense, and Patheon will promptly report to the Client in writing the results of any such investigation.

### **6.3 Disposition of Defective or Recalled Product**

The Client shall not dispose of any damaged, defective, returned or Recalled Product in relation to which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct the Client to return such Product to Patheon at Patheon's expense, provided that Client will reimburse Patheon for the cost of such shipping if it is determined that Patheon does not bear any liability for such damaged, defective, returned or Recalled Product. Patheon shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Product in relation to which it bears responsibility under Section 6.1 or 6.2 hereof. In all other circumstances, the Client shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Product.

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**6.4 Customer Questions and Complaints.**

The Client shall have the sole responsibility for responding to questions and complaints from the Client's customers. Questions or complaints received by Patheon from the Client's customers shall be promptly referred to the Client. Patheon shall co-operate as reasonably required to allow the Client to determine the cause of and resolve any customer questions and complaints. Such assistance shall include follow-up investigations, including testing. In addition, within ten (10) days from the date of request, Patheon shall provide the Client with all necessary information in Patheon's possession or control that will enable the Client to respond properly to questions or complaints relating to the Product. If it is determined that the cause of any customer complaint resulted from a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications and cGMPs and any additional procedures agreed upon in writing by Patheon and the Client, or a breach of this Agreement by Patheon, all costs incurred in respect of this Section 6.4 shall be borne by Patheon. In all other circumstances, the Client shall bear the cost incurred with respect to this Section 6.4.

**6.5 Sole Remedy.**

Except for the indemnity provided in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 shall be the Client's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws or any additional procedures agreed upon in writing by the Client and Patheon.

**ARTICLE 7**

**CO-OPERATION**

**7.1 Quarterly Review.**

Each party shall forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers shall meet not less than quarterly to review the current status of the business relationship, including, but not limited to, equipment and facilities updates, current and anticipated manufacturing capacity, planned work or changes to the Manufacturing Site where the Product is being produced and anticipated shut downs of such site, and manage any issues that have arisen.

**7.2 Governmental Agencies.**

Subject to Section 7.7 and the Confidentiality Agreement (as defined in Section 11.1), Patheon may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Product, regarding the manufacture by Patheon of the Product if in the opinion of Patheon's counsel, such communication is necessary to

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comply with the terms of this Agreement or the requirements of any law, governmental order or regulation; provided, however, that unless in the reasonable opinion of Patheon's counsel there is a legal prohibition against doing so, Patheon shall permit the Client to accompany and take part in Patheon's communications with the agency, and to receive copies of all such communications from such agency to Patheon.

### **7.3 Records and Accounting by Patheon.**

Patheon shall keep records of the manufacture, testing and shipping of the Product, and retain samples of such Product as are necessary to comply with the Specifications and all manufacturing regulatory requirements and Laws applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples shall be retained for a period of [ \* ] following the date of Product expiry, or longer if required by Law, after which Patheon may destroy such records or samples; provided, however, Patheon shall notify the Client in writing at least thirty (30) days prior to such destruction and shall retain or deliver such records or samples to the Client, at the Client's option and expense, if the Client so requests.

### **7.4 Inspection; Audit.**

The Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, provided a Patheon representative is present during any such inspection. Furthermore, the Client shall have the right, if Client reasonably deems it necessary, to request additional documentation from Patheon to verify Patheon's calculation of [ \* ] and Patheon will use its reasonable commercial efforts to provide such documentation.

### **7.5 Access.**

Patheon shall provide the Client with reasonable access at mutually agreeable times to its Manufacturing Site in which the Product is manufactured, stored, handled or shipped in order to permit the Client's verification of Patheon's compliance with the Patheon Manufacturing Responsibilities and with all applicable Laws. Patheon agrees to permit the Client to review Patheon's standard operating procedures for the manufacture of the Product and those associated with the general facilities, equipment, or procedures required for compliance with cGMPs or DEA requirements. For greater certainty, the right of access provided in this Section 7.5 shall not include a right to access or inspect Patheon's financial records. Patheon shall [ \* ] obtain the right for the Client to have similar inspection rights with respect to all third party suppliers used by Patheon to provide the Components. If deficiencies are found by the Client during the course of such inspections, the parties will promptly meet to discuss and resolve them, and the Client will be entitled to make reasonable follow up inspections to monitor correction of the deficiencies. Patheon shall notify the Client of any inspections by, or communications with, any governmental agency involving the Product. Patheon shall furnish to the Client all material information supplied to, or supplied by, such regulatory Authority or third party supplier to the extent that such report relates to Product, or the ability of Patheon to supply such Product, within three (3) Business Days of their receipt of such information or delivery of such information, as the case may be. Patheon will promptly correct any deficiencies noted by governmental agencies in any such inspections.

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## 7.6 Reports.

Patheon will supply on [ \* ] basis all Product data, including release test results, complaint test results, all investigations (in manufacturing, testing and storage), and the like, that the Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any annual product report that the Client is required to file with the FDA. Patheon will supply the Client, no later than five (5) days following the last day of the preceding month, with a written summary report of the Active Material inventory for such prior month, in such detail requested and satisfactory to the Client, in order that the Client may properly account for the Active Material held by Patheon pursuant to this Agreement. At the Client's request and subject to an additional fee to be agreed by the parties, Patheon will prepare on behalf of the Client additional specialized [ \* ] product reports in accordance with the Client's instructions. At the Client's request and expense, Patheon will provide the data described in this Section 7.6 on a [ \* ] basis.

## 7.7 Regulatory Filings.

(a) Regulatory Filings. The Client shall have the sole responsibility for filing all documents with the FDA and other regulatory Authorities and taking any other actions that may be required of Client to obtain Regulatory Approval for the commercial manufacture of the Product (except as provided in the last sentence of this clause 7.7(a)). Patheon shall use commercially reasonable efforts to assist the Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain FDA and other regulatory approval for the commercial manufacture of the Product by Patheon as quickly as reasonably possible. Copies of all relevant Chemistry and Manufacturing Controls ("CMC") submissions and any related FDA correspondence are to be provided to Patheon by the Client. Patheon shall have the sole responsibility to obtain and maintain any required local, federal or other permits or approvals (other than the NDA or foreign equivalents) to allow Patheon to perform Manufacturing Services hereunder.

(b) [ \* ] Data. [ \* ] filing any CMC-related documents with the FDA or other regulatory Authority that incorporate data generated by Patheon, [ \* ] incorporating such data so as to [ \* ] of such documents [ \* ] data.

(c) [ \* ] CMC. At least [ \* ] filing with the FDA the CMC section of a NDA covering manufacture of the Product by Patheon, the Client [ \* ] supporting documents which have been relied upon to prepare the CMC portion so as to [ \* ] the CMC portion accurately describes the work [ \* ] pursuant to this Agreement.

(d) Pre-Approval Inspection. Subject to subsection (e) below, if [ \* ] under paragraph (c) above within the time stipulated in these paragraphs and if [ \* ] reasonably believes that [ \* ] with the FDA may be jeopardized, [ \* ] may, in its reasonable, good faith discretion, [ \* ] provided that such [ \* ] within [ \* ] of [ \* ].

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(e) **Deficiencies.** If in [ \* ] good faith discretion, acting reasonably, [ \* ] determines that any of the information [ \* ] in accordance with [ \* ] is [ \* ] in any material manner (the "[ \* ]"), [ \* ] within [ \* ] of receipt of such information from [ \* ]. Failure to notify the Client within the applicable period set forth above will constitute [ \* ] acceptance of the [ \* ] in accordance with [ \* ]. Until such [ \* ] or agreement has been reached with the [ \* ], [ \* ] reserves the right [ \* ]. In such event, [ \* ] shall not be construed as a breach of any of its obligations under this Agreement. Any such [ \* ] that is delayed shall be rescheduled as soon as reasonably practicable.

(f) **Client Responsibility.** For clarity, the parties agree that in [ \* ] the documents referred to in [ \* ] above, Patheon's role will be limited to [ \* ] of the description of the [ \* ]. As such, Patheon shall not assume any responsibility for the accuracy of a Regulatory Filing except as to [ \* ]. Subject to Patheon's obligation to cooperate with the Client pursuant to the terms and conditions of this Agreement, the responsibility of the preparation and filing of a Regulatory Filing shall be borne by the Client.

## ARTICLE 8

### TERM AND TERMINATION

#### **8.1 Initial Term.**

This Agreement shall become effective as of the date hereof and shall continue until five (5) years following the Manufacturing Commencement Date (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance with Article 8 of this Agreement; provided further that the Client shall have the option, in its sole discretion, to extend the Initial Term of this Agreement for successive terms of two years each by providing Patheon with written notice of such election not less than twelve (12) months prior to the expiration of the then current term.

#### **8.2 Termination for Cause.**

(a) Either party at its sole option may terminate this Agreement upon written notice in circumstances where the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under this Agreement within sixty (60) days following receipt of a written notice (the "**Remediation Period**") of said breach that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement pursuant to this Section 8.2(a) may only be exercised for a period of sixty (60) days following the expiry of the Remediation Period (in circumstances where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party shall be deemed to have waived the breach of the representation, warranty or obligation described in the Breach Notice.

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(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party in the event that: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party; or (iii) this Agreement is assigned by such other party for the benefit of creditors.

(c) The Client may terminate this Agreement upon thirty (30) days' prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents the Client from importing, exporting, purchasing or selling the Product.

(d) Patheon may terminate this Agreement at any time on or after [ \* ] on [ \* ] days' prior written notice if the Client has not delivered written notice specifying a Manufacturing Commencement Date as of the date of such notice.

(e) Patheon may terminate this Agreement on [ \* ] prior written notice if the Client assigns pursuant to Section 13.6 any of its rights under this Agreement to an assignee that, [ \* ], is: (i) [ \* ] under this Agreement; or (ii) [ \* ] provided, however, no [ \* ] shall be permitted to have access to the Manufacturing Site. For purposes of this Agreement, a [ \* ] is a legal entity, [ \* ] pharmaceutical contract manufacturing services.

### **8.3 Termination by the Client.**

(a) The Client may terminate this Agreement at any time upon [ \* ] prior written notice to Patheon.

(b) The Client may terminate this Agreement at any time on or after [ \* ] upon [ \* ] days notice if Patheon has not (i) obtained approval as a manufacturer of the Product, including approval of Patheon's facility by the FDA and any other applicable regulatory Authority or (ii) obtained a Quota for the Product for calendar year [ \* ].

### **8.4 Termination due to Product Discontinuation.**

Except as provided in Section 8.2(c), the Client may terminate this Agreement upon [ \* ] days' prior notice if it intends to no longer order the Product due to the Product's discontinuance in the market.

### **8.5 Obligations on Termination.**

If this Agreement expires or is terminated in whole or in part for any reason, then (in addition to any other remedies either party may have in the event of default by the other party):

(a) subject to Sections 6.1 and 6.2, the Client shall take delivery of and pay for all undelivered Product (i) that is manufactured and/or packaged pursuant to a Firm Order and (ii) that meets the Specifications and (iii) was manufactured in accordance with cGMPs and any additional procedures agreed upon in writing by the parties, at the price in effect at the time the Firm Order was placed;

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(b) the Client shall purchase, [ \* ], the Inventory applicable to the Product which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given;

(c) the Client shall [ \* ] pursuant to Patheon's orders with suppliers of Components, provided such orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2; and

(d) Patheon shall return to the Client all unused Active Materials (with shipping and related expenses, if any, to be borne by [ \* ]).

Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this Agreement.

#### **8.6 Survival.**

The provisions of Articles 1, 6, 9, 10, 11 and 12 and Sections 2.2, 5.5, 7.3, 7.6, 8.5, 8.6, 13.1, 13.2, 13.3, 13.5, 13.6, 13.8, 13.9, 13.12, 13.13, 13.14, and 13.15, shall survive the termination of this Agreement for any reason.

### **ARTICLE 9**

#### **REPRESENTATIONS, WARRANTIES AND COVENANTS**

##### **9.1 Authority.**

Each party covenants, represents and warrants that it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

##### **9.2 Client Warranties.**

The Client represents and warrants that:

- (a) The Client has the right to disclose the Specifications to Patheon; and
- (b) Except with respect to the Patheon Intellectual Property as to which the Client makes no representations or warranties, the Client is not aware of any Intellectual Property of any third party that is necessary for the Client to make, have made, use or sell the Product as contemplated hereby;

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- (c) The Client is not aware of any action or other legal proceedings alleging that third party Intellectual Property rights would be infringed by the manufacture of the Product as contemplated hereby.

### **9.3 Patheon Warranties.**

Patheon covenants, represents and warrants that (a) it shall perform the Manufacturing Services in accordance with the Specifications, cGMPs and all applicable Laws and that any Product supplied by it hereunder at the time of shipment, shall comply with the Specifications, (b) Patheon is not aware of any Intellectual Property of any third party that is necessary for Patheon to manufacture the Product as contemplated hereby and (c) the Active Material will not be used for any purpose beyond or different from the scope of the Manufacturing Services or otherwise in violation of the terms and conditions of this Agreement. Patheon acknowledges that the Product is controlled under Schedule III of the Controlled Substances Act and, as such, is subject to regulations and restrictions concerning its sale and distribution. Patheon agrees to comply with all such regulations and restrictions, as well as any reasonable instructions from the Client with respect to the use and storage of the Product. Without limiting the foregoing, (a) Patheon will obtain and/or maintain in force during the term of the Agreement all licenses and authorizations from the Drug Enforcement Administration or any other regulatory or governmental agency which are necessary for it to manufacture and possess the Product; and (b) Patheon will keep the Product in a secure location with access limited to authorized employees.

### **9.4 Debarred Persons.**

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Act.

### **9.5 Regulatory Approvals.**

The Client shall be solely responsible for obtaining or maintaining, on a timely basis, any regulatory approvals in respect of the marketing of the Product by the Client or the regulatory approval of the Specifications, including, without limitation, all marketing and post-marketing approvals. Patheon shall be solely responsible for obtaining and maintaining all permits, approvals and quotas necessary in order for Patheon to manufacture the Product in its facilities as contemplated hereby, and for those facilities themselves.

### **9.6 Compliance with Laws.**

Each party, in connection with its performance under this Agreement, shall comply with all applicable Laws.

**9.7 No Warranty.**

NEITHER PATHEON NOR THE CLIENT MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCT.

ARTICLE 10

**REMEDIES AND INDEMNITIES**

**10.1 Consequential Damages.**

Neither party shall be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or for any liability, damage, costs or expense of any kind incurred by the other party of an indirect or consequential nature.

**10.2 Limitation of Liability.**

(a) [ \* ]. Except as to the extent caused by the negligence or willful misconduct of Patheon, its employees or agents, under no circumstances whatsoever shall Patheon be responsible for any loss or damage to the [ \* ]. Patheon's maximum liability for loss or damage to the [ \* ] shall not exceed the [ \* ].

(b) Product. Except as expressly provided by applicable law or regulation or to the extent that Patheon has failed to provide the Manufacturing Services in accordance with the Specifications, cGMPs or all applicable Laws, Patheon shall not be liable nor have any responsibility for any deficiencies in, or other liabilities associated with, any Product manufactured by it, including, without limitation, the costs and expenses of any Recall (collectively, "**Product Claims**"). For greater certainty, Patheon shall have no obligation for any Product Claims to the extent such Product Claim (i) is caused by [ \* ] provided by the Client, the [ \* ] or any distribution thereof, (ii) results from a defect in a Component supplied by the Client or the Active Material that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) is caused by actions of third parties occurring after such Product is shipped by Patheon pursuant to Section 5.5, (iv) is due to packaging or labelling defects or omissions for which Patheon has no responsibility, or (v) is due to any other breach by the Client of its obligations under this Agreement.

(c) [ \* ]. Except as set forth in this subsection (c), [ \* ] under this Agreement for any reason whatsoever, including, without limitation, any [ \* ] hereof or resulting from a breach of its representations, warranties or other obligations under this Agreement shall [ \* ]. For purposes of determining [ \* ] hereunder, the [ \* ] will be based upon the [ \* ] Notwithstanding the foregoing, [ \* ]

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under this Agreement, for any liability under Section 10.3 hereof for personal injury, sickness, disease or death that results from the failure by Patheon to provide the Manufacturing Services in accordance with the Specifications and cGMPs shall not [ \* ].

### **10.3 Patheon.**

Subject to Sections 10.1 and 10.2, Patheon agrees to defend, indemnify and hold the Client, its officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favor of third parties other than Affiliates, (together, "Losses") resulting from, or relating to any claim of personal injury or property damage to the extent that such injury or damage is the result of (i) a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs or all applicable Laws, or (ii) the gross negligence or willful misconduct of Patheon or (iii) the breach of this Agreement by Patheon, including without limitation, any representation or warranty of Patheon contained herein, and in each case, except to the extent that any such losses, damages, costs, claims, demands, judgments and liability are due to the gross negligence or wrongful act(s) of the Client, its officers, employees or agents or Affiliates.

In the event of a claim, the Client shall: (a) promptly notify Patheon of any such claim; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with Patheon in the defence of such claim; (d) permit Patheon to control the defence and settlement of such claim, all at Patheon's cost and expense.

### **10.4 Client.**

Subject to Sections 10.1 and 10.2, the Client agrees to defend, indemnify and hold Patheon, its officers, employees and agents (together "Patheon Indemnitees") harmless against any and all Losses resulting from, or relating to (a) any claim of personal injury or property damage to the extent that such injury or damage is the result of a breach of this Agreement by the Client, including, without limitation, any representation or warranty of Client contained herein, (b) any claim that the Specifications for the Product do not conform to all applicable cGMPs, laws and regulations and (c) any claim that the Product, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs (i) may not be lawfully sold and distributed in every jurisdiction in which the Client markets such Product, or (ii) is not safe for human consumption, except to the extent that any such Losses are due to the gross negligence or wrongful act(s) of Patheon, its officers, employees or agents or Affiliates.

Subject to Sections 10.1 and 10.2, Client agrees to defend, indemnify and hold the Patheon Indemnitees harmless against any and all Losses resulting from or relating to any claim that the manufacture, use or sale of the Product infringes any Third Party Rights, except to the extent such infringement or alleged infringement results from Patheon's manufacturing processes. In the event of any claim described in this Section 10.4, Patheon shall: (a) promptly notify the Client of any such claims; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with the Client in the defence of such claim; (d) permit the Client to control the defence and settlement of such claim, all at the Client's cost and expense.

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### **10.5 Reasonable Allocation of Risk.**

The parties acknowledge and agree that the provisions of this Agreement (including, without limitation, this Article 10) are reasonable and create a reasonable allocation of risk having regard to the relative profits the parties respectively expect to derive from the Product, and that Patheon, in its fees for the provision of the Manufacturing Services, has not accepted a greater degree of the risks arising from the manufacture, distribution and use of the Product, based on the fact that the Client has developed and holds the marketing approval for the Product and requires Patheon to manufacture and label the Product strictly in accordance with the Specifications, and that the Client and not Patheon is in a position to inform and advise potential users of the Product as to the circumstances and manner of use of the Product.

## **ARTICLE 11**

### **CONFIDENTIALITY**

#### **11.1 Confidentiality.**

The Confidentiality Agreement effective March 13, 2007 between the parties (the "Confidentiality Agreement") will govern the confidentiality obligations of the parties hereunder; provided, however, that:

(a) Confidential Information disclosed orally need not be summarized in writing as provided in Paragraph 4 of the Confidentiality Agreement and;

(b) The Confidentiality Agreement will continue in effect until termination of this Agreement; and

(c) The obligations of confidentiality and non-use under the Confidentiality Agreement will continue until [ \* ] years after termination of this Agreement for any reason, including the end of its term.

## **ARTICLE 12**

### **DISPUTE RESOLUTION**

#### **12.1 Commercial Disputes.**

In the event of any dispute arising out of or in connection with this Agreement (other than a dispute determined in accordance with Section 6.1(b) or a Technical Dispute), the parties shall first try to solve it amicably. In this regard, any party may send a notice of dispute to the other, and each party

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shall appoint, within [ \* ] Business Days from receipt of such notice of dispute, a single representative having full power and authority to solve the dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If these representatives fail to solve the matter within [ \* ] from their appointment, or if a party fails to appoint a representative within the [ \* ] Business Day period set forth above, such dispute shall immediately be referred to the Chief Operating Officer, Executive Vice President, Operations or Chief Business Officer (or such other officer as they may designate) of each party who will meet and discuss as necessary in order to try to solve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, their dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

## **12.2 Technical Dispute Resolution.**

In the event of a dispute (other than disputes in relation to the matters set out in Sections 6.1(b) and 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, quality control testing, handling, storage or other activities under this Agreement (a "**Technical Dispute**"), the parties shall make all reasonable efforts to resolve the dispute by amicable negotiations. In this regard, senior representatives of each party shall, as soon as practicable and in any event no later than [ \* ] Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. In the event that the parties cannot agree whether a dispute is a Technical Dispute or are unable to resolve a Technical Dispute, Section 12.1 shall prevail. For greater certainty, the parties agree that the release of the Product for sale or distribution pursuant to the applicable marketing approval for such Product shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing Services and further that nothing in this Agreement (including Schedule F) shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Product is to be released for sale or distribution.

## **ARTICLE 13**

### **MISCELLANEOUS**

#### **13.1 Inventions.**

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services solely for the manufacture of the Product for the Client.

(b) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use and sale of the Product that is the subject of the Manufacturing Services, shall be the exclusive property of Client.

(c) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services which are not related to or derived from the Client's Intellectual Property or specific to, or dependent upon, the Product and which have general application to manufacturing

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processes or formulation development of drug product or drug delivery systems shall be the exclusive property of Patheon (the "Patheon Intellectual Property Rights"). Patheon hereby grants to Client, a non-exclusive, paid-up, royalty-free, transferable license of the Patheon Intellectual Property Rights which Client may use for the manufacture of the Product.

(d) Patheon shall give the Client written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Product or processes or technology owned or otherwise controlled by Client.

(e) Each party shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on its own Inventions.

(f) Each party agrees and acknowledges that it will not acquire by virtue of this Agreement any interest in or to any trademarks or trade names of the other party; provided, however, that the Client shall have the right to identify Patheon as the manufacturer of the Product.

### **13.2 Intellectual Property.**

Subject to Section 13.1, all Intellectual Property of the Client shall be owned by the Client and all Intellectual Property of Patheon shall be owned by Patheon. The Client and Patheon hereby acknowledge that neither party has, nor shall it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Each party agrees not to use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement. Each party agrees to execute all applications, assignments or other instruments reasonably requested by the other party, in order for such party to establish its ownership of such Intellectual Property and to obtain whatever protection for such Intellectual Property, including patent and copyright rights, in any and all countries on such Intellectual Property as the requesting party will determine. Each party further agrees to cooperate fully with the other party in the process of securing and enforcing the other party's rights to such Intellectual Property, applicable.

### **13.3 Insurance.**

Each party shall maintain commercial general liability insurance, through the term of this Agreement, which insurance shall afford limits of not less than \$[ \* ] for each occurrence for personal injury or property damage liability. Furthermore, each party shall maintain products liability insurance, through the term of this Agreement and for a period of [ \* ] years thereafter, which insurance shall afford limits of not less than \$[ \* ] in the aggregate per annum with respect to product and completed operations liability. This insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement. If requested each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of thirty (30) days' written notice to the insured of a cancellation of, or material

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change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

#### **13.4 Independent Contractors.**

The parties are independent contractors and this Agreement shall not be construed to create between Patheon and the Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the parties hereto.

#### **13.5 No Waiver.**

Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.

#### **13.6 Assignment.**

- (a) Patheon may not assign this Agreement or any of its rights or obligations hereunder except with the written consent of the Client, such consent not to be unreasonably withheld, provided that any assignee shall covenant in writing to be bound by the terms of this Agreement.
- (b) Subject to Section 8.2(d), the Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon; provided, however, that (i) the Client shall give prompt written notice of any assignment to Patheon after the assignment, and (ii) any assignee shall covenant in writing to be bound by the terms of this Agreement.
- (c) Notwithstanding the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, provided that such assignee executes an agreement with the non-assigning party hereto whereby it agrees to be bound hereunder.

#### **13.7 Force Majeure.**

Neither party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such party's reasonable control, including, but not limited to, strikes or other labour disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components (a "Force Majeure Event"). A party claiming a right to excused performance under this Section 13.7 shall immediately notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control

that prevents such performance and shall use its commercially reasonable efforts to eliminate, cure and overcome any of such causes and resume the performance of its obligations. Neither party shall be entitled to rely on a Force Majeure Event [ \* ] which would otherwise [ \* ] under this Agreement.

**13.8 Notices.**

Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to the other party by personal delivery, by facsimile communication or by sending the same by first class mail, postage prepaid to the mailing address, or facsimile number set forth below:

If to the Client:

Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
U.S.A.

Attention: Vice President, Product Development

Facsimile No.: (650) 496-3781

with a copy to:

Jazz Pharmaceuticals Inc  
3180 Porter Drive  
Palo Alto, CA 04304

Attention: General Counsel

Facsimile No.: (650) 496-3781

If to Patheon:

Patheon Pharmaceuticals Inc.  
c/o Patheon Inc.,  
7070 Mississauga Road, Suite 350  
Mississauga, Ontario L5N 7J8  
Canada

Attention: President

Facsimile No.: (905) 812-6705



with a copy to:

Patheon Pharmaceuticals Inc  
2110 East Galbraith Road  
Cincinnati, Ohio 45237-1625  
Attention: Director of Legal Services

Facsimile No.: (513)948-6927

or to such other addresses or facsimile number provided to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery or by facsimile shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five (5) days after being deposited in the United States or Canadian mail, postage prepaid or upon receipt, whichever is sooner.

**13.9 Severability.**

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such determination shall not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct.

**13.10 Entire Agreement.**

This Agreement, together with the Quality Agreement, Confidentiality Agreement, that certain Capital Expenditure and Equipment Agreement dated as of the date hereof, and that certain Pharmaceutical Development Services Agreement dated as of January 2, 2007, in each case by and between Patheon and the Client, to the extent expressly incorporated herein, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, this Agreement will prevail.

**13.11 Other Terms.**

The parties agree that no terms, provisions or conditions of any purchase order or other business form or written authorization used by the Client or Patheon will have any effect on the rights, duties or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of the Client or Patheon to object to such terms, provisions, or conditions unless such document specifically refers to this Agreement and is signed by both parties.

**13.12 Third Party Beneficiary.**

Nothing in this Agreement shall confer or be construed as conferring on any other third party any benefit or the right to enforce any express or implied term of this Agreement.

**13.13 Exclusivity.**

During the term of this Agreement and for [ \* ] thereafter, Patheon will not develop, make, have made, use, sell, have sold, offer for sale, import or commercialize, or assist any other third party, in any of the foregoing with respect to the Product, other than the Client pursuant to this Agreement.

**13.14 Publicity.**

Each party agrees not to issue any press release or other public statement disclosing the existence of, or relating to this Agreement, without the prior written consent of the other party; provided, however, that neither party shall be prevented from complying with any duty of disclosure it may have pursuant to applicable Laws or governmental orders.

**13.15 Execution in Counterparts.**

This Agreement may be executed in two counterparts, by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**13.16 Governing Law.**

This Agreement shall be construed and enforced in accordance with the laws of the State of New York.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

**PATHEON PHARMACEUTICALS INC.**

By  /s/ Riccardo Trecroce

Name: Riccardo Trecroce

Title: Secretary

**JAZZ PHARMACEUTICALS, INC.**

By  /s/ Janne Wissel

Name: Janne Wissel

Title: Sr VP, Development

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**SCHEDULE A**

**PRODUCT SPECIFICATIONS**

If the Specifications provided are subsequently amended, then the Client shall provide Patheon with copies of such revised Specifications. Upon receipt of the revised Specifications, Patheon shall provide the Client with a signed and dated receipt evidencing such acceptance of the revised Specifications by Patheon.

[ \* ]

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**SCHEDULE B**

**MINIMUM RUN QUANTITY, ANNUAL VOLUME, FEES & PRICE ADJUSTMENTS**

**1. Xyrem Oral Solution – [ \* ] mL Bottle**

Batch Size (L)			[ * ]		
Market		US		EU/Canada	
Minimum Annual Qty (bottle)		[ * ]		[ * ]	
Run Quantity (bottles)	[ * ]		[ * ]	[ * ]	[ * ]
Pkg Run Quantity (batch)	[ * ]		[ * ]	[ * ]	[ * ]
Materials	[ * ]		[ * ]	[ * ]	[ * ]
Conversion Cost	[ * ]		[ * ]	[ * ]	[ * ]
Price per Bottle*	[ * ]		[ * ]	[ * ]	[ * ]

Split Lot Charge - [ \* ]

This charge is for splitting off a portion of a US lot for “EU” type bottles for the Canadian market.

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**Price for Double Batch Size****Xyrem oral solution: [ \* ] ml/bottle**

Batch size	[ * ]	[ * ]
Market	US	EU
Annual Qty (bottles)	[ * ]	[ * ]
Run Quantity (bottles)	[ * ]	[ * ]
Materials	[ * ]	[ * ]
Conversion	[ * ]	[ * ]
Price per bottle*	[ * ]	[ * ]
Split lot charge [ * ]	[ * ]	[ * ]

This charge is for splitting off a portion of a US lot for "EU" type bottles for the Canadian market.

\* Pricing is based on the fact that Patheon will do the following:

Procurement of raw materials and packaging components as defined in schedule J. Jazz Pharmaceuticals will furnish the API, Sodium Oxybate. Price does include the performance of all QC testing requirements for raw materials, packaging components and finished product.

**Manufacturing Assumptions [ \* ]****Packaging Assumptions [ \* ]****Product Release Testing for Non-Patheon Product [ \* ]**

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## 2. Subsequent Years' Pricing.

The fees for the Manufacturing Services provided pursuant to the terms of this Agreement during any Year following December 31, 2008 shall be determined in accordance with the following:

- (a) **Manufacturing and Component Costs.** On the first day of the applicable Year during the term of this Agreement, Patheon shall [ \* ] (i) for [ \* ] in respect of the Product [ \* ] to reflect [ \* ], unless the parties otherwise agree in writing; and (ii) for [ \* ] in such costs. [ \* ].
- (b) **Pricing Basis.** The Client acknowledges that the fee for Manufacturing Services in respect of a Product in any Year is [ \* ] and is subject to change if [ \* ] unless Client agrees [ \* ] provided that such Product [ \* ]. In addition, if Patheon and the Client agree that the [ \* ] in respect of a Product shall be reduced whether as a result of a [ \* ] or otherwise and, as a result of such reduction, [ \* ], then Patheon shall be entitled to [ \* ].

In connection with a [ \* ] pursuant to clause 2 of this Schedule B, Patheon shall [ \* ] a revised Schedule B in draft form and a statement outlining (i) [ \* ] upon which such [ \* ] is based and (ii) the [ \* ] to Patheon [ \* ] upon which any [ \* ] is based, if applicable. In connection with all [ \* ] pursuant to clauses 2(b) of this Schedule B, Patheon shall deliver to the Client by not later than [ \* ] a revised Schedule B in draft form and such [ \* ]. Upon delivery of such a request, each of the Client and Patheon shall forthwith [ \* ] in respect of the Product and [ \* ]. Such [ \* ] shall be effective with respect to any [ \* ] after the end of the [ \* ].

## 3. Adjustments to Pricing.

During any Year of this Agreement, the fees set out in Schedule B shall be subject to adjustment in accordance with the following:

- (a) **[ \* ] Pricing.** The Manufacturing Fees describe the fees that are payable by Client for Product based on the [ \* ]. The parties shall estimate the Manufacturing Fees payable by Client in any Year based on the [ \* ]. Within [ \* ] of the end of the each Year, the parties shall reconcile the difference which may be payable by either party based on the [ \* ].
- (b) [ \* ].

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In connection with a [ \* ] pursuant to this clause 3 of Schedule B, Patheon shall deliver to the Client a revised Schedule B and such [ \* ]. Upon delivery of such a request, each of the Client and Patheon shall forthwith [ \* ].

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**SCHEDULE C**

**STABILITY TESTING**

[ \* ]

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**SCHEDULE D**

**ACTIVE MATERIALS**

Active Materials  
Sodium Oxybate, Powder

Supplier  
Lonza, Inc.

[ \* ]

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**SCHEDULE E**

**BATCH NUMBERING & EXPIRATION DATES**

Each batch of the Product manufactured by Patheon will bear a unique batch number using the Patheon batch numbering system. This number will appear on all documents relating to the particular batch of Product.

Patheon will calculate the expiration date for the Product for each batch by adding the expiration period of the Product supplied by the Client to the date of Manufacture of each batch.

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**SCHEDULE F**

**TECHNICAL DISPUTE RESOLUTION**

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 shall be resolved in the following manner: [ \* ]

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**SCHEDULE G**

**QUALITY AGREEMENT**

{This Schedule G has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

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SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: JAZZ PHARMACEUTICALS, INC.  
FROM: PATHEON PHARMACEUTICALS INC.  
RE: Active Materials quarterly inventory report pursuant to Section 2.3(a) of the Manufacturing Services Agreement dated • (the "Agreement")

[ \* ]  
Capitalized terms used in this report have the meanings given to such terms in the Agreement.

DATE: \_\_\_\_\_

PATHEON PHARMACEUTICALS INC.

Per: \_\_\_\_\_  
Name:  
Title:

[ \* ]

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**SCHEDULE I**

**REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND  
CALCULATION OF ACTUAL ANNUAL YIELD.**

**Intentionally Left Blank**

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SCHEDULE J

COMPONENTS PURCHASING SUMMARY

Dated: October 19, 2006

[ \* ]

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**SCHEDULE K**

**POTENTIAL BILL-BACK ITEMS**

[ \* ]

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**SCHEDULE L**  
**PACKAGING CONFIGURATIONS**

Referenced in the definition section

[ \* ]

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**QUALITY AGREEMENT**

**This AGREEMENT** is executed as of the 13th day of **March, 2007**

between

**Jazz Pharmaceuticals, Inc.**

**3180 Porter Drive**

**Palo Alto, CA 94304**

**USA**

a corporation existing under the laws of the state of Delaware, USA

(hereinafter referred to as "**Jazz Pharmaceuticals**")

and

**Patheon Pharmaceuticals Inc.**

2110 East Galbraith Road

Cincinnati, OH 45237-1625

**USA**

a corporation existing under the laws of the state of Delaware, USA

(hereinafter referred to as "**Patheon**")

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[ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

## 1. Objective

- 1.1. The purpose of this Quality Agreement is to ensure a mutual understanding and agreement of key responsibilities between Jazz Pharmaceuticals and Patheon with respect to the Xyrem® (sodium oxybate) oral solution (the “Product”), for use and sale in the United States, Europe and Canada.
- 1.2. To assure the Product is produced in accordance with cGMPs approved standard operating procedures (SOPs), specifications and all applicable governing regulations.

## 2. Scope

- 2.1. To document the responsibilities of Jazz Pharmaceuticals and Patheon regarding:
  - 2.1.1. Manufacture of the Product
  - 2.1.2. Packaging, testing, release, storage and shipment of the Product
  - 2.1.3. Complaint reporting and investigations related to the Product
  - 2.1.4. Testing, release and storage of API and Raw Materials

## 3. Definitions

- 3.1. API: the Active Pharmaceutical Ingredient – (Sodium Oxybate)
- 3.2. Batch: A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits and is produced according to a manufacturing formula or a batch record by a continuous manufacturing process.
- 3.3. cGMPs: Current Good Manufacturing Practices as defined in the United States (U.S. 21 CFR parts 210 and 211) regulations
- 3.4. C of A: Certificate of Analysis
- 3.5. C of C: Certificate of Compliance
- 3.6. CDER: Center for Drug Evaluation and Research
- 3.7. EU: European Union
- 3.8. DEA: Drug Enforcement Agency
- 3.9. FDA: United States Food and Drug Administration or any successor entity (CDER) charged with the approval and regulation of pharmaceutical products in the United States.
- 3.10. ICH: International Conference on Harmonisation
- 3.11. IQ: Installation Qualification; documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer’s recommendation and/or user requirements.

- 3.12. NDA: New Drug Application; Application in the United States to market a new drug for human use.
- 3.13. Non-Conformance: Any deviation from an approved written procedure, method or a Specification.
- 3.14. OQ: Operational Qualification; documented verification that the equipment or systems, as installed or modified, perform as intended and that it meets the previously defined functional and performance specifications.
- 3.15. PQ: Process Qualification; documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process methods and specifications.
- 3.16. Product: Xyrem<sup>®</sup> (sodium oxybate) oral solution packaged in bulk unlabeled bottles or in its final configuration.
- 3.17. Raw Material: Any ingredient intended for use in the manufacture of the drug Product, including those that do not appear in such drug Product.
- 3.18. Specifications: Parameters, test values as they relate to test methods, procedures, analytical specifications or equipment.
- 3.19. USP, NF: The United States Pharmacopoeia, National Formulary is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, drug substance, excipient and other healthcare products manufactured and sold in the United States.

#### 4. General

- 4.1. This Quality Agreement specifies the responsibilities of the parties hereto with respect to quality control matters related to the manufacture of the Product. If there is a conflict between this Agreement and the Manufacturing Services and Supply Agreement (the "Supply Agreement") between Jazz Pharmaceuticals and Patheon dated March 13, 2007 (as may be amended from time to time, the "Supply Agreement"), the Supply Agreement shall govern. In the event of a quality conflict between any of the provisions in the Supply Agreement and this Quality Agreement, this Quality Agreement shall govern. Any capitalized terms utilized herein and not otherwise defined herein shall have the meanings set forth in the Supply Agreement.
- 4.2. In the event that a dispute arises between Patheon and Jazz Pharmaceuticals regarding the nonconformity of a batch of the Product or regarding other matters, the senior management of the quality departments from both companies shall in good faith promptly attempt to resolve disputed issues. If the parties cannot reach agreement, the matter shall be resolved in accordance with dispute resolution provisions of the Supply Agreement.
- 4.3. Patheon will manufacture, package, test and store the Product in accordance with the cGMPs, approved SOPs, Specifications and all applicable governing regulations including:
  - Current Good Manufacturing Practices (cGMPs), U.S. 21 CFR parts 210 and 211
  - U.S. Federal Food Drug and Cosmetic Act (FD&C Act)
  - EU and Canadian Regulations
  - All applicable USP, NF, Ph Eur. and ICH requirements

- DEA Regulations (if applicable)
  - Environmental and occupational health and safety laws
- 4.4. Patheon will not subcontract any work related to the manufacture and testing of the Product to a third party vendor without the prior written consent, approval of Jazz Pharmaceuticals.

## 5. Regulatory

- 5.1. Patheon agrees to allow any regulatory authorities to inspect its facilities and all records as required under the cGMPs in connection with the Product.
- 5.2. Patheon will notify Jazz Pharmaceuticals within one (1) business day of any regulatory inspection (local, state, federal from US, or other foreign government agency) or regulatory request for product samples, batch documentation or other information related to the Product. Jazz Pharmaceuticals may request to be present onsite during a regulatory inspection by a government body related to the Product. Patheon will not make any representations to any government authority regarding any actions taken by Jazz Pharmaceuticals without Jazz Pharmaceuticals expressed prior approval.
- 5.3. Patheon will notify Jazz Pharmaceuticals, within one (1) business day of receipt of any Form 483s or warning letters from any governing regulatory agencies relating to: (1) the Product and (2) the facilities used in the manufacture, packaging, testing and storage of the Product.
- 5.4. Patheon will provide redacted copies to Jazz Pharmaceuticals of all written communication from any Health Authority (e.g. FDA 483) that are specifically related to the Product or to the facilities used in manufacture, packaging, testing and storage of the Product. Patheon will provide copies of the above documentation promptly, no more than three (3) business days after such communications are available for distribution. Jazz Pharmaceuticals may participate in the development and approval of corrective action plans that are directly related to the Product.
- 5.5. Patheon is responsible for registering the facilities with the FDA and to maintain the registration form such that it is readily available for any regulatory inspection. Patheon is responsible for drug listing as the manufacturer of the Product for Jazz Pharmaceuticals, while Jazz Pharmaceuticals is responsible for drug listing as the distributor of the Product.
- 5.6. Jazz Pharmaceuticals will provide Patheon with all required information to register the Product with the regulatory agency. Jazz Pharmaceuticals will notify Patheon of changes in the countries of market and scheduled Product launch, where applicable.
- 5.7. Jazz Pharmaceuticals is responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with regulatory agencies prior to shipment/human administration. Jazz Pharmaceuticals will provide a copy of the applicable product registration as applicable to support regulatory inspection activities.
- 5.8. Jazz Pharmaceuticals will initiate and control all NDA Field Alert Reports and Product Recalls for Product not meeting the regulatory requirements. Patheon will provide documentation, data and assistance if the field alert or recall is related to the Product manufactured at Patheon. Jazz Pharmaceuticals will provide Patheon copies of any regulatory correspondence related to the field alert or Product recall. In the event that Patheon has reason to believe that any Product should be recalled or withdrawn from distribution, Patheon shall promptly inform Jazz Pharmaceuticals in writing. Patheon and Jazz Pharmaceuticals agree to cooperate fully

regarding any proposed recall, product withdrawal, or field correction; and the Parties agree to keep each other advised, and to exchange copies of such documentation as may be required, to assure regulatory compliance.

- 5.9. Upon request from Jazz Pharmaceuticals, Patheon will provide any documentation and data related to the Product or the facilities and the process used in the manufacture of the Product that may be required by Jazz Pharmaceuticals for regulatory filings and submissions.
- 5.10. Patheon will allow Jazz Pharmaceuticals to audit all relevant facilities used in the manufacture, packaging, testing and storage of the Product, including the applicable procedures and documentation, at least once in each calendar year (and additional times, if the deficiencies are noted, to monitor correction thereof) at a mutually agreed upon date. Jazz Pharmaceuticals will provide a thirty (30) calendar days notification for all planned audits conducted by Jazz Pharmaceuticals.
- 5.11. Jazz Pharmaceuticals will provide a written report of all observations within thirty (30) business days to Patheon. Within thirty (30) business days of receipt of the audit report, Patheon will provide a written response to all findings that require corrective action and the expected time-frame of implementation. Patheon will follow-up to ensure that all corrective actions are addressed and implemented.
- 5.12. Jazz Pharmaceuticals will provide Patheon at least five (5) business days notice prior to scheduling any visits (non-audits) to witness manufacturing operations or laboratory testing related to the Product. Access to the manufacturing facility or laboratories for non-audit purposes must be agreed upon by Patheon in advance and such access, if justifiable, should not be unreasonably withheld or delayed.

## **6. GMP**

- 6.1. Patheon or Jazz Pharmaceuticals will notify and obtain approval from the other party in writing prior to implementing any proposed changes to the process, materials, testing, equipment or premises that may affect the quality, purity, safety or integrity of the Product.
- 6.2. Patheon will not change or deviate from the defined manufacturing process, testing procedures and/or Specification directly relating to the Product or alter materials, or change suppliers without obtaining prior written approval from Jazz Pharmaceuticals.
- 6.3. Patheon will provide Jazz Pharmaceuticals an annual product review (APR) report for the Product. The information provided in the APR report will consist at the minimum the following information: the batches processed, open and closed deviations, open and closed complaints, retain inspection, statistical trending of analytical data, active stability studies and change controls (documentation, equipment and processes). The report shall be completed in writing and sent to Jazz Pharmaceuticals no later than sixty (60) business days after the scheduled APR start date.
- 6.4. Jazz Pharmaceuticals will be responsible for submitting the Annual Report for the Product to the agencies as required by applicable regulations, including 21 CFR 314.70 and 314.81. Jazz Pharmaceuticals will notify Patheon as to the approval date of the regulatory license. At least ninety (90) calendar days before the Annual Report due date, Jazz shall request in writing from Patheon the chemistry, manufacturing, and controls data required for submission of the Annual Report. Patheon will provide the requested information to Jazz Pharmaceuticals within sixty (60) calendar days.

- 6.5. Patheon will retain reserve samples of the Product (bulk unlabeled or finished drug product) for at least one year after product expiration or longer as required by law.
- 6.6. Patheon will maintain records and evidence on the testing of API and all raw materials until five years after the materials were last used in the manufacture or packaging/labelling of the Product.
- 6.7. Patheon will retain all batch production and control records, laboratory testing and distribution records for at least [ \* ] after the expiry date of the Product or longer as required by the law.

## **7. Validation**

- 7.1. Patheon will establish and maintain a validation plan for the facility and the process used in the manufacture, packaging testing and storage of the Product.
- 7.2. Patheon will qualify (IQ/OQ/PQ) all facilities, utilities, processes and test equipment used in the manufacture, packaging and testing of the Product.
- 7.3. Patheon will validate all manufacturing, packaging and testing activities for the Product in accordance with cGMPs and all other applicable governing regulations, including:
  - 7.3.1. Process validation: All processes used in the manufacture and packaging of the Product
  - 7.3.2. Methods validation: All test methods for the API and the Product
  - 7.3.3. Facilities/Utilities: Facilities used in the manufacture, packaging, testing and storage of the Product, and all utility systems (e.g., HVAC, water, computer systems, etc.)
  - 7.3.4. Cleaning validation: All cleaning procedures of production equipment
- 7.4. Patheon will provide Jazz Pharmaceuticals copies of all protocols and the reports related to the Product for review and approval prior to execution and closure.

## **8. Specifications and Test Methods**

- 8.1. Jazz Pharmaceuticals will provide Patheon all Specifications for the API, raw materials, packaging materials and the Product.
- 8.2. Jazz Pharmaceuticals will provide Patheon all test methods for testing the API and the Product.
- 8.3. Patheon will send Jazz Pharmaceuticals all specifications for the API and the Product for review and approval.
- 8.4. Patheon will send Jazz Pharmaceuticals all test methods for testing the API and the Product for review and approval.
- 8.5. Any changes to the approved Product Specifications and test methods must be sent to Jazz Pharmaceuticals for review and approval.



## 9. API and Raw Materials

- 9.1. Patheon will qualify and approve all raw material suppliers in accordance with Patheon SOPs. Jazz Pharmaceuticals will qualify and approve the API supplier.
- 9.2. Patheon will procure Raw materials only from Qualified Suppliers for use in the manufacture and packaging of the Product.
- 9.3. Patheon will procure Raw materials with the appropriate certificate of analysis (C of A), certificate of compliance (C of C) and will retain these documents along with the receiving or testing records.
- 9.4. Patheon will test, release and approve the API and all raw materials prior to use in production. Patheon will only use approved API and raw materials for use in the manufacture and packaging of the Product.
- 9.5. Patheon will store the API and all Raw materials in accordance with cGMPs, approved SOPs, DEA regulations (if applicable) and the Specifications.
- 9.6. Patheon will pull and retain a reserve sample for each batch of API, at least twice the quantity necessary to perform all test required as per Specification.
- 9.7. Patheon will hold the API reserve samples for at least [ \* ] or longer as required by the law. Patheon will notify and obtain approval from Jazz Pharmaceuticals in writing prior to destruction of any API reserve samples.
- 9.8. Patheon will retain reserve samples of inactive ingredients for a minimum of [ \* ] as required by law.
- 9.9. Patheon will provide Jazz Pharmaceuticals with a BSE/TSE certificate of compliance for each raw material confirming that any bovine, caprine, or ovine derived raw materials purchased/used in the manufacture of the Product are appropriate for use in human pharmaceuticals. Jazz Pharmaceuticals will be responsible for procuring the BSE/TSE certification from the API supplier.
- 9.10. Upon request, Patheon will provide copies of all Raw material C of A's to Jazz Pharmaceuticals. Jazz Pharmaceuticals will provide C of A for the API to Patheon.

## 10. Manufacturing and Packaging

- 10.1. Patheon will create, control, issue and execute the master batch record. The Master Batch Record (original) used in the manufacture/ packaging of the Product will be submitted to Jazz Pharmaceuticals QA for approval prior to issuance for production.
- 10.2. Patheon will assign a unique identifier (batch number) for each unit operation of the Product manufactured per Patheon SOPs.
- 10.3. Patheon will calculate the expiration date for each batch of Product by adding the expiration period supplied by Jazz Pharmaceuticals to the date of Manufacture of each batch.
- 10.4. Patheon will only use approved API and Raw materials for the manufacture and packaging of the Product.

- 10.5. Patheon will pull and retain a reserve sample (twice the quantity required to perform all test per Specifications) that is representative of each batch of drug Product manufactured/packaged and stored with accordance to cGMPs.
- 10.6. Patheon will be responsible for the accuracy, completeness and maintenance of batch records used in the manufacturing and packaging processes.
- 10.7. Upon request, Patheon will provide Jazz Pharmaceuticals with copies of fully executed batch production and control records, laboratory testing records and any other associated documentation related to the manufacturing, packaging, testing and release of the Product.
- 10.8. Patheon will not rework or reprocess a batch or intermediate that does not conform to standards or specifications without prior written consent and approval from Jazz Pharmaceuticals.

## **11. Change Controls**

- 11.1. Changes to the following (but not limited to) must be covered under a change control:
  - 11.1.1. Revision to Master Batch Records, Test Methods, Specifications for the API, Raw materials and the Product
  - 11.1.2. Packaging Specifications
  - 11.1.3. Major facility and Equipment changes
- 11.2. Patheon will notify Jazz Pharmaceuticals of any general procedural changes at Patheon that pertain to the manufacture, packaging or testing of the Product for Jazz Pharmaceuticals review and assessment with respect to validation, quality, and regulatory impact.

## **12. Deviations**

- 12.1. Patheon will not deviate from approved procedures, methods or the Specifications used in the manufacture, packaging, testing and storage of the API, Raw materials or the Product. Deviations (if any) to approved procedures must be investigated and documented under the established change control or non-conformance.
- 12.2. Patheon will obtain Jazz Pharmaceuticals written approval on all deviations having an impact on safety, identity, quality, purity and/or potency of the Product. In addition, all confirmed OOS deviations pertaining to testing of the Product must be approved by Jazz Pharmaceuticals.
- 12.3. Patheon will inform Jazz Pharmaceuticals of any major or critical deviations impacting the safety, identity, quality, purity and/or potency of the Product within three (3) business days of occurrence.
- 12.4. Jazz Pharmaceuticals will provide written comments and approval to Patheon within three (3) business days of notification of any deviation.
- 12.5. Patheon will notify Jazz Pharmaceuticals of any suspected or actual out-of-Specification (OOS) results within one business day after such results are confirmed.
- 12.6. Patheon will investigate and close all deviations (procedural, equipment, OOS etc) within thirty (30) calendar days from the time of initiation of the deviation notice. A written justification must be provided by Patheon wherever deviations cannot be closed within the thirty (30) calendar days.
- 12.7. Patheon will promptly provide copies of all completed deviations to Jazz Pharmaceuticals.

### 13. Product Complaints

- 13.1. Jazz Pharmaceuticals will coordinate all customer-related contact and activities related to the Product complaints. Jazz Pharmaceuticals will maintain the Product complaint files.
- 13.2. Jazz Pharmaceuticals is responsible for the Product complaints and will be responsible for agency notification for any adverse event complaints.
- 13.3. Any complaints received directly by Patheon related to the Product will be forwarded to Jazz Pharmaceuticals within one (1) business day of receipt.
- 13.4. Jazz Pharmaceuticals will notify Patheon of all Product complaints (medical and technical) that will require an investigation from Patheon.
- 13.5. Patheon will complete its investigation per Patheon policies (no later than forty five (45) calendar days for technical complaints and fifteen (15) calendar days for medical complaints). Upon request, Patheon will provide Jazz Pharmaceuticals copies of the investigation for review prior to closure.
- 13.6. Patheon will maintain complete documentation of all complaint investigation conducted at Patheon related to the Product and will provide Jazz Pharmaceuticals copy of all completed investigations.

### 14. Product Release

- 14.1. The Quality Assurance unit of Patheon is responsible for batch record review and release of the Product to Jazz Pharmaceuticals in accordance with approved procedures, Specifications and all applicable regulations (cGMPs, US 21 CFR parts 210 and 211, regulations and all applicable USP, NF requirements).
- 14.2. Patheon will provide a certificate of compliance for each batch manufactured, packaged and released. The Certificate of Compliance at the minimum shall include the following:
  - 14.2.1. A product description with a unique identifier (item, batch number, product name and strength).
  - 14.2.2. The quantity packaged for shipment and the manufacturing site.
  - 14.2.3. The manufacture date for the Product with the expiration date.
  - 14.2.4. A statement that the Product was manufactured and packaged in accordance with cGMPs and Specifications.
  - 14.2.5. The certificate will be reviewed, signed and dated by Patheon's Quality department.
- 14.3. Jazz Pharmaceuticals has the sole responsibility for the final release of the finished Product to the market.
- 14.4. Upon Jazz Pharmaceuticals QA release, Patheon may ship the Product to a site specified by the Jazz Pharmaceuticals for further processing, storage or distribution.

- 14.5. Patheon in certain limited cases, may ship the Product in “quarantine” status to a site specified by Jazz Pharmaceuticals. In such exceptional cases, Jazz Pharmaceuticals QA will provide a written authorization to release the Product in “quarantine” status for further processing. The terms of the quarantine shipment to be agreed by Patheon and Jazz Pharmaceuticals QA.

#### **15. Stability**

- 15.1. Patheon will store the stability samples in accordance with cGMPs and all applicable regulations and Specifications.
- 15.2. Patheon will perform stability testing for the Product as described in the approved stability protocol.
- 15.3. Patheon will notify Jazz Pharmaceuticals of any suspect or actual stability failure for the Product within one business day of verification of the aberrant test data.
- 15.4. Patheon will provide stability data to Jazz Pharmaceuticals as agreed to in writing by both parties.
- 15.5. In the event of the termination of this Quality Agreement, Patheon will continue to provide Jazz Pharmaceuticals with stability data until all Product distributed by Jazz Pharmaceuticals has reached the end of its shelf life.

#### **16. Review of Quality Agreement**

- 16.1. This Quality Agreement will be reviewed annually.
- 16.2. Modifications can be made as required to ensure continued compliance with all applicable laws, regulations and procedures. Any such modifications must be in writing and approved by both Patheon and Jazz Pharmaceuticals.

## 17. Quality Contacts

### Jazz Pharmaceuticals, Inc.

3180 Porter Drive  
Palo Alto, CA 94304  
USA  
650.496.3777 (main)

[ \* ]  
Director, Quality Sciences  
Jazz Pharmaceuticals, Inc.

3180 Porter Drive  
Palo Alto, CA 94304  
USA

[ \* ]  
650.496.2641 (fax)  
[ \* ]

[ \* ]  
Director, Regulatory Affairs/Compliance  
Jazz Pharmaceuticals, Inc.

3180 Porter Drive  
Palo Alto, CA 94304  
USA

[ \* ]  
650.496.2641 (fax)  
[ \* ]

### Patheon Pharmaceuticals Inc.

2110 East Galbraith Road  
Cincinnati, OH 45237-1625  
USA  
513 948-9111 (main)

[ \* ]  
Manager, GMP Services  
Patheon Pharmaceuticals Inc.

2110 East Galbraith Road  
Cincinnati, OH 45237-1625  
USA

[ \* ]  
[ \* ]  
[ \* ]

[ \* ]  
Manager, Quality Assurance  
Patheon Pharmaceuticals Inc.

2110 East Galbraith Road  
Cincinnati, OH 45237-1625  
USA

[ \* ]  
[ \* ]  
[ \* ]

## 18. Approvals

### Jazz Pharmaceuticals, Inc.

Name: Janne Wissel  
Title: Senior Vice President, Development  
Signature: /s/ Janne Wissel  
Date: March 13, 2007

### Patheon Pharmaceuticals Inc.

Name: Jack Domet  
Title: Director, Quality Operations  
Signature: /s/ Jack Domet  
Date: March 13, 2007

### Jazz Pharmaceuticals, Inc.

Name: Gopi Kurse  
Title: Senior Director, Quality Sciences  
Signature: /s/ Gopi Kurse  
Date: March 13, 2007

## COMMERCIAL LEASE

THIS LEASE is entered into as of June 2, 2004 (the "**Effective Date**"), by and between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, a body having corporate powers under the laws of the State of California ("**Landlord**"), and JAZZ PHARMACEUTICALS, INC., a Delaware corporation ("**Tenant**").

**1. BASIC LEASE INFORMATION.** The following is a summary of basic lease information. Each item in this Article 1 incorporates all of the terms set forth in this Lease pertaining to such item and to the extent there is any conflict between the provisions of this Article 1 and any other provisions of this Lease, the other provisions shall control. Any capitalized term not defined in this Lease shall have the meaning set forth in the Glossary that appears at the end of this Lease.

Description of Premises:	43,848 square feet of Rentable Area within the two-story building shown on the site plan attached hereto as <b><u>Exhibit A</u></b>
Address of Premises:	3180 Porter Drive Palo Alto, California 94304
Rentable Area of Premises:	43,848 square feet of Rentable Area
Initial Term:	Forty-eight (48) months
Options to Extend - Renewal Options and Renewal Terms:	
Option 1:	12 months (months 49-60)
Option 2:	24 months (months 61-84)
Option 3:	24 months (months 85-108)
Option 4:	12-48 months (months 109-156)
Scheduled Date for Delivery of the Premises:	The Effective Date
Commencement Date:	The actual date of delivery of the Premises
Rent Commencement Date:	The earlier of (a) the termination date of the Sublease between Tenant and McKinsey for the premises located at 630 Hansen Way, Palo Alto, and (b) August 30, 2004; provided that in no event shall the Rent Commencement Date be earlier than August 16, 2004.
Initial Term Expiration Date:	Forty-eight (48) months after the Rent Commencement Date

Base Rent:

Months 1-6: \$26,308.80 per month (\$1.20 per sq. ft. on 21,924 sq. ft.)  
Months 7-12: \$42,751.80 per month (\$1.30 per sq. ft. on 32,866 sq. ft.)  
Months 13-24: \$59,194.80 per month (\$1.35 per sq. ft. on 43,848 sq. ft.)  
Months 25-36: \$61,387.20 per month (\$1.40 per sq. ft. on 43,848 sq. ft.)  
Months 37-48: \$65,772.00 per month (\$1.50 per sq. ft. on 43,848 sq. ft.)

Security Deposit: \$151,275, payable on the Commencement Date

Parking: 3.3 spaces per 1,000 sq. ft. of Rentable Area for a total of 145 spaces (all parking areas on the Property)

Use: Research and development, wet laboratory use and associated administrative office uses

Tenant Improvement Allowance: \$500,000 (\$11.40 per sq. ft. of Rentable Area) payable by Landlord to Tenant in accordance with Section 9 hereof.

Addresses for Notice:

Landlord: The Board of Trustees of the  
Leland Stanford Junior University  
Stanford Management Company  
2770 Sand Hill Road  
Menlo Park, CA 94025  
Attention: Managing Director, Stanford Research Park

with a copy to: Carol K. Dillon, Esq.  
Bingham McCutchen LLP  
1900 University Avenue  
East Palo Alto, CA 94303

Tenant: Jazz Pharmaceuticals, Inc.  
Attention: Facilities Manager  
3180 Porter Drive  
Palo Alto, CA 94304

with a copy to: Senior Vice President and General Counsel  
3180 Porter Drive  
Palo Alto, CA 94304

Pre-Occupancy: 630 Hansen Way  
Palo Alto, CA 94304

Brokers: CRESA Partners



## 2. PREMISES

**2.1 Premises.** Subject to the terms, covenants and conditions set forth in this Lease, Landlord hereby leases to Tenant and Tenant hereby leases from Landlord those premises (the "**Premises**") shown on the site plan attached as **Exhibit A**. The approximate total Rentable Area of the Premises is specified in Article 1. The Rentable Area of the Premises shall be conclusively presumed to be as stated in Article 1, and shall not be subject to adjustment by either Landlord or Tenant during the Term.

**2.2 Exterior Area.** Landlord hereby grants to Tenant and its employees, agents, contractors and invitees (collectively, "**Tenant's Agents**") a license to use the public areas, sidewalks, driveways, parking areas and other public amenities associated with the Premises (the "**Exterior Area**") during the Term. Together, the Premises and the Exterior Area are sometimes referred to in this Lease as the "**Property**." Tenant's rights to the Exterior Area shall be subject to Landlord's reserved rights described in Article 16.

**2.3 Parking.** Tenant shall have the right to use the number of parking spaces specified in Article 1. Tenant's rights shall not be assigned, sublet or otherwise transferred separately from the Premises. Except during construction of the Tenant Improvements, Tenant shall not at any time park or permit the parking of commercial trucks in any portion of the Exterior Area not designated by Landlord for such use by Tenant. Except during construction of the Tenant Improvements, Tenant shall not park nor permit to be parked any inoperative vehicles or store any materials or equipment on any portion of the parking area or other areas of the Exterior Area. Tenant agrees to assume responsibility for compliance by Tenant's Agents with the parking provisions contained in this Section.

**2.4 Furniture.** Pursuant to the terms and conditions of the Bill of Sale attached hereto as **Exhibit B**, Landlord shall sell to Tenant the movable furniture located in the Premises as of the Commencement Date (the "**Movable Furniture**"). In addition to the foregoing, Tenant shall have the right to use the furniture affixed to the Premises as of the Commencement Date, including, without limitation, any modular workstations (the "**Affixed Furniture**", and together with the Movable Furniture, the "**Existing Furniture**"). Landlord and Tenant acknowledge and agree that the list of furniture attached hereto as **Exhibit C** is generally the parties' understanding of the furniture included within the definition of Existing Furniture. Notwithstanding the foregoing, Landlord does not make any express or implied representation or warranty that **Exhibit C** is an accurate or correct representation of the furniture included within the definition of Existing Furniture. Tenant shall maintain the Affixed Furniture in substantially the same condition and repair as it is on the Commencement Date and at the end of the Term shall surrender the Affixed Furniture in the same condition as it was in as of the Commencement Date (normal wear and tear and damage by casualty excepted), which Landlord acknowledges is in used condition. Notwithstanding the foregoing, Tenant may remove any Affixed Furniture from the Premises that is in unusable condition or becomes worn in the ordinary course of business such that it is no longer appropriate for Tenant's use, as reasonably determined by Tenant, and shall not have an obligation to surrender such Affixed Furniture at the end of the Term.

### 3. ACCEPTANCE

The Premises as furnished by Landlord consist of the improvements as they exist as of the Effective Date and Landlord shall have no obligation for construction work or improvements on or to the Premises to prepare the Premises for Tenant's occupancy, except for the repairs set forth on **Schedule 3** attached hereto (the "**Landlord Repairs**"). Landlord shall, at its sole cost and expense (not to exceed \$15,000), complete the Landlord Repairs within two (2) weeks after the Effective Date and shall cooperate and not materially interfere with Tenant's construction of the Tenant Improvement Work. Within five (5) business days after completion of the Landlord Repairs, Tenant and Landlord shall conduct a walk-through of the Premises for the purpose of confirming substantial completion of the Landlord Repairs and developing a list of any items that have not been completed ("**Punch List Items**"). Landlord shall complete the Punch List Items, if any, within a reasonable period of time, not to exceed thirty (30) days, after Landlord and Tenant conduct the walk-through. Notwithstanding the foregoing, to the extent the aggregate cost of the Landlord Repairs and Punch List Items exceed \$15,000, Landlord shall not be responsible for such excess amount. Upon completion of the Landlord Repairs and Punch List Items, if any, Tenant shall execute a written acknowledgment that the Landlord Repairs and Punch List Items have been completed, and shall reimburse Landlord for any excess costs incurred by Landlord in connection with the Landlord Repairs and Punch List Items. Notwithstanding any of the foregoing, in the event Landlord determines in its reasonable judgment that the compressors 1A and 2A listed on **Schedule 3** need to be replaced, Landlord shall be responsible for the cost of such replacement and the \$15,000 cap on the aggregate cost of the Landlord Repairs shall not apply to such replacement. Prior to entering into this Lease, Tenant has made a thorough and independent examination of the Premises and all matters related to Tenant's decision to enter into this Lease. Tenant is familiar with all aspects of the Premises and the Existing Furniture and, except for the Landlord Repairs, is satisfied that they are in an acceptable condition and meet Tenant's needs. Except as expressly provided in this Lease, Tenant does not rely on, and Landlord does not make, any express or implied representations or warranties as to any matters including, without limitation, (a) the physical condition of the Premises, Building Structure, Building Systems, the Existing Furniture or the Exterior Area, (b) the existence, quality, adequacy or availability of utilities serving the Premises, (c) the use, habitability, merchantability, fitness or suitability of the Premises for Tenant's intended use, (d) the likelihood of deriving business from Tenant's location or the economic feasibility of Tenant's business, (e) Hazardous Materials in the Premises, or on, in, under or around the Property, (f) zoning, entitlements or any laws, ordinances or regulations which may apply to Tenant's use of the Premises or business operations, or (g) any other matter. Tenant has satisfied itself as to such suitability and other pertinent matters by Tenant's own inquiries and tests into all matters relevant in determining whether to enter into this Lease. Except for the Landlord Repairs, Tenant accepts the Premises and the Existing Furniture in their existing "as-is" condition. Notwithstanding any of the foregoing, Landlord represents and warrants that, to Landlord's actual knowledge, as of the Effective Date, the Premises is in compliance with the ADA (as defined in Section 11.1) without regard to any compliance with the ADA that may be required due to Tenant's Alterations (including, without limitation, the Tenant Improvement Work) to the Premises.

#### 4. TERM

**4.1 Term.** The Premises are leased for an initial term (the “**Initial Term**”) commencing on the date Landlord delivers possession of the Premises to Tenant (the “**Commencement Date**”) and expiring on the Initial Term Expiration Date. All of Tenant’s obligations under this Lease other than the payment of Rent (which shall commence on the Rent Commencement Date) shall be effective as of the Commencement Date. As used herein, the term “**Term**” shall mean the Initial Term plus all Renewal Terms as to which Tenant exercises its Renewal Option, and the term “**Expiration Date**” shall mean the Initial Term Expiration Date, or the last day of the last such Renewal Term, as applicable. The Term shall end on the Expiration Date, or such earlier date on which this Lease terminates pursuant to its terms. The date upon which this Lease actually terminates, whether by expiration of the Term or earlier termination pursuant to the terms of this Lease, is sometimes referred to in this Lease as the “**Termination Date**”. Upon delivery of possession, Landlord shall specify in a written notice to Tenant, substantially in the form of **Exhibit D**, the Commencement Date, Rent Commencement Date and Expiration Date of the Initial Term of this Lease. Such notice shall be delivered promptly after all of the information set forth in the notice has been determined; provided that Landlord’s failure to do so shall not in any way affect either party’s rights or obligations under this Lease. Notwithstanding the foregoing, Landlord represents and warrants that, as of the Effective Date, the lease agreement between Landlord and Lucent Technologies Inc. (“**Lucent**”) dated May 26, 1998, pursuant to which Landlord leased the Premises to Lucent, has been terminated.

**4.2 Renewal Option.** Tenant shall have four consecutive options (each, a “**Renewal Option**”) in Tenant’s sole discretion, to extend the Term for the following time periods: (a) first Renewal Option is for twelve (12) months after the Initial Term; (b) second Renewal Option is for a consecutive twenty-four (24) months; (c) third Renewal Option is for a consecutive twenty-four (24) months, and (d) fourth Renewal Option is for a consecutive twelve (12), twenty-four (24), thirty-six (36) or forty-eight (48) months, as elected by Tenant in its sole discretion at the time Tenant exercises its fourth Renewal Option (each, a “**Renewal Term**”). Each Renewal Option shall be automatically void if an Event of Default by Tenant exists and remains uncured at the time of exercise of the Renewal Option. Each Renewal Option must be exercised, if at all, by written notice from Tenant to Landlord given not less than six (6) months prior to the expiration of Initial Term or then-current Renewal Term. Each Renewal Option (other than the first Renewal Option) is personal to Tenant and shall be inapplicable and null and void if Tenant assigns its interest under this Lease, except in the event of an assignment pursuant to Section 14.7. Each Renewal Term shall be upon the same terms and conditions as the original Term, except that the Base Rent shall be determined as follows:

- (i) First Renewal Term:  
Months 49-60: \$67,964.44 per month (\$1.55 per sq. ft. of Rentable Area)
- (ii) Second Renewal Term:  
Months 61-72: Prevailing Market Rent as of the commencement of the second Renewal Term (as determined pursuant to **Exhibit E**).  
Months 73-84: 103% of Base Rent for Months 61-72.

- (iii) Third Renewal Term:  
Months 85-96: Prevailing Market Rent as of the commencement of the third Renewal Term (as determined pursuant to **Exhibit E**).  
Months 97-108: 103% of Base Rent for Months 85-96.
- (iv) Fourth Renewal Term:  
Months 12, 24, 36 or 48 (109-122, 132, 144, or 156): Prevailing Market Rent as of the commencement of the Fourth Renewal Term (as determined pursuant to **Exhibit E**).

## 5. RENT

**5.1 Base Rent.** Commencing upon the Rent Commencement Date, and thereafter during the Term, Tenant shall pay to Landlord the monthly Base Rent specified in Article 1 on or before the first day of each month, in advance, at the address specified for Landlord in Article 1, or at such other place as Landlord designates in writing, without any prior notice or demand and without any deductions or setoff whatsoever (except as otherwise expressly provided in this Lease). If the Rent Commencement Date occurs on a day other than the first day of a calendar month, or the Termination Date occurs on a day other than the last day of a calendar month, then the Base Rent for such fractional month will be prorated on the basis of the actual number of days in such month.

**5.2 Additional Rent.** All sums due from Tenant to Landlord under the terms of this Lease (other than Base Rent) shall be additional rent ("**Additional Rent**"), including without limitation the charges for Operating Expenses (described in Article 7) and all sums incurred by Landlord and reimbursable hereunder by Tenant to Landlord due to Tenant's failure to perform its obligations under this Lease. Except as otherwise expressly provided herein, all Additional Rent that is payable to Landlord shall be paid at the time and place that Base Rent is paid. Landlord will have the same remedies for a default in the payment of any Additional Rent as for a default in the payment of Base Rent. Together, Base Rent and Additional Rent are sometimes referred to in this Lease as "**Rent**".

**5.3 Late Payment.** Any unpaid Rent shall bear interest from the date due until paid at the rate of interest charged by Bank of America at its offices in San Francisco as its prime or reference rate, plus 4% (the "**Interest Rate**"). In addition, Tenant recognizes that late payment of any Rent will result in administrative expense to Landlord, the extent of which expense is difficult and economically impracticable to determine. Therefore, Tenant agrees that if Tenant fails to pay any Rent within five (5) days after its due date, an additional late charge of five percent (5%) of the sums so overdue shall become immediately due and payable; provided, however, if such a failure occurs only once in any twelve (12) month period, such late charge will not be payable with respect to such a failure. Tenant agrees that the late payment charge is a reasonable estimate of the additional administrative costs and detriment that will be incurred by Landlord as a result of such failure by Tenant. In the event of nonpayment of interest or late charges on overdue Rent, Landlord shall have, in addition to all other rights and remedies, the rights and remedies provided in this Lease and by law for nonpayment of rent.

**5.4 Security Deposit.** Concurrently with the execution of this Lease, Tenant shall deliver to Landlord the Security Deposit described in Article 1 in the form of cash or a letter of credit which is payable as provided herein. The Security Deposit shall be held by Landlord as security for the faithful performance of this Lease by Tenant of all of the terms, covenants and conditions of this Lease. If there is an Event of Default by Tenant with respect to any provisions of this Lease, including but not limited to the payment of Rent, Landlord may (but shall not be obligated to), without waiving any of Landlord's other rights and remedies under this Lease, apply the Security Deposit in whole or in part to remedy any failure by Tenant to pay any sums due under this Lease, to repair or maintain the Premises (with respect to repairs and maintenance that are Tenant's obligation hereunder), to perform any other terms, covenants or conditions of Tenant contained in this Lease, or to compensate Landlord for any costs, loss or damages which Landlord may suffer due to Tenant's Event of Default. To the extent inconsistent with the foregoing, Tenant hereby waives any restriction on the uses to which the Security Deposit may be applied as contained in Section 1950.7(c) of the California Civil Code and/or any successor statute, if applicable. Should Landlord so apply any portion of the Security Deposit, Tenant shall replenish the Security Deposit to the original amount within ten (10) business days after written demand by Landlord and Tenant's failure to do so shall, at Landlord's option, be an Event of Default by Tenant under this Lease. Landlord shall not be required to keep the Security Deposit separate from its general funds, and Tenant shall not be entitled to interest on the Security Deposit. No trust relationship is created herein between Landlord and Tenant with respect to the Security Deposit. If Landlord transfers the Premises or the Property during the Term, Landlord may pay the Security Deposit to any subsequent assignee or transferee in conformity with the provisions of Section 1950.7 of the California Civil Code and/or any successor statute, in which event the transferring landlord shall be released from all liability for the return of the Security Deposit. Tenant specifically grants to Landlord (and Tenant hereby waives the provisions of California Civil Code Section 1950.7 to the contrary) a period of thirty (30) days following the surrender of the Premises by Tenant to Landlord within which to inspect the Premises, make required restorations and repairs, receive and verify workmen's billings therefore, and prepare a final accounting with respect to the Security Deposit. In no event shall the Security Deposit be considered prepaid rent, except to the extent Landlord elects to apply such proceeds to rent becoming due in the future. If Tenant elects to use a letter of credit as the Security Deposit, the letter of credit shall be issued by a bank (the "**L-C Bank**") reasonably approved by Landlord and shall be in a form that is reasonably acceptable to Landlord in Landlord's reasonable discretion. The L-C Bank shall be a bank that accepts deposits, maintains accounts, has a local Santa Clara County office that will negotiate the letter of credit, or if no local office then the letter of credit shall provide for draws by Landlord upon delivery of the written draw request by courier or by fax (to be confirmed by telephone and with original to follow within three (3) business days) and payment to be made by wire transfer to Landlord's account as directed by Landlord upon receipt of the original or fax request. The deposits of the L-C Bank shall be insured by the Federal Deposit Insurance Corporation. Tenant shall pay all expenses, points, or fees incurred by Tenant in obtaining the letter of credit. The letter of credit shall: (a) name Landlord as beneficiary; (b) allow Landlord to make partial and multiple draws thereunder up to the face amount, as determined by Landlord in accordance with this Lease; (c) require the L-C Bank to pay to Landlord the amount of a draw upon receipt by the L-C Bank of a sight draft signed by Landlord and presented to the L-C Bank accompanied by a certification by Landlord that an Event of Default has occurred and is continuing or that Tenant

has failed to renew the letter of credit at least thirty (30) days prior to its expiration, and stating that the amount requested by Landlord is the amount needed to compensate Landlord in accordance with this Section 5.4; and (d) provide that Landlord can freely transfer it upon an assignment or other transfer of its interest in this Lease to the assignee or transferee without having to obtain the consent of Tenant or the L-C Bank. The letter of credit shall by its terms expire not less than one (1) year from the date issued, and shall provide for automatic one (1) year extensions unless Landlord is notified in writing not less than sixty (60) days prior to such expiration from the L-C Bank that the letter of credit will not be extended. In any event, unless Tenant deposits with Landlord a comparable cash Security Deposit or a replacement letter of credit, said letter of credit shall be renewed by Tenant for successive periods of not less than one (1) year. Tenant's failure to renew (including specifically but not limited to the delivery to Landlord of such renewal not less than thirty (30) days prior to expiration of the letter of credit) and maintain such letter of credit, shall entitle Landlord to draw on the letter of credit. Tenant shall be entitled to change banks issuing the letter of credit from time to time, subject to Landlord's reasonable approval and provided that the letter of credit meets the other conditions of this Section. Landlord shall be entitled to draw upon the letter of credit in accordance with this Section or at any time within thirty (30) days prior to the expiration date of the letter of credit in accordance with the terms of this Lease, unless Tenant shall have delivered to Landlord a replacement letter of credit meeting the requirements of this Section.

## 6. USE OF PREMISES AND CONDUCT OF BUSINESS

**6.1 Permitted Use.** Tenant may use and occupy the Premises during the Term solely for the uses specified and permitted in Article 1 and for no other purpose without the prior written consent of Landlord, such consent to be granted or withheld in Landlord's sole discretion; provided that, subject to Article 14, (a) during the first two (2) years of the Term, Tenant shall have the right to Sublease up to fifty percent (50%) of the Premises for service office use (i.e. law firms, accounting firms, consulting firms and other professional service uses, other than medical clinics, medical offices or dental offices) ("**Service Office Use**"), and (b) at any other time during the Term, Tenant shall have the right to Sublease up to twenty-five (25%) of the Premises for Service Office Use, without Landlord's approval of a change in use. Tenant's use of the Property shall in all respects comply with all Applicable Laws (as defined in Section 11.1).

**6.2 Prohibited Uses.** Tenant shall not use the Premises or allow the Premises to be used for any purpose that (a) is illegal, (b) in any manner causes, creates or results in a waste or a private or public nuisance, (c) is of a nature to involve substantial hazard, such as the manufacture or use of explosives, chemicals or products that may explode or that otherwise may harm the health or welfare of persons or the physical environment (provided that the research, development and manufacture of pharmaceutical and biotechnology products shall not be deemed to be inherently hazardous and is specifically permitted hereunder, subject to the provisions of Article 12), or (d) involves the release of any Hazardous Materials, except for Hazardous Materials that Tenant has the right to use on the Premises pursuant to Section 12.3. Tenant shall not place any loads upon the floors, walls, or ceiling which endanger the structure, or place any Hazardous Material in the drainage system of the Premises, or overload existing electrical or other mechanical systems. Tenant shall not use any machinery or equipment which causes any substantial noise or vibration. No waste materials or refuse shall be dumped upon or

permitted to remain upon any part of the Premises or outside of the Premises except in trash containers placed inside exterior enclosures designated by Landlord for that purpose or inside of the Premises where approved by Landlord. No materials, supplies, equipment, finished products or semi-finished products, raw materials or articles of any nature shall be stored outside or permitted to remain outside the Premises or on any portion of the Exterior Area unless otherwise approved by Landlord in its sole discretion. No loudspeaker or other device, system or apparatus that can be heard by the occupants of any neighboring property shall be used in or at the Premises without the prior written consent of Landlord, which consent shall not be unreasonably withheld. No explosives or firearms shall be brought into the Premises.

## 7. OPERATING EXPENSES

**7.1 Net Lease.** This Lease is intended to be a net lease, and the Base Rent and all Additional Rent are to be paid by Tenant absolutely net of all costs and expenses relating to Landlord's ownership, operation and maintenance of the Property, except as specifically provided in this Lease. The provisions of this Article 7 for the payment of Operating Expenses are intended to pass on to Tenant all such costs and expenses that are incurred by Landlord in connection with the ownership, operation and maintenance of the Property beginning on the Rent Commencement Date.

**7.2 Operating Expenses.** For purposes of this Article 7, "**Operating Expenses**" means the total costs and expenses paid or incurred by Landlord in connection with the ownership, management, operation, maintenance, repair and replacement of the Property, beginning on the Rent Commencement Date, including, without limitation, all costs of:

(a) taxes, assessments and charges levied upon or with respect to the Property or any personal property of Landlord used in the operation of the Property, or on Landlord's interest in the Property or its personal property ("**Real Estate Taxes**"). Real Estate Taxes shall include, without limitation, all general real property taxes and general and special assessments, charges, fees, or assessments for transit, housing, police, fire, or other governmental services or purported benefits to the Property or the occupants thereof, service payments in lieu of taxes that are now or hereafter levied or assessed against Landlord by the United States of America, the State of California or any political subdivision thereof, or any other political or public entity, and shall also include any other tax, assessment or fee, however described, that may be levied or assessed as a substitute for, or as an addition to, in whole or in part, any other Real Estate Taxes, whether or not now customary or in the contemplation of the parties as of the Effective Date. Real Estate Taxes shall also include reasonable legal fees, costs, and disbursements incurred in connection with proceedings to contest, determine, or reduce Real Estate Taxes. Real Estate Taxes shall not include franchise, transfer, succession, gift, inheritance, gross receipts or capital stock taxes or income taxes measured by the net income of Landlord unless, due to a change in the method of taxation, any of such taxes is levied or assessed against Landlord as a substitute for, or as an addition to, in whole or in part, any other tax that would otherwise constitute a Real Estate Tax. Without limiting the generality of the foregoing, Landlord shall have the right, in its sole discretion, to cause all Real Estate Taxes applicable to the Property to be segregated from other real property owned by Landlord, and to have such Real Estate Taxes billed directly to Tenant by the Santa Clara County Assessor. In the event Landlord exercises such right, Tenant shall be liable for and shall pay before delinquency

all such Real Estate Taxes applicable to the Term and shall deliver satisfactory evidence of such payment to Landlord. As soon as reasonably possible after the Commencement Date (taking into account the schedule of the Santa Clara County Tax Assessor) (i) Landlord shall apply for a reduction in all taxes based upon the value of the Premises, (ii) Landlord shall diligently pursue such reduction, (iii) all costs of such application and pursuance shall be the sole responsibility and expense of Landlord, and (iv) any reduction for periods during the Term of this Lease (including any retroactive reduction) shall be immediately passed on and credited to Tenant hereunder. Notwithstanding the foregoing, during the first six (6) months after the Rent Commencement Date, Tenant shall only be required to pay fifty percent (50%) of the Real Estate Taxes that would otherwise be due and payable under this Lease (taking into account any reductions obtained by Landlord pursuant to this Section (i.e. 50% based on any lower valuation obtained)), unless Tenant enters into an Assignment or Sublease of the Premises (except for an Assignment or Sublease pursuant to Section 14.7) during such six (6) month period, in which event one hundred (100%) of the Real Estate Taxes shall be due during the period of such Assignment or Sublease. To the extent any taxes are assessed that are payable by Tenant hereunder and as to which Landlord could elect to pay a lump sum or installments over time, Landlord will elect to pay in installments, and Tenant shall be responsible for only those installments due during the Term.

(b) repair, maintenance, replacement and supply of air conditioning, heating, ventilating, mechanical, elevator, sanitary and storm drainage systems and all other mechanical systems (the "**Building Systems**");

(c) landscaping and gardening of the Exterior Area;

(d) repaving, repairing, maintaining and restriping of parking areas, amortized over its useful life as reasonably determined by Landlord;

(e) repairs and maintenance to the Exterior Area, and all labor and material costs related thereto;

(f) repair, maintenance and replacement of any security systems and fire protection systems installed in the Premises;

(g) reasonable general maintenance, janitorial services, trash removal, cleaning and service contracts and the cost of all supplies, tools and equipment required in connection therewith;

(h) all premiums and costs for reasonable insurance carried by Landlord on the Premises, the Exterior Area and the Property, or in connection with the use or occupancy thereof (including all amounts paid as a result of loss sustained that would be covered by such policies but for deductible or self-insurance provisions up to \$25,000), including, but not limited to, the premiums and cost of fire and extended coverage, earthquake, vandalism and malicious mischief, public liability and property damage, worker's compensation insurance, rental income insurance and any other insurance commonly carried by prudent owners of comparable buildings, provided that Tenant shall not be responsible for the costs of terrorism or mold insurance;



(i) to the extent not included in subsection (j) below, wages, salaries, payroll taxes and other labor costs and employee benefits for all persons (excluding executives of Landlord or Landlord's managing agent) engaged in the operation, management, maintenance and security of the Property;

(j) a commercially reasonable management fee that, as long as The Board of Trustees of the Leland Stanford Junior University (or any affiliate of it) is the Landlord under this Lease, is payable to an entity other than Landlord (or any affiliate of Landlord);

(k) fees, charges and other costs of all independent contractors engaged by Landlord to provide services to be provided by Landlord hereunder;

(l) license, permit and inspection fees for work required to be performed by Landlord hereunder;

(m) the cost of any transit services or traffic mitigation programs that Landlord implements in the Stanford Research Park, including without limitation charges for service and surcharges imposed directly or indirectly on the Property by any governmental agencies on or with respect to transit (including transit services which may be provided in the future to occupants of the Stanford Research Park) or automobile usage or parking facilities (collectively, "**Transit Fees**"). Tenant's share of Transit Fees shall be assessed pro rata and on a non-discriminatory basis, based on a reasonable standard applied in a non-discriminatory manner (that is not based on whether other tenants of Landlord are obligated to pay such Transit Fees) by Landlord (for example, based on the rentable area of the Premises as compared to the total rentable area of the Stanford Research Park (or the area being served by the service, if less than the entire Stanford Research Park), or based on the average employee headcount in the Premises as compared to the overall employee density of the Stanford Research Park). Tenant shall not be required to pay any Transit Fees for programs that do not serve the Premises. Notwithstanding the foregoing, Landlord represents that, as of the Effective Date, there are no Transit Fees applicable to the Premises;

(n) Tenant's pro rata share (based on the Rentable Area of the Premises as compared to the Rentable Area of the other properties of Landlord that use such supplies, tools, machines and equipment) of the cost of supplies, tools, machines and equipment used in operation and maintenance of the Exterior Area;

(o) any reasonable capital improvements to the Property that are (i) necessary to satisfy Landlord's maintenance and repair obligations under this Lease, (ii) made to the Property as a labor-saving or energy saving device, (iii) made to the Property to reduce Operating Expenses, or (iv) required due to any change in Applicable Law after the date of this Lease; provided that the cost of any such capital improvements shall be amortized over the useful life of the improvement in question (determined in accordance with applicable tax laws), together with interest on the unamortized balance at an interest rate equal to Landlord's cost of funds used for the purpose of constructing such capital improvements;

(p) the cost of contesting the validity or applicability of any governmental enactments that may affect Operating Expenses;

(q) audit and bookkeeping fees, legal fees and expenses incurred in connection with the operation or management of the Property, including, without limitation, the costs of audits by certified public accountants of Operating Expense records (excluding costs incurred in connection with negotiations or disputes with tenants or prospective tenants);

(r) to the extent not included within subsection (j) above, Tenant's pro rata share (based on the Rentable Area of the Premises as compared to the Rentable Area of all of Landlord's properties within the Stanford Research Park supported by such office) of the costs for an off-site property management office; and

(s) any other expenses of any kind whatsoever reasonably incurred in connection with the management, operation, maintenance and repair of the Property.

Notwithstanding anything to the contrary herein, (i) all capital improvements included within the definition of Operating Expenses shall be amortized over the useful life of the improvement in question (determined in accordance with applicable tax laws), and (ii) Operating Expenses shall not include the repairs and replacements to the Building Structure that shall be performed at Landlord's sole cost and expense pursuant to Section 8.1.

**7.3 Payment of Operating Expenses.** Commencing on the Rent Commencement Date, Tenant shall pay to Landlord as Additional Rent one twelfth (1/12) of the Operating Expenses for each calendar year or portion thereof during the Term, in advance, on or before the first day of each month in an amount estimated by Landlord as stated in a written notice to Tenant. Landlord may by written notice to Tenant revise such estimates from time to time and Tenant shall thereafter make payments on the basis of such revised estimates. With reasonable promptness after the expiration of each calendar year, Landlord will furnish Tenant with a statement ("**Landlord's Expense Statement**") setting forth in reasonable detail the actual Operating Expenses for the prior calendar year and, if requested by Tenant, including reasonable back-up documentation. If the actual Operating Expenses for such year exceed the estimated Operating Expenses paid by Tenant for such year, Tenant shall pay to Landlord (whether or not this Lease has terminated) the difference between the amount of estimated Operating Expenses paid by Tenant and the actual Operating Expenses within twenty (20) days after the receipt of Landlord's Expense Statement. If the total amount paid by Tenant for any year exceeds the actual Operating Expenses for that year, the excess shall be credited against the next installments of Base Rent due from Tenant to Landlord, or, if after the Termination Date, the excess shall first be credited against any unpaid Base Rent or Additional Rent due and any remaining excess shall be refunded to Tenant concurrently with the furnishing of Landlord's Expense Statement.

**7.4 Proration.** If either the Rent Commencement Date or the Termination Date occurs on a date other than the first or last day, respectively, of a calendar year, Operating Expenses for the year in which the Rent Commencement Date or Termination Date occurs shall be prorated based on a 365-day year.

**7.5 Utility Costs.** Commencing on the Commencement Date, Tenant shall be solely responsible for and shall make all arrangements for all utilities and other services exclusively furnished to or used at the Premises, including, without limitation, water, gas, electricity, telephone and other electronic communications services, sewer service, waste pick-up and any other utilities, materials and services.

**7.6 Taxes on Tenant's Property and Business.** Tenant shall pay prior to delinquency all taxes levied or assessed by any local, state or federal authority upon the conduct of Tenant's business in the Premises or upon Tenant's Property (as defined in Section 9.5) and shall deliver satisfactory evidence of such payment to Landlord. If the assessed value of the Property is increased by the inclusion of a value placed upon Tenant's Property, Tenant shall pay to Landlord, upon written demand, the taxes so levied against Landlord, or the portion of Landlord's taxes resulting from said increase in assessment, as determined from time to time by Landlord.

**7.7 Tenant's Right to Perform.** Notwithstanding any of the foregoing, Tenant may elect at any time by written notice to Landlord to undertake the service, repair, maintenance and replacement obligations set forth in Sections 7.2 and 8.1, or any portion thereof; provided that in all circumstances Landlord shall continue to pay, and be reimbursed by Tenant for, the costs set forth in Section 7.2(a), (h), (m) and (o). In the event Tenant elects to undertake a portion of such obligations, the management fee owing to Landlord pursuant to Section 7.2(j) shall be equitably reduced as reasonably determined by Landlord and in the event Tenant elects to undertake all of such obligations (excepting those set forth in Section 7.2(a), (h), (m) and (o)), Tenant shall not owe Landlord any management fee or any amounts under Sections 7.2(i), (n) or (r). Notwithstanding the foregoing, Landlord shall have the right to take over the service, repair, maintenance and replacement obligations set forth in Sections 7.2 and 8.1 upon written notice to Tenant in the event: (a) Tenant elects to undertake such obligations but fails to perform such obligations in a manner commensurate with comparable office buildings located in the Stanford Research Park and such failure is not cured within thirty (30) days after receipt of written notice from Landlord of such failure (the "**Failure Notice**"), (b) Landlord delivers in good faith more than three (3) Failure Notices within any twelve (12) month period, or (c) Tenant enters into an Assignment of this Lease or a Sublease of more than fifty (50%) of the Premises, except for an Assignment or Sublease in accordance with Section 14.7. In the event Tenant elects to undertake such obligations, or any portion thereof, Landlord shall have the right at least once in any twelve (12) month period, after five (5) days notice to Tenant, to conduct an inspection of the Premises to ensure that Tenant is meeting the requirements set forth in this Section 7.7 and Tenant shall reimburse Landlord for its reasonable costs incurred in conducting such investigation within twenty (20) days after receipt of an invoice from Landlord.

**7.8 Tenant's Audit Rights.** Notwithstanding anything in this Lease to the contrary, Tenant shall have the right, after reasonable notice, at reasonable times, and no more than once in any calendar year, to inspect and photocopy at Landlord's office Landlord's accounting records relating to the operation and management of the Property. If, after such inspection and photocopying, Tenant disputes the amount of Operating Expenses, Tenant shall have the right to engage an independent certified public accountant reasonably approved by Landlord to audit and/or review Landlord's records to determine the proper amount of Operating Expenses. If it shall be finally determined by such audit that there was an error in calculating the Operating Expenses, then either (a) Landlord shall at its election reimburse Tenant for any overpayment or credit the amount of such overpayment against the next monthly installment of Operating Expenses payable under this Lease, or (b) Tenant shall within twenty (20) days after

such determination pay any amounts due to Landlord. If Landlord desires to contest such audit results, Landlord may do so by submitting the results of the audit to arbitration through JAMS San Jose or San Francisco offices within thirty (30) days after receipt of the results of the audit, and the arbitration shall be final and binding upon Landlord and Tenant. Tenant agrees to pay the cost of such audit, provided that, if the audit reveals that Landlord's determination of Operating Expenses was in error in Landlord's favor by more than five percent (5%), Landlord shall pay the cost of such audit. Nothing in this Section 7.8 shall entitle Tenant to withhold any disputed portion of Operating Expenses pending the results of the audit.

## **8. REPAIRS, MAINTENANCE AND SERVICES**

**8.1 Landlord's Obligations.** Except as specifically provided in this Lease, Landlord shall not be required to furnish any services, facilities or utilities to the Premises or to Tenant, and Tenant assumes full responsibility for obtaining and paying for all services, facilities and utilities to the Premises. Landlord will repair, replace and maintain the Building Systems, the Exterior Area, and the structural portions of the Premises, including the foundation, floor/ceiling slabs, roof, curtain wall, mullions, columns, beams, shafts (including elevator shafts), stairs, stairwells, and elevators (collectively, the "**Building Structure**"). Tenant shall notify Landlord in writing when it becomes aware of the need for any repair, maintenance or replacement which is Landlord's responsibility under this Section. The costs of such repair, replacement and maintenance shall be included in Operating Expenses; provided, however, that Operating Expenses will not include costs (and Tenant will not be billed for such costs) for any capital repair to or replacement of the Building Structure (excluding the costs of non-capital repair and maintenance of the Building Structure). Notwithstanding the foregoing, Tenant shall reimburse Landlord upon written demand as Additional Rent for the cost of any repair to the Premises, Building Structure, Building Systems or Exterior Area which is attributable to the conduct (other than Tenant's use of the Premises in the ordinary course of business) of Tenant or Tenant's Agent. This reimbursement shall be Additional Rent. Tenant hereby waives and releases any right it may have under any law, statute or ordinance now or hereafter in effect to make any repairs which are Landlord's obligation under this Section.

**8.2 Tenant's Obligations.** Except as provided in Sections 8.1, 12.2(b), 12.5(b) and 12.5(c), Tenant assumes full responsibility for the repair, replacement and maintenance of the Premises. Tenant shall take good care of the Premises and keep the Premises (other than the Exterior Area, Building Structure and Building Systems which are the responsibility of Landlord) in good working order and in a clean, safe and sanitary condition. All repairs and replacements by Tenant shall be made and performed: (a) at Tenant's cost and expense, (b) by contractors or mechanics approved by Landlord, in accordance with Section 9.3(a), (c) so that same shall be at least equal in quality, value and utility to the original work or installation at the Effective Date, (d) in a manner and using equipment and materials that will not interfere with or impair the operation of the Building Systems, and (e) in accordance with Article 9 (if applicable), and all Applicable Laws.

**8.3 Security.** Tenant shall be solely responsible for the security of the Premises and Tenant's Agents while in or about the Premises. Any security services provided to the Property by Landlord shall be at Landlord's sole discretion and Landlord shall not be liable to Tenant or Tenant's Agents for any failure to provide security services or any loss, injury or damage suffered as a result of a failure to provide security services.

**8.4 Special Services.** If Tenant requests any services from Landlord other than those for which Landlord is obligated under this Lease, Tenant shall make its request in writing and Landlord may elect in its sole discretion whether to provide the requested services. If Landlord provides any special services to Tenant, Landlord shall charge Tenant for such services at the actual cost incurred by Landlord in providing the services and Tenant shall pay the cost of such services as Additional Rent within fifteen (15) business days after receipt of Landlord's invoice.

## **9. INITIAL IMPROVEMENT WORK; ALTERATIONS**

**9.1 Tenant Improvements.** Tenant shall be responsible for the design and construction of all initial improvements to the Premises (the "**Tenant Improvement Work**") and shall use diligent efforts to cause the construction of the Tenant Improvement Work in a first class manner and in compliance with all Applicable Laws. Without limiting any other provision of this Lease, all of the provisions of this Article 9 and of Article 10 (Liens) shall apply to the Tenant Improvement Work. Landlord shall provide to Tenant a Tenant Improvement Allowance in the amount of \$11.40 per square foot of Rentable Area, for a total Tenant Improvement Allowance of \$500,000. Any costs in excess of the Tenant Improvement Allowance shall be paid by Tenant. The Tenant Improvement Allowance shall be used for the cost of developing and constructing the improvements to the Premises as set forth in the Site Plan dated May 14, 2004 and hereby approved by Landlord (including architects, design, inspection, construction and project management costs and related services and expenses, insurance and utilities) and shall not be used for any items of personal property. Landlord shall pay the Tenant Improvement Allowance to Tenant after the later of: (a) the date Tenant occupies the Premises and commences its business operations from the Premises, and (b) the Rent Commencement Date; provided that Tenant has provided to Landlord (x) an itemized statement of Tenant Improvement Work expenses, accompanied by reasonably detailed invoices and other supporting information as is reasonably requested by Landlord, and (y) either (i) unconditional lien releases in the form required under California Civil Code Section 3262 from all contractors, subcontractors and materialmen who shall have furnished materials or supplies or performed work or services in connection with the Tenant Improvement Work or (ii) evidence that Tenant has bonded over any liens that are in good faith disputed by Tenant. In the event Tenant does not expend all of the Tenant Improvement Allowance in construction of the Tenant Improvement Work, Landlord shall pay such excess amount to Tenant with the payment of the expended Tenant Improvement Allowance pursuant to the foregoing sentence. Notwithstanding the foregoing, Landlord shall have no obligation to pay the Tenant Improvement Allowance to the extent that (i) an Event of Default by Tenant exists under this Lease; (ii) a lien has been filed with respect to the Tenant Improvement Work that has not been released (subject to Tenant's right to bond over any liens that are in good faith disputed by Tenant); (iii) Tenant is not in compliance with the terms of all applicable permits for the Tenant Improvement Work; or (iv) the insurance required under this Lease is not in full force and effect; in each case until such Event of Default or failure to comply is cured, at which time payment will be made.

**9.2 Alterations by Tenant.** After completion of the Tenant Improvement Work, Tenant shall not make or permit any alterations to the Building Systems, and shall not make or permit any alterations, installations, additions or improvements, structural or otherwise (collectively, “Alterations”) in or to the Premises without Landlord’s prior written consent, which Landlord shall not unreasonably withhold, condition or delay. Landlord shall respond to any request by Tenant to make any Alteration within ten (10) business days after receipt of such request for consent from Tenant. Notwithstanding the foregoing, Landlord’s consent shall not be required (a) in the case of interior, cosmetic non-structural Alterations that do not require a permit, or affect the Building Systems, or affect the entryways or elevators, or (b) in the case of other Alterations that do not exceed a total price of One Hundred Thousand Dollars (\$100,000) per project and do not affect the Building Systems or the structural integrity of the Premises. All Alterations shall be done at Tenant’s sole cost and expense, including without limitation the cost and expense of obtaining all permits and approvals required for any Alterations.

**9.3 Project Requirements.** The following provisions of this Section 9.3 shall apply to all Alterations, whether or not requiring Landlord’s approval (unless otherwise noted):

(a) Prior to entering into a contract for Alterations requiring Landlord’s approval, Tenant shall obtain Landlord’s written approval, which approval shall not be unreasonably withheld, conditioned or delayed, of the identity of each of the design architect and the general contractor. Notwithstanding the foregoing, for purposes of the Tenant Improvement Work, the following architects and general contractors are hereby approved by Landlord: Dowler-Gruman Associates and SC Builders, Inc.

(b) Before commencing the construction of any Alterations, Tenant shall procure or cause to be procured the insurance coverage (either as part of Tenant’s regular insurance policy or by separate policies) described below and provide Landlord with certificates of such insurance in form reasonably satisfactory to Landlord. All such insurance shall comply with the following requirements of this Section and of Section 13.2.

(i) During the course of construction, to the extent not covered by property insurance maintained by Tenant pursuant to Section 13.2, comprehensive “all risk” builder’s risk insurance, including vandalism and malicious mischief, excluding earthquake and flood, covering all improvements in place on the Premises, all materials and equipment stored at the site and furnished under contract, and all materials and equipment that are in the process of fabrication at the premises of any third party or that have been placed in transit to the Premises when such fabrication or transit is at the risk of, or when title to or an insurable interest in such materials or equipment has passed to, Tenant or its construction manager, contractors or subcontractors (excluding any contractors’, subcontractors’ and construction managers’ tools and equipment, and property owned by the employees of the construction manager, any contractor or any subcontractor), such insurance to be written on a completed value basis in an amount not less than the full estimated replacement value of Alterations.

(ii) Commercial general liability insurance covering Tenant, Landlord and each construction manager, contractor and subcontractor engaged in any work on the Premises, which insurance may be effected by endorsement, if obtainable, on the policy required to be carried pursuant to Section 13.2, including insurance for completed operations,

elevators, owner's, construction manager's and contractor's protective liability, products completed operations for one (1) year after the date of acceptance of the work by Tenant, broad form blanket contractual liability, broad form property damage and full form personal injury (including but not limited to bodily injury), covering the performance of all work at or from the Premises by Tenant, its construction manager, contractors and subcontractors, and in a liability amount not less than the amount at the time carried by prudent owners of comparable construction projects, but in any event not less than Two Million Dollars (\$2,000,000) combined single limit, which policy shall include thereunder for the mutual benefit of Landlord and Tenant, bodily injury liability and property damage liability, and automobile insurance on any non-owned, hired or leased automotive equipment used in the construction of any work.

(iii) Workers' Compensation Insurance approved by the State of California, in the amounts and coverages required under workers' compensation, disability and similar employee benefit laws applicable to the Premises, and Employer's Liability Insurance with limits not less than One Million Dollars (\$1,000,000) or such higher amounts as may be required by law.

(c) All construction and other work in connection with any Alterations shall be done at Tenant's sole cost and expense and in a prudent and first class manner. Tenant shall construct the Alterations in accordance with all Applicable Laws, and with plans and specifications that are in accordance with the provisions of this Article 9 and all other provisions of this Lease.

(d) Prior to the commencement of any Alteration in excess of Ten Thousand Dollars (\$10,000), Landlord shall have the right to post in a conspicuous location on the Premises and to record in the public records a notice of Landlord's nonresponsibility. Tenant covenants and agrees to give Landlord at least ten (10) days prior written notice of the commencement of any such Alteration in order that Landlord shall have sufficient time to post such notice.

(e) Tenant shall take all necessary safety precautions during any construction.

(f) Tenant shall prepare and maintain (i) on a current basis during construction, annotated plans and specifications showing clearly all changes, revisions and substitutions during construction, and (ii) upon completion of construction of the Alterations, as-built drawings showing clearly all changes, revisions and substitutions during construction, including, without limitation, field changes and the final location of all mechanical equipment, utility lines, ducts, outlets, structural members, walls, partitions and other significant features. These as-built drawings and annotated plans and specifications shall be kept at the Premises and Tenant shall update them as often as necessary to keep them current. The as-built drawings and annotated plans and specifications shall be made available for copying and inspection by Landlord at all reasonable times.

(g) Upon completion of the construction of any Alterations in excess of Ten Thousand Dollars (\$10,000) during the Term, Tenant shall file for recordation, or cause to be filed for recordation, a notice of completion and shall deliver to Landlord evidence

satisfactory to Landlord of payment of all costs, expenses, liabilities and liens arising out of or in any way connected with such construction (except for liens that are contested in the manner provided herein).

**9.4 Ownership of Improvements.** Except as provided in Section 9.5, all Tenant Improvement Work, Alterations, and any other appurtenances, fixtures, improvements, equipment, additions and property permanently attached to or installed in the Premises at the commencement of or during the Term, shall at the end of the Term become Landlord's property without compensation to Tenant, or be removed in accordance with this Section. Upon written request by Tenant, Landlord shall notify Tenant in writing at the time of Landlord's approval of Alterations whether or not the proposed Alterations will be required to be removed by Tenant at the end of the Term. Tenant shall have no obligation to remove any (a) Alterations that Landlord has not designated in writing for removal, or (b) the Tenant Improvement Work. Tenant shall repair or pay the cost of repairing any damage to the Premises caused by the removal of Alterations. If Tenant fails to perform its repair obligations, without limiting any other right or remedy, Landlord may on five (5) business days prior written notice to Tenant perform such obligations at Tenant's expense and Tenant shall reimburse Landlord within twenty (20) days after demand for all reasonable out-of-pocket costs and expenses incurred by Landlord in connection with such repair. Tenant's obligations under this Section shall survive the termination of this Lease. Notwithstanding the foregoing, wet laboratory case work, fume hoods, flow hoods, high density filing systems and cabinets, computing and telecommunications equipment, appliances and Tenant's Property will be considered trade fixtures owned by Tenant, and subject to Section 9.5, Tenant shall have the right to remove or leave them at the end of the Term.

**9.5 Tenant's Personal Property.** All furniture, trade fixtures, furnishings, equipment and articles of movable personal property installed in the Premises by or for the account of Tenant (except for ceiling and related fixtures, HVAC equipment and floor coverings, which shall become the property of Landlord at the end of the Term), and which can be removed without structural or other material damage to the Premises (collectively, "**Tenant's Property**") shall be and remain the property of Tenant and may be removed by it at any time during the Term. Notwithstanding the foregoing, Tenant's Property shall not include the Affixed Furniture. Tenant shall remove from the Premises all Tenant's Property on or before the Termination Date, except such items as the parties have agreed pursuant to the provisions of this Lease or by separate agreement are to remain and to become the property of Landlord. Tenant shall repair or pay the cost of repairing any damage to the Premises resulting from such removal, and the provisions of Section 9.4 above shall apply in the event Tenant fails to do so. Any items of Tenant's Property which remain in the Premises after the Termination Date may, on five (5) business days prior written notice to Tenant, at the option of Landlord, be deemed abandoned and in such case may either be retained by Landlord as its property or be disposed of, without accountability, at Tenant's expense in such manner as Landlord may see fit.

## **10. LIENS**

Tenant shall keep the Premises free from any liens arising out of any work performed, material furnished or obligations incurred by or for Tenant and not paid when due. If Tenant does not, within ten (10) days following notice of the imposition of any such lien, cause the lien



to be released of record by payment or posting of a proper bond, Landlord shall have, in addition to all other remedies provided in this Lease and by law, the right but not the obligation to cause any such lien to be released by such means as it shall deem proper, including payment of the claim giving rise to such lien. All such sums paid by Landlord and all expenses reasonably incurred by it in connection therewith (including, without limitation, reasonable counsel fees) shall be payable to Landlord by Tenant upon demand with interest from the date incurred at the Interest Rate. Landlord shall have the right at all times to post and keep posted on the Premises any notices permitted or required by law or that Landlord shall deem proper for the protection of Landlord and the Premises from mechanics' and materialmen's liens, as more specifically provided in Section 9.3(d).

## 11. COMPLIANCE WITH LAWS AND INSURANCE REQUIREMENTS

**11.1 Applicable Laws.** Tenant, at Tenant's cost and expense, shall comply with all applicable laws, statutes, codes, ordinances, orders, rules, regulations, conditions of approval, and requirements, of all federal, state, county, municipal and other governmental authorities and the departments, commissions, boards, bureaus, instrumentalities, and officers thereof, and all administrative or judicial orders or decrees and all permits, licenses, approvals and other entitlements issued by governmental entities, and rules of common law, relating to or affecting the Premises or the use, operation or occupancy of the Premises by Tenant, whether now existing or hereafter enacted (collectively, "**Applicable Laws**"); provided that Tenant shall have no responsibility for compliance with Applicable Laws relating to (i) the Pre-Existing Environmental Condition (as defined in Section 12.2), or (ii) any Third Party Environmental Condition (as defined in Section 12.5(c)), except to the extent the acts or negligent omissions of Tenant or Tenant's Agents or subtenants on or about the Premises cause an exacerbation of the Pre-Existing Environmental Condition or any Third Party Environmental Condition. Without limiting the foregoing, Tenant shall be solely responsible for compliance with and shall make or cause to be made all such improvements and alterations to the Premises (including, without limitation, removing barriers and providing alternative services) as shall be required to comply with all applicable building codes, laws and ordinances relating to public accommodations associated with or arising from Tenant's use of the Premises or Tenant's Alterations, including the Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12111 et seq. (the "**ADA**"), and the ADA Accessibility Guidelines promulgated by the Architectural and Transportation Barriers Compliance Board, the public accommodations title of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000a et. seq., the Architectural Barriers Act of 1968, 42 U.S.C. §§ 4151 et. seq., as amended, Title V of the Rehabilitation Act of 1973, 29 U.S.C. §§ 790 et. seq., the Minimum Guidelines and Requirements for Accessible Design, 36 C.F.R. Part 1190, the Uniform Federal Accessibility Standards, and Title 24 of the California Code of Regulations, as the same may be amended from time to time, or any similar or successor laws, ordinances and regulations, now or hereafter adopted. Tenant's liability shall be primary and Tenant shall indemnify Landlord in accordance with Section 13.1 in the event of any failure or alleged failure of Tenant to comply with Applicable Laws. Any work or installations made or performed by or on behalf of Tenant or any person or entity claiming through or under Tenant pursuant to the provisions of this Section shall be made in conformity with and subject to the provisions of Article 9.

**11.2 Insurance Requirements.** Tenant shall not do anything, or permit anything to be done, in or about the Premises that would subject Landlord to any liability or

responsibility for injury to any person or property by reason of any business operation being conducted in the Premises. Landlord shall have the right to terminate this Lease, effective upon notice to Tenant, in the event Tenant does anything or permits anything to be done, in or about the Premises that (a) invalidates or is in conflict with the provisions of or causes any increase in the applicable rates for any fire or other insurance policies covering the Premises or any property located therein (unless Tenant pays for such increased costs), or (b) results in a refusal by fire insurance companies of good standing to insure the Premises or any such property in amounts reasonably satisfactory to Landlord (which amounts shall be comparable to the amounts required by comparable landlords of comparable buildings). Tenant, at Tenant's expense, shall comply with all rules, orders, regulations or requirements of the American Insurance Association (formerly the National Board of Fire Underwriters) and with any similar body that shall hereafter perform the function of such Association.

## 12. HAZARDOUS MATERIALS

**12.1 Definitions.** As used in this Lease, the following terms shall have the following meanings:

(a) **"Environmental Laws"** mean all Applicable Laws, now or hereafter in effect, relating to environmental conditions, industrial hygiene or Hazardous Materials on, under or about the Property, including without limitation the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 42 U.S.C. Section 9601, et seq., the Hazardous Materials Transportation Act, 49 U.S.C. Section 1801, et seq., the Solid Waste Disposal Act, 42 U.S.C. Section 6901, et seq., the Clean Water Act, 33 U.S.C. Section 1251, et seq., the Clean Air Act, 42 U.S.C. Section 7401, et seq., the Toxic Substances Control Act, 15 U.S.C. Section 2601 through 2629, the Safe Drinking Water Act, 42 U.S.C. Sections 300f through 300j, and any similar state and local laws and ordinances and the regulations now or hereafter adopted and published and/or promulgated pursuant thereto.

(b) **"Hazardous Material"** means any chemical, substance, medical or other waste, living organism or combination thereof which is or may be hazardous to the environment or human or animal health or safety due to its radioactivity, ignitability, corrosivity, reactivity, explosivity, toxicity, carcinogenicity, mutagenicity, phytotoxicity, infectiousness or other harmful or potentially harmful properties or effects. Hazardous Materials shall include, without limitation, petroleum hydrocarbons, including MTBE, crude oil or any fraction thereof, asbestos, radon, polychlorinated biphenyls (PCBs), methane, lead, urea formaldehyde foam insulation, microbial matter (including mold) and all substances which now or in the future may be defined as "hazardous substances," "hazardous wastes," "extremely hazardous wastes," "hazardous materials," "toxic substances," "infectious wastes," "biohazardous wastes," "medical wastes," "radioactive wastes" or which are otherwise listed, defined or regulated in any manner pursuant to any Environmental Laws.

(c) **"Tenant Environmental Activity"** means any use, treatment, keeping, storage, holding, release, emission, discharge, manufacturing, generation, processing, abatement, removal, disposition, handling, transportation, deposit, leaking, spilling, injecting, dumping or disposing of any Hazardous Materials from, into, on or under the Premises, the Exterior Area or the Property caused or permitted by Tenant or Tenant's Agents or subtenants,

and shall include any exacerbation of the Pre-Existing Environmental Condition or any Third Party Environmental Condition caused by the acts or negligent omissions of Tenant or any of Tenant's Agents or subtenants.

(d) "**Negligent omission**" as referred to in this Lease as to any Pre-Existing Environmental Condition or any Third Party Environmental Condition, shall not include any failure of Tenant to control any migration of any Hazardous Material which constitutes any component of the Pre-Existing Environmental Condition or the Third Party Environmental Condition.

#### **12.2 Environmental Releases.**

(a) Tenant represents to Landlord that Tenant is aware that detectable amounts of Hazardous Materials have come to be located on, beneath and/or in the vicinity of the Premises as described in the documents listed on **Schedule 12.2** attached hereto (the "**Pre-Existing Environmental Condition**"). Tenant acknowledges and agrees that the Property and Tenant's interest under this Lease are subject to an Access Agreement for Monitoring Wells, Groundwater Extraction Wells, a Conveyance Pipeline, and Water Treatment Plant at 3176 Porter Drive, 3180 Porter Drive, 3210 Porter Drive and 3277 Miranda Avenue, Palo Alto, California dated December 4, 1992 between Landlord and Loral/Librascope Corporation (the "**Access Agreement**"), a copy of which is attached hereto as **Exhibit F**. Tenant has made such investigations and inquiries as it deems appropriate to ascertain the effects, if any, of the Pre-Existing Environmental Condition on its operations and persons using the Premises and the Exterior Area. Landlord makes no representation or warranty with regard to any aspect of the environmental condition of the Premises, the Exterior Area or the Property. Subject to Section 12.5(b), Tenant, on behalf of itself and its successors and assigns, hereby releases Landlord and Landlord's officers, directors, trustees, agents and employees from any and all claims, demands, debts, liabilities, and causes of action of whatever kind or nature, whether known or unknown or suspected or unsuspected which Tenant or any of Tenant's Agents may have, claim to have, or which may hereafter accrue against the released parties or any of them, arising out of or relating to or in any way connected with the Pre-Existing Environmental Condition. In connection with such release, Tenant hereby waives any and all rights conferred upon it by the provisions of Section 1542 of the California Civil Code, which reads as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor.

or by the provisions of any similar statute. Nothing in the foregoing shall be deemed to release Landlord (i) from its indemnity obligation set forth in Section 12.5(b), or (ii) from any claim that a third party may have directly against Landlord under law.

(b) Landlord hereby releases Tenant from any and all claims, demands, debts, liabilities, and causes of action of whatever kind or nature, whether known or unknown or suspected or unsuspected which Landlord may have, claim to have, or which may hereafter accrue against Tenant, arising out of or relating to or in any way connected with the Pre-Existing

Environmental Condition, except to the extent the acts or negligent omissions of Tenant or Tenant's Agents or subtenants on or about the Premises cause an exacerbation of the Pre-Existing Environmental Condition. In connection with such release, Landlord hereby waives any and all rights conferred upon it by the provisions of Section 1542 of the California Civil Code, which reads as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor.

or by the provisions of any similar statute. Nothing in the foregoing shall be deemed to release Tenant from any obligations or indemnities it has expressly agreed to or assumed under this Lease.

**12.3 Use of Hazardous Materials.** Tenant shall not cause or permit any Hazardous Materials to be used, stored, discharged, released or disposed of in the Premises or cause any Hazardous Materials to be used, stored, discharged, released or disposed of in, from, under or about, the Property, or any other land or improvements in the vicinity of the Property, excepting only the types and minor quantities of Hazardous Materials which are normally used in connection with Tenant's permitted use of the Premises and then only in strict accordance with all Applicable Laws, including all Environmental Laws. As of the Commencement Date, Tenant shall provide Landlord a complete list of all Hazardous Materials (excluding standard janitorial and office products) used or stored by Tenant or any of Tenant's Agents or subtenants at the Premises. Throughout the Term, Tenant shall continue to update this list so that it remains current. Without limiting the foregoing, Tenant shall, at its own expense, procure, maintain in effect and comply with all conditions of any and all permits, licenses, and other governmental and regulatory approvals required for Tenant's use of Hazardous Materials at the Premises, including, without limitation, discharge of appropriately treated materials or wastes into or through any sanitary sewer serving the Premises. Tenant shall in all respects handle, treat, deal with and manage any and all Hazardous Materials in total conformity with all Environmental Laws and prudent industry practices regarding management of such Hazardous Materials.

**12.4 Remediation of Hazardous Materials.** Tenant shall, upon demand of Landlord, and at Tenant's sole cost and expense, promptly take all actions to remediate the Premises from any adverse effects of any Tenant Environmental Activity. Such actions shall include, but not be limited to, the investigation of the environmental condition of the Premises, the preparation of any feasibility studies, reports or remedial plans, and the performance of any cleanup, remediation, containment, operation, maintenance, monitoring or restoration work, whether on or off of the Property. Tenant shall take all actions necessary to remediate the Premises from the effects of such Tenant Environmental Activity to a condition allowing unrestricted use of the Premises (i.e. to a level that will allow any future use of the Premises, including residential, hospital, or day care, without any engineering controls or deed restrictions) notwithstanding any lesser standard of remediation allowable under Applicable Laws; provided that Tenant shall be responsible for remediation to the foregoing standard only with respect to the effects of Tenant's Environmental Activity and not with respect to the results of any Pre-Existing Environmental Condition or Third Party Environmental Condition (except to the extent included within the definition of Tenant's Environmental Activity). All work shall be performed

by one or more contractors selected by Tenant and reasonably approved in advance and in writing by Landlord. Tenant shall proceed continuously and diligently with such investigatory and remedial actions, provided that in all cases such actions shall be in accordance with all Applicable Laws. Any such actions shall be performed in a good, safe and workmanlike manner. Tenant shall pay all costs in connection with such investigatory and remedial activities, including but not limited to all power and utility costs, and any and all taxes or fees that may be applicable to such activities. Tenant shall promptly provide to Landlord copies of testing results and reports that are generated in connection with the above activities and any that are submitted to any governmental entity. Promptly upon completion of such investigation and remediation, Tenant shall permanently seal or cap all monitoring wells and test holes in accordance with sound engineering practice and in compliance with Applicable Laws, remove all associated equipment, and restore the Premises to the maximum extent possible, which shall include, without limitation, the repair of any surface damage, including paving, caused by such investigation or remediation.

#### **12.5 Indemnities.**

(a) Tenant shall indemnify, defend (by counsel reasonably acceptable to Landlord), protect and hold Landlord and Landlord's trustees, directors, officers, agents and employees and their respective successors and assigns (collectively, "**Landlord's Indemnitees**"), free and harmless from and against any and all claims, liabilities, penalties, forfeitures, losses or expenses (including reasonable attorneys' and consultants' fees and oversight and response costs) to the extent arising from (a) any Tenant Environmental Activity; or (b) failure of Tenant or Tenant's Agents to comply with any Environmental Law with respect to any Tenant Environmental Activity; or (c) Tenant's failure to remove any Hazardous Materials resulting from any Tenant Environmental Activity as required in Section 12.4. Tenant's obligations hereunder shall include, but not be limited to, the burden and expense of defending all claims, suits and administrative proceedings (with counsel reasonably approved by Landlord), even if such claims, suits or proceedings are groundless, false or fraudulent; conducting all negotiations of any description; and promptly paying and discharging when due any and all judgments, penalties, fines or other sums due against or from Landlord or the Premises. Prior to retaining counsel to defend such claims, suits or proceedings, Tenant shall obtain Landlord's written approval of the identity of such counsel, which Landlord shall reasonably approve or disapprove within three (3) business days after receipt of an approval request from Tenant; provided that if Landlord fails to respond within such three (3) business day period, such counsel shall be deemed approved. In the event Tenant's failure to surrender the Premises at the expiration or earlier termination of this Lease free of Hazardous Materials resulting from any Tenant Environmental Activity prevents Landlord from reletting the Premises, or reduces the fair market and/or rental value of the Premises or any portion thereof, Tenant's indemnity obligations shall include all losses to Landlord arising therefrom.

(b) Landlord shall indemnify, defend (by counsel reasonably acceptable to Tenant), protect and hold Tenant and Tenant's directors, officers, agents, and employees and their respective successors and assigns (not including any subtenants) (collectively, "**Tenant's Indemnitees**"), free and harmless from and against (i) any government-required investigations and remediation costs incurred by Tenant and (ii) any third party claims brought against Tenant (other than those brought by Tenant's employees), in either event only to the extent caused by a Pre-Existing Environmental Condition (except to the extent caused by the exacerbation of any

Pre-Existing Environmental Condition arising out of or resulting from the acts or negligent omissions of Tenant or Tenant's Agents or subtenants on or about the Premises). Landlord's obligations hereunder shall include, but not be limited to, the burden and expense of defending all such claims, suits and administrative proceedings (with counsel reasonably approved by Tenant), even if such claims, suits or proceedings are groundless, false or fraudulent; conducting all negotiations of any description; and promptly paying and discharging when due any and all judgments, penalties, fines or other sums due against or from Tenant or the Premises. Landlord's indemnification obligations hereunder shall extend only to Tenant's actual costs.

(c) Notwithstanding the foregoing, the provisions of this Article 12 and the indemnities and releases provided herein shall not apply to, and neither Landlord nor Tenant shall have any contractual liability under this Lease with respect to any Hazardous Materials that may (i) exist in, on or under the Premises or the Property as of the Effective Date (other than the Pre-Existing Environmental Condition), (ii) be deposited or released in, on or under the Premises or the Property after the Effective Date by any third party other than Tenant or any of Tenant's Agents or any subtenants of Tenant, (iii) migrate into, on or under the Premises or the Property from any other property after the Effective Date (other than the Pre-Existing Environmental Condition), or (iv) arise from any activities by Loral/Librascope Corporation or its successors, assigns, contractors, consultants or agents under the Access Agreement (except to the extent included within the definition of Tenant Environmental Activity or to the extent arising out of Tenant's interference with Loral/Librascope Corporation's rights under the Access Agreement) (collectively, as described in clauses (i) through (iv), "**Third Party Environmental Condition**").

**12.6 No Lien.** Tenant shall not suffer any lien to be recorded against the Premises or the Property as a consequence of any Tenant Environmental Activity, including any so called state, federal or local "super fund" lien related to the remediation of any Hazardous Materials resulting from any Tenant Environmental Activity in or about the Premises or the Property.

**12.7 Investigation.** Landlord shall have the right to enter and conduct an inspection of the Premises, including invasive tests, at any reasonable time and upon reasonable advance notice, to determine whether Tenant is complying with the terms of this Lease, including but not limited to the compliance of the Premises and the activities thereon with Environmental Laws (the "**Environmental Investigation**"). Landlord shall have the right, but not the obligation, to retain at its expense an independent professional consultant to enter the Premises to conduct such an inspection, and to review any report prepared by or for Tenant concerning such compliance. In the event the Environmental Investigation identifies any deficiencies in the compliance of the Premises with Environmental Laws due to any Tenant Environmental Activity, Tenant shall promptly correct any such deficiencies identified in the Environmental Investigation, and document to Landlord that corrective action has been taken. In such event, Tenant shall also reimburse Landlord for the reasonable cost of the Environmental Investigation. If the Environmental Investigation identifies any such deficiency in compliance of the Premises with Environmental Laws due to any Tenant Environmental Activity, then, within nine (9) months of the date of the Environmental Investigation, Landlord may request a detailed review of the status of such violation by a consultant selected by Landlord (the "**Supplemental Investigation**"). Tenant shall pay for the reasonable cost of any Supplemental Investigation. A copy of the Supplemental Investigation shall be promptly supplied to Landlord and Tenant when it becomes available.

**12.8 Right to Remediate.** Should Tenant fail to initiate performance and diligently pursue such performance or initiate observance of any of its obligations or agreements pertaining to Hazardous Materials or Environmental Laws within a grace period of ten (10) business days after written notice by Landlord to Tenant, then Landlord shall have the right, but not the obligation, without limitation of any other rights of Landlord hereunder, to enter the Premises personally or through Landlord's agents, employees and contractors and perform the same. Tenant agrees to indemnify Landlord for the costs thereof and liabilities therefrom as set forth above in this Article 12.

**12.9 Notices.** Tenant shall immediately notify Landlord of any inquiry, test, claim, investigation or enforcement proceeding by or against Tenant or the Premises or the Property known to Tenant concerning any Hazardous Materials. Tenant shall immediately notify Landlord of any release or discharge of Hazardous Materials on, in under or about the Property. Landlord and Tenant shall, at Tenant's expense, cooperate with each other regarding any negotiation, defense, approval and appeal of any action taken or order issued by any applicable governmental authority as a result of any Tenant Environmental Activity; provided that, in the event of any enforcement action by any applicable governmental authority, Landlord shall have exclusive control over such negotiation, defense, approval or appeal, but with input from Tenant.

**12.10 Enforcement of Indemnity.** In the event any Hazardous Materials are identified on the Property that Landlord reasonably believes are the responsibility of Lucent as the prior tenant of the Property, Landlord shall use commercially reasonable efforts to enforce, for the mutual benefit of Landlord and Tenant, any indemnity claim it has against Lucent with respect to such Hazardous Materials. If Tenant suffers actual damage or liability as a result of such Hazardous Materials, any award that Landlord receives as a result of the exercise of such right shall be equitably shared with Tenant to compensate Tenant for such damage or liability. Similarly, in the event of any deposit, release or migration of any Hazardous Materials in, on or under the Property as a result of any activities by Loral/Librascope Corporation or its successors, assigns, contractors, consultants or agents under the Access Agreement, which requires any remediation beyond that already being pursued by Loral/Librascope Corporation or which potentially imposes any liability upon Tenant, Landlord shall use commercially reasonable efforts to enforce, for the mutual benefit of Landlord and Tenant, any indemnity claim it has against Loral/Librascope Corporation with respect to such Hazardous Materials. If Tenant suffers actual damage or liability as a result of such Hazardous Materials, any award that Landlord receives as a result of the exercise of such right shall be equitably shared with Tenant to compensate Tenant for such damage or liability.

**12.11 Tenant's Inspection Right.** Tenant shall have the right to conduct invasive testing of the Property to determine whether Tenant is in compliance with its obligations under this Lease, provided that Tenant obtains Landlord's prior written consent, such consent not to be unreasonably withheld. Landlord's environmental consultant may attend any test or investigation at the Property and shall be entitled, without cost, to duplicates of any samples taken by Tenant (or, if duplicates are not reasonably attainable, Tenant may elect to deliver the actual samples after testing) and to copies of all written reports and data prepared by or on behalf

of Tenant. Any request for consent must be delivered to Landlord, together with a reasonably detailed investigation plan sufficient for Landlord to determine the scope and logistics of the proposed investigation, at least three (3) business days before the desired test. Any invasive sampling or testing permitted by Landlord shall be performed at Tenant's sole cost in compliance with all Environmental Laws. Promptly after any physical inspection of the Property, Tenant shall, at its sole cost, restore the Property to the condition that existed immediately prior to such inspection.

**12.12 Surrender.** Tenant shall surrender the Premises to Landlord, upon the expiration or earlier termination of the Lease, free of Hazardous Materials resulting from any Tenant Environmental Activity in accordance with the provisions of this Article 12.

**12.13 Survival; Insurance.** The provisions of this Article 12 shall survive the expiration or earlier termination of this Lease. The provisions of Article 13 (Insurance) shall not limit in any way Tenant's obligations under this Article 12.

### **13. INDEMNITY; INSURANCE**

**13.1 Indemnity.** Tenant shall indemnify, protect, defend and save and hold Landlord and Landlord's Indemnitees harmless from and against any and all losses, costs, liabilities, claims, judgments, liens, damages and expenses, including, without limitation, reasonable attorneys' fees and costs (including Landlord's in-house counsel), and reasonable investigation costs, incurred in connection with or arising from: (a) any default by Tenant in the observance or performance of any of the terms, covenants or conditions of this Lease on Tenant's part to be observed or performed, or (b) the use or occupancy or manner of use or occupancy of the Premises and the Property by Tenant and Tenant's Agents, (c) the condition of the Premises, and any occurrence on the Premises (including injury to or death of any person, or damage to property) or the Property from any cause whatsoever occurring after the Effective Date, except to the extent caused by the active negligence or willful misconduct of Landlord or Landlord's employees, contractors or agents or to the extent released by Landlord pursuant to Section 12.2(b), and (d) any acts or omissions or negligence of Tenant or of Tenant's Agents, in, on or about the Premises or the Exterior Area. In case any action or proceeding be brought, made or initiated against Landlord relating to any matter covered by Tenant's indemnification obligations under this Section or under Section 12.5, Landlord will provide prompt written notice of such action or proceeding and Tenant, upon notice from Landlord, shall at its sole cost and expense, resist or defend such claim, action or proceeding by counsel approved by Landlord, such approval not to be unreasonably withheld; provided that Landlord shall not disapprove any counsel designated by Tenant's insurance carrier. Notwithstanding the foregoing, in the event Landlord is reasonably concerned about Tenant's solvency or a claim under this indemnity is not fully covered (less a reasonable deductible) by Tenant's insurance, Landlord may retain its own counsel to defend or assist in defending any claim, action or proceeding involving potential liability of Five Million Dollars (\$5,000,000) or more, and Tenant shall pay the reasonable fees and disbursements of such counsel. Tenant's obligations under this Section shall survive the expiration or earlier termination of this Lease.



**13.2 Insurance.** Tenant shall procure at its sole cost and expense and keep in effect during the Term:

(a) commercial general liability insurance covering Tenant's operations in the Premises and the use and occupancy of the Premises and the Property and any part thereof by Tenant. Such insurance shall include broad form contractual liability insurance coverage insuring Tenant's obligations under this Lease. Such coverage shall be written on an "occurrence" form and shall have a minimum combined single limit of liability of not less than two million dollars (\$2,000,000.00). Notwithstanding the foregoing, in the event Tenant elects to perform Landlord's management and maintenance obligations pursuant to Section 7.7, Tenant shall procure and keep commercial general liability insurance with a minimum combined single limit of liability of not less than three million dollars (\$3,000,000.00) for so long as Tenant continues to perform such management and maintenance obligations, unless Tenant hires a professional third-party property management firm to perform such management and maintenance obligations and such firm carries commercial general liability insurance satisfying the requirements of this Section with a minimum combined single limit of liability of not less than three million dollars (\$3,000,000.00). Tenant's policy shall be written to apply to all bodily injury, property damage, personal injury and other covered loss (however occasioned) occurring during the policy term, with at least the following endorsements to the extent such endorsements are generally available for businesses comparable to that of Tenant: (i) deleting any employee exclusion on personal injury coverage, (ii) providing broad form property damage coverage and products completed operations coverage (where applicable), and (iii) providing host liquor liability coverage. Such insurance shall name Landlord and any other party designated by Landlord as an additional insured, shall specifically include the liability assumed hereunder by Tenant, shall provide that it is primary insurance, shall provide for severability of interests, shall further provide that an act or omission of one of the named insureds which would void or otherwise reduce coverage shall not reduce or void the coverage as to any additional insured, shall afford coverage for claims based on acts, omissions, injury or damage which occurred or arose (or the onset of which occurred or arose in whole or in part during the policy period), and shall provide that Landlord will receive fifteen (15) days' written notice from the insurer prior to any cancellation or material change of coverage;

(b) commercial property insurance, including sprinkler leakages, vandalism and malicious mischief and plate glass damage covering all the items specified as Tenant's Property and all other property of every description including stock-in-trade, furniture, fittings, installations, alterations, additions, partitions and fixtures or anything in the nature of a leasehold improvement made or installed by or on behalf of the Tenant in the Premises in an amount of not less than one hundred percent (100%) of the full replacement cost thereof as shall from time to time be determined by Tenant in form reasonably satisfactory to Landlord;

(c) Worker's Compensation Insurance in the amounts and coverages required under worker's compensation, disability and similar employee benefit laws applicable to Tenant and/or the Premises from time to time, and Employer's Liability Insurance, with limits of not less than one million dollars (\$1,000,000), or such higher amounts as may be required by law, which insurance may be carried by Tenant's payroll provider;

(d) business interruption insurance with extra expense insurance in an amount of \$500,000 during any interruption of Tenant's business by reason of the Premises or Tenant's Property being damaged by casualty; and

(e) any other form or forms of insurance as Landlord may reasonably require from time to time in amounts and for insurable risks against which a prudent tenant similarly situated to Tenant would protect itself to the extent landlords of comparable buildings in the vicinity of the in the Property require their tenants to carry such other form(s) of insurance.

**13.3 Policies.** All policies of insurance required of Tenant shall be issued by insurance companies with general policyholders' rating of not less than A, as rated in the most current available "Best's Insurance Reports," and not prohibited from doing business in the State of California, and shall, with the exception of Workers Compensation Insurance and business interruption insurance, include as additional insureds Landlord, and such other persons or entities as Landlord specifies from time to time. Such policies, with the exception of Worker's Compensation Insurance and business interruption insurance, shall be for the mutual and joint benefit and protection of Landlord, Tenant and others specified by Landlord. Executed copies of Tenant's policies of insurance or certificates thereof shall be delivered to Landlord prior to or upon delivery of possession of the Premises to Tenant and thereafter within twenty (20) days prior to the expiration of the term of each such policy. All commercial general liability and property damage policies shall contain a provision that Landlord and any other additional insured, although named as additional insureds, shall nevertheless be entitled to recover under said policies for a covered loss occasioned by it, its servants, agents and employees, by reason of Tenant's negligence. As often as any policy shall expire or terminate, renewal or additional policies shall be procured and maintained by Tenant in like manner and to like extent. All such policies of insurance shall provide that the company writing said policy will give to Landlord fifteen (15) days notice in writing in advance of any cancellation or lapse or of the effective date of any reduction in the amounts of insurance. All commercial general liability, property damage and other casualty policies shall be written on an occurrence basis. Landlord's coverage shall not be contributory. No policy shall have a deductible in excess of \$50,000 for any one occurrence.

**13.4 Landlord's Rights.** Should Tenant fail to take out and keep in force each insurance policy required under this Article 13, or should such insurance not be approved by Landlord and should the Tenant not rectify the situation within two (2) business days after written notice from Landlord to Tenant, Landlord shall have the right, without assuming any obligation in connection therewith, to purchase such insurance at the sole cost of Tenant, and all costs incurred by Landlord shall be payable to Landlord by Tenant within twenty (20) days after demand as Additional Rent and without prejudice to any other rights and remedies of Landlord under this Lease.

**13.5 Landlord's Insurance.** Landlord shall maintain in effect, provided it is obtainable, a policy or policies of property insurance or self insurance covering loss or damage to the Property in the amount of at least one hundred percent (100%) of the insurable replacement cost thereof (except with respect to earthquake coverage), including fire and extended coverage, vandalism, malicious mischief, special extended perils (all risk) and, if Landlord elects in its sole discretion, earthquake coverage, and the cost thereof shall be included in Operating Expenses. Nothing herein shall require Landlord to carry any insurance with respect to risks or property required to be insured by Tenant under this Lease.

**13.6 Waiver of Subrogation.** Notwithstanding anything to the contrary contained herein, to the extent permitted by their respective policies of insurance and to the extent of insurance proceeds received (or which would have been received had the party carried the insurance required by this Lease) with respect to the loss, Landlord and Tenant each hereby waive any right of recovery against the other party and against any other party maintaining a policy of insurance with respect to the Property or any portion thereof or the contents of the Premises for any loss or damage sustained by such other party with respect to the Premises or the Property, or any portion thereof, or the contents of the same or any operation therein, whether or not such loss is caused by the fault or negligence of such other party. Either party shall promptly notify the other party if the policy of insurance carried by it does not permit the foregoing waiver.

**13.7 No Liability.** No approval by Landlord of any insurer, or the terms or conditions of any policy, or any coverage or amount of insurance, or any deductible amount shall be construed as a representation by Landlord of the solvency of the insurer or the sufficiency of any policy or any coverage or amount of insurance or deductible and Tenant assumes full risk and responsibility for any inadequacy of insurance coverage or any failure of insurers.

#### **14. ASSIGNMENT AND SUBLETTING**

**14.1 Consent Required.** Tenant shall not directly or indirectly, voluntarily or by operation of law, sell, assign, encumber, pledge or otherwise transfer or hypothecate all or any part of its interest in or rights with respect to the Premises or its leasehold estate (collectively, "**Assignment**"), or permit all or any portion of the Premises to be occupied by anyone other than itself or sublet all or any portion of the Premises (collectively, "**Sublease**") without Landlord's prior written consent, such consent not to be unreasonably withheld (subject to Landlord's rights as described in Section 14.5).

**14.2 Notice.** If Tenant desires to enter into a Sublease of all or any portion of the Premises or Assignment of this Lease that requires Landlord's consent, it shall give written notice (the "**Transfer Notice**") to Landlord of its intention to do so, which notice shall contain (a) the name and address of the proposed assignee, subtenant or occupant (the "**Transferee**"), (b) the nature of the proposed Transferee's business to be carried on in the Premises, (c) the general terms and provisions of the proposed Assignment or Sublease, and (d) such financial information as Landlord may reasonably request concerning the proposed Transferee. Without limitation of any other provision hereof, it shall not be unreasonable for Landlord to withhold its consent if (i) an Event of Default is then in existence, (ii) the use of the Premises would not comply with the provisions of this Lease, and (iii) in Landlord's reasonable judgment, the proposed Transferee in the case of an Assignment does not have the financial capability to perform its obligations under this Lease with respect to the Premises which are the subject of the Assignment or Sublease.

**14.3 Terms of Approval.** Landlord shall respond to Tenant's request for approval within ten (10) business days after receipt of the Transfer Notice. If Landlord approves the proposed Assignment or Sublease, Tenant may, not later than ninety (90) days thereafter, enter into the Assignment or Sublease with the proposed Transferee upon the terms and conditions set forth in the Transfer Notice.

**14.4 Excess Rent.** For any Assignment or Sublease, except an Assignment or Sublease pursuant to Section 14.7, fifty percent (50%) of the Excess Rent received by Tenant shall be paid to Landlord as and when received by Tenant. **“Excess Rent”** means the gross revenue received from the Transferee during the Sublease term or with respect to the Assignment, less (a) the gross revenue paid to Landlord by Tenant during the period of the Sublease term or concurrently with or after the Assignment; (b) any tenant improvement allowance or other economic concession (planning allowance, moving expenses, etc.) that is reasonably documented and paid by Tenant to the Transferee, and the cost of tenant improvements made by Tenant for the Transferees in the subleased space; (c) customary and reasonable external brokers’ commissions to the extent paid and documented; (d) reasonable attorneys’ fees; (e) the actual cost of demising the subleased space, if applicable; (f) the unamortized cost of the Tenant Improvement Work calculated on a straight line basis over forty-eight (48) months, in excess of the Tenant Improvement Allowance (or, in the case of a Sublease, the amount thereof proportionate to the term of the sublease and proportionate share of the Premises subject to such Sublease); and (g) reasonable costs of advertising the space for Sublease or Assignment (collectively, **“Transfer Costs”**). Tenant shall not have to pay to Landlord any Excess Rent until Tenant has recovered all of its Transfer Costs. In addition, notwithstanding the foregoing, Tenant shall not be obligated to pay any Excess Rent to Landlord for any Sublease(s) of up to an aggregate of fifty (50%) of the Premises during the first two (2) years of the Term.

**14.5 Right of First Refusal.** If Tenant desires to assign Tenant’s interest in the Premises or to sublease one hundred percent (100%) of the Premises for more than three (3) years or for the balance of the Term (collectively, a **“Transfer”**), Tenant’s Transfer Notice shall also include a written offer that includes all of the substantial business terms that Tenant has offered to a Transferee which Tenant would execute if Landlord does not accept Tenant’s offer (the **“Offer”**), and shall offer to Transfer Tenant’s interest in the Premises to Landlord on such terms and conditions. Landlord shall have fifteen (15) days from Landlord’s receipt of the Offer to accept the Offer by written notice to Tenant or to approve or disapprove the Transfer as provided in Section 14.3. If Landlord accepts the Offer, Landlord and Tenant shall consummate the Transfer within fifteen (15) days after Landlord’s written notice of acceptance or such later date as set forth in the Offer. The Transfer shall be consummated by Tenant’s delivery to Landlord of a good and sufficient assignment of lease, lease termination or sublease and Tenant shall be released from liability arising out of or relating to events occurring after the effective date of the Transfer and arising out of Tenant’s obligations under this Lease as to the portion of the Premises subject to the Transfer. If Landlord does not accept the Offer, but approves the Transfer, then in the event the economic terms of the Transfer are materially changed during subsequent negotiations to be more favorable to the Transferee, Tenant shall again deliver to Landlord an Offer in accordance with this Section, offering the interest to Landlord on such more favorable terms. Landlord shall then have another period of five (5) business days after receipt of such Offer to accept such Offer. For purposes of this Section 14.5, “materially changed” shall mean that the economic benefit to Tenant as stated in the Offer shall have been reduced by ten percent (10%) or more.

**14.6 No Release.** No Sublease or Assignment by Tenant nor any consent by Landlord thereto shall relieve Tenant of any obligation to be performed by Tenant under this Lease. Any Sublease or Assignment that is not in compliance with this Article shall be null and

void and, at the option of Landlord, shall constitute an Event of Default by Tenant under this Lease, and Landlord shall be entitled to pursue any right or remedy available to Landlord under the terms of this Lease or under the laws of the State of California. The acceptance of any Rent or other payments by Landlord from a proposed Transferee shall not constitute consent to such Sublease or Assignment by Landlord or a recognition of any Transferee, or a waiver by Landlord of any failure of Tenant or other Transferor to comply with this Article.

**14.7 Permitted Transfers.** Notwithstanding anything to the contrary contained herein, Landlord's consent shall not be required for an Assignment or Sublease to (a) a subsidiary or affiliate of Tenant, or (b) a successor-in-interest that acquires Tenant through a merger, consolidation or sale of substantially all of the assets of Tenant; provided that Tenant notifies Landlord of such Assignment or Sublease within thirty (30) days after such Assignment or Sublease.

**14.8 Assumption of Obligations.** Any Transferee taking an Assignment of this Lease, from and after the effective date of the Assignment, assume all obligations of Tenant under this Lease and shall be and remain liable jointly and severally with Tenant for the payment of Base Rent and Additional Rent, and for the performance of all of the terms, covenants, conditions and agreements herein contained on Tenant's part to be performed for the Term. No Assignment shall be binding on Landlord unless Tenant delivers to Landlord a counterpart of the Assignment and an instrument that contains a covenant of assumption reasonably satisfactory in substance and form to Landlord, and consistent with the requirements of this Section.

## 15. DEFAULT

**15.1 Event of Default.** The occurrence of any of the following shall be an "*Event of Default*" on the part of Tenant:

(a) Failure to pay any part of the Base Rent or Additional Rent, or any other sums of money that Tenant is required to pay under this Lease, where such failure continues for a period of five (5) business days after written notice of default from Landlord to Tenant. Landlord's notice to Tenant pursuant to this subsection shall be deemed to be the notice required under California Code of Civil Procedure Section 1161.

(b) Failure to perform any other covenant, condition or requirement of this Lease when such failure shall continue for a period of thirty (30) days after written notice thereof from Landlord to Tenant; provided that if the nature of the default is such that more than thirty (30) days are reasonably required for its cure, then an Event of Default shall not be deemed to have occurred if Tenant shall commence such cure within said thirty (30) day period and thereafter diligently and continuously prosecute such cure to completion. Landlord's notice to Tenant pursuant to this subsection shall be deemed to be the notice required under California Code of Civil Procedure Section 1161.

(c) The abandonment or vacating of the Premises by Tenant.

(d) Tenant shall admit in writing its inability to pay its debts generally as they become due, file a petition in bankruptcy, insolvency, reorganization, dissolution or

liquidation under any law or statute of any government or any subdivision thereof either now or hereafter in effect, or Tenant shall make an assignment for the benefit of its creditors, consent to or acquiesce in the appointment of a receiver of itself or of the whole or any substantial part of the Premises.

(e) A court of competent jurisdiction shall enter an order, judgment or decree appointing a receiver of Tenant or of the whole or any substantial part of the Premises and such order, judgment or decree shall not be vacated, set aside or stayed within sixty (60) days after the date of entry of such order, judgment, or decree, or a stay thereof shall be thereafter set aside.

(f) A court of competent jurisdiction shall enter an order, judgment or decree approving a petition filed against Tenant under any bankruptcy, insolvency, reorganization, dissolution or liquidation law or statute of the federal or state government or any subdivision of either now or hereafter in effect, and such order, judgment or decree shall not be vacated, set aside or stayed within sixty (60) days from the date of entry of such order, judgment or decree, or a stay thereof shall be thereafter set aside.

**15.2 Remedies.** Upon the occurrence of an Event of Default, Landlord shall have the following rights and remedies:

(a) The right to terminate this Lease upon written notice to Tenant, in which event Tenant shall immediately surrender possession of the Premises in accordance with Article 20.

(b) The right to bring a summary action for possession of the Premises.

(c) The rights and remedies described in California Civil Code Section 1951.2, including without limitation the right to recover from Tenant all Rent due through the date this Lease terminates (with interest at the Interest Rate until paid), plus the present worth of the Rent payable hereunder for the balance of the Term, plus any amount necessary to compensate Landlord for the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom which includes, without limitation, (i) the unamortized portion of any brokerage or real estate agent's commissions paid in connection with the execution of this Lease, (ii) any direct costs or expenses incurred by Landlord in recovering possession of the Premises, maintaining or preserving the Premises after such default, (iii) preparing the Premises for reletting to a new tenant, (iv) any repairs or alterations to the Premises for such reletting, (v) leasing commissions, architect's fees and any other costs necessary or appropriate either to relet the Premises or, if reasonably necessary in order to relet the Premises, to adapt them to another beneficial use by Landlord and (vi) such amounts in addition to or in lieu of the foregoing as may be permitted from time to time by Applicable Law to the extent that such payment would not result in a duplicative recovery. Notwithstanding the foregoing, if Landlord enters into a replacement lease for a term longer than the Initial Term or the then Current Renewal Term, as applicable, then the amounts payable under clauses (iii), (iv) and (v) will be proportionately reduced.

(d) The rights and remedies described in California Civil Code Section 1951.4 which allow Landlord to continue this Lease in effect and to enforce all of Landlord's rights and remedies under this Lease, including the right to recover Base Rent, Additional Rent and other charges payable hereunder as they become due. Acts of maintenance or preservation, efforts to relet the Premises or the appointment of a receiver upon Landlord's initiative to protect its interest under this Lease shall not constitute a termination of Tenant's right to possession.

(e) The right and power, as attorney-in-fact for Tenant, to sublet the Premises, to collect rents from all subtenants and to provide or arrange for the provision of all services and fulfill all obligations of Tenant under any permitted subleases. Landlord is hereby authorized on behalf of Tenant, but shall have absolutely no obligation, to provide such services and fulfill such obligations and to incur all such expenses and costs as Landlord deems necessary. Landlord is hereby authorized, but not obligated, to relet the Premises or any part thereof on behalf of Tenant, to incur such expenses as may be necessary to effect a relet and make said relet for such term or terms, upon such conditions and at such rental as Landlord in its reasonable discretion may deem proper. Tenant shall be liable immediately to Landlord for all costs and expenses Landlord incurs in reletting the Premises including, without limitation, brokers' commissions, expenses of remodeling the Premises required by the reletting, and the cost of collecting rents and fulfilling the obligations of Tenant to any subtenant. If Landlord relets the Premises or any portion thereof, such reletting shall not relieve Tenant of any obligation hereunder, except that Landlord shall apply the rent or other proceeds actually collected by it as a result of such reletting against any amounts due from Tenant hereunder to the extent that such rent or other proceeds compensate Landlord for the nonperformance of any obligation of Tenant hereunder. Such payments by Tenant shall be due at such times as are provided elsewhere in this Lease, and Landlord need not wait until the termination of this Lease, by expiration of the Term or otherwise, to recover them by legal action or in any other manner. Landlord may execute any sublease made pursuant to this Section in its own name, and the tenant thereunder shall be under no obligation to see to the application by Landlord of any rent or other proceeds, nor shall Tenant have any right to collect any such rent or other proceeds. Landlord shall not by any reentry or other act be deemed to have accepted any surrender by Tenant of the Premises or Tenant's interest therein, or be deemed to have otherwise terminated this Lease, or to have relieved Tenant of any obligation hereunder, unless Landlord shall have given Tenant express written notice of Landlord's election to do so as set forth herein.

(f) The right to enjoin, and any other remedy or right now or hereafter available to a Landlord against a defaulting tenant under the laws of the State of California or the equitable powers of its courts, and not otherwise specifically reserved herein.

**15.3 Cumulative Remedies.** The various rights and remedies reserved to Landlord, including those not specifically described herein, shall, to the extent that the exercise of such right and/or remedy does not result in a duplicative recovery, be cumulative and shall be in addition to every other right or remedy provided for in this Lease or now or hereafter existing at law or in equity and the exercise of the rights or remedies provided for in this Lease or now or hereafter existing at law or in equity shall not preclude the simultaneous or later exercise by Landlord of any or all other rights and remedies.

**15.4 Waiver of Redemption by Tenant.** Tenant hereby waives any right to relief against forfeiture of this Lease pursuant to California Code of Civil Procedure Section 1179.

**15.5 Landlord's Right to Cure.** If Tenant shall fail or neglect to do or perform any covenant or condition required under this Lease and such failure shall not be cured within any applicable grace period after written notice by Landlord to Tenant, Landlord may, on five (5) additional days notice to Tenant, but shall not be required to, make any payment payable by Tenant hereunder, discharge any lien, take out, pay for and maintain any insurance required hereunder, or do or perform or cause to be done or performed any such other act or thing (entering upon the Premises for such purposes, if Landlord shall so elect), and Landlord shall not be or be held liable or in any way responsible for any loss, disturbance, inconvenience, annoyance or damage resulting to Tenant on account thereof. Tenant shall repay to Landlord within twenty (20) days after demand the entire out-of-pocket cost and expense reasonably incurred by Landlord in connection with the cure, including, without limitation, compensation to the agents, consultants and contractors of Landlord and reasonable attorneys' fees and expenses. Landlord may act upon shorter notice or no notice at all if necessary in Landlord's reasonable judgment to meet an emergency situation or governmental or municipal time limitation or to protect Landlord's interest in the Premises. Landlord shall not be required to inquire into the correctness of the amount of validity or any tax or lien that may be paid by Landlord and Landlord shall be duly protected in paying the amount of any such tax or lien claimed and in such event Landlord also shall have the full authority, in Landlord's sole judgment and discretion and without prior notice to or approval by Tenant, to settle or compromise any such lien or tax. Any act or thing done by Landlord pursuant to the provisions of this Section shall not be or be construed as a waiver of any such failure by Tenant, or as a waiver of any term, covenant, agreement or condition herein contained or of the performance thereof.

**15.6 Landlord's Default.** Landlord shall be in default under this Lease if Landlord fails to perform obligations required of Landlord within thirty (30) days after written notice by Tenant to Landlord and to the holder of any first mortgage or deed of trust covering the Premises whose name and address shall have heretofore been furnished to Tenant in writing, specifying wherein Landlord has failed to perform such obligations; provided, however, that if the nature of Landlord's obligations is such that more than thirty (30) days are required for performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion. Tenant shall be entitled to actual (but not consequential) damages in the event of an uncured default by Landlord, but the provisions of Article 17 shall apply to any Landlord default and Tenant shall not have the right to terminate this Lease as a result of a Landlord default.

## **16. LANDLORD'S RESERVED RIGHTS**

**16.1 Control of Exterior Area.** Landlord reserves the right, at any time and from time to time, to make alterations, additions, repairs, replacements or improvements to all or any part of the Premises that are Landlord's responsibility under the terms of this Lease (including the Building Structure and Building Systems), the Exterior Area and the Property pursuant to its rights and obligations set forth in this Lease. Landlord may make changes at any



time and from time to time in the size, shape, location, use and extent of the Exterior Area, and no such change shall entitle Tenant to any abatement of rent or damages; provided that Landlord shall not materially adversely affect Tenant's use of or access to the Property. Landlord may at any time and from time to time during the Term restrain any use or occupancy of the Exterior Area or temporarily close any portion of the Exterior Area for repairs, maintenance, replacements or alterations, to prevent a dedication or the accrual of prescriptive rights, or for any other reasonable purpose; provided, however, that Landlord shall not materially adversely affect Tenant's use of or access to the Property. Tenant's rights in and to the Exterior Area shall at all times be subject to the rights of Landlord and Tenant shall keep the Exterior Area free and clear of any obstructions created or permitted by Tenant or resulting from Tenant's operations.

**16.2 Access.** Landlord reserves (for itself and its agents, consultants, contractors and employees) the right to enter the Premises at all reasonable times and, except in cases of emergency, after giving Tenant reasonable notice, to inspect the Premises (including, without limitation, invasive environmental testing and as set forth in Section 12.7); to supply any service to be provided by Landlord hereunder; to show the Premises to prospective purchasers or mortgages; to show the Premises to prospective tenants during the last six (6) months of the Term; to post notices of nonresponsibility; and to repair or maintain the Premises as required by Section 7.1, without abatement of Rent, and may for that purpose erect, use and maintain necessary structures in and through the Premises where reasonably required by the character of the work to be performed, but all in a manner so as to minimize disruption and interference with Tenants' business. Tenant hereby waives any claim for damages for any injury or inconvenience to or interference with Tenant's business, any loss of occupancy or quiet enjoyment of the Premises or any other loss occasioned thereby. All locks for all of the doors in, upon and about the Premises, excluding Tenant's vaults and safes or special security areas (designated in advance in writing by Tenant) shall at all times be keyed to a master system and Landlord shall at all times have and retain a key with which to unlock all of said doors. Landlord shall have the right to use any and all means that Landlord may deem necessary or proper to open said doors in an emergency in order to obtain entry to any portion of the Premises, and any such entry to the Premises or portions thereof obtained by Landlord by any of said means, or otherwise, shall not under any circumstances be construed or deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or an eviction, actual or constructive, of Tenant from the Premises or any portion thereof. Notwithstanding the foregoing, (a) Landlord's access to laboratories in the Premises shall be in accordance with all laws and regulations relating to Tenant's pharmaceutical business, (b) Landlord shall abide by Tenant's reasonable safety procedures, and (c) Tenant shall have the right to temporarily restrict or delay Landlord's access to laboratories in the Premises for a reasonable amount time as necessary to not materially interfere with Tenant's research activities in such areas.

**16.3 Easements.** Landlord reserves the right to grant or relocate all easements and rights of way which Landlord in its reasonable discretion may deem necessary or appropriate; provided that Tenant's right to use and have access to the Property is not materially impeded.

**16.4 Subordination.** This Lease shall be subject and subordinate at all times to: (a) all covenants, conditions and restrictions, and any ground leases or underlying leases which may now exist or hereafter be executed affecting the Property (and Landlord hereby

represents that as of the date hereof, none exist), and (b) the lien of any mortgage or deed of trust which may now exist (and Landlord hereby represents that as of the date hereof, none exist) or hereafter be executed in any amount for which the Property, or any ground leases or underlying leases, or Landlord's interest or estate in any of said items, is specified as security, so long as any such document executed after the Effective Date does not otherwise purport to diminish Tenant's rights hereunder. Notwithstanding the foregoing, Landlord shall have the right to subordinate or cause to be subordinated to this Lease any of the items referred to in clause (a) or (b) above, subject to compliance with the condition precedent set forth below. In the event that any ground lease or underlying lease terminates for any reason or any mortgage or deed of trust is foreclosed or a conveyance in lieu of foreclosure is made for any reason, (i) no person or entity which as a result of the foregoing succeeds to the interest of Landlord under this Lease, (a "Successor") shall be liable for any default by Landlord or any other matter that occurred prior to the date the Successor succeeded to Landlord's interest in this Lease, and (ii) Tenant shall, notwithstanding any subordination, attorn to and become the tenant of the Successor, at the option of the Successor. Tenant covenants and agrees, however, to execute and deliver, upon demand by Landlord and in the form reasonably requested by Landlord, any additional documents evidencing the priority or subordination of this Lease with respect to any such ground leases, underlying leases, reciprocal easement agreements or similar documents or instruments, or with respect to the lien of any such mortgage or deed of trust and Tenant's failure to execute and deliver any such document within ten (10) business days after such demand by Landlord shall constitute an Event of Default without further notice. As a condition to any such subordination by Landlord, Landlord shall obtain the written agreement of the mortgagee or trustee named in any mortgage, deed of trust or other encumbrance, and any landlord under any ground lease or underlying lease, that so long as an Event of Default by Tenant is not in existence, neither this Lease nor any of Tenant's rights hereunder shall be terminated or modified, nor shall Tenant's possession of the Premises be disturbed or interfered with, by any trustee's sale or by an action or proceeding to foreclose said mortgage, deed of trust or other encumbrance.

**17. LIMITATION OF LANDLORD'S LIABILITY**

**17.1 Limitation.** Except as otherwise expressly provided in this Lease, Landlord shall not be responsible for or liable to Tenant and Tenant hereby releases Landlord, waives all claims against Landlord and assumes the risk for any injury, loss or damage to any person or property in or about the Premises, or the Property by or from any cause whatsoever (other than Landlord's active negligence, willful misconduct or breach of its obligations under this Lease) including, without limitation, (a) acts or omissions of persons occupying adjoining premises, (b) theft or vandalism, (c) burst, stopped or leaking water, gas, sewer or steam pipes, (d) loss of utility service, (e) accident, fire or casualty, (f) nuisance, and (g) work done by Landlord in the Premises or the Exterior Area. There shall be no abatement of Rent and no liability of Landlord by reason of any injury to or interference with Tenant's business arising from the making of any repairs, alterations or improvements to any portion of the Premises or to fixtures, appurtenances and equipment in the Premises; provided, however, that in the event Landlord's repair, alterations or improvements are performed in a negligent manner which results in Tenant being unable to operate its business in all or any portion of the Premises for a period of more than three (3) days, then Tenant shall be entitled to an abatement of Rent commencing on the fourth (4<sup>th</sup>) day Tenant is unable to operate and continuing until the Premises are again available for operation of Tenant's business. Such Rent abatement shall be Tenant's

only remedy in the event of a negligent interference with Tenant's business and Tenant shall not be entitled to damages or to termination of this Lease arising from Landlord's repairs, alterations or improvements. No interference with Tenant's operations in the Premises shall constitute a constructive or other eviction if Tenant. Tenant hereby waives and releases any right it may have to make repairs at Landlord's expense under Sections 1941 and 1942 of the California Civil Code, or under any similar law, statute or ordinance now or hereafter in effect.

**17.2 Sale of Property.** It is agreed that Landlord may at any time sell, assign or transfer its interest as landlord in and to this Lease, and may at any time sell, assign or transfer its interest in and to the Property. In the event of any transfer of Landlord's interest in this Lease or in the Property, the transferor shall be automatically relieved of any and all of Landlord's obligations and liabilities accruing from and after the date of such transfer; provided that the transferee assumes all of Landlord's obligations under this Lease and delivers a copy of such assumption to Tenant. Tenant hereby agrees to attorn to Landlord's assignee, transferee, or purchaser from and after the date of notice to Tenant of such assignment, transfer or sale, in the same manner and with the same force and effect as though this Lease were made in the first instance by and between Tenant and the assignee, transferee or purchaser.

**17.3 No Personal Liability.** In the event of any default by Landlord hereunder, Tenant shall look only to Landlord's interest in the Property and rents therefrom and any available insurance or condemnation proceeds for the satisfaction of Tenant's remedies, and no other property or assets of Landlord or any trustee, partner, member, officer or director thereof, disclosed or undisclosed, shall be subject to levy, execution or other enforcement procedure for the satisfaction of Tenant's remedies under or with respect to this Lease.

## **18. DESTRUCTION**

**18.1 Landlord's Repair Obligation.** If the Property or any portion thereof are damaged by fire or other casualty, Landlord shall repair the same (including any Tenant Improvement Work but not Tenant's Alterations); provided that (a) such repairs can be made under the laws and regulations of the federal, state and local governmental authorities having jurisdiction within six (6) months after the date of such damage (or in the case of damage occurring during the last twelve (12) months of the Term, provided that such repairs can be made within ninety (90) days after the date of such damage), (b) such repairs are fully covered (except for any deductible and a deficiency of insurance proceeds of up to 5% of the full insured value of the Premises) by the proceeds of insurance maintained by Landlord, (c) the estimated cost to repair does not exceed 50% of the full insured value of the Premises, and (d) with regard to Landlord's obligation to repair the Tenant Improvement Work, the Tenant Improvement Work is permanently affixed to the Premises such that it has become a part of the Premises (and is not deemed a trade fixture) and therefore is covered by Landlord's real property insurance. If Landlord has elected to partially or fully self-insure as permitted by Section 13.5, the limitations of clause (b) above shall not apply unless such self-insurance maintained by Landlord is part of its funded program of self-insurance that provides coverage comparable to commercial third-party insurance.

**18.2 Notice.** Landlord shall notify Tenant within forty-five (45) days after the date of damage whether or not Landlord will repair and reconstruct the Property, and the

estimated time of completion. If the requirements set forth in Section 18.1 are not met, Landlord shall have the option, exercisable within forty-five (45) days after the date of such damage either to: (a) notify Tenant of Landlord's intention to repair such damage, in which event this Lease shall continue in full force and effect (unless terminated by Tenant pursuant to Section 18.3 below), or (b) notify Tenant of Landlord's election to terminate this Lease as of the date of the damage. If such notice to terminate is given by Landlord, this Lease shall terminate as of the date of such damage.

**18.3 Termination by Tenant.** If Landlord elects to repair or is required to repair the damage and any such repair is not commenced by Landlord within one-hundred twenty (120) days after the occurrence of such damage or destruction or is not or cannot practicably be substantially completed by Landlord within six (6) months after the occurrence of such damage or destruction (or in the case of damage occurring in the last twelve (12) months of the Term, within ninety (90) days), then in either such event Tenant may, at its option, upon written notice to Landlord to be delivered within fifteen (15) days after receipt of Landlord's notice or the expiration of the 120-day commencement period, elect to terminate this Lease as of the date of the occurrence of such damage or destruction.

**18.4 Rent Adjustment.** In case of termination pursuant to Sections 18.2 or 18.3 above, the Base Rent and Operating Expenses shall be reduced by a proportionate amount based upon the extent to which such damage interfered with the business carried on by Tenant in the Premises, and Tenant shall pay such reduced Base Rent and Operating Expenses up to the date of vacation of the Premises. If Landlord is required or elects to make repairs, and Tenant does not terminate this Lease pursuant to Section 18.3, this Lease shall remain in full force and effect except that Tenant shall be entitled to a proportionate reduction of Base Rent and Operating Expenses from the date of such casualty and during the period such repairs are being made by a proportionate amount based upon the extent of interference with Tenant's operations in the Premises. The full amount of Base Rent and Operating Expenses shall again become payable immediately upon the completion of such work of repair, reconstruction or restoration and return of the Premises to Tenant with all required permits and approvals for occupancy by Tenant. The repairs to be made by Landlord under this Article shall not include, and Landlord shall not be required to repair, any casualty damage to the Tenant's Property or any Alterations.

**18.5 Tenant Obligations.** If Landlord elects or is required to repair, reconstruct or restore the Premises after any damage or destruction and Tenant does not elect to terminate the Lease pursuant to Section 18.3, Tenant shall be responsible at its own expense for the repair and replacement of the Tenant's Property and any Alterations which Tenant elects to replace. If the Lease is terminated, Tenant is relieved of all of its obligations under Article 20 hereof, except with respect to the removal of Hazardous Materials which are the responsibility of Tenant pursuant to Article 12.

**18.6 No Claim.** Tenant shall have no interest in or claim to any portion of the proceeds of any property insurance or self-insurance maintained by Landlord in connection with the damage. If Landlord is entitled and elects not to rebuild the Premises, Landlord shall relinquish to Tenant such claim as Landlord may have for any part of the proceeds of any insurance maintained by Tenant under Section 13.2 of this Lease.

**18.7 No Damages.** Subject to the rent abatement provisions set forth in Section 18.4, if Landlord is required or elects to make any repairs, reconstruction or restoration of any damage or destruction to the Premises under any of the provisions of this Article 18, Tenant shall not be entitled to any damages by reason of any inconvenience or loss sustained by Tenant as a result thereof. Except as expressly provided in Section 18.4, there shall be no reduction, change or abatement of any rental or other charge payable by Tenant to Landlord hereunder, or in the method of computing, accounting for or paying the same. Tenant hereby waives the provisions of Section 1932(2) and Section 1933(4) of the California Civil Code, or any other statute or law that may be in effect at the time of a casualty under which a lease is automatically terminated or a tenant is given the right to terminate a lease due to a casualty.

## **19. EMINENT DOMAIN**

**19.1 Taking.** If all or any part of the Premises shall be taken as a result of the exercise of the power of eminent domain or any transfer in lieu thereof, this Lease shall terminate as to the part so taken as of the date of taking or as of the date of final judgment, whichever is earlier, and, in the case of a partial taking of any of the Premises, either Landlord or Tenant shall have the right to terminate this Lease as to the balance of the Premises by written notice to the other within thirty (30) days after such date, provided, however, that a condition to the exercise by Tenant of such right to terminate shall be that the portion of the Premises taken shall be of such extent and nature as substantially to handicap, impede or impair Tenant's use of the balance of the Premises or shall render the balance of the Premises insufficient for the conduct of all or part of Tenant's business formerly conducted on the Premises. If any material part of the Exterior Area shall be taken as a result of the exercise of the power of eminent domain or any transfer in lieu thereof, such that Tenant's access to, parking for or use of the Premises is materially adversely affected, Tenant shall have the right to terminate this Lease by written notice to Landlord within thirty (30) days of the date of taking.

**19.2 Award.** In the event of any taking, Landlord shall be entitled to any and all compensation, damages, income, rent, awards, or any interest therein whatsoever which may be paid or made in connection therewith, and Tenant shall assign to Landlord any right to compensation or damages for the condemnation of its leasehold interest; provided that Tenant may file a claim for (a) Tenant's relocation expenses, goodwill and business interruption and (b) the taking of Tenant's Property.

**19.3 Partial Taking.** In the event of a partial taking of the Premises or the Property which does not result in a termination of this Lease, the Base Rent and Operating Expenses shall be adjusted as follows:

(a) In the event of a partial taking, if this Lease is not terminated pursuant to this Article 19, Landlord shall repair, restore or reconstruct the Premises and the Property to a useable state; provided that Landlord shall not be required to expend any sums other than those received pursuant to Section 19.2. If Landlord does not repair, restore or reconstruct the Premises or the Property due to the insufficiency of the award received pursuant to Section 19.2, Tenant shall have the right to terminate this Lease by written notice to Landlord;

(b) During the period between the date of the partial taking and the completion of any necessary repairs, reconstruction or restoration, Tenant shall be entitled to a reduction of Base Rent and Operating Expenses by a proportionate amount based upon the extent of interference with Tenant's operations in the Premises and on the Property; and

(c) Upon completion of said repairs, reconstruction or restoration, and thereafter throughout the remainder of the Term, the Base Rent and Operating Expenses shall be equitably adjusted to reflect the extent to which such taking adversely affected Tenant's use of the Premises and the Property.

**19.4 Temporary Taking.** Notwithstanding any other provision of this Article, if a taking occurs with respect to all or any portion of the Premises for a period of six (6) months or less, this Lease shall remain unaffected thereby and Tenant shall continue to pay Base Rent and Additional Rent and to perform all of the terms, conditions and covenants of this Lease, provided that Tenant shall have the right to terminate this Lease if the taking continues beyond six (6) months. In the event of any such temporary taking, and if this Lease is not terminated, Tenant shall be entitled to receive that portion of any award which represents compensation for the use or occupancy of the Premises during the Term.

**19.5 Sale in Lieu of Condemnation.** A voluntary sale by Landlord of all or any part of the Property to any public or quasi-public body, agency or person, corporate or otherwise, having the power of eminent domain, either under threat of condemnation or while condemnation proceedings are pending, shall be deemed to be a taking under the power of eminent domain for the purposes of this Article.

**19.6 Waiver.** Except as provided in this Article, Tenant hereby waives and releases any right it may have under any Applicable Law to terminate this Lease as a result of a taking, including without limitation Sections 1265.120 and 1265.130 of the California Code of Civil Procedure, or any similar law, statute or ordinance now or hereafter in effect.

## 20. SURRENDER

**20.1 Surrender.** Upon the Termination Date, Tenant shall surrender the Premises to Landlord in good order and repair, reasonable wear and tear and damage by casualty, and any maintenance and repairs that Landlord is obligated to perform excepted, free and clear of all letting and occupancies and free of any Hazardous Materials that Tenant is required to remove pursuant to Article 12. Subject to Article 9, upon any termination of this Lease all improvements, except for Tenant's Property, shall automatically and without further act by Landlord or Tenant, become the property of Landlord, free and clear of any claim or interest therein by Tenant, and without payment therefore by Landlord.

**20.2 Holding Over.** Any holding over after the expiration of the Term with the consent of Landlord shall be construed to automatically extend the Term on a month-to-month basis at a Base Rent equal to 125% of the prevailing rate at which Landlord is then leasing space in buildings reasonably determined by Landlord to be comparable to the Premises, and shall otherwise be on the terms and conditions of this Lease to the extent applicable. Any holding over without Landlord's consent shall entitle Landlord to exercise any or all of its remedies provided in Article 15, notwithstanding that Landlord may elect to accept one or more payments of Base Rent and Operating Expenses from Tenant.

**20.3 Quitclaim.** At the expiration or earlier termination of this Lease, Tenant shall execute, acknowledge and deliver to Landlord, within ten (10) days after written demand from Landlord to Tenant, any quitclaim deed or other document required by any reputable title company, licensed to operate in the State of California, to remove the cloud or encumbrance created by this Lease from the Property.

## **21. FINANCIAL STATEMENTS**

Subject to any limitations imposed by Applicable Law, Tenant shall tender to Landlord within ten (10) business days after receipt of written request Tenant's financial statements provided to its Board of Directors for the last two (2) years, along with any background information and support documentation maintained by Tenant in the ordinary course of business and reasonably requested by Landlord to clarify Tenant's financial statements. Landlord shall be entitled to rely upon the information provided in determining whether or not to enter into this Lease or for the purpose of any financing or other transaction subsequently undertaken by Landlord. Tenant hereby represents and warrants to Landlord that all financial statements provided by Tenant to Landlord will be true, correct and accurate. Landlord shall keep all such information delivered by Tenant to Landlord pursuant to this Article 21 confidential. Notwithstanding the foregoing, Landlord shall have the right to disclose such information to its employees and agents and to any ground lessee, potential ground lessee, lender or potential lender, provided that Landlord shall cause any such third party to keep the information confidential. The foregoing obligation shall not apply to information that (a) was in the possession of, or was known by, Landlord prior to its receipt from Tenant without a duty to keep confidential, (b) is or becomes generally known to the public without violation of Landlord's obligations under this Article, or (c) Landlord is required by Applicable Law to disclose.

## **22. TENANT CERTIFICATES**

Tenant, at any time and from time to time within ten (10) business days after receipt of written notice from Landlord, shall execute, acknowledge and deliver to Landlord or to any potential purchaser, lender, auditor or any other party with an interest or potential interest in the Premises designated by Landlord, a certificate of Tenant stating, to the best of Tenant's knowledge: (a) that Tenant has accepted the Premises, (b) the Commencement Date, the Rent Commencement Date and Expiration Date of this Lease, (c) that this Lease is unmodified and in full force and effect (or, if there have been modifications, that same is in full force and effect as modified and stating the modifications), (d) whether or not there are then existing any defenses against the enforcement of any of the obligations of Tenant under this Lease (and, if so, specifying same), (e) whether or not there are then existing any defaults by Landlord in the performance of its obligations under this Lease (and, if so, specifying same), (f) the dates, if any, to which the Base Rent and Operating Expenses have been paid, and (g) any other factual information relating to the rights and obligations under this Lease that may reasonably be required by any of such persons. Failure to deliver such certificate when due shall constitute an Event of Default. At the request of Tenant, Landlord shall execute, acknowledge and deliver to Tenant a certificate with similar types of information and in the time period set forth above.

Failure by either Landlord or Tenant to execute, acknowledge and deliver such certificate shall be conclusive evidence that this Lease is in full force and effect and has not been modified except as may be represented by the requesting party. Delivery of such a certificate by Tenant shall not constitute a waiver of any known default of Landlord as to Landlord, but not as to any other party receiving the estoppel.

### **23. SIGNS**

Without Landlord's written consent, which may be given or withheld in Landlord's reasonable discretion, Tenant shall not place or permit to be placed on the front of the Premises any sign, picture, advertisement, name, notice, marquee or awning; provided that (a) upon Landlord's reasonable approval, Tenant shall have the right to place a sign on or adjacent to the entrance doors to Tenant's Premises identifying Tenant, and (b) with Landlord's approval (which shall not be unreasonably withheld or delayed) and the approval of the City of Palo Alto, Tenant shall have the right to place a sign on the existing monument sign or signs in the front of the landscaping area.

### **24. INABILITY TO PERFORM**

Subject to the other provisions of this Lease (including those provisions relating to damage and destruction and abatement of rent), if Landlord is unable to fulfill or is delayed in fulfilling any of Landlord's obligations under this Lease, by reason of acts of God, accidents, breakage, repairs, strikes, lockouts, other labor disputes, inability to obtain utilities or materials or by any other reason beyond Landlord's reasonable control, then no such inability or delay by Landlord shall constitute an actual or constructive eviction, in whole or in part, or entitle Tenant to any abatement or diminution of Base Rent or Additional Rent, or relieve Tenant from any of its obligations under this Lease, or impose any liability upon Landlord or Landlord's Indemnitees by reason of inconvenience, annoyance, interruption, injury or loss to or interference with Tenant's business or use and occupancy or quiet enjoyment of the Premises or any loss or damage occasioned thereby. If Tenant is unable to fulfill or is delayed in fulfilling any of Tenant's obligations under this Lease (other than the payment of Rent), by reason of acts of God, accidents, breakage, repairs, strikes, lockouts, other labor disputes, inability to obtain utilities or materials or by any other reason beyond Tenant's reasonable control, then such inability or delay by Tenant shall excuse the performance of Tenant for a period equal to the duration of such prevention, delay or stoppage. Tenant hereby waives and releases any right to terminate this Lease under Section 1932(1) of the California Civil Code, or any similar law, statute or ordinance now or hereafter in effect.

### **25. NOTICES**

Notices or other communications given or required to be given under this Lease shall be effective only if rendered or given in writing, sent by certified mail with a return receipt requested, or delivered in person or by reputable overnight courier (e.g., Federal Express, DHL, etc.): (a) to Tenant (i) at Tenant's address set forth in Article 1, if sent prior to the Rent Commencement Date, Attention: General Counsel or (ii) at the Premises and at the address specified in Article 1 if sent subsequent to the Rent Commencement Date, Attention: Chief Financial Officer or (iii) at the place where Tenant designates subsequent to Tenant's vacating,



deserting, abandoning or surrendering the Premises; or (b) to Landlord at Landlord's address set forth in Article 1; or (c) to such other address as either Landlord or Tenant may designate as its new address for such purpose by notice given to the other in accordance with the provisions of this Article. Any such notice or other communication shall be deemed to have been rendered or given five (5) days after the date mailed, if sent by certified mail, or upon the date of delivery in person or by courier, or when delivery is attempted but refused.

## **26. QUIET ENJOYMENT**

Landlord covenants that so long as an Event of Default by Tenant is not in existence, Tenant shall peaceably and quietly enjoy the Premises, subject to the terms and provisions of this Lease.

## **27. AUTHORITY**

If Tenant is a corporation or a partnership, Tenant represents and warrants as follows: Tenant is an entity as identified in Article 1, duly formed and validly existing and in good standing under the laws of the state of organization specified in Article 1 and qualified to do business in the State of California. Tenant has the power, legal capacity and authority to enter into and perform its obligations under this Lease and no approval or consent of any person is required in connection with the execution and performance hereof. The execution and performance of Tenant's obligations under this Lease will not result in or constitute any default or event that would be, or with notice or the lapse of time would be, a default, breach or violation of the organizational instruments governing Tenant or any agreement or any order or decree of any court or other governmental authority to which Tenant is a party or to which it is subject. Tenant has taken all necessary action to authorize the execution, delivery and performance of this Lease and this Lease constitutes the legal, valid and binding obligation of Tenant. Upon Landlord's request, Tenant shall provide Landlord with the Board resolutions or a certificate of a corporate officer confirming the foregoing representations and warranties.

## **28. BROKERS**

Tenant and Landlord warrant that they have had dealings with only the real estate brokers or agents listed in Article 1 in connection with the negotiation of this Lease and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Lease. The brokerage commission earned in connection with this transaction shall be paid by Landlord. Tenant and Landlord shall indemnify, defend and hold the other harmless from and against all liabilities arising from any other claims of brokerage commissions or finder's fees based on Tenant's or Landlord's respective dealings or contacts with brokers or agents other than those listed in Article 1.

## **29. MISCELLANEOUS**

**29.1 Entire Agreement.** This Lease, including the exhibits which are incorporated herein and made a part of this Lease, contains the entire agreement between the parties and all prior negotiations and agreements are merged herein. Tenant hereby acknowledges that neither Landlord nor Landlord's Indemnitees have made any representations or warranties with respect to the Premises, the Property, or this Lease except as expressly set forth herein, and no rights, easements or licenses are or shall be acquired by Tenant by implication or otherwise unless expressly set forth herein.

**29.2 No Waiver.** No failure by Landlord or Tenant to insist upon the strict performance of any obligation of Tenant or Landlord under this Lease or to exercise any right, power or remedy consequent upon a breach thereof, no acceptance of full or partial Base Rent or Additional Rent during the continuance of any such breach by Landlord, or payment of Base Rent or Additional Rent by Tenant to Landlord, and no acceptance of the keys to or possession of the Premises prior to the expiration of the Term by any employee or agent of Landlord shall constitute a waiver of any such breach or of such term, covenant or condition or operate as a surrender of this Lease. No waiver of any breach shall affect or alter this Lease, but each and every term, covenant and condition of this Lease shall continue in full force and effect with respect to any other then-existing or subsequent breach thereof. The consent of Landlord or Tenant given in any instance under the terms of this Lease shall not relieve Tenant or Landlord, as applicable, of any obligation to secure the consent of the other in any other or future instance under the terms of this Lease.

**29.3 Modification.** Neither this Lease nor any term or provisions hereof may be changed, waived, discharged or terminated orally, and no breach thereof shall be waived, altered or modified, except by a written instrument signed by the party against which the enforcement of the change, waiver, discharge or termination is sought.

**29.4 Successors and Assigns.** The terms, covenants and conditions contained in this Lease shall bind and inure to the benefit of Landlord and Tenant and, except as otherwise provided or limited herein, their respective personal representatives and successors and assigns.

**29.5 Validity.** If any provision of this Lease or the application thereof to any person, entity or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such provision to persons, entities or circumstances other than those as to which it is invalid or unenforceable, shall not be affected thereby, and each provision of this Lease shall be valid and be enforced to the full extent permitted by law.

**29.6 Jurisdiction.** This Lease shall be construed and enforced in accordance with the laws of the State of California. Any action that in any way involves the rights, duties and obligations of the parties under this Lease may (and if against Landlord, shall) be brought in the courts of the State of California or the United States District Court for the Northern District of California, and the parties hereto hereby submit to the personal jurisdiction of said courts.

**29.7 Attorneys' Fees.** In the event that either Landlord or Tenant fails to perform any of its obligations under this Lease or in the event a dispute arises concerning the meaning or interpretation of any provision of this Lease, the defaulting party or the party not prevailing in such dispute, as the case may be, shall pay any and all costs and expenses incurred by the other party in enforcing or establishing its rights hereunder, including, without limitation, court costs, costs of arbitration and reasonable attorneys' fees.

**29.8 Waiver of Jury Trial.** Landlord and Tenant each hereby voluntarily and knowingly waive and relinquish their right to a trial by jury in any action, proceeding or

counterclaim brought by either against the other on any matter whatsoever arising out of or in any way connected with this Lease, the relationship of Landlord with Tenant, or Tenant's use of occupancy of the Premises, including any claim of injury or damage, and any emergency and other statutory remedy with respect thereto.

**29.9 Light and Air.** Tenant covenants and agrees that no diminution of light, air or view by any structure on property other than the Premises that may hereafter be erected (whether or not by Landlord) shall entitle Tenant to any reduction of the Base Rent or Additional Rent under this Lease, result in any liability of Landlord to Tenant, or in any other way affect this Lease or Tenant's obligations hereunder.

**29.10 Lease Memorandum.** Neither Landlord or Tenant shall record this Lease or a short form memorandum hereof without the consent of the other.

**29.11 Confidentiality.** The parties agree that neither of them shall make public the terms and conditions of this Lease or the fact that they have entered into this Lease to any person other than a party's accountants, attorneys, investors, agents, consultants or financial advisors without first obtaining the written permission from the other party, except to the extent otherwise required by Applicable Law.

**29.12 Terms.** The term "Premises" includes the space leased hereby and any improvements now or hereafter installed therein or attached thereto. The words "Landlord" and "Tenant" as used herein shall include the plural as well as the singular. If there is more than one Tenant or Landlord, the obligations under this Lease imposed on Tenant or Landlord shall be joint and several. The captions preceding the articles of this Lease have been inserted solely as a matter of convenience and such captions in no way define or limit the scope or intent of any provision of this Lease.

**29.13 Review and Approval.** The review, approval, inspection or examination by Landlord of any item to be reviewed, approved, inspected or examined by Landlord under the terms of this Lease or the exhibits attached hereto shall not constitute the assumption of any responsibility by Landlord for either the accuracy or sufficiency of any such item or the quality of suitability of such item for its intended use. Any such review, approval, inspection or examination by Landlord is for the sole purpose of protecting Landlord's interests in the Property and under this Lease, and no third parties, including, without limitation, Tenant or any person or entity claiming through or under Tenant, or the contractors, agents, servants, employees, visitors or licensees of Tenant or any such person or entity, shall have any rights hereunder with respect to such review, approval, inspection or examination by Landlord.

**29.14 No Beneficiaries.** This Lease shall not confer or be deemed to confer upon any person or entity other than the parties hereto, any right or interest, including without limitation, any third party status or any right to enforce any provision of this Lease.

**29.15 Time of the Essence.** Time is of the essence in respect of all provisions of this Lease in which a definite time for performance is specified.

**29.16 Modification of Lease.** In the event of any ruling or threat by the Internal Revenue Service, or opinion of counsel, that all or part of the Rent paid or to be paid to Landlord

under this Lease will be subject to the income tax or unrelated business taxable income, Tenant agrees to modify this Lease to avoid such tax; provided that such modifications will not result in any increase in Rent, or any increased obligations of Tenant under this Lease, or any diminution of the Premises or Tenant's rights hereunder. Landlord will pay all Tenant's reasonable costs incurred in reviewing and negotiating any such lease modification, including reasonable attorneys' and accountants' fees.

**29.17 Construction.** This Lease has been negotiated extensively by Landlord and Tenant with and upon the advice of their respective legal counsel, all of whom have participated in the drafting hereof. Consequently, Landlord and Tenant agree that no party shall be deemed to be the drafter of this Lease and in the event this Lease is ever construed by a court of law, such court shall not construe this Lease or any provision of this Lease against any party as the drafter of the Lease.

**29.18 Use of Name.** Tenant acknowledges and agrees that the names "*The Leland Stanford Junior University*," "*Stanford*" and "*Stanford University*," and all variations thereof, are proprietary to Landlord. Tenant shall not use any such name or any variation thereof or identify Landlord in any promotional advertising or other promotional materials to be disseminated to the public or any portion thereof or use any trademark, service mark, trade name or symbol of Landlord or that is associated with it, without Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion. Notwithstanding the foregoing, Tenant may use the term "Stanford Research Park" only to identify the location of the Premises.

**29.19 Survival.** The obligations of this Lease shall survive the expiration of the Term to the extent necessary to implement any requirement for the performance of obligations or forbearance of an act by either party hereto which has not been completed prior to the termination of this Lease. Such survival shall be to the extent reasonably necessary to fulfill the intent thereof, or if specified, to the extent of such specification, as same is reasonably necessary to perform the obligations and/or forbearance of an act set forth in such term, covenant or condition. Notwithstanding the foregoing, in the event a specific term, covenant or condition is expressly provided for in such a clear fashion as to indicate that such performance of an obligation or forbearance of an act is no longer required, then the specific shall govern over this general provisions of this Lease.

*[signatures located on following page]*

**29.20 Counterparts.** This Lease may be executed in counterparts, each of which shall be an original, and all of which together shall constitute one original of the Lease.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the date first above written.

LANDLORD:

TENANT:

THE BOARD OF TRUSTEES OF THE  
LELAND STANFORD JUNIOR  
UNIVERSITY

JAZZ PHARMACEUTICALS, INC.

By Stanford Management Company

By: /s/ Carol Gamble

Its: Senior Vice President and General Counsel

By: /s/ Jean Snider

By: /s/ Matthew K. Fust

Its: Managing Director, Stanford Research Park

Its: Senior Vice President and Chief Financial Officer

DEFINITIONS

As used in this Lease, the following terms shall have the following meanings, applicable, as appropriate, to both the singular and plural form of the terms defined below:

**“Abated Rent”** is defined in Section 15.2(g).

**“Access Agreement”** is defined in Section 12.2(a).

**“ADA”** is defined in Section 11.1.

**“Additional Rent”** is defined in Section 5.3.

**“Adjustment Date”** is defined in Section 5.2.

**“Affixed Furniture”** is defined in Section 2.4.

**“Alterations”** is as defined in Section 9.2.

**“Applicable Laws”** are defined in Section 11.1.

**“Assignment”** is defined in Section 14.1.

**“Base Rent”** means the amount stated in Article 1, to be adjusted and payable in accordance with Article 5.

**“Building Structure”** is defined in Section 8.1.

**“Building Systems”** are defined in Section 7.2(b).

**“business days”** means Monday through Friday, excluding Saturdays, Sundays and federal and state legal holidays.

**“Commencement Date”** means the date specified in Article 1.

**“Environmental Investigation”** is defined in Section 12.7.

**“Environmental Laws”** are defined in Section 12.1(a).

**“Event of Default”** is defined in Section 15.1.

**“Excess Rent”** is defined in Section 14.4.

**“Existing Furniture”** is defined in Section 2.4.

**“Expiration Date”** is defined in Section 4.1.

**“Exterior Area”** is defined in Section 2.2.

**“Failure Notice”** is defined in Section 7.7.

**“Hazardous Material”** is defined in Section 12.1(b).

**“Initial Term Expiration Date”** is defined in Article 1.

**“Initial Term”** is defined in Article 1 and Section 4.1.

**“Interest Rate”** is defined in Section 5.4.

**“Landlord Repairs”** is defined in Article 3.

**“Landlord’s Indemnitees”** is defined in Section 12.5(a).

**“Landlord’s Expense Statement”** is defined in Section 7.3.

**“L-C Bank”** is defined in Section 5.5.

**“Lucent”** is defined in Section 4.1.

**“Moveable Furniture”** is defined in Section 2.4.

**“negligent omission”** is defined in Section 12.1(d).

**“Offer”** is defined in Section 14.5.

**“Operating Expenses”** are defined in Section 7.2(b).

**“Premises”** is defined in Section 2.1.

**“Prevailing Market Rent”** is defined in Exhibit E.

**“Property”** is defined in Section 2.2.

**“Punch List Items”** is defined in Article 3.

**“Real Estate Taxes”** are defined in Section 7.2(a).

**“Renewal Option”** is defined in Section 4.2.

**“Renewal Term”** is defined in Section 4.2.

**“Rent”** means Base Rent, Additional Rent, and all other sums due from Tenant under this Lease.

**“Rentable Area”** means the enclosed areas of the Premises measured to the outside face of the exterior wall or glass line (whichever is greater) and including all second floor vertical shafts and penetrations, but excluding outside balconies, arcades and covered entrances.

**“Scheduled Date for Delivery of the Premises”** is specified in Article 1.

**“Security Deposit”** is defined in Article 1.

**“Sublease”** is defined in Section 14.1.

**“Successor”** is defined in Section 16.5.

**“Supplemental Investigation”** is defined in Section 12.7.

**“Tenant Environmental Activity”** is defined in Section 12.1(c).

**“Tenant Improvement Allowance”** is specified in Article 1.

**“Tenant Improvement Work”** is defined in Section 9.1.

**“Tenant’s Agents”** is defined in Section 2.2.

**“Tenant’s Indemnitees”** is defined in 12.5(b).

**“Tenant’s Property”** is defined in Section 9.5.

**“Term”** is defined in Section 4.1.

**“Termination Date”** is defined in Section 4.1.

**“Termination Notice”** is defined in Section 4.2.

**“Third Party Environmental Condition”** is defined in Section 12.5(c).

**“Transfer”** is defined in Section 14.5.

**“Transfer Costs”** is defined in Section 14.4.

**“Transfer Notice”** is defined in Section 14.2.

**“Transferee”** is defined in Section 14.2.

**“Transit Fees”** is defined in Section 7.2(m).



**SCHEDULE 3**

**LANDLORD REPAIRS**

**Electrical/Lighting:**

- Repair (2) rooftop receptacles not working at this time.
- Repair all interior building and exterior parking-lot lighting.
- Repair office motion switches.

**HVAC:**

- Replace or clean all filters (some filters are the washable variety).
- Replace belts on supply and return fans.
- Repair compressors 1A and 2A, or replace as deemed necessary by Landlord.
- Charge Split System Cooling Units by ATS and repair leaks if needed.

**Roof:**

**Built-up Roofing**

1. Perform maintenance on small to moderately sized areas of previous repairs over the cap sheet surfacing. (See Photo Nos. 4 & 5).
2. Perform maintenance at minor occurrences of partially disbonded end laps at various parapet wall and equipment curb/platform locations.
3. Coat areas at base flashing surface sheets where pattern cracking occurs. (See Photo No. 6).
4. Retighten loose bolts at drain clamp rings.
5. Remove accumulation of loose mineral granules at perimeters and drain sumps as well as construction fasteners and other debris at roof level, primarily within the HVAC equipment area.
6. Perform sealant joint maintenance on the coping at the south parapet wall over the window wall assembly to correct separation.
7. Replace fiberboard material which is deteriorating on underside of exposed wood blocks at service lines that extend horizontally across the roof. (See Photo No. 7).

8. Permanently install one penetration flashing and provide an umbrella counter flashing over the top edge of the penetration flashing collar. (See Photo No. 8).
9. Add flashing collar to one plumbing pipe penetration. (See Photo No. 9).
10. Inspect and repair if needed one lead penetration flashing collar which has folded over itself.
11. Perform maintenance on the sealant at intersecting detail treatments and at corners and miters (see Photo No. 10).
12. Confirm that screws do not penetrate the roofing and reset unistruts on protection pads at the apparent tenant added small HVAC units horizontal service line piping. (see Photo No. 11)
13. Perform maintenance on sealant at sight screen support bolts. (See Photo No. 12).

#### Metal Roofing

1. Remove soil and debris in gutters.

#### Non-Roofing Related Items

1. Patch horizontal row of holes present in the ducting, above the roof curb elevation. (see Photo No. 13)
2. Perform maintenance on the sealant and joinery components at air handling duct joints. (see Photo No. 14)

#### Other:

- Perform start up and maintenance on the water fountain at the rear of the building so it is clean and fully operational.
- Perform repairs on windows and doors so they are operational.

**SCHEDULE 12.2**

**PRE-EXISTING ENVIRONMENTAL CONDITION**

Site Clean-up Order

3176 Porter Drive

Lead Agency

State of California EPA,  
Dept. of Toxic Substances Control (DTSC)

Order Number and Date

#HSA 86/87-012EO (11/12/86)  
amended 11/27/91 and 7/31/95

Hillview-Porter  
Regional Order

DTSC

#HSA 88/89-016 (12/9/88)  
First amendment 6/30/97  
Supersedes 12/9/88 agt.

Fact Sheets

DTSC Fact Sheet for Teledyne-Singer Site, dated November 2003

DTSC Fact Sheet for Hillview-Porter Regional Program, dated April 2001

Reports

- Executive Summary, Final Remedial Action Plan, Teledyne Singer Site, 3176 Porter Drive, JMM Consulting Engineers, dated 12/92
- Executive Summary, Feasibility Study Report, 3176 Porter Drive, dated November 15, 1990
- Executive Summary, Addendum to the Feasibility Study Report, 3176 Porter Drive, by Riedel Environmental Services, dated December 6, 1992
- Five Year Remedial Action Review, by Arcadis G&M, Inc., dated January 30, 2004
- Executive Summary, Remedial Action Plan, Hillview-Porter Regional Program, by Levine Fricke, dated December 19, 1994
- Executive Summary, Five-Year Remedial Action Status Report and Effectiveness Evaluation, Hillview-Porter Regional Program, by Secor, Int., dated January 30, 2001

Indices

- List of reports for 3176 Porter Drive, dated from 1/23/87 through 1/30/04.
- List of reports for Hillview-Porter Drive, dated from 10/87 through 7/11/03.

Access Agreements for 3180 Porter Drive

- December 4, 1992 access agreement between Stanford and Loral Librascope
- July 30, 2003, amendment to December 4, 1992 agreement between Stanford and Loral/Librascope

With respect to on-site environmental data, sampling performed during the site's redevelopment in 1998.

- Sampling and Analysis of Concrete Floor and Demolition Debris Management Plan, by Geomatrix Consultants, dated July 2, 1998

- 
- Demolition Observation Report, by Geomatrix Consultants, dated October 6, 1999, and
  - Stockpile Sample Results for Soil Export, by Geomatrix Consultants, dated November 19, 1998.

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***EXHIBIT A***

**PREMISES**

[Site Plan for 3180 Porter Drive]

**EXHIBIT B**

**BILL OF SALE**

THIS BILL OF SALE is made as of \_\_\_\_\_, 2004 by The Board of Trustees of the Leland Stanford Junior University ("**Transferor**") in favor of Jazz Pharmaceuticals, Inc. ("**Transferee**").

Transferor and Transferee are parties to a Lease dated as of \_\_\_\_\_, 2004 (the "**Lease**"), pursuant to which Transferor has agreed to convey to Transferee all of Transferor's right, title and interest in certain items of personal property.

Now therefore, for good and valuable consideration, and a purchase price of \$1.00, receipt and sufficiency of which are acknowledged, Transferor hereby transfers, conveys and delivers to Transferee those items of personal property listed on the attached Schedule 1 (the "**Personal Property**"), which are being transferred to Transferee "**AS IS, WHERE IS,**" with no representations, warranties or guaranties of any kind including, without limitation, as to the physical condition, state of repair, capacity, operability or functionality thereof, except as expressly set forth herein. Without limitation, this also excludes warranties of merchantability and fitness for a particular use or purpose. Notwithstanding the foregoing, Transferor warrants that it owns the Personal Property free and clear of any and all liens and encumbrances of any party claiming by through or under Transferor or Lucent Technologies Inc., but not otherwise.

Transferor will, at the request and expense of Transferee, execute and deliver to Transferee such instruments of sale, transfer and conveyance, and such consents, assurances, powers of attorney and other instruments, as may be reasonably requested by Transferee or its counsel in order to vest in Transferee all right, title and interest of Transferor in and to the Personal Property and otherwise to carry out the purpose and intent of this Bill of Sale.

Notwithstanding any other provision of this Bill of Sale to the contrary, nothing contained in this Bill of Sale shall in any way supersede, modify, replace, amend, change, rescind, waive, exceed, expand, enlarge or in any way affect the provisions of the Lease. This Bill of Sale is intended only to effect the transfer of certain assets to be transferred pursuant to the Lease and shall be governed entirely in accordance with the terms and conditions of that Lease.

IN WITNESS WHEREOF, this Bill of Sale has been executed as of the day and year first above written.

THE BOARD OF TRUSTEES OF THE  
LELAND STANFORD JUNIOR UNIVERSITY

By Stanford Management Company

By: \_\_\_\_\_

Its: \_\_\_\_\_

**EXHIBIT C**

**EXISTING FURNITURE**

<b>Item #</b>	<b>Furniture Category</b>	<b>Quantity</b>	<b>Furniture Description</b>	<b>Size</b>	<b>Manufacturer</b>	<b>Color/Finish</b>
1	Office	13	Modular workstation		Steelcase	
2	Office	124	Private office		Steelcase	
3						6205-B399
4	Office	83	Task Chair		Steelcase	Black fabric
5	Office	41	Task Chair		Steelcase	6205-59DD
6	Office	21	Lab Chair			Gold fabric
7	Office	64	4-drawer lateral file	36" wide	Steelcase	
8	Office	8	2-drawer lateral file	36" wide	Steelcase	
9	Office	44	Storage cabinet/lateral file combo	42" wide	Steelcase	
10	Office	3	Storage cabinet	36" W x 65" H	Steelcase	
11	Office	2	Small desk		Steelcase	
12	Office	4	Round table	36" D	Metro	Black laminate tops/red trim
13	Office	1	Round table	42" D	Metro	Black laminate tops/red trim
14	Office	1	Round table	42" D		Wood top
15	Office	1	Round table	48" D	Metro	Black laminate tops/red trim
16	Office	2	Bookcases (metal) 6-shelf	42" wide	Steelcase	
17	Office	55	Bookcases (metal) 2-shelf	42" wide	Steelcase	
18	Office	8	Library style 6-shelf bookcases			Maple wood
19	Conference Room	2	Conference room tables (first floor)	96" x 54"		
17	Conference Room	1	Conference room tables (first floor)	180" x 54"		
18	Conference Room	3	Conference room tables (second floor)	72" x 48"		
18	Conference Room	1	Conference room tables (second floor)	60" x 168"		

Item #	Furniture Category	Quantity	Furniture Description	Size	Manufacturer	Color/Finish
19	Conference Room	34	Conference room chairs		Steelcase	6205-5999 Purple fabric
20	Conference Room	37	Conference room chairs		Steelcase	6205-5999 Green fabric
21	Conference Room	9	Executive style conference room side chairs			
22	Conference Room	10	Executive style conference room chairs (first floor)			Periwinkle fabric
23	Training Room	12	Training tables (large)	72" x 24"		White laminate tops
24	Training Room	3	Training tables (small)	72" x 18"		Black laminate tops
25	Training Room	77	Stacking chairs			Black/Chrome
26	Lobby/Open Office	26	Club chairs			Red fabric
27	Lobby/Open Office	4	Club chairs			Gold/Brown fabric
28	Lobby/Open Office	1	Loveseat			Gold/Brown fabric
29	Lobby/Open Office	1	Sofa			Gold/Brown fabric
31	Lobby/Open Office	10	Small round tables (low)	30" D	Metro	Black laminate tops/red trim
32	Breakroom	6	Round tables (large)	54" D	Metro	Black laminate tops/red trim
33	Breakroom	20	Breakroom chairs		Metro	Black/red
34	Breakroom	6	Breakroom stools		Metro	Black/red
35	Fitness Room	1	Treadmill - Hyperdrive Clubtrack		Quinton	
36	Fitness Room	1	Stairstepper 330i		Schwinn	
37	Fitness Room	1	Metabolic system		Cybex	
38	Fitness Room	1	Stationary bike		Schwinn	
39	Miscellaneous	1	Konica 7040 Printer		Konica	
40	Miscellaneous	1	Konica 7040 Copier		Konica	
41	Miscellaneous	1	Xerox Panafax fax machine UF-770		Xerox	
42	Miscellaneous	1	Xerox Printer N24		Xerox	
43	Miscellaneous	2	Paper shredders		Xerox	



**EXHIBIT D**

**NOTICE OF COMMENCEMENT DATE, RENT COMMENCEMENT DATE,  
EXPIRATION DATE, BASE RENT AND RENTABLE AREA**

*(Letterhead of Stanford Management Company)*

(Date)

\_\_\_\_\_

Attention: \_\_\_\_\_

Re: Lease between The Board of Trustees of the Leland Stanford Junior University (Landlord), and \_\_\_\_\_ (Tenant), for premises located at \_\_\_\_\_, Palo Alto, California

Gentlemen/Ladies:

This letter will confirm the following for all purposes under the Lease:

- The Commencement Date is \_\_\_\_\_
- The Rent Commencement Date is \_\_\_\_\_
- The Expiration Date of the Initial Term is \_\_\_\_\_
- The Rentable Area of the Premises is \_\_\_\_\_
- The Initial Base Rent is \_\_\_\_\_

Please acknowledge your acceptance of this letter by signing and returning two copies of this letter.

Very truly yours,  
Stanford Management Company

By: \_\_\_\_\_  
Its: \_\_\_\_\_

Accepted and Agreed:  
\_\_\_\_\_

By: \_\_\_\_\_  
Its: \_\_\_\_\_  
Dated: \_\_\_\_\_

**EXHIBIT E**

**DETERMINATION OF PREVAILING MARKET RENT**

The term "**Prevailing Market Rent**" means the base monthly rent per rentable square foot (net of all expenses) for space of comparable size and location to the Premises and in buildings similar in age and quality to the Premises, taking into account any additional rent and all other payments or escalations then being charged and allowances and economic concessions being given in the Stanford Research Park for such comparable space over (but without regard to Tenant Improvements made by Tenant) a comparable term. The Prevailing Market Rent shall be determined by Landlord and Landlord shall give Tenant written notice of such determination not later than thirty (30) days after delivery by Tenant of Tenant's notice of exercise of the Renewal Option. If Tenant disputes Landlord's determination of the Prevailing Market Rent, Tenant shall so notify Landlord within ten (10) business days following Landlord's notice to Tenant of Landlord's determination and, in such case, the Prevailing Market Rent shall be determined as follows:

(a) Within thirty (30) days following Tenant's notice to Landlord that it disputes Landlord's determination of the Prevailing Market Rent, Landlord and Tenant shall meet no less than two (2) times, at a mutually agreeable time and place, to attempt to agree upon the Prevailing Market Rent.

(b) If within this 30-day period Landlord and Tenant cannot reach agreement as to the Prevailing Market Rent, and upon written notice from either party they shall each select one appraiser to determine the Prevailing Market Rent. Each such appraiser shall arrive at a determination of the Prevailing Market Rent and submit his or her conclusions to Landlord and Tenant within thirty (30) days after such notice.

(c) If only one appraisal is submitted within the requisite time period, it shall be deemed to be the Prevailing Market Rent. If both appraisals are submitted within such time period, and if the two appraisals so submitted differ by less than five (5) percent of the higher of the two, the average of the two shall be the Prevailing Market Rent. If the two appraisals differ by more than five (5) percent of the higher of the two, then the two appraisers shall immediately select a third appraiser who will within thirty (30) days of his or her selection make a determination of the Prevailing Market Rent and submit such determination to Landlord and Tenant. This third appraisal will then be averaged with the closer of the two previous appraisals and the result shall be the Prevailing Market Rent.

(d) All appraisers specified pursuant hereto shall be members of the American Institute of Real Estate Appraisers with not less than five (5) years experience appraising office, research and development and industrial properties in Northern California. Each party shall pay the cost of the appraiser selected by such party and one-half of the cost of the third appraiser plus one-half of any other costs incurred in the third appraiser's determination.

**EXHIBIT F**

**Access Agreement for Monitoring Wells, Groundwater Extraction Wells, a Conveyance Pipeline, and Water Treatment Plant at 3176 Porter Drive, 3180 Porter Drive, 3210 Porter Drive and 3277 Miranda Avenue, Palo Alto, California**

This Access Agreement for Monitoring Wells, Groundwater Extraction Wells, a Conveyance Pipeline, and Water Treatment Plant at 3176 Porter Drive, 3180 Porter Drive, 3210 Porter Drive and 3277 Miranda Avenue, Palo Alto, California (the "ACCESS AGREEMENT") is entered into by the Board of Trustees of the Leland Stanford Junior University ("STANFORD"), a body having corporate powers under the laws of the State of California, and Loral/Librascope Corporation ("LORAL/LIBRASCOPE"), a Delaware corporation. The above-identified entities are sometimes referred to below as "party" or designated collectively as "parties."

RECITALS

This ACCESS AGREEMENT is entered into on the basis of the following facts, understandings and intentions of the parties:

1. LORAL/LIBRASCOPE, formerly the Librascope Division of The Singer Company, and STANFORD, among others, are each named as a Respondent in Order No. HSA 86/87-012EO, as amended in 1991 ("ORDER"), issued by the State of California - Environmental Protection Agency Department of Toxic Substances Control ("DTSC"), with respect to the property located at 3176 Porter Drive, Palo Alto, California (the "SITE").

2. Pursuant to the ORDER, a Remedial Investigation/ Feasibility Study was conducted for the SITE, which has been submitted and approved by DTSC. The ORDER further requires that a Remedial Action Plan ("RAP") for the SITE be submitted and approved by the DTSC. In June 1992, LORAL/LIBRASCOPE submitted a preliminary draft RAP pursuant to the ORDER. Once approved by DTSC following public hearing and comment, the draft RAP will be adopted as the final RAP pursuant to Section 25356.1 of the California Health and Safety Code.

3. LORAL/LIBRASCOPE has requested STANFORD's permission to enter 3176 Porter Drive, 3180 Porter Drive, 3210 Porter Drive and 3277 Miranda Avenue (collectively "the PROPERTIES") to continue activities necessary to the implementation of the remedy required by DTSC in the RAP, including, but not limited to, the construction, operation, maintenance, inspection, monitoring and removal of the groundwater monitoring and extraction wells, an underground conveyance pipeline, and groundwater treatment facilities shown on the attached drawing ("the REMEDIATION ACTIVITIES"). The conveyance pipeline shall provide double containment between the extraction wells and groundwater treatment facilities located at the SITE (as shown on the attached drawing).

4. Effective July 31 1992, STANFORD and LORAL/LIBRASCOPE entered into a Settlement Agreement, Release And Covenant Not To Sue (the "AGREEMENT"). Contingent upon LORAL/LIBRASCOPE's performance of its obligations under the AGREEMENT, STANFORD, as the fee owner of the PROPERTIES, has agreed to grant LORAL/LIBRASCOPE, its employees, contractors, subcontractors, agents and successors in interest access to the PROPERTIES for the purpose of investigating, constructing, operating, and maintaining the remedy set forth in the final RAP for the SITE, or any reopeners or amendments thereto.

AGREEMENT

NOW, THEREFORE, in reliance on the above recitals and in consideration of the mutual agreements, covenants, and other obligations set forth in the AGREEMENT, STANFORD hereby grants LORAL/LIBRASCOPE access to the PROPERTIES to conduct the REMEDIATION ACTIVITIES on the terms and conditions set forth below:

1. LORAL/LIBRASCOPE shall have received the written permission of the master tenant(s) and any occupant(s) of the PROPERTIES to conduct the REMEDIATION ACTIVITIES.

2. Upon completion of well drilling, LORAL/LIBRASCOPE shall secure the wells in an appropriate manner (e.g., install locked caps).
3. At its sole expense, LORAL/LIBRASCOPE shall repair any damage to the PROPERTIES or improvements resulting from the REMEDIATION ACTIVITIES or LORAL/LIBRASCOPE's presence on the PROPERTIES.
4. If LORAL/LIBRASCOPE is required to install remediation equipment or other improvements on the surface of the PROPERTIES that will affect the aesthetic appearance or have a physical impact on the PROPERTIES, including but not limited to any trees located thereon, LORAL/LIBRASCOPE shall obtain prior written consent from STANFORD, which consent shall not be unreasonably withheld.
5. LORAL/LIBRASCOPE shall provide STANFORD with the results of any tests it conducts on STANFORD lands, including but not limited to the PROPERTIES.
6. LORAL/LIBRASCOPE shall take all reasonable safety and security precautions in connection with the REMEDIATION ACTIVITIES.

7. In the event that any master lease pertaining to the PROPERTIES, or any portion thereof, is terminated or expires by its terms and a new master lessee or STANFORD, should STANFORD elect not to enter into a new master lease, requests that the conveyance pipeline be moved to a different location on the leased property, STANFORD may for good cause, taking into account the costs associated therewith, require LORAL/LIBRASCOPE, at LORAL/LIBRASCOPE's sole expense, to move and relocate the conveyance pipeline as requested; however no such movement or relocation may occur without the prior approval of DTSC. The movement and relocation of the pipeline shall occur within sixty (60) days' of written notice to LORAL/LIBRASCOPE of DTSC approval.
8. LORAL/LIBRASCOPE shall allow a STANFORD archeologist (or suitable representative) to inspect any excavation for the presence of significant archeological artifacts. The PROPERTIES are not archaeologically sensitive; therefore, STANFORD agrees that in no case shall such inspection take the form of job stoppage unless required by law.
9. Where excavation is necessary and the possibility exists of encountering existing underground utility lines, LORAL/LIBRASCOPE shall call the Underground Service Alert organization (800/642-2444) two working days prior to commencing excavation.

10. LORAL/LIBRASCOPE shall indemnify, defend, save and hold harmless STANFORD from and against (and hereby waives any and all claims against STANFORD for) any and all claims, suits and demands of liability, loss, injury, death or damage resulting from LORAL/LIBRASCOPE's presence on the PROPERTIES or the REMEDIATION ACTIVITIES. Such liability, loss, injury, death or damage shall include, but not be limited to, attorneys' fees, as well as contamination or further contamination to any person or persons or property proximately caused by LORAL/LIBRASCOPE's activities herein permitted. LORAL/LIBRASCOPE shall comply with all applicable laws, rules, ordinances, codes, and regulations, and shall indemnify STANFORD against all liabilities, losses, damages and costs resulting from any failure of LORAL/LIBRASCOPE to do so.

As used in this subparagraph, STANFORD shall include and be deemed to include The Board of Trustees of the Leland Stanford Junior University, its trustees, directors, officers, employees, faculty, students, agents, affiliated organizations and insurance carriers, if any.



11. Nothing in this ACCESS AGREEMENT limits any rights or privileges STANFORD may have under its master leases for the PROPERTIES, nor does it modify any obligation, duty or right of any tenant or subtenant of the PROPERTIES.
12. This ACCESS AGREEMENT shall be effective from the date hereof until LORAL/LIBRASCOPE's completion of the remedies required by DTSC in the final RAP for the SITE.
13. The access granted herein is exclusive to LORAL/LIBRASCOPE and its authorized representatives, agents, successors in interest, and independent contractors and is not assignable.
14. This ACCESS AGREEMENT shall supercede any prior license(s) or agreement(s) between STANFORD and LORAL/LIBRASCOPE providing LORAL/LIBRASCOPE access to the PROPERTIES to conduct the REMEDIATION ACTIVITIES.

BY: LORAL/LIBRASCOPE CORPORATION

Name: /s/ Jay C. Wilcox

Jay C. Wilcox

Title: President

Date: 12-04-92

BY: THE BOARD OF TRUSTEES OF THE LELAND  
STANFORD JUNIOR UNIVERSITY

: \_\_\_\_\_

: \_\_\_\_\_

Date: \_\_\_\_\_

BY: LORAL/LIBRASCOPE CORPORATION

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

BY: THE BOARD OF TRUSTEES OF THE LELAND  
STANFORD JUNIOR UNIVERSITY

By: The Stanford Management Company

By: /s/ Diane M. Healey \_\_\_\_\_

Its: Managing Director Real Estate

Date: \_\_\_\_\_

**SUBLEASE AGREEMENT**

for 3400 Hillview Avenue, Building 2, First Floor  
Palo Alto, California  
with Jazz Pharmaceuticals, Inc.

**THIS SUBLEASE**, dated for reference purposes the 25<sup>th</sup> day of February, 2007, by and between **XEROX CORPORATION**, a New York corporation, having its principal office at 800 Long Ridge Road, Stamford, Connecticut 06904 (hereinafter referred to as "Sublandlord") and **JAZZ PHARMACEUTICALS, INC.**, a California corporation having its principal offices at 3180 Porter Drive, Palo Alto, CA 94304 (hereinafter referred to as "Subtenant"), as a sublease under a certain Master Lease as more particularly described below.

**WITNESSETH:**

**WHEREAS**, the Board of Trustees of the Leland Stanford Junior University ("Stanford") and QTC VENTURE, a California General Partnership and the predecessor in interest to Equity Office Properties (hereinafter referred to as "Landlord") entered into a certain ground lease ("Ground Lease") pursuant to that certain Extension, Amendment, Assignment, Assumption and Consent to Assignment of Lease dated November 17, 1989, whereby Landlord leased from Stanford that certain parcel of land located in Palo Alto, California, commonly known as 3400 Hillview Avenue.

**WHEREAS**, Landlord and Sublandlord entered into a lease dated the 1st day of March 1990, as amended by the First Amendment to Lease dated October 23, 1990, as supplemented by the Consent to Sublease dated October 26, 1990, the Acknowledgment of Lease Assignment, Estoppel, Subordination, Non-Disturbance and Attornment Agreement dated December 19, 1990, the Consent to First Amendment of Lease dated December 20, 1990, and as further amended by the Second Amendment to Lease dated October 21, 1991 (the "Second Amendment"), the Letter Agreement dated November 25, 1991, the Consent to Second Amendment of Lease dated February 11, 1992, the Third Amendment to Lease dated December 20, 2000 and the Consent to Third Amendment to Lease dated December 20, 2000 (said Lease, as so amended and supplemented, hereinafter referred to as the "Master Lease"), whereby Landlord leased to Sublandlord the Demised Premises, as more particularly described in the Master Lease, a copy of which Master Lease is attached hereto as Exhibit A.

**WHEREAS**, Sublandlord desires to sublease to Subtenant and Subtenant desires to sublease from Sublandlord a certain portion of the Demised Premises.

**1. DESCRIPTION OF SUBLEASED PREMISES**

Sublandlord subleases to Subtenant and Subtenant subleases from Sublandlord approximately 12,782 rentable square feet located on the first floor of the building known as Building 2 located at 3400 Hillview Ave, in the City of Palo Alto, State of California (the "Building"), as more particularly shown on Exhibit B attached hereto and made a part hereof (the "Subleased Premises"), which building is part of the five (5) building complex referred to herein as the Demised Premises and leased to Sublandlord pursuant to the terms of the Master Lease. Subtenant shall also have the non-exclusive right to use, in common with other tenants, Subtenants and occupants of the Building, the first and back Building entrances, all exterior common areas of the Building including the parking lot, walkways and driveways. Subtenant shall not interfere with or restrict the use of the Building's elevators and First Floor Non-Exclusive Areas by other tenant, Subtenants and occupants of the Building, or their employees, agents and invitees. Subtenant shall not place or install or permit any other party to place or install any furniture, equipment or product displays in the first floor Non-Exclusive Areas, except that Sublandlord shall have the right to place or install any equipment or improvement as may be required by applicable law, or as may be deemed reasonably necessary by Sublandlord for the efficient use, occupancy and maintenance of the Building. Without limiting the generality of the foregoing, Sublandlord shall have the right, but not the obligation, to install a building directory in the lobby of the Building. Subtenant shall have the right to enter the demark room in the Demised Premises from time to time with the prior approval and escort of Sublandlord.

**2. TERM**

The term of this Sublease shall commence on the later of (i) March 1, 2007, or (ii) the date that Sublandlord obtains the written consent of Master Landlord to this Sublease in a form reasonably acceptable to Subtenant and Sublandlord. (the "Commencement Date"), and end on August 31, 2008 or the earlier termination of this Sublease in accordance with the terms hereof. Sublandlord shall deliver possession of the Subleased Premises to Subtenant promptly after receipt of Landlord's and Stanford's written consents to this Sublease.

**3. RENT**

a. Subtenant agrees to pay Sublandlord as fixed rent ("Rent") commencing on June 1, 2007 (the "Rent Commencement Date") the following:

From the Commencement Date to May 31, 2007	\$	0/month
From June 1, 2007 to February 28, 2008	\$	38,346.00/month
From March 1, 2008 to August 31, 2008	\$	40,007.66/month

Beginning on March 1, 2008 through the termination or expiration of the Sublease term, Rent shall include Subtenant's share of Real Estate Taxes, Common Area Insurance Costs and Common Area Maintenance costs.

b. Rent shall be paid in advance on the first day of each month during the Sublease term without setoff, offset or reduction. If the Rent Commencement Date occurs, or if the term of the Sublease expires on a date other than the first or last day of a month, the rental installment for that month shall be prorated. All payments shall be made to Xerox Corporation, Attention: CRE Lease Administration, 800 Long Ridge Road, Post Office Box 1600, Stamford, CT 06904, or to such other person or place as may be designated by Xerox Corporation in writing. Subtenant shall pay to Sublandlord upon Subtenant's submission of the partially executed Sublease to Sublandlord the sum of Thirty Eight Thousand Three Hundred Forty Six Dollars (\$38,346.00) to be applied as and for the first installment of Rent owed to Sublandlord.

c. Sublandlord and Subtenant acknowledge that the Rent specified herein is a fixed rent and, except as may be provided in this Sublease, is intended to include all normal costs and expenses related to operating the Building including, without limitation, real property taxes, utilities, common area maintenance, repair and replacement, Complex and Building insurance, interior and exterior building maintenance, repair and replacement, Complex and Building groundskeeping and landscaping maintenance, sprinkler and fire alarm maintenance, repair and replacement, janitorial and trash removal services and Building security (as described in Section 3(d) below). The general maintenance and janitorial services to be provided by Sublandlord shall be as shown in Exhibit C attached hereto. Sublandlord hereby agrees that it shall cause services adequate for the intended use of the Subleased Premises to be provided in conformity with those services furnished in first-class buildings in the Stanford Research Park in Palo Alto, California. These services shall be provided between the hours of 6:00 a.m. to 6:00 p.m. on normal business days Monday through Friday ("Normal Business Hours"). If HVAC is required outside of Normal Business Hours, Sublandlord shall make it available, and Subtenant will pay an additional \$60 per hour to Sublandlord. Notwithstanding the foregoing, nothing contained in this Sublease shall be construed to require Sublandlord to incur any cost or expense to perform any item of maintenance, repair or replacement if such maintenance, repair or replacement is necessary as a result of the negligent act or omission or willful misconduct of Subtenant, its employees, agents contractors or invitees. If any such maintenance, repair or replacement as described in the immediately preceding sentence is performed by or on behalf of Sublandlord following reasonable notice to Subtenant, then promptly upon Sublandlord's written demand, Subtenant shall reimburse Sublandlord for the cost and expenses incurred by Sublandlord in performing such work.

d. Sublandlord represents that as of the date hereof, (i) the Building is equipped with a security system that requires a card key for access to the Building on Saturdays, Sundays and holidays, and from 7 p.m. to 7 a.m. on business days, and permits unrestricted access to the Building at all other times,

and (ii) one unarmed roving security guard patrols the parking lots and other exterior areas of the Demised Premises, twenty-four (24) hours a day, seven (7) days per week. Sublandlord represents that during the term of this Sublease, it will continue to provide the security system described in subsection (i) of this section (d); however, Sublandlord reserves the right to terminate the security guard service described in subsection (ii) of this section (d) in its sole discretion. Sublandlord shall not be responsible for providing any security arrangements for the Subleased Premises, the personal property of Subtenant, or for Subtenant's, agents, employees, contractors or invitees except as may be expressly provided in this section (d). Subtenant shall have the right to install its own security devices and providing for other security in accordance with the terms of this Sublease, including Section 21 hereof.

#### 4. USE

a. The Subleased Premises may be used and occupied for research and development (as normally conducted in office buildings in conjunction with normal office usage and not involving the use of hazardous, toxic, flammable, or other dangerous materials or substances other than normal quantities of such materials and substances customarily used in the conduct of general administrative and executive office activities (e.g., copier fluids and cleaning supplies), training, and ancillary office use including the use of computers and various other electronic equipment typically used in offices and software needed for Subtenant's business. Sublandlord represents that to Sublandlord's actual knowledge, that there are no zoning ordinances, provisions of the underlying Ground Lease, or any other prohibitions restricting or limiting the use of the Subleased Premises for the purpose herein specified. Should any law, regulation or governmental order "substantially interfere" with the use of the Subleased Premises for the purposes described above in this Section 4 then upon written notice to Sublandlord within ninety (90) days following that date upon which Subtenant shall have become aware of such law, regulation or order, Subtenant shall have a right to terminate this Sublease if such law, regulation or order shall still be applicable to Subtenant at the end of said 90 day period, and thereafter neither party shall have any further obligation to the other hereunder with respect to any period after the aforementioned ninety (90) day period. During said ninety (90) day period, Sublandlord shall have the right, but not the obligation, to appeal or otherwise challenge the legality or enforceability of such law, regulation or order as it applies to Subtenant. For purposes of this Section "substantially interfere" excludes any zoning change under which Subtenant's use as permitted by the terms of this Section above, is a lawful nonconforming use for substantially all of the remaining term of the Sublease.

b. Subtenant shall not use or occupy the Subleased Premises in violation of the Ground Lease, the Master Lease or in violation of law, and shall, upon written notice from Sublandlord, Landlord, Stanford or and governmental authority or agency having jurisdiction ("Governmental Authority"), discontinue any use of the Subleased Premises which is declared by such Governmental

Authority to be a violation of law Subtenant shall comply, at its sole cost and expense, with any Governmental Authority direction coming into effect after the Commencement Date which by reason of the nature of Subtenant's particular use or particular occupancy of the Subleased Premises imposes any duty upon Subtenant or Sublandlord with respect to the Subleased Premises, or with respect to Subtenant's particular use and particular occupancy thereof. Subtenant shall comply, at its sole cost and expense with implementation of a Transportation Demand Management ("TDM") program or similar program if required by City ordinance or otherwise legally required, or required by the terms of the Master Lease.

c. Notwithstanding the foregoing, Subtenant shall not be required to comply with any laws, rules or regulations coming into effect after the Commencement Date requiring Alterations or improvements unless the compliance with such laws, rules and regulations is necessitated solely due to Subtenant's particular use of the Subleased Premises.

d. At all times during the terms of this Sublease, Subtenant shall keep the Subleased Premises in a neat condition and shall conduct its business in a manner that does not create a nuisance, or unreasonable disturbance for the other occupants of the Building.

**5. INCORPORATED MASTER LEASE PROVISIONS.**

a. The Paragraphs contained in the Master Lease which are delineated in Section 5.b below are hereby incorporated by reference herein with the same force and effect as if fully set forth; provided that the term "Tenant" as defined therein shall for the purpose of this Sublease be deemed to be "Subtenant" as defined herein and the term "Landlord" as defined therein shall for the purposes of this Sublease be deemed to be "Sublandlord". The term "Demised Premises" shall be deemed to mean the "Subleased Premises" and the term "Lease" as defined therein shall be deemed to mean this Sublease. All other capitalized terms not defined herein shall have the definitions set forth in the Master Lease.

b. Sublandlord shall use reasonable efforts to cause Landlord to perform as expeditiously as possible all the Landlord's obligations under the Master Lease, provided that nothing contained in this Sublease (including, without limitation, the provisions of Section 5(a) above) shall be construed as requiring Sublandlord to perform any obligation or discharge any duty which the Landlord may be required to perform or discharge under the Master Lease (including, without limitation, providing utilities, building systems, maintenance, repairs, replacements, Alterations, restoration, and building modifications necessary to comply with applicable laws, and the remediation, investigation and other matters related to Hazardous Materials to the extent that these are obligation of the Landlord under the terms of the Master Lease) in connection with the Subleased Premises. If Landlord fails or refuses to comply with any of



the provisions of the Master Lease insofar as they affect Subtenant's occupancy of the Subleased Premises during the term of this Sublease, upon the request of Subtenant, Sublandlord shall exercise commercially reasonable efforts (without thereby being required to commence any legal action or proceeding, expend any monies or incur any expenses) to cause Landlord to do so. However, except as otherwise expressly set forth in this Sublease, Sublandlord shall not be liable to Subtenant, and Subtenant's obligations hereunder shall not be impaired nor the performance thereof be excused, because of any failure or delay by Landlord in performing its obligations under the Master Lease as affecting Subtenant's occupancy of the Subleased Premises during the term of the Sublease. If Landlord so defaults and such default has not been cured within the time period specified in the Master Lease (or within a reasonable time if no such period is specified) despite the exercise of Sublandlord's commercially reasonable efforts to obtain such cure as hereinabove provided, Subtenant may, in the name of Sublandlord or its own name and at Subtenant's sole expense, attempt to enforce Landlord's performance of its obligations under the Master Lease; provided, however, that prior to the commencement of any litigation by Subtenant against Landlord with respect to such default, Subtenant shall have given Sublandlord not less than thirty (30) days written notice of its intent to commence such litigation and Sublandlord has not within such thirty (30) day period have given Subtenant notice of Sublandlord's intent to commence such litigation. Sublandlord shall promptly forward to Landlord each notice which Subtenant delivers to Sublandlord advising of any default under the Master Lease by Landlord relating to Subtenant's occupancy of the Subleased Premises and shall cooperate with Subtenant, at Subtenant's sole cost and expense, in the prosecution of any legal action or proceeding that is commenced under this section. Subtenant hereby agrees to indemnify and hold harmless Sublandlord from and against any claim, liability, cost or expense incurred in connection with such litigation or resulting therefrom, except to the extent however, of any negligent act or omission or willful misconduct of Sublandlord, its employees, agents contractors or invitees.

It is understood and agreed by the parties hereto that Sublandlord is not making and Sublandlord is not responsible for and shall have no liability with respect to any representation, warranty or indemnity made by Landlord under the terms of the Master Lease.

Nothing contained in this Sublease shall be construed to grant Subtenant any right to renew or extend the term of this Sublease, or to downsize or expand the Subleased Premises.

c. Any inconsistencies between the terms of this Sublease and the terms of the Master Lease shall be resolved in favor of this Sublease. Nevertheless, if the construction of terms as provided for in the immediately preceding sentence would cause Sublandlord to be in default under the terms of the Master Lease, then any aforementioned inconsistency shall be resolved in favor of the Master Lease. Nothing contained in the sentence immediately preceding this one shall be construed to increase the obligations of Subtenant

under the terms of this Sublease. Except where in conflict with the other terms, conditions and provisions of this Sublease, which shall in such event govern and prevail, the following Paragraphs of the Master Lease, to the extent provided below, are hereby included and incorporated into this Sublease pursuant to Section 5 (a) above:

- Paragraph 3: Paragraph 3 and 4 only (as amended by the Second Amendment)
- Entire Paragraph 6: Except that the last sentence of the first paragraph (in the original Master Lease and as amended by the Second Amendment dated 10/21/91) shall be deleted.
- Except in the last sentence of the first paragraph and the first three sentences of the second paragraph (as amended by the Second Amendment dated 10/21/91) Sublandlord shall provide the maintenance and repair services described in these three sentences at the sole cost and expense of Sublandlord except to the extent of damage caused by the negligence or willful misconduct of Subtenant, its employees, agents, contractors or invitees.
- Except that the fifth paragraph (as added pursuant to the Second Amendment dated 10/21/91) shall be deleted.
- Entire Paragraph 7: Except that the term Landlord shall refer to Sublandlord and Landlord and all Alterations made by Subtenant shall be subject to Sublandlord's and Landlord's approval (which approval shall not be unreasonably withheld) except certain non-structural alterations costing less than \$25,000 pursuant to the terms of Paragraph 9 of this Sublease.
- Except in the Seventh line of the first paragraph the phrase "fifteen (15)" are deleted and replaced with the phrase "twenty (20)."
- Entire Paragraph 9: Except that the second and third sentences of Paragraph 9(a) shall be deleted.
- Except that the last sentence of Paragraph 9(b) shall be deleted.
- Paragraph 9(c) is not deleted as stated in the Second Amendment dated 10/21/91 and will remain in full force and effect.

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Entire Paragraph 10: Entire Paragraph.

Entire Paragraph 12: Entire Paragraph

Entire Paragraph 13: Entire first paragraph

Entire Paragraph 19: Entire Paragraph

Entire Paragraph 20: Except that the term "Landlord" shall refer to Sublandlord.  
Except paragraph (d).

Entire Paragraph 21: Except that the term "Landlord" shall refer to Sublandlord.

Entire Paragraph 31: Entire Paragraph

Entire Paragraph 35: Except that the last sentence shall be deleted and 125% shall be deleted and 150% shall be substituted therefore in the first sentence.

Entire Paragraph 36: Except paragraph (b).

Entire Paragraph 37: Entire Paragraph

Entire Paragraph 38: Entire Paragraph

Entire Paragraph 39: Entire Paragraph

Entire Paragraph 40: Except last sentence.

Entire Paragraph 41: Entire Paragraph

Entire Paragraph 42: Except this section shall apply to both Landlord and Sublandlord.

Entire Paragraph 43: Entire Paragraph

Entire Paragraphs 49, 50, 51, 52 and 53: Entire Paragraph

**6. DAMAGE AND CONDEMNATION**

a. If all or any portion of the Subleased Premises are condemned by any governmental authority, or damaged or destroyed by any peril or casualty and the Master Lease is not terminated, or the parties thereto are not entitled to terminate said Master Lease pursuant to its terms, then if the Subleased Premises cannot be fully restored within one hundred twenty (120) days after said casualty or condemnation, then Subtenant shall have the option to terminate the Sublease if the Subleased Premises cannot be, or are not in fact, fully restored by Landlord within such period to their condition promptly prior to the date of the peril or casualty. If the Sublease is not so terminated, Rent hereunder shall abate to the extent that the Subleased Premises are inaccessible or unusable and for so long as such portion is inaccessible or unusable (or in the event of a condemnation, to the extent the Subleased Premises has been reduced).

b. If during the final twelve (12) months of the term of this Sublease (or any extension term) the Subleased Premises are wholly or partially damaged, destroyed or rendered inaccessible and Subtenant is unable, in its sole reasonable discretion, to carry on its normal operations in all or a substantial portion of the Subleased Premises, Subtenant may, at its option, terminate the Sublease upon written notice to Sublandlord.

c. If all or substantially all of the Subleased Premises shall be condemned for public use or voluntarily transferred to a public or quasi-public body in lieu of proceeding to a judgment of condemnation, this Sublease shall terminate and Rent shall be adjusted to the date of condemnation

**7. SUBTENANT'S INSURANCE**

a. Subtenant agrees to provide at its sole cost and expense before the Commencement Date and to keep in force at all times during the term of this Sublease (i) "special risk" property insurance covering the full replacement value of Subtenant's personal property (including all of Subtenant's furniture, fixtures, equipment, supplies and inventory, excluding any such items that are owned by Sublandlord and lease to Subtenant pursuant to the terms of this Sublease) and improvements and betterments in the Subleased Premises constructed by Subtenant, (ii) comprehensive general liability insurance (a/k/a public liability insurance) with a combined single limit of One Million Dollars (\$1,000,000), which shall include contractual liability coverage, in respect of Subtenant's conduct and operation of its business in the Building and umbrella or excess liability insurance, on an occurrence basis, that applies excess of the

comprehensive general liability insurance, with a combined single limit of Four Million Dollars (\$4,000,000); and (iii) workers compensation insurance as required by applicable law. All insurance required hereunder shall comply with the requirements, if any, set forth in the Ground Lease. On or before the Commencement Date and thereafter upon the reasonable request of Sublandlord not more often than once in any six (6) month period, Subtenant shall deliver to Sublandlord reasonably acceptable insurance certificates evidencing such policies and issued by insurers that are reasonably acceptable to Sublandlord. With respect to the aforementioned comprehensive general liability insurance policy, Sublandlord, Landlord, Stanford and their mortgagees, if any, shall be named as additional insureds. The limits of any such insurance described herein shall not limit the liability of Subtenant under the terms of this Sublease. Notwithstanding anything contained in this Sublease to the contrary, Sublandlord shall have no liability for any damage, loss, theft or injury to (i) any furniture, fixtures, equipment, inventory, improvements or betterments or other personal property of Subtenant, or (ii) any vehicle on or about the Demised Premises, including any vehicle in the parking lot. Each insurance policy described in this section shall be issued by an insurance company reasonably acceptable to Sublandlord, and Subtenant shall not materially reduce coverage, cancel or terminate any insurance policy required hereunder without thirty (30) days prior written notice to Sublandlord.

b. Notwithstanding anything to the contrary contained herein, the parties hereto for themselves, their successors, assigns, Subtenant, and sub-Subtenants release each other and their respective agents, employees, successors and assigns from all liability for damage to any property that is actually covered by property insurance in force or which would normally be covered by full replacement value all risk property insurance, without regard to the negligence or willful misconduct of the entity so release. Each party shall cause each such insurance policy it obtains to include a waiver of subrogation regarding the liabilities released hereby.

**8. NOTICES**

All notices shall be sent U. S. Registered Mail, Return Receipt Requested to the following addresses:

**TO SUBLANDLORD:**

Xerox Corporation  
Attn: CRE&GS Lease Administration  
800 Long Ridge Road  
P. O. Box 1600  
Stamford, Connecticut 06904

**TO SUBTENANT:**

Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, California 94304  
Attn: General Counsel

**WITH A COPY TO:**

Xerox Corporation  
Attention: Barbara West  
Manager, North America Acquisitions & Dispositions  
18980 Upper Belmont  
Leesburg, VA 20176

Xerox Corporation  
800 Phillips Road, B304-13S  
Webster, NY 14580  
Attn: Sharon Rehm  
CRE Surplus Dispositions Manager

Any notice shall be deemed to have been given on the earlier of (a) the date set forth on the Return Receipt, (b) the date of delivery as shown on the Post Office records, or (c) the date delivery was refused as shown on the Post Office records. Any notice delivered to Sublandlord at the Demised Premises shall be null and void and of no force and effect. Subtenant and Sublandlord each agree to promptly provide to the other copies of any notice of demand or default under the Master Lease or any other notice received by either of them which relates to the Subleased Premises.

**9. CONDITION OF SUBLEASED PREMISES AND ALTERATIONS**

a. Subtenant hereby agrees to accept possession of the Subleased Premises in an "AS IS" condition. Subtenant acknowledges that it has been given full access and opportunity to thoroughly inspect and examine the Subleased Premises and Subtenant further acknowledges that it has examined the Subleased Premises and is as familiar with the physical condition thereof as Subtenant deems necessary. Sublandlord has not made and does not make any representation or warranty as to the physical condition, the use to which the Subleased Premises may be put, or any other matter or thing affecting or relating to the Subleased Premises except as may be herein expressly set forth. Notwithstanding the foregoing, Sublandlord agrees that (i) as of the Commencement Date the structural portions of the Subleased Premises (including, without limitation, the exterior walls and the foundation) shall be in good order, condition and repair or Sublandlord shall promptly use commercially reasonable efforts to cause Landlord to put such structural portion of the Subleased Premises into good order, condition and repair after notice from Subtenant that any of said portions of the Subleased Premises are not in good order, condition and repair, (ii) as of the Commencement Date the Subleased Premises shall be in compliance with all applicable laws and building codes (including, without limitation, the Americans with Disabilities Act) or promptly after notice from Subtenant which is received by Sublandlord within twenty (20) days of the Commencement Date that any portion of the Subleased Premises is not in compliance, Sublandlord shall use commercially reasonable efforts to cause Landlord to put the Subleased Premises into compliance with said laws and

codes. In no event shall Subtenant be required to incur any expense in order to cause the Subleased Premises to be in compliance with applicable laws and building codes as of the Commencement Date, and (iii) all heating, ventilating, air-conditioning, plumbing, life-safety and electrical systems serving the Subleased Premises shall be in good working order and condition on the Commencement Date.

b. Subtenant shall have the right to make non-structural modifications and alterations (“Alterations”) to the Subleased Premises subject to Subtenant preparing acceptable plans and specifications and Landlord’s and Sublandlord’s approval; provided, however, no such approval shall be required with respect to Alterations not affecting the Building structure or systems and costing less than \$25,000.00, but Subtenant shall give Sublandlord at least twenty (20) days advance notice of such Alterations, and within fifteen (15) days after their completion Subtenant shall provide Sublandlord a copy of the plans and specifications for any such Alterations if available. Notwithstanding the foregoing, Sublandlord agrees that Subtenant may perform the initial Alterations stated on Exhibit D hereto shortly following the Commencement Date. Subtenant will confirm that all Alterations materially meet and comply with all code requirements. Any and all contractors hired by Subtenant must comply with the comprehensive general liability and worker’s compensation insurance required by Section 7 of this Sublease.

c. Sublandlord’s grant or denial of its approval of the Alterations as provided for herein, shall be done as promptly as reasonably possible, and Sublandlord’s failure to approve or disapprove the Initial Alterations within ten (10) business days of receipt of the plans and specifications shall be deemed an approval thereof subject, however, to Landlord’s approval thereof. Sublandlord shall submit the preliminary space plan to Landlord at the same time it submits this Sublease to Sublandlord for approval, and the plans and specifications shall be submitted to Landlord thereafter, promptly upon Sublandlord’s receipt of plans and specifications from Subtenant. Any damage to the Building resulting from such Alterations or modifications shall be repaired at Subtenant’s expense. Subtenant shall make reasonable efforts to ensure its contractors coordinate alteration activities with Sublandlord and use reasonable efforts to minimize interference with other tenants or subtenants in the Building.

If Subtenant’s Alterations and modifications are special use features not typically found in general office space, Landlord shall have the right, by giving Subtenant notice at the time of approval, to require Subtenant to remove such Alterations and modifications upon the expiration or termination of the Lease term and to restore the affected portion of the ordinary wear and tear excepted. The term “special use” features” shall be deemed to mean such Alterations to the Subleased Premises that may be made by or on Subtenant’s behalf, that are not ordinary or customary in office space, that are made for Subtenant’s peculiar use of the Subleased Premises, or that involve Alterations to the slab, ceiling, HVAC, plumbing or electrical systems.

d. Sublandlord agrees to make best efforts to remove any existing furniture in the Subleased Premises prior to the Commencement Date.

e. The requirements for Alterations as set forth in this Section 9 shall be in addition to the requirements as set forth in the Master Lease to the extent those terms of the Master Lease are incorporated herein by reference pursuant to the terms of Section 5 of this Sublease.

f. At all times Subtenant shall keep the Subleased Premises and the Subleased Premises free from any liens arising out of the work performed, materials furnished or obligations incurred by Subtenant.

**10. BROKERAGE**

Sublandlord and Subtenant acknowledge that Cushman and Wakefield of California, Incorporated is the real estate broker for Sublandlord and Cresa Partners is the broker for Subtenant which brought about this sublease transaction, and Sublandlord shall pay the brokerage commission to such brokers pursuant to a separate agreement. Sublandlord hereby agrees to indemnify Subtenant against the claims of any other broker arising from Sublandlord's acts, and Subtenant hereby agrees to indemnify Sublandlord against the claims of any other broker arising from Subtenant's acts.

**11. INDEMNIFICATION**

a. Except to the extent of any negligence or wilful misconduct of Sublandlord, its employees or its agents, Subtenant shall indemnify and hold harmless Sublandlord against and from any and all causes and claims arising from Subtenant's use of the Subleased Premises or the conduct of its business in the Subleased Premises or from any activity, work done, permitted or suffered by the Subtenant in or about the Subleased Premises, and shall further indemnify and hold harmless Sublandlord against and from any and all claims arising from any breach or default in the performance of any obligation of Subtenant's part to be performed under the terms of this Sublease, or arising from any action, neglect, fault or omission of the Subtenant, or of its agents or employees arising from the performance of any obligation of Subtenant's part to be performed under the terms of this Sublease, and from and against all costs, reasonable attorney's fees, expenses and liabilities incurred in or about such claim or any action or proceeding brought thereon, and in case any action or proceeding be brought against Sublandlord by reason of any such claim, Subtenant upon notice from Sublandlord shall defend the same at Subtenant's expense by counsel reasonably satisfactory to Sublandlord. Subtenant, as a material part of the consideration to Sublandlord, hereby assumes all risk of damage to property or injury to persons in, upon or about the Subleased Premises from any cause whatsoever except to the extent caused by Sublandlord's negligence, willful misconduct or failure of Sublandlord to observe any of the terms and conditions to this Sublease, or to the extent covered by any



indemnity. Sublandlord shall give Subtenant prompt written notice, with full particulars, of any claim subject to this indemnity. Subtenant shall have no obligation to pay any amount in connection with any settlement reached without Subtenant's consent, which shall not be unreasonably withheld or delayed.

b. Subtenant covenants and agrees that Stanford University shall not any time or to any extent whatsoever be liable, responsible or in any way accountable for any loss, injury, death, or damage to persons or property or otherwise, whether direct or consequential including without limitation, loss or damage to the Subleased Premises and the Building, attorney's fees, which at any time may be suffered or sustained by Subtenant or by any person whosoever may at any time be using or occupying or visiting the Subleased Premises or be in, on or about the same, whether such loss, injury, death or damage shall be caused by or in any way result from or arise out of any act, omission or negligence of Subtenant or of any occupant, sub-subtenant, visitor or user of any portion of the Subleased Premises, or shall result from or be caused by any other person, matter or thing whether of the same kind as, or of a different kind than, the persons, matters or things above set forth except to the extent that any loss, injury, death, or damage may be caused by the negligence or willful misconduct of Stanford University. Subtenant shall forever indemnify, defend, hold and save Stanford University free and harmless of, from and against any and all claims, liability, loss or damage whatsoever on account of any such loss, injury, death or damage except to the extent that any loss, injury, death or damage may be caused by the negligence or willful misconduct of Stanford University. Subtenant hereby waives all claims against Stanford University for damages to the Subleased Premises and to the property of Subtenant in, upon or about the Subleased Premises, and for injuries to persons or property in or about the Subleased Premises,, from any cause arising at any time except to the extent that any, injury, death or damage may be caused by the negligence or willful misconduct of Stanford University.

c. Without limiting the generality of the foregoing, Subtenant agrees that the provisions of this Section 11 apply to all Hazardous Materials used, stored, generated, treated, disposed or released ("Used") on, in or under the Subleased Premises by Subtenant and that Subtenant will indemnify, defend, hold and save Stanford University free and harmless from claims, liability, loss or damage on account of such Hazardous Substances used by Subtenant and that Subtenant will remove such substances used by Subtenant that are now or hereafter on, in or under the Subleased Premises in a safe and prudent manner and within a reasonable time that is agreed to by Stanford University. The parties hereto recognize and agree that from time to time Stanford University in its reasonable discretion may require the removal of Hazardous Materials or other remediation even though such Stanford University requirements are in excess of or in the absence of applicable governmental requirements. Any dispute with regard to such Stanford University removal or remediation requirements that are in excess of or in the absence or applicable governmental requirements shall be subject to arbitration pursuant to the terms of Paragraph 38 of the Ground Lease; provided, however, that if there is a contemporaneous

dispute with regard to governmental required remediation of Hazardous Substances then Stanford University may join the dispute with regard to its independent requirements with a legal action in court of competent jurisdiction with respect to the government required remediation instead of the arbitration.

As used in this Section 11, Stanford University shall include and be deemed to include The Board of Trustees of the Leland Stanford Junior University and its trustees, directors, officers, employees, faculty, students, agents, and affiliated organizations.

d. The obligations under this Section 11 shall survive the expiration or sooner termination of this Sublease.

e. Neither party to this Sublease shall be liable to the other with respect to any consequential or incidental damages including, without limitation, loss of profits or loss of rental value.

## **12. SIGNS**

Subtenant shall be entitled to install signage on the entry glass (applied to the glass but not etched in the glass) at the entrance to Building 2, 1st floor on the wall adjacent to the entry door. All such signage requires prior written approval from Sublandlord and subject to the approval of Landlord and Stanford to the extent such approval is required under the Master Lease and the Ground Lease, respectively. Sublandlord shall include Subtenant's name in all Campus Directories. Subtenant shall have the right, subject to the prior written consent of Sublandlord, which shall not be unreasonably withheld, conditioned or delayed, to place a sign on the interior lobby wall adjacent to the entry door.

## **13. ASSIGNMENT AND SUBLEASE**

a. In the event Subtenant desires to assign this Sublease or to Sub- sublease all of the Subleased Premises, Subtenant shall first offer Sublandlord the option to recapture the Subleased Premises which Subtenant proposes to assign or sub-sublease. Subtenant agrees to set forth in its notice to Sublandlord the date on which the Subleased Premises shall be available for recapture, assignment or sub-sublease. Sublandlord shall, after written notice from Subtenant, have fifteen (15) days in which to notify Subtenant whether or not Sublandlord desires to exercise its option to recapture.

b. In the event Sublandlord does not exercise its option to recapture, Subtenant shall have the right to assign this Sublease or to sub- sublease all of the Subleased Premises, with Sublandlord's consent which consent may be withheld on any reasonable basis. Should Sublandlord fail to respond to Subtenant's request within thirty (30) days, Sublandlord consent shall be

deemed given, subject to the approval rights of Landlord. In the event that such assignment or sub-subleasing does not occur within 180 days after Sublandlord declines to recapture the subject space then such space shall once again be offered to Sublandlord for recapture in the event that thereafter Subtenant desires to so assign or sub-sublet said space. Any such assignment or subletting shall not relieve Subtenant of its obligations hereunder.

c. In the event the rent received by Subtenant from any Sub-tenant or assignee exceeds the Rent and other charges allocable to such space being paid by Subtenant to Sublandlord, then and in such event, after deducting from such excess Subtenant's reasonable expense (including, without limitation, reasonable brokers commissions and reasonable attorneys' fees, and the unamortized cost of modifications, Alterations and improvements constructed by Subtenant with respect to the space so sublet or assigned) in connection with such subletting or assignment, Subtenant shall pay to Sublandlord the Rent and other charges due under the terms of this Sublease without reduction, and in addition thereto, when received from a sub-Subtenant or assignee, fifty percent (50%) of the amount received by Subtenant from such Sub-Subtenant or assignee in excess of the Rent and other charges paid by Subtenant to Sublandlord with respect to the space so sublet or assigned.

d. If Subtenant requests that Sublandlord consent to an assignment or subletting, Subtenant shall reimburse Sublandlord, within fifteen (15) days of request by Sublandlord, for Sublandlord's actual, reasonable out-of-pocket expenditures in such regard (including, without limitation, expenditures for reasonable attorney's fees and architect/engineer's fees), not to exceed an aggregate of \$1,500 for any such request for consent, with the invoice for such services to accompany Sublandlord's request for reimbursement.

e. Notwithstanding anything contained herein to the contrary in this Section 12, Subtenant may, without Sublandlord's consent (but with 10 days prior notice) and without being subject to any recapture or excess rent provisions of this Sublease, sublet the Subleased Premises or assign this Sublease to (a) an entity controlling, controlled by or under common control with Subtenant, (b) a successor corporation related to Subtenant by merger, consolidation or reorganization, or (c) a purchaser of substantially all of the assets of Subtenant. The term "control," as used herein, shall mean the power to direct or cause the direction of the management and policies of the controlled entity through the ownership of more than fifty percent (50%) of the voting securities in such controlled entity.

f. No assignment of this Sublease by Subtenant or sub-sublease of the Subleased Premises shall release or relieve Subtenant of its liability and responsibility for the full performance of all of its obligations under the terms of this Sublease.

**14. SUBORDINATION OF SUBLEASE**

This Sublease is subject and subordinate to the Master Lease and Ground Lease, and Subtenant shall have no greater rights in and to the Subleased Premises than Sublandlord has as tenant under the Master Lease.

**15. TERMINATION OF MASTER LEASE**

a. Subject to the terms of the nondisturbance agreement (if any) in the Landlord’s consent form pursuant to Section 17 of this Sublease, in the event that the Master Lease shall terminate by operation of law or otherwise, or Landlord or Sublandlord as tenant under the Master Lease cancels or terminates the Master Lease, as expressly provided therein, or in the event that the Landlord shall terminate the Master Lease for any reason, this Sublease shall thereupon automatically be canceled and terminated, and both parties hereto shall thereupon be relieved of all further liability hereunder; except the obligations which shall survive the expiration or earlier termination of this Sublease and those obligations that shall have accrued prior to the effective date of such termination.

b. Notwithstanding the foregoing provisions of this Section 15, Sublandlord shall be liable to Subtenant for any Claims incurred or suffered by Subtenant as a result of a termination of the Master Lease as a result of (i) a voluntary termination of the Master Lease by Sublandlord unless such termination was due to the default of Landlord under the terms of the Master Lease or pursuant to a express right of termination granted in the Master Lease in the event of casualty or condemnation, (ii) an act or omission by Sublandlord (which is not caused by Subtenant, its agents, employees, licensees, contractors or invitees) which entitles Master Landlord to terminate the Master Lease, or (iii) a default by Sublandlord under the Master Lease that does not result from a violation of the terms of the Master Lease by Subtenant or a default by Subtenant under the terms of this Sublease. Sublandlord’s liability as set forth in the immediately preceding sentence shall survive the termination of this Sublease.

c. Notwithstanding the foregoing provisions of this Section 15, Subtenant shall be liable to Sublandlord for any Claims incurred or suffered by Sublandlord as a result of (i) a termination of the Master Lease as a result of any act or omission of Subtenant, its employees, agents, invitees or contractors, or (ii) any breach by Subtenant in the performance of its obligations under the terms of this Sublease. Subtenant’s liability as set forth in the immediately preceding sentence shall survive the termination of this Sublease.

d. Sublandlord shall fully perform all obligations of “Tenant” under the terms of the Master Lease except for such matters as shall be the obligation of Subtenant to perform pursuant to the terms of this Sublease. In addition, Sublandlord shall not agree to amend the Master Lease or the Ground Lease in a manner that would adversely affect Subtenant’s rights under this Sublease without Subtenant’s prior written consent, which consent may be withheld in Subtenant’s sole but reasonable discretion.

**16. ENTIRE AGREEMENT**

This Sublease represents the entire agreement between the parties, and supersedes all prior understandings and agreements both written and oral between the parties and/or their brokers or other representatives, and may be amended only by a written agreement executed by the parties. The terms, covenants and conditions of this Sublease shall be binding upon and shall inure to the benefit of Sublandlord and Subtenant and their respective successors and permitted assigns.

**17. CONSENT**

a. This Sublease is subject to the written consent of Landlord, and Stanford (the "Consenting Parties"). If such consents are not obtained within thirty (30) days of Subtenant's and Sublandlord's execution of this Sublease then Sublandlord and Subtenant shall both have the right to terminate this Sublease by written notice to the other delivered at any time prior to the date the consents of Landlord and Stanford are received by Sublandlord. In the event that this Sublease is terminated pursuant to the terms of this section then neither party shall have any liability or responsibility to the other with respect to any matter relating to this Sublease or the Subleased Premises, except that Sublandlord shall promptly return to Subtenant any Security Deposit Subtenant may have paid. Subtenant shall promptly provide such information as Landlord and/or Stanford may reasonably request and Subtenant shall execute such reasonable consent document(s) as may be reasonably required by the Consenting Parties. Any fees charged by the Consenting Parties for such consents shall be the sole responsibility of Sublandlord.

b. Landlord shall not be deemed to have consented to the Sublease unless such executed consent document shall include provisions substantially similar to the following, or unless Subtenant shall waive the requirement that said provisions be included in the consent:

(i) Subtenant may, without Landlord's consent and without being subject to any recapture or excess rent provisions of this Sublease, sublet the Subleased Premises or assign this Sublease to (a) an entity controlling, controlled by or under common control with Subtenant, (b) a successor corporation related to Subtenant by merger, consolidation or reorganization, or (c) a purchaser of substantially all of the assets of Subtenant.

c. At the same time Sublandlord requests that Landlord consent to the Sublease, Sublandlord shall also ask that Landlord's consent include provisions substantially similar to the following:

(i) Landlord agrees that Section 16(d) of the Master Lease shall also apply as between Landlord and Subtenant; and

(ii) So long as Subtenant is not then in default under the Sublease beyond applicable notice and cure periods, in the event of any termination of the Master Lease, the Sublease shall not terminate as a result thereof and Subtenant shall instead automatically become primary tenant of the Subleased Premises on the terms and conditions of the Sublease. In such event, Subtenant shall be bound and attorn to Landlord, and Landlord shall recognize and shall not disturb the rights and interest of Subtenant under all of the terms and conditions of the Sublease as if Landlord had been the original "Sublandlord" under the Sublease.

In the event that Landlord refuses to include in its consent the matters described herein above in this section (c) then Subtenant shall have the right, but not the obligation, to directly contact Landlord to request the same; provided, however, no such refusal on the part of Landlord shall be deemed a denial of Landlord's consent to the Sublease.

d. With respect to any consent or approval required of Sublandlord under the terms of this Sublease wherein Sublandlord is required to be reasonable, Sublandlord may withhold its consent if it is reasonable to do so, and Sublandlord may condition the effectiveness of its consent or approval, if granted, upon obtaining Landlord's consent or approval if Landlord is required to consent or approve of such matter pursuant to the terms of this Sublease or the Master Lease.

## **18. SECURITY DEPOSIT**

a. Upon the execution of this Sublease, Subtenant shall deliver an irrevocable letter of credit (the "Letter of Credit") to Sublandlord, as a security deposit for the full and faithful performance by Subtenant of all of its obligations under this Sublease. The Letter of Credit shall be substantially in the form attached hereto as Exhibit E and shall run in favor of Sublandlord. The Letter of Credit shall be issued by a national bank acceptable to Sublandlord and shall be in the amount of Eighty Five (\$85,000) Thousand U.S. Dollars, which amount shall be subject to adjustment from time to time in accordance with the adjustment schedule which shall be set forth in said Letter of Credit and which schedule shall state the specific dollar amount of each adjustment and the date said adjustment shall occur, all of which shall be in accordance with the terms set forth below. The Letter of Credit shall be (a) at sight and irrevocable and (b) maintained in effect, throughout the entire Term of this Sublease, and shall not terminate until this Sublease shall have been terminated or expired and Sublandlord shall have been paid all sums due under this Sublease including all sums actually expended by Sublandlord to cure any default by Subtenant. The terms and conditions of the Letter of Credit (and the bank issuing the same which party is referred to herein as the "Bank") shall be reasonably acceptable to Sublandlord and shall provide, among other things, that Sublandlord, shall have the right to draw down an amount up to the face amount of the Letter of Credit upon the presentation to the Bank of Sublandlord's statement

that such amount is due to Sublandlord under the terms and conditions of this Sublease. Subtenant further covenants and warrants that it shall not assign or encumber the Letter of Credit or any part thereof without Sublandlord's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. If an event of default under this Sublease occurs, Sublandlord may, but without obligation to do so, use the Security Deposit by presenting the Letter of Credit to the Bank accompanied by Sublandlord's demand to draw down on said Letter of Credit, or any portion thereof, in an amount not to exceed the amount required to cure the default and to compensate Sublandlord for any and all losses, expenses and damages sustained by Sublandlord resulting from Subtenant's default (including, but not limited to, reasonable legal and other related expenses, and any deficiency in reletting the Sublease Premises), whether occurring before or after re-entry by Sublandlord. It is understood by Sublandlord that **SILICON VALLEY BANK** is acceptable to Sublandlord to issue the Letter of Credit.

b. In the event that Sublandlord shall use all or a portion of the Security Deposit as provided for above, Subtenant shall, within ten (10) days following Sublandlord's written demand, deliver to Sublandlord another irrevocable letter of credit, which shall be similar in form and substance to the Letter of Credit, in an amount equal to the portion of the Security Deposit so applied or used so as to replenish the amount of the Security Deposit to the amount that it was immediately prior to Sublandlord's application of a portion of said Security Deposit to Subtenant's default. In lieu of providing an additional letter of credit, Subtenant may deposit cash with Sublandlord in an amount sufficient to satisfy the requirements of this section.

c. In the event that Sublandlord uses all or a portion of the Security Deposit as provided for herein, Subtenant shall not be deemed to have cured its default which gave rise to the use of such funds unless Subtenant shall have deposited, as soon as practicable following Sublandlord's written demand, an additional letter of credit or cash with Sublandlord in the amount so applied so that the amount so applied shall be fully replenished and Sublandlord shall have the full amount of the Security Deposit as set forth above restored at all times during the term of this Sublease.

d. Sublandlord shall have the absolute right and option at any time after the expiration of the Fifteen Day Period to terminate the Sublease if Subtenant shall fail to deliver the Letter of Credit to Sublandlord.

#### **19. FITNESS CENTER USAGE**

a. During the term of this Sublease, Subtenant's officers and employees shall have the non-exclusive right to use the fitness center (which includes the exercise room, the showers and locker rooms and the furniture,

fixtures and equipment contained therein) located in Building 1 of the Demised Premises (the "Fitness Center"), on Monday through Friday (excluding holidays) during such hours as Sublandlord's employees are permitted to use the Fitness Center. As of the date hereof, such Fitness Center hours of operation are 7 a.m. to 6 p.m. as may be subject to change. Subject to the terms of Section 19.b. below, Sublandlord shall charge each of Subtenant's officers and employees who desires to the Fitness Center (each, a "Jazz User") a monthly fee in the amount set forth on Exhibit F hereto, payable in advance, for Fitness Center use and the furnishing and laundering of towels. Each Jazz User shall be required to sign an application, a release agreement substantially in the form of Exhibit F hereto, and such other documentation as Sublandlord shall deem reasonably appropriate prior to using the Fitness Center. Each Jazz User shall be required to conform to such reasonable written rules and regulations as may be promulgated from time to time by Sublandlord for the efficient operation of the Fitness Center, and the failure by any Jazz User to abide to such rules and regulations shall constitute grounds for the termination of his or her right to use the Fitness Center, in Sublandlord's sole reasonable discretion.

b. Upon not less than thirty (30) days advance written notice to Subtenant, Sublandlord shall have the right to modify the Fitness Center's hours of operations in its discretion and/or to increase the monthly Jazz User fee; provided, however, any such changes shall be equally applicable to both Jazz Users and to other Fitness Center users; and further provided that no such fee increase during any twelve (12) month period shall exceed Five (\$5.00) Dollars per month per Jazz User. Sublandlord shall have the right in its sole discretion to temporarily or permanently close the Fitness Center upon not less than thirty (30) days advance written notice to Subtenant. At any time, Sublandlord shall have the right to terminate the right to use the Fitness Center with (30) days advance notice if Sublandlord no longer occupies Building 1 of the Demised Premises. In the event of any such closure, Sublandlord shall promptly return all monies, if any, paid in advance by any Jazz User for use of the Fitness Center for any period after the date of such closure. Sublandlord shall have no liability or responsibility to Subtenant or its officers or employees with respect to any such closure.

c. Sublandlord and Subtenant hereby release each other and waive any and all rights of recovery against each other with respect to any and all losses, damages, costs and expenses (including, without limitation, attorneys' fees) incurred by the waiving party arising from or related to any death or injury which occurs in, on or about the Fitness Center, whether due to the negligence of either party, their agents, employees, officers, licensees, invitees or contractors, or otherwise.

**20. PARKING**

Subtenant shall be entitled to the nonexclusive use of forty-two (42) parking spaces in the parking area serving the Building at no additional cost to Subtenant. In addition, Subtenant shall be entitled to the non-exclusive use of



the bike lockers serving the Building on a first come first serve basis; provided, however, Sublandlord shall have the right in its sole discretion to discontinue such use (on a non-discriminatory basis) or completely remove said lockers, all without incurring any liability to Subtenant or its employees.

**21. SUBTENANT'S SECURITY SYSTEM**

Subtenant shall have the right, but not the obligation, to install a security access and alarm system securing the Subleased Premises at its sole cost and expense, subject to such rights of approval as Sublandlord may have pursuant to the terms of Section 9 of this Sublease, except that any approval required of Sublandlord for such security access and alarm system shall be granted or denied as provided for herein, as promptly as reasonably possible and shall be deemed given if Sublandlord does not approve or reasonably disapprove of such security access and alarm system within ten (10) business days of request for consent, subject to any right that Landlord may have to consent to such security and alarm system.

**22. INTENTIONALLY DELETED**

**23. SUBTENANT'S RIGHT OF QUIET ENJOYMENT**

Subtenant shall peacefully have, hold and enjoy the Subleased Premises, subject to the terms and conditions of the Sublease, provided that there is no event of default by Subtenant.

In the event that Sublandlord shall fail to (i) make any non-structural repairs to the Subleased Premises (or shall fail to commence to make such repairs and thereafter diligently pursue the completion thereof) that are required to be made by Sublandlord as tenant under the Master Lease, or (ii) provide the janitorial services for the interior portions of the Building as described in Exhibit C attached hereto, and such failure shall continue for ten (10) business days after receipt of written notice from Subtenant that such repairs are necessary or such janitorial services are not being provided as required by this Sublease, and thereafter Subtenant shall have given Sublandlord a second notice (the "Second Notice") which states that Subtenant intends to perform such repairs or perform such janitorial services (as the case may be) at Sublandlord's reasonable expense, if Sublandlord does not commence to make such repairs or properly perform such janitorial services (as the case may be) within ten (10) days of receipt of the Second Notice and thereafter diligently pursue the completion thereof, then Subtenant shall have the right to make such repairs or perform such janitorial services (as the case may be) and thereafter demand that Sublandlord reimburse Subtenant for the reasonable cost thereof. Sublandlord shall reimburse Subtenant for the reasonable cost of such work within fifteen (15) days of receipt of Subtenant's demand accompanied by invoices and such other documentation as Sublandlord may reasonably require substantiating such expenditures.

**24. EXHIBITS.**

The following exhibits are attached hereto and made a part hereof:

- A. Master Lease
- B. Subleased Premises
- C. Maintenance and Janitorial Service
- D. Initial Improvements
- E. Security Deposit (Letter of Credit)
- F. Fitness Center Agreement

**25. SUBLEASE ANNUAL REPORTS**

Within fifteen (15) days from request by Sublandlord, but not more than once during any calendar year, Subtenant shall make available to Subtenant or to any prospective purchaser or lender of the building, audited financial statements of Subtenant or any guarantor, provided Sublandlord or any such prospective purchaser or lender agrees, in writing, the form and substance of which shall be reasonable acceptable to Subtenant, to maintain such statements and information in confidence, and provided further that if audited financial statements of Subtenant are not available at the time of such request, Subtenant may deliver un-audited statements prepared in accordance with generally accepted accounting principles consistently applied and certified to be true and correct by Subtenant's chief financial officer. Notwithstanding the foregoing, so long as the stock of Subtenant is traded on a public exchange, Subtenant shall satisfy the requirements of this Section 25 by delivering Subtenant's annual report.

**26. OVERDUE AMOUNTS**

In the event any payment due from Sublandlord is not received within five (5) days after its due date, then in addition to any other right or remedy available to Sublandlord, Subtenant shall pay to Sublandlord a "late charge" equal to 5% of the past due amount in order to compensate Sublandlord for its administrative and other overhead expenses, provided, however the foregoing late charge shall not apply to the first two (2) late payments made by Subtenant in any calendar year. Any such late charge shall be payable as Rent hereunder and shall be payable promptly upon Sublandlord's written demand, provided such demand is made in writing within sixty (60) days.

**27. INTENTIONALLY OMITTED.**

**28. OPTION TO EXTEND.**

a. In the event that the Sublease Premises have not been subleased following the expiration of the Term of this Sublease, and Sublandlord does not reoccupy the Sublease Premises, then Subtenant shall have the right and option (the "Extension Option") to extend the Term of this Sublease for one additional period of six (6) months (the "Extension Term"), commencing immediately upon expiration of the initial Sublease term (the "Adjustment Date"). In all cases, Subtenant's Option to Extend shall be subject and subordinate to the rights of any existing or future subtenants in the Demised Premises who has provided notice to Sublandlord of interest in subleasing the Subleased Premises, and such sublease transaction would result in a net premises greater in size than the size of the Subleased Premises. To exercise Subtenant's Extension Option, Subtenant must deliver written notice not later than three (3) months prior to the last day of the Sublease Term.

b. The Extension Term shall be on the terms and conditions stated in this Sublease, except that the Rent for the Extension Term shall be \$41,607.97 per month, which amount is four percent (4%) greater than the Rent on the last day of the initial Sublease term. Sublandlord and Subtenant shall enter into a sublease amendment confirming the terms of such extension; provided, however, such amendment shall not increase Subtenant's obligations or liabilities hereunder or otherwise be inconsistent with the terms of this Sublease. In the event that Subtenant fails to provide notice within the time period stated in subparagraph (a) above, then this Option to Extend shall be null and void.

## **29. WAIVER**

The waiver by either party of any breach of any term, covenant or condition herein contained shall not be deemed to be a waiver of any subsequent breach of the same or any other term, covenant or condition herein contained, nor shall any custom or practice which may arise between the parties in the administration of the terms hereof be deemed a waiver of, or in any way affect, the right of Sublandlord to insist upon the performance by Subtenant in strict accordance with said terms.

## **30. COUNTERPARTS**

This Sublease may be executed in counterparts and shall constitute an agreement binding on all parties notwithstanding that the parties are not signatories to the original or the same counterpart provided that both parties are furnished a copy or copies thereof reflecting the signature of both parties.

## **31. ANTI-TERRORISM**

a) Definitions. As used in this Paragraph 31,

i) The term "Person" shall mean, collectively, any one or more individuals, any entity or organization (whether designated a corporation, general partnership, limited partnership, limited liability company, limited liability corporation, professional corporation,

professional association or otherwise) and any nation or other governmental or quasi-governmental body, organization, unit or authority;

ii) The term "Blocked Person" shall mean:

(1) any Person named or designated as a terrorist by any Executive Order of the President of the United States or by the United States Treasury Department or by any other governmental body, organization, unit or authority having jurisdiction;

(2) any Person named or designated as a "Specially Designated National and Blocked Person" by the United States Treasury Department, Office of Foreign Assets Control ("OFAC") or by any other governmental body, organization, unit or authority having jurisdiction; and

(3) any Person otherwise banned or blocked from engaging in transactions in United States of America by any Executive Order of the President of the United States or by any treaty, statute, law, rule, order, ordinance, regulation and/or the like, including, without limitation, any treaty, statute, law, rule, order, ordinance, regulation and/or the like that is enforced or administered (either entirely or in concert with others) by the United States Treasury Department, Office of Foreign Assets Control.

b) Subtenant warrants and represents to Sublandlord that:

i) Subtenant is not a Blocked Person;

ii) Subtenant is not knowingly and intentionally acting for or on behalf of any Blocked Person in entering into this Lease;

iii) Subtenant is not knowingly and intentionally planning to use the Subleased Premises, or permit any third parties to use or occupy the Subleased Premises, on behalf of, or for the benefit of, any Blocked Person.

c) Subtenant expressly covenants and agrees that Subtenant shall not knowingly and intentionally use or occupy any portion of the Subleased Premises, or knowingly and intentionally permit any third parties to use or occupy any portion of the Subleased Premises, on behalf of, or for the benefit of, any Blocked Person.

d) Sublandlord warrants and represents to Subtenant that:

i) Sublandlord is not a Blocked Person;

- ii) Sublandlord is not knowingly and intentionally acting for or on behalf of any Blocked Person in entering into this Lease; and
  - iii) Sublandlord is not knowingly and intentionally planning to use the Building, or permit any third parties to use or occupy the Building, on behalf of, or for the benefit of, any Blocked Person.
- e) Sublandlord expressly covenants and agrees that Sublandlord shall not knowingly and intentionally use or occupy any portion of the Building, or knowingly and intentionally permit any third parties to use or occupy any portion of the Building, on behalf of, or for the benefit of, any Blocked Person.

\*\*\*\*\* INTENTIONALLY LEFT BLANK \*\*\*\*\*

**IN WITNESS WHEREOF**, Sublandlord and Subtenant are deemed to have executed this Sublease as of the date and year first above written.

**WITNESS**

/s/ Peter Soparker

Peter Soparker

**Jazz Pharmaceuticals (Subtenant)**

By: /s/ Matthew K. Fust

Title: Chief Financial Officer

Date: March 2, 2007

**WITNESS**

/s/ William Etter

William Etter

**Xerox Corporation (Sublandlord)**

By: /s/ Bruce E. Bender

Bruce E. Bender

Western Region Acquisitions

Date: March 5, 2007

**Exhibit A**  
**Master Lease**

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**THIS LEASE** dated, for reference purposes, the 1st day of March, 1990 between **QTC VENTURE**, a California general partnership, having its principal office at 700 Emerson, Palo Alto, California, (hereinafter referred to as "Landlord"), and **XEROX CORPORATION**, a New York corporation having its principal office at 800 Long Ridge Road, Stamford, Connecticut 06904 (hereinafter referred to as "Tenant").

**WITNESSETH:**

**1. DESCRIPTION**

Landlord will construct a development on certain land, as shown on Exhibit A attached hereto and made a part hereof (hereinafter referred to as the "Complex"), which will contain parking areas, common areas and five (5) buildings, containing approximately 206,150 rentable square feet, and located at 3400 Hillview Avenue, in the City of Palo Alto, State of California (hereinafter referred to as the "Buildings").

Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the total rentable space of four (4) of the buildings in the Complex, the total space consisting of approximately 167,366 rentable square feet as shown on Exhibit B attached hereto and made a part hereof (hereinafter referred to as the "Demised Premises" or the "Premises"), together with the use in common with other tenants of the Complex common areas and facilities of the Complex appurtenant thereto, and together with the sidewalks, driveways and parking facilities provided for in Paragraph 9 (b) hereof (all together hereinafter referred to as the "Premises").

Landlord agrees, at Landlord's sole cost and expense, to commence construction of the Buildings on or before October 1, 1990 and to complete construction of the Buildings and the Premises (except as provided in Exhibit C hereof) on or before July 1, 1991, and if Landlord fails to do so, Tenant shall have the right to liquidated damages and termination of this Lease as provided in Paragraph 46 hereof. The phrase "commence construction of the Building" as used herein means demolition of the existing Building, approval by the Palo Alto Architectural Review Board, execution of a construction contract, and commencement of excavation work. The phrase "complete construction of the Building and the Premises" as used herein shall mean (a) with respect to the Building, finished floor slabs; all foundations, walls, exterior surfaces, glass installation and roof completely installed and watertight so as to allow no material leakage; all heating, ventilating, air-conditioning, plumbing and sprinkler systems installed and operational; telephone lines installed and electrical systems completed and run to panels servicing the Demised Premises; at least two elevators and the shipping dock as required by Tenant, completed and operational; security and fire alarm systems installed and operational, lobby and public restrooms completed and all Tenant Improvements complete pursuant to paragraph 5 hereof, and certificate of occupancy or final Building Inspection Certificate permitting Tenant's lawful occupation and use of the Buildings issued, all in compliance with all applicable codes, and (b) with respect to the Premises, access available to and from the Building, all exterior lighting installed, parking areas and walkways completed, landscaping installed or bonded for, and areas free of construction materials and safe for public use.

**2. TERM**

The term of this Lease is Ten (10) year(s), to commence on the 1st day of July, 1991 (hereinafter referred to as the "Commencement Date"), and to end on the 30th day of June, 2001 (hereinafter referred to as the "Expiration Date"), both dates inclusive, unless the term be extended pursuant to Paragraphs 14, and 26 hereof, or earlier terminated as provided herein, or in accordance with applicable law. If Landlord has not completed construction of the Building and Premises and the Premises are not ready for Tenant's occupancy by July 1, 1991, the term shall commence on the date on which the Building and Premises are completed and ready for Tenant's occupancy. Such date shall be the date certified by Landlord's architect or contractor or the date of issuance of final Building Inspection Certificate or certificate of occupancy permitting Tenant's lawful occupation and use of the Premises. The foregoing shall not be construed to alter or derogate from Paragraph 46 of this Lease or Paragraph 13 of the accompanying Work Letter.

**3. RENT**

The rent shall be:

		<u>Per Month</u>	<u>Annual</u>
Years	1-5	\$343,100.30	\$4,117,203.60
Years	6-10	\$356,489.58	\$4,277,874.96

Paid in advance on the first day of each month without deduction, offset or setoff during the term hereof; provided, however, that if the term of this Lease should commence on the date other than the first day of the month, the first and last month's rent shall be prorated. Tenant shall be permitted a three (3) month fixturing period without payment of rent following the Commencement Date.

If Tenant fails to pay any installment of rent when due, Tenant shall pay Landlord, in addition to the delinquent rental due, a late charge equal to five percent (5%) of the amount due after seven (7) days' written notice from Landlord to Tenant. For the third and subsequent late payments in any twelve (12) month period, late charges shall be due and payable on the due date.

The rent figures stated above are based upon the estimated rentable square footage of 167,366. The actual amounts shall be determined upon determination of the actual square footage of the Buildings, at a rate per square foot during years one (1) through five (5) of \$2.05 and six (6) through ten (10) of \$2.13.

#### 4. USE

The Demised Premises may be used and occupied for research and development, training, receiving, storing, prototype manufacturing and ancillary office use including the use of computers and various other electronic equipment needed for Tenant's business. Landlord covenants, to the best of Landlord's knowledge, that there are no zoning ordinances, provisions of the underlying ground lease ("Ground Lease"), or any other prohibitions restricting or limiting the use of the Demised Premises for the purpose herein specified. Should any law, regulation or other governmental order substantially interfere with Tenant's use of the Demised Premises, then Tenant may cancel this Lease upon written notice to Landlord within ninety (90) days following that date upon which Tenant shall have become aware of such law, regulation or order and thereupon Tenant shall have no further obligation to Landlord. For purposes of this paragraph, "substantial interference" excludes any zone change under which Tenant's use as permitted above, is a lawful nonconforming use for the remaining term of the Lease and any unexercised option periods.

Tenant shall not use or occupy the Premises in violation of the Ground Lease or in violation of law, and shall, upon written notice from Landlord, discontinue any use of the Premises which is declared by any governmental authority having jurisdiction to be a violation of law. Tenant shall have the right, with Landlord's cooperation, to appear before any governmental authority or to bring any action to contest any zoning change or similar change in use restrictions which may impair Tenant's use of the Premises as permitted herein. Tenant shall comply with any direction of any governmental authority having jurisdiction, which shall by reason of the nature of Tenant's use or occupancy of the Premises impose any duty upon Tenant or Landlord with respect to the Premises, or with respect to the use or occupation thereof. Tenant shall comply with all conditions of approval for development permits issued for the Complex, including implementation of a Transportation Demand Management ("TDM") program if required by City ordinance. Landlord shall not agree to any amendment to the Ground Lease materially affecting Tenant's use without Tenant's prior written consent, which Tenant may withhold in Tenant's sole but reasonable discretion

Tenant may, if Tenant so elects, and for Tenant's sole use, install and operate within the Demised Premises microwave ovens and install and operate within the Demised Premises vending machines to dispense hot and cold beverages, ice cream, candy, food and cigarettes; such machines shall be maintained in a neat and sanitary condition and shall comply with all applicable laws and ordinances.

5. **DELETED**

6. **MAINTENANCE AND REPAIRS**

Landlord shall-keep in good order and repair the following: (a) the structural parts of each of the Building that comprise the Premises, including the foundation, subflooring, floor slab, exterior walls, structural walls, roof, and utilities outside the exterior of each Building and under the floors and floor slabs, together with all interior and/or glass damage due to any structural failure or defect, (b) the roof membrane, (c) all paved areas, including parking lot and walkways, and (d) landscaping. Tenant shall promptly notify Landlord in writing of any items which need maintenance or repair. Landlord shall be solely responsible for capital costs and maintenance and repair costs of the structural parts of the Building described in item (a) and for capital costs for the roof membrane. Maintenance and repair costs for items (b) through (d), including routine maintenance and repair costs and capital costs chargeable to Tenant shall be paid by Tenant to Landlord pursuant to the Rider attached hereto.

Tenant shall maintain and repair all interior portions of the Demised Premises including all interior non-structural walls, ceilings, lighting, floor coverings, glass, heating, ventilating and air conditioning equipment, elevators, interior electrical and plumbing fixtures, except when such damage results from any structural failure or defect. Tenant shall furnish its own cleaning services, trash removal and maintenance of the HVAC system and elevators. Upon notification by Tenant, Landlord shall promptly repair any damage to or defect in the Premises and the Building; provided, however, that if such damage is occasioned by fault or neglect of the Tenant (except as provided in paragraph 16 hereof) and there shall not be in effect at the time such damage occurred a policy or policies of insurance insuring Landlord against any loss resulting from such damage, then Tenant shall reimburse Landlord for the reasonable actual cost of repairs or if the proceeds of such insurance are insufficient to cover such cost, then Tenant shall reimburse Landlord the difference between such cost and the proceeds which Landlord received.

Landlord shall ensure that, as of the Commencement Date, all existing building systems, if any, shall be in good working order.

Tenant hereby waives all rights under and any benefit of the provisions of Sections 1932 (1), 1941 and 1942 of the California Civil Code and any similar or successor law, statute or ordinance now or hereafter enacted.

7. **ALTERATIONS**

After the Commencement Date, Tenant shall make no alterations, decorations, additions or improvements (“Alterations”) in or to the Premises without Landlord’s prior written consent, which shall not be unreasonably withheld. Landlord’s consent shall also state whether the Alterations must be removed upon termination of the Lease. The contractors or mechanics used by Tenant for any Alterations shall be subject to Landlord’s reasonable approval. If Landlord fails to respond to Tenant’s request for consent within fifteen (15) business days after such request, Landlord’s consent shall be deemed given and Tenant shall not be required to remove the Alterations specified in Tenant’s request upon termination of the Lease. Notwithstanding the foregoing, Landlord’s consent is not required for nonstructural Alterations costing less than

Twenty-Five Thousand and no/100ths Dollars (\$25,000.00). Tenant shall not construct any partititons or other obstructions which might interfere with Landlord's free access to mechanical installations or service facilities of the Premises or interfere with the moving of Landlord's equipment to or from the enclosures containing said installations or facilities. Tenant covenants that all work done by Tenant shall be performed in full compliance with all laws, rules, orders, ordinances, directions, regulations and requirements of all governmental agencies, offices, departments, bureaus and boards having jurisdiction and with all applicable requirements of the Ground Lease. Before commencing any work, Tenant shall give Landlord and Stanford University at least ten (10) days' prior written notice of the proposed commencement of such work. Tenant shall, if required by Landlord or Stanford University, secure at Tenant's own cost and expense a completion and lien indemnity bond, reasonably satisfactory to Landlord and Stanford, for such work.

Tenant further covenants that any mechanic's lien filed against the Premises or against the Complex for work claimed to have been done for, or materials claimed to have been furnished to Tenant, will be discharged by Tenant at the expense of Tenant, by bond or otherwise, within fifteen (15) days after written notice of the existence of such lien. Tenant shall at all times retain title to and receive any depreciation or tax benefits available from the Alterations installed at Tenant's expense. Such Alterations shall become Landlord's property upon termination of the Lease if they are not removed by Tenant upon the expiration or termination of the Lease. Landlord shall have no interest in any of Tenant's personal property located in the Premises, and Landlord hereby waives all such interest. Landlord shall, within ten (10) days following Tenant's request, execute documents, in the form satisfactory to Landlord, evidencing Landlord's waiver of all right, title, lien and interest in Tenant's personal property located on the Premises. Tenant shall be entitled to all insurance proceeds or condemnation awards paid with respect to Tenant's personal property.

All personal property, trade fixtures, office machinery and equipment, furniture and movable partititons owned by Tenant or installed by Tenant at its expense in the Premises shall be and remain the property of Tenant and may be removed by Tenant at any time during the Lease term. Tenant shall repair any damage caused by removal of its property. If Tenant shall fail to remove all of its effects from the Premises upon termination of this Lease for any cause whatsoever, Landlord after ten (10) days' written notice to Tenant may, at its option, remove the same in any manner that Landlord shall choose, and store such property without liability to Tenant for loss thereof. Tenant shall pay Landlord upon demand any and all expenses incurred in such removal, including court costs, reasonable attorneys' fees and storage charges on such effects for any length of time that the same shall be in Landlord's possession; or Landlord may, at its option, without notice, sell said effects, or any of the same, at private sale and without legal process, for such price as Landlord may obtain and apply the proceeds of such sale upon any amounts due under this Lease from Tenant to Landlord and upon the expenses incident to the removal and sale of said effects. In the event of an early termination of the Lease, through no fault of Tenant, Tenant shall have a reasonable period of time to remove its personal property before Landlord is entitled to remove and store the same.

**8. SIGNS**

Tenant shall have the right to be listed on the Building directory, if any, and to have identification signs inside and/or outside of the Demised Premises. Tenant shall have the right to install and/or remove in conformance with Tenant's specifications and Landlord's sign program for the Complex, a monument sign, provided such sign does not violate any governmental law, ordinance or regulation, or the Ground Lease. All signs shall be installed at Tenant's expense.

**9. SERVICES**

Landlord shall furnish the following installations and/or services to Tenant, all of which shall be adequate for the intended use of the Premises and in conformity with that furnished in local office buildings of similar nature, but in no event shall these services be provided less than 24 hours per day, seven (7) days per week.

- (a) Landlord shall, at Landlord's sole expense, install separate meters for each Building in the Complex and the common areas and provide connections to all utilities used by Tenant during the term of this Lease. Tenant shall obtain service and pay for the cost of such utilities for each of the Buildings that comprise the Premises. In addition, Landlord shall furnish all necessary utilities including electricity, to the exterior common areas, including the walkways, driveways, and parking area, and Tenant shall reimburse Landlord as provided in the Rider attached hereto for its proportional share of such costs.
- (b) Landlord acknowledges that the availability of sufficient parking is a material inducement to the entering into of this Lease by Tenant. Landlord represents that it has sufficient parking available to provide at no cost to Tenant and for Tenant's exclusive use at least 3.3 paved parking spaces for every 1,000 square feet in the Demised Premises excluding cafeteria and physical fitness rooms (and similar floor space, if any, not used by the City of Palo Alto in determining the number of legally required parking spaces) which shall be in an open parking area. If so requested by Tenant, Landlord shall designate by marking or otherwise up to 40 visitor spaces, such spaces as exclusive for Tenant visitors.
- (c) Tenant shall not at any time park or permit the parking of Tenant's trucks or other vehicles or the trucks and vehicles of Tenant's suppliers or visitors, in any portion of the Complex that may be designated for use by other tenants of the Complex and their visitors or permit parking by Tenant's employees in excess of the number of spaces allocated for Tenant's use in Paragraph 9(b). Tenant agrees to assume responsibility for compliance by its employees with the parking provisions contained herein. Tenant hereby authorizes Landlord, at Tenant's sole expense, to tow away from the Complex any vehicle belonging to Tenant or Tenant's employees parked in violation of these provisions, or to attach violation stickers or notices to such vehicles. Landlord shall post a notice of intent to tow violators' cars.

Tenant acknowledges that any one or more of the services provided for in Paragraph 9 hereof may be interrupted or suspended by reason of accident, repair, alterations or improvements necessary to be made, strikes, lockout, and except as hereinafter provided, Landlord shall not be liable to Tenant therefore, provided however, that (a) Landlord shall use its best efforts to restore such services as soon as reasonably possible, (b) in the event such service is not restored within five (5) business days, if through the fault of Landlord, to the extent that Tenant cannot reasonably use all or any part of the Premises, rent and other charges shall abate as to such part, effective on the sixth (6th) business day and continue abated until such service is restored, and (c) in the event such interruption continues for twelve (12) months, whether or not through the fault of Landlord, then Tenant shall have the right and option to cancel and terminate this Lease, on ten (10) days written notice to Landlord, and thereafter shall be relieved of all further liability under this Lease.

**10. COMPLIANCE WITH LAW**

Landlord represents to the best of Landlord's knowledge that the Premises and the Building, and the fixtures and appurtenances thereto (except those installed by Tenant) will as of the Commencement Date conform or that Landlord shall promptly cause them to conform to every applicable requirement of law or duly constituted authority or of any Board of Underwriters, rating bureau or similar organization, or the requirements of the carriers of all insurance on or relating to the Demised Premises, the Premises or the Building whether such insurance be furnished by Landlord or Tenant (through a program of self-insurance or otherwise) and that Landlord will, at its sole risk and expense other than for requirements arising from Tenant's particular use of the Premises, at all times during the term hereof promptly comply with all such requirements. The Tenant shall comply with all applicable statutes, ordinances, rules and regulations of federal, state and municipal governments and all applicable rules and regulations of the Board of Fire Underwriters as such statutes, ordinances, rules and regulations pertain to Tenant's use of the Demised Premises.

Landlord shall also comply with all applicable city, county, state and federal ordinances in effect from time to time with respect to facilities for the handicapped in the Demised Premises, the Premises and the Building.

**11. LANDLORD'S TITLE, AUTHORITY, AND QUIET ENJOYMENT**

Landlord covenants and represents that:

- (a) It has to the best of its knowledge after reasonable inquiry good leasehold title to the Building and the Complex, -free from any lien, encumbrance, covenant condition or restriction affecting Tenant's proposed use and enjoyment of the Premises other than any item disclosed in the Binder No. B290-373 issued by Lawyers Title Insurance Company, a copy which has been delivered to Tenant by Landlord.

- (b) The Ground Lease is in full force and effect; there have been no material defaults by either party thereto, and no circumstances exist that would, with notice or lapse of time, constitute a material default.

In the event this Lease or the leasehold estate created hereunder is subject to the prior rights of any mortgagee or ground lessor, then Landlord shall secure from each mortgagee or lessor a written agreement in recordable form satisfactory to Tenant whereby Tenant, so long as Tenant is not in material default hereunder, may remain in possession of the Demised Premises pursuant to the terms hereof should Landlord become in default with respect to such mortgage or ground lease or should the Premises become the subject of any action to foreclose any mortgage, terminate the Ground Lease or to dispossess Landlord. Such agreements shall be secured and furnished to Tenant at least thirty (30) days prior to the Commencement Date, or Tenant may at its option, terminate this Lease.

Landlord covenants and represents that it has full and complete authority to enter into this Lease under all of the terms, conditions and provisions set forth herein, and so long as Tenant keeps and substantially performs each and every term, provision and condition herein contained on the part of Tenant to be kept and performed, Tenant shall peacefully and quietly enjoy the Premises without hindrance or molestation by Landlord or by any other person claiming by, through or under Landlord.

## **12. SUBORDINATION**

Tenant shall, if so requested by Landlord's lender or ground lessor execute any documents necessary to subordinate the priority of this Lease and the leasehold estate created hereunder to the lien of any mortgage or ground lease covering the Buildings, Complex or Premises; provided, however, that the mortgagee or ground lessor, as the case may be, shall deliver to Tenant at or prior to the time that this Lease becomes so subordinate a written agreement in recordable form satisfactory to Tenant whereby Tenant, so long as Tenant is not in material default hereunder, may remain in possession of the Premises pursuant to the terms hereof and should Landlord become in default with respect to such mortgage or ground lease or should the Complex, Buildings or Premises become the subject of any action to foreclose any mortgage, terminate the Ground Lease or to dispossess Landlord. Any fee which Landlord's lender or ground lessor may charge for such agreement shall be paid by Landlord.

This Lease shall be subject and subordinate at all times to the Ground Lease, and to the lien of any mortgages or deeds of trust now placed on or against the Premises or Landlord's estate or interest therein.



**13. ASSIGNMENT AND SUBLEASE**

Tenant shall not voluntarily or by operation of law assign, transfer, mortgage or otherwise encumber all or any part of Tenant's interest in the Lease or in the Premises without the prior written consent of Landlord, which consent shall not be unreasonably withheld. Landlord's consent shall not be required for any sublease of all or any portion of the Premises, provided, however, that Tenant shall inform Landlord of all subleases and Landlord shall have the right to disapprove any proposed subtenant if the subtenant's use of the Premises is inconsistent with the Ground Lease or applicable zoning. If Landlord disapproves a proposed subtenant as permitted, the sublease shall be void. No sublease shall extend beyond expiration of the then term of the Lease. Any attempted assignment, transfer, mortgage, or encumbrance without Landlord's consent shall, at the option of Landlord, constitute grounds for termination of the Lease. Landlord shall respond to Tenant's request for consent within fifteen (15) days or Landlord's consent shall be deemed given. Tenant may assign the Lease to the following entities without obtaining the Landlord's consent: (i) a subsidiary, affiliate, division or corporation controlled or under common control with Tenant; or (ii) a successor corporation related to Tenant by merger, consolidation, non-bankruptcy reorganization, purchase or exchange of stock. Each proposed subletting is also subject to any rights of Stanford University under the Ground Lease, including any rights of first refusal and approval of leases.

Each subletting or assignment shall be by an instrument in writing in form reasonably satisfactory to Landlord and shall be executed by the sublessor or assignor and by the sublessee or assignee in each instance, as the case may be, and each sublessee or assignee shall agree in writing for the benefit of the Landlord herein to assume, to be bound by and to perform the terms, covenants, and conditions of this Lease to be done, kept and performed by the Tenant. One executed copy of such written instrument shall be delivered to the Landlord.

No subletting or assignment shall relieve Tenant of its obligation to pay rent and to perform all of the other obligations to be performed by Tenant hereunder. The acceptance of rent by Landlord from any other person shall not be deemed to be a waiver by Landlord of any provision of this Lease or to be a consent to any assignment.

**14. LEASE EXTENSION**

- (a) If this Lease, shall not have been terminated pursuant to any provisions hereof and no material defaults then exist of which Tenant has received notice, then Tenant may, at Tenant's option, extend the term of this Lease for Two (2) successive additional terms of Five (5) years each, commencing on the expiration of the original term, or the immediately preceding additional term as the case may be. Tenant shall give Landlord nonbinding notice of intent to extend or not to extend not later than twelve (12) months prior to expiration of the then term. Tenant may exercise such option by giving Landlord written notice at least two hundred seventy (270) days prior to the expiration of the original or additional term as the case may be. If after giving nonbinding notice of its intent to extend, Tenant decides not to extend, the Lease term shall be extended to be twelve (12)

months from notice to Landlord not to extend. Upon the giving by Tenant to Landlord of such written notice and the compliance by Tenant with the foregoing provisions of this Paragraph 14, this Lease shall be deemed to be automatically extended upon all the covenants, agreements, terms, provisions, and conditions, set forth in this Lease except for such terms and conditions as are expressly inapplicable during any additional term or in connection with this Paragraph 14 and except for rent which shall be determined in accordance with the provisions of Paragraph 14(b). If Tenant fails or omits to so give to Landlord the first written notice referred to above, it shall be deemed, without further notice and without further agreement between the parties hereto, that Tenant elected not to exercise the options granted Tenant pursuant to this Paragraph 14, to extend the term of this lease for additional periods. This extension option is personal to Xerox Corporation and shall expire upon expiration of any sublease coterminous with the then term or upon assignment to any entity other than an assignee for whom consent is not required under Paragraph 13.

- (b) The rental rate for each Option Period shall be determined as follows:
- (i) The parties shall have fifteen (15) days after Landlord receives Tenant's Notice within which to agree on the rental rate for the Option Period in question based upon ninety-five percent (95%) of then fair market rental value of the Premises as defined in Paragraph 2(c). If the parties agree on the rental rate for that Option Period within fifteen (15) days, they shall immediately execute an amendment to this Lease stating the rental rate for that Option Period.
  - (ii) If the parties are unable to agree on the rental rate for an Option Period within such fifteen (15) day period, then, the rental rate for that Option Period shall be ninety-five percent (95%) of then current fair market rental value of the Premises as determined in accordance with Paragraph 14(b)(iv) below.
  - (iii) The "then fair market value of the Premises" shall be defined to mean the fair market rental value of the Premises as of the commencement of the Option Period in question, taking into consideration the uses permitted under this Lease, the quality, size, design and location of the Premises; tenant improvement allowances, free rent periods and other adjustments; and the rent for comparable buildings located in comparable areas of Santa Clara County; but excluding the value of any improvements made to the Premises by Tenant at Tenant's expense.
  - (iv) Within seven (7) days after the expiration of the fifteen (15) day period set forth in Paragraph 14 (b)(i), each party, at its cost and by giving notice to the other party, shall appoint an M.A.I. real estate appraiser with at least five (5) years' full-time commercial appraisal experience in northern Santa Clara County and southern San Mateo County to appraise and set the then fair market rental value of the Premises for the Option Period in question. If a party does not appoint an appraiser within ten (10) days after the other party has given notice of the name of its appraiser, the single appraiser

appointed shall be the sole appraiser and shall set the then fair market rental value of the Premises. If the two (2) appraisers are appointed by the parties as stated in this paragraph, they shall meet promptly and attempt to set the then fair market rental value of the Premises. If they are unable to agree within thirty (30) days after the second appraiser has been appointed, they shall attempt to select a third appraiser meeting the qualifications stated in this paragraph within ten (10) days after the last day the two (2) appraisers are given to set the then fair market rental value of the Premises. If they are unable to agree on the third appraiser, either of the parties to this Lease, by giving ten (10) days' notice to the other party, can apply to the then President of Santa Clara County Real Estate Board, or the then Presiding Judge of the Santa Clara County Superior Court, for the selection of a third appraiser who meets the qualifications stated in this paragraph. Each of the parties shall bear one-half (1/2) of the cost of appointing the third appraiser and of paying the third appraiser's fee. The third appraiser, however selected, shall be a person who has not previously acted in any capacity for either party.

Within thirty (30) days after the selection of the third appraiser, a majority of the appraisers shall set the then fair market rental value of the Premises. If a majority of the appraisers are unable to set the then fair market rental value of the Premises within the stipulated period of time, the three (3) appraisals shall be added together and their total divided by three (3); the resulting quotient shall be the then fair market rental value of the Premises.

If, however, the low appraisal and/or the high appraisal are/is more than ten percent (10%) lower and/or higher than the the middle appraisal, the low appraisal and/or the high appraisal shall be disregarded. If only one appraisal is disregarded, the remaining two (2) appraisals shall be added together and their total divided by two (2); the resulting quotient shall be the then fair market rental value of the Premises. If both the low appraisal and the high appraisal are disregarded as stated in this paragraph, the middle appraisal shall be the then fair market rental value of the Premises.

After the then fair market rental value of the Premises has been set, the appraisers shall immediately notify the parties and the parties shall amend this Lease within fifteen (15) days of such notice to set forth ninety-five percent (95%) of such amount as the rental rate for the Option Period in question.

#### ARBITRATION OF DISPUTES

All disputes between Landlord and Tenant with respect to Paragraph 14 of this Lease, with respect to the determination of fair market value rental rates, shall be decided by arbitration. Tenant shall have the right, by giving written notice to Landlord, setting forth in detail the nature of the dispute, to request arbitration. The dispute shall be submitted to arbitration as follows:

Within fifteen (15) business days after delivery of the above notice, each party (Landlord and Tenant) shall appoint a person to act as an arbitrator in its behalf. Within five (5) business days thereafter, the two appointed arbitrators shall jointly appoint a third arbitrator. The dispute shall be arbitrated by said three arbitrators. A majority decision of the three arbitrators shall control. All of the arbitrators shall be persons having at least ten (10) years experience in dealing with commercial leases in office buildings within Santa Clara and/or San Mateo Counties, and none shall have any interest in the Building or the Complex or be or have been associated or affiliated with either Landlord or Tenant.

In the event Landlord and Tenant, or the two arbitrators fail or refuse to appoint an arbitrator within the time set forth herein, then either party shall have the right to petition the senior judge (in terms of years of service), of the United States District Court of the applicable Federal District in which the Building is situate, to appoint such arbitrator and the arbitrator appointed by said judge shall serve in said capacity.

**NOTICE: BY INITIALLING IN THE SPACE BELOW YOU ARE AGREEING TO HAVE ANY DISPUTE ARISING OUT OF THE MATTERS INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION DECIDED BY NEUTRAL ARBITRATION AS PROVIDED BY CALIFORNIA LAW, AND YOU ARE GIVING UP ANY RIGHTS YOU MIGHT POSSESS TO HAVE THE DISPUTE LITIGATED IN A COURT OR JURY TRIAL. BY INITIALLING IN THE SPACE BELOW, YOU ARE GIVING UP YOUR JUDICIAL RIGHTS TO DISCOVERY AND APPEAL, UNLESS SUCH RIGHTS ARE SPECIFICALLY INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION. IF YOU REFUSE TO SUBMIT TO ARBITRATION AFTER AGREEING TO THIS PROVISION, YOU MAY BE COMPELLED TO ARBITRATE UNDER THE AUTHORITY OF THE CALIFORNIA CODE OF CIVIL PROCEDURE. YOUR AGREEMENT TO THIS ARBITRATION PROVISION IS VOLUNTARY. WE HAVE READ AND UNDERSTAND THE FOREGOING AND AGREE TO SUBMIT DISPUTES ARISING OUT OF THE MATTERS INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION TO NEUTRAL ARBITRATION.**

/s/  
\_\_\_\_\_  
**Initialed by Landlord**

/s/  
\_\_\_\_\_  
**Initialed by Tenant**

**15. TAXES, ETC.**

Subject to reimbursement by Tenant as provided on the Rider attached hereto, Landlord shall pay all real estate taxes, assessments, water and sewer rates and charges, and any other charges which may be levied, assessed or charged against the Buildings and/or the land upon which the Buildings are situated. Landlord shall further make all payments required to be made under the terms of any mortgage or deed of trust which is now or hereafter a lien on the Building or the land thereunder which is superior to this Lease and all payments required to be made under any ground lease.

**16. INSURANCE AND WAIVER OF LIABILITY**

(a) Subject to Tenant's rights to insure, provided below, and Tenant's obligation to reimburse, as provided on the attached Rider, Landlord shall obtain and maintain

the following kinds and amounts of insurance coverage throughout the term of this Lease:

- (1) Fire and extended coverage for the replacement cost of the Complex, with a five percent (5%) deductible including all Tenant Improvements within the Premises, but excluding Tenant's furnishings, fixtures, equipment and other personal property. The risks insured against shall include earthquake (when required by the Ground Lease and otherwise if available at a commercially reasonable cost) and war and invasion insurance when and to the extent required by the Ground Lease.
- (2) Comprehensive general liability insurance covering property damage, injuries and death arising out of the construction, use or operation of the Complex (but outside the Premises) with a combined single limit of at least Five Million Dollars (\$5,000,000) (or such greater amount as Tenant may reasonably require provided that if Tenant occupies less than all of the Complex, the limit shall be commercially reasonable). Landlord's liability insurance shall include coverage for operation of motor vehicles, all boilers and pressure vessels within the Complex, but outside the Premises, and, if available at commercially reasonable rates, environmental protection liability insurance with limits of not less than Three Million Dollars (\$3,000,000) per occurrence and Six Million Dollars (\$6,000,000) annual aggregate for sudden accidental occurrences and nonsudden accidental occurrences.
- (3) Rent loss insurance in an amount equal to at least twelve (12) months' rent hereunder.

During construction of the Complex and Tenant Improvements, Landlord shall also maintain builder's all risk coverage for the replacement cost of the Complex, including all Tenant Improvements, as well as any public liability or other insurance that may be required to comply with the Ground Lease.

(b) Tenant shall obtain and maintain the following kinds and amounts of insurance coverage throughout the term of this Lease:

- (1) Fire and extended coverage, including a sprinkler leakage endorsement, for Tenant's furnishings, fixtures, equipment and other personal property, in amounts and with deductibles reasonably determined by Tenant.
- (2) Comprehensive general liability insurance covering property damage, injuries and death arising from Tenant's possession and use of the Premises with a combined single limit of at least Five Million Dollars (\$5,000,000) (or such greater amount as Tenant may reasonably require). Tenant's liability insurance shall include coverage for all boilers and pressure vessels within the Premises and, if available at commercially reasonable rates, environmental protection liability insurance with limits of not less than

Three Million Dollars (\$3,000,000) per occurrence and Six Million Dollars (\$6,000,000) annual aggregate for sudden accidental occurrences and nonsudden accidental occurrences.

- (3) Workers' compensation insurance, as required by law.
- (c) Tenant shall have the right to obtain Landlord's fire and extended coverage insurance, and may insure some or all risks under its blanket policies or self-insurance program subject to Stanford University's reasonable approval. All insurance provided by third parties shall be issued by carriers admitted in California and rated A:XII in Best's Insurance Guide. Each party's insurance policies shall name the other party, Stanford and Landlord's lender as an additional insured, and provide that they may not be canceled, or reduced in amount, without at least fifteen (15) business days' written notice to the other party. Upon request, each party shall furnish the other and Stanford University with certificates of insurance or other appropriate evidence of coverage for all required insurance. Any deductible must be approved by Landlord, who shall not unreasonably withhold approval. Insurance obtained by Tenant, under its blanket policies or otherwise, may provide deductibles in excess of five percent (5%), subject to Landlord's reasonable approval. In that event, Tenant shall be responsible for all covered losses in excess of five percent (5%) of the loss up to the deductible amount.
- All insurance shall comply with the requirements of the Ground Lease. In particular, and without limiting the generality of the preceding sentence, all liability insurance shall be subject to adjustment in accordance with the Ground Lease. If Stanford University notifies Landlord that it proposes to increase the liability insurance requirements pursuant to the Ground Lease, Landlord shall notify Tenant and shall provide Tenant the opportunity to take part in any arbitration proceeding concerning the proposed limit if Tenant believes that the proposed limit is excessive or unreasonable.
- (d) Each party hereby releases the other from any and all claims against the other for damage to persons or property caused by or resulting from risks coverable by an insurance required by this Lease. Each party shall notify its insurance carriers of the existence of this waiver, and shall use its best efforts to cause each insurance policy to include a waiver of all rights of recovery by way of subrogation.

## 17. DAMAGE

- (a) If at any time prior to expiration or termination of this Lease, the Premises are wholly or partially damaged, destroyed or rendered inaccessible by a risk fully covered (excluding deductibles) by insurance maintained by Landlord or for Landlord's benefit, and the Tenant is unable, in its sole but reasonable discretion, to carry on its normal operations in all or a substantial portion of the Premises, then, Tenant shall give Landlord notice and within the later of thirty (30) days after Tenant's notice or sixty (60) days after the damage or destruction, Landlord shall give Tenant notice of its reasonable determination that the Premises can or cannot be fully restored and ready for occupancy within one (1) year from the date of damage or destruction, without payment of overtime or other premiums.

- (1) If Landlord determines that the Premises can be so restored within one (1) year, (i) this Lease shall remain in full force, (ii) rent shall be abated proportionally for such portion of the Premises as is inaccessible or unusable, for so long as such portion is inaccessible or unusable; and (iii) Landlord shall proceed diligently to repair the damage or destruction, including all Tenant Improvements, using materials of at least the quality used in the original construction of the Complex, Premises and Tenant Improvements with a minimum of interference in Tenant's normal operations. If, in Tenant's sole but reasonable judgment, Landlord shall not have performed any of the above obligations in strict compliance therewith, then Tenant may, but shall not be required to, undertake such obligations, and reasonable, actual costs incurred as a result thereof shall be reimbursed by Landlord within thirty (30) days after Tenant's request for payment.
  - (2) If Landlord determines that the Premises cannot be so restored within one (1) year, then either Landlord or Tenant may, at its option, (i) terminate this Lease with respect to the Buildings substantially damaged or destroyed, or, if (ii) damage exceeds fifty percent (50%) of the replacement cost of the Premises, terminate the Lease. Upon partial termination, rent shall be reduced proportionally to reflect the reduced area of the leased Premises.
- (b) If any time prior to expiration or termination of this Lease, the Premises are wholly or partially damaged, destroyed or rendered inaccessible by a risk not fully covered (excluding deductibles) by insurance maintained by Landlord or for Landlord's benefit, and the Tenant is unable, in its sole but reasonable discretion, to carry on its normal operations in all or a substantial portion of the Premises, then Tenant shall give Landlord notice and within sixty (60) days after the damage or destruction, Landlord shall give Tenant notice informing Tenant whether Landlord intends to repair such damage or destruction, and if so, whether such damage or destruction can be fully restored and ready for occupancy within one (1) year from the date of damage or destruction, without payment of overtime or other premiums.
- (1) If Landlord elects to repair and such damage or destruction can be fully restored within one (1) year, (i) this Lease shall remain in full force, (ii) rent shall be abated proportionally for such portion of the Premises as is inaccessible or unusable, for so long as such portion is inaccessible or unusable; and (iii) Landlord shall proceed diligently to repair the damage or destruction, including all Tenant Improvements, using materials of at least the quality used in the original construction of the Complex, Premises and Tenant Improvements with a minimum of interference in Tenant's normal operations. If, in Tenant's sole but reasonable judgment, Landlord shall not have performed any of the above obligations in strict compliance therewith, then Tenant may, but shall not be required to, undertake such obligations, and reasonable, actual costs incurred as a result thereof shall be reimbursed by Landlord within thirty (30) days after Tenant's request for payment.

- (2) If Landlord does not elect to repair or determines that the Premises cannot be so restored within one (1) year, then Tenant may, at its option, (i) terminate this Lease with respect to the Buildings substantially damaged or destroyed, or, if (ii) damage exceeds fifty percent (50%) of the replacement cost of the Premises, terminate the Lease. Upon partial termination, rent shall be reduced proportionally to reflect the reduced area of the leased Premises.
- (c) If during the final twelve (12) months of the term of this Lease (or any extension term) the Premises are wholly or partially damaged, destroyed or rendered inaccessible and the Tenant is unable, in its sole but reasonable discretion, to carry on its normal operations in all or a substantial portion of the Premises, either Landlord or Tenant may terminate this Lease with respect to affected Buildings or the entire Premises, by giving Landlord written notice of its election to terminate. Upon partial termination, rent shall be reduced proportionally to reflect the reduced area of the leased Premises.

**18. CONDEMNATION**

- (a) If all or substantially all of the Premises shall be condemned for public use or voluntarily transferred to a public or quasi-public body in lieu of proceeding to a judgment of condemnation (hereinafter, "taken"), this Lease shall terminate and rent shall be adjusted to the date of termination.
- (b) If any portion of the Premises or Complex shall be taken and Tenant is unable, in Tenant's sole but reasonable discretion, to carry on its normal business operations, Tenant shall have the right to (i) terminate this Lease with respect to the Buildings or portions thereof taken or, if (ii) fifty percent (50%) or more of the area of the Premises is taken, terminate the Lease. Upon any partial taking, if Tenant does not terminate the Lease,
  - (1) Rent shall be reduced proportionally to reflect the reduced area of the leased Premises.
  - (2) All repairs necessary to restore the Premises or Buildings as nearly as possible to their original condition shall be commenced within thirty (30) days after the taking or transfer; performed in a diligent and workmanlike manner with material of at least the quality used in the original construction of the Buildings and Premises; and completed by Landlord at Landlord's sole expense with a minimum of interference in Tenant's normal operations. If, in Tenant's sole but reasonable judgment, Landlord shall not have performed any of the above obligations in strict compliance therewith, then Tenant may, but shall not be required to, undertake such obligations, and reasonable, actual costs incurred as a result thereof shall be reimbursed by Landlord within thirty (30) days after Tenant's request for payment. Tenant is hereby granted a lien upon any award or settlement resulting from the condemnation to the extent that Tenant has not been reimbursed for any such cost incurred, subject, however, to any prior rights or liens of Stanford or Landlord's lender.



- (c) If all or any portion of the Premises or Complex shall be temporarily taken for a period of less than one (1) year, and Tenant is unable, in Tenant's sole but reasonable discretion, to carry on its normal business operations, rent shall be proportionally abated, and Tenant shall receive from the award or settlement its reasonable costs of relocation.
- (d) If all or any portion of the Premises or Complex shall be temporarily taken for a period of one (1) year or more, and Tenant is unable, in Tenant's sole but reasonable discretion, to carry on its normal business operations, (i) terminate this Lease with respect to the Buildings wholly or partially taken or, if (ii) fifty percent (50%) or more of the usable area of the Premises is taken, terminate the Lease. Upon partial termination, rent shall be reduced proportionally to reflect the reduced area of the leased Premises, and Tenant shall receive from the award or settlement its reasonable costs of relocation.
- (e) Landlord shall give Tenant prompt written notice, with full particulars, of any condemnation proceedings, threats or notices thereof, or offers or negotiations for sale in lieu of condemnation. Tenant shall have the right to participate in such proceedings or negotiations, and to recover, in addition to relocation costs, costs of damage to its property or Tenant Improvements, the fair market value of its leasehold interest. For this purpose, the fair market value of Tenant's leasehold interest shall be the net present value of the difference, if any, between rent due hereunder and fair market rent during the remainder of the then current term of this Lease (or such lesser period as all or a portion of the Premises may be taken), excluding any unexercised option periods. The discount rate for calculating the value of the leasehold interest shall be the rate explicitly or implicitly used by Landlord and the condemning authority in any agreement or by the court in establishing the award by judgment.

**19. DEFAULT BY TENANT**

The occurrence of any one or more of the following events shall constitute a material breach by Tenant:

- (a) The failure by Tenant to make any payment of rent or any other payment required to be made by Tenant hereunder, as and when due, where such failure shall continue for a period of ten (10) days after receipt by Tenant of written notice thereof from Landlord provided, however, that any such notice shall be in lieu of, and not in addition to, any notice required pursuant to Section 1151 of the California Code of Civil Procedure regarding unlawful detainer proceedings;
- (b) The failure by Tenant to observe or perform any of the covenants, conditions or provisions of this Lease where such failure shall continue for a period of thirty (30) days after receipt by Tenant of written notice thereof from Landlord; provided,

however, that if the nature of Tenant's default is such that it cannot be cured solely by payment of money and that more than thirty (30) days may be reasonably required for such cure, then Tenant shall not be deemed to be in default if Tenant shall commence such cure within such thirty (30) day period and shall thereafter diligently prosecute such cure to completion;

- (i) the making of any general arrangement or any assignment by Tenant for the benefit of creditors;
- (ii) the filing by or against Tenant of a petition to have Tenant adjudged a bankrupt or a petition of reorganization or arrangement under any law relating to bankruptcy (unless, in the case of a petition filed against Tenant, the petition is dismissed within ninety (90) days);
- (iii) the appointment of a trustee or receiver to take possession of substantially all of Tenant's assets;
- (iv) the attachment, execution or other judicial seizure of substantially all of Tenant's assets.

## **20. LANDLORD'S REMEDIES**

- (a) In the event of any material breach of this Lease by Tenant, then Landlord in addition to other rights or remedies it may have, shall have the right to terminate this Lease upon fifteen (15) days written notice to Tenant, and also the right, with or without termination of this Lease, of reentry upon and taking possession of the Demised Premises and Landlord may remove all persons and property from the Demised Premises; such property may be removed and stored in any other place in the Building or in any other reasonably secure place for the account of and at the expense and risk of Tenant. Tenant hereby waives all claims for damages which may be caused by the reentry of Landlord and taking possession of the Demised Premises or removing or storing the furniture and property as herein provided and shall save Landlord harmless from any costs or damages occasioned Landlord thereby, and no such reentry shall be considered or be construed to be a forcible entry. Should Landlord elect to reenter, as herein provided, or should it take possession pursuant to legal proceedings or pursuant to any notice provided for by law, Landlord may either terminate this Lease or, Landlord may from time to time, without terminating this Lease, relet the Demised Premises or any part thereof for such term or terms and at such rental or rentals and upon such other terms and conditions as may be reasonable, with the right to make minor alterations and repairs to the Demised Premises. Rental received by Landlord from such reletting shall be applied first to the payment of any costs of such reletting including reasonable brokerage and attorney's fees; and the residue, if any, shall be held by Landlord and applied in payment of future rent as the same may become due and payable hereunder. Should such rentals received from such reletting during any month be less than one-twelfth (1/12) of the annual rental reserved hereunder, then Tenant shall pay such deficiency to Landlord. Such deficiency shall be calculated and paid monthly. No such reentry or taking

possession of the Demised Premises by Landlord shall be construed as an election on its part to terminate this Lease, unless a written notice of such intention be given to Tenant, in which event Tenant's obligations to Landlord shall forthwith cease, or unless the termination thereof be decreed by a court of competent jurisdiction.

- (b) If Landlord elects to terminate this Lease pursuant to this Paragraph 20, Landlord may recover from Tenant:
- (i) The worth at the time of award of any unpaid rent which had been earned at the time of such termination; plus
  - (ii) The worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss Tenant proves could have been reasonably avoided; plus
  - (iii) The worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss Tenant proves could be reasonably avoided; plus
  - (iv) Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom.

As used in subparagraphs (i) and (ii) above, the "worth at the time of award" is computed by allowing interest at the prevailing discount rate of the Federal Reserve Bank of San Francisco at the time of the award plus five percent (5%), but not more than the maximum rate permissible by law. As used in subparagraph (iii) above, the "worth at the time of award" is computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus five percent (5%).

- (c) In the event of Tenant's default, Landlord shall also have the right to maintain Tenant's right to possession whether or not Tenant has abandoned the Premises, and in such event, Landlord shall be entitled to enforce all of Tenant's obligations and to recover Rent as it becomes due.
- (d) The failure by Tenant to make any material, undisputed payment of Property Expenses required to be made by Tenant hereunder, within ten (10) business days after written notice thereof by Landlord to Tenant, shall constitute a default. In the event of such default, Landlord shall have the remedies in Paragraphs (b) and (c) above and the right to bring an action against the Tenant to collect such sums.

**21. DEFAULT BY LANDLORD**

The occurrence of any one or more of the following events shall constitute a material breach by Landlord:

- (a) The failure by Landlord to make any payment required to be made by Landlord hereunder, as and when due, where such failure shall continue for a period of ten (10) days after receipt by Landlord of written notice thereof from Tenant;
- (b) The failure by Landlord to observe or perform any of the covenants, conditions or provisions of this Lease where such failure shall continue for a period of thirty (30) days after receipt by Landlord of written notice thereof from Tenant; provided, however, that if the nature of Landlord's default is such that it cannot be cured solely by payment of money and that more than thirty (30) days may be reasonably required for such cure, then Landlord shall not be deemed to be in default if Landlord shall commence such cure within such thirty (30) day period and shall thereafter diligently prosecute such cure to completion.

**22. RIGHT TO CURE LANDLORD'S DEFAULTS**

In addition to Tenant's other rights and remedies, if Landlord fails to perform any of its obligations herein regarding maintenance of the Premises, obtaining insurance, or paying Real Property Taxes, and if such failure continues for thirty (30) days, or fifteen (15) days in the event of roof leaks, after written notice from Tenant to Landlord and any mortgage of Landlord whose name and address is furnished to Tenant in writing, or if Landlord fails to commence such cure within thirty (30) days and to diligently prosecute the same to completion if a longer period is reasonably required in light of the nature of the breach, Tenant may, but shall not be obligated to, cure such breach at Landlord's expense. Landlord shall reimburse Tenant upon demand for all reasonable expenses incurred by Tenant, together with interest at the rate of two percent (2%) plus the Bank of America prime rate from the date incurred until paid.

**23. ADDITIONAL SPACE-OPTION**

Tenant has a twelve (12) month option from the date this Lease is fully executed, to lease the remaining rentable space of approximately 37,000 square feet (the "Additional Space"), to be constructed in the Complex, provided that during the last three (3) month period of this Lease Landlord may offer space to other tenants subject to Tenant's election not to exercise its option.

Landlord shall submit to Tenant all offers for the Additional Space executed by the Landlord and other tenant. Tenant shall notify Landlord within thirty (30) days of receipt of such offer of Tenant's election to exercise or not exercise its option to lease the Additional Space.

If Tenant exercises its option to lease the Additional Space, all the terms and conditions of this Lease shall apply, including preparation of Tenant's space and Tenant Improvement Allowance of which shall be increased proportionally. Rent for entire

Premises during the initial term shall be adjusted to reflect the Additional Space taken, and computed at the rate of \$1.87 per square foot per month for years one (1) through five (5), inclusive; and \$2.05 per square foot per month for years six (6) through ten (10), inclusive. Tenant's percentage share of Common Area Maintenance and similar costs shall be adjusted proportionally to reflect the Additional Space.

**24. SECOND RIGHT OF OFFER TO PURCHASE**

If, at any time during the initial lease term, Landlord intends to sell, transfer or assign its interest in the Premises -independently from the Complex, or the entire Complex (collectively the "Offered Property"), then Landlord shall offer to Tenant as provided in this Paragraph the opportunity to purchase the Offered Property, provided that such right is subject to any rights of Stanford under the Ground Lease. Tenant's right shall not apply to sales at foreclosure or a deed in lieu of foreclosure, but the purchaser at such sale or receipt of the deed in lieu of foreclosure shall take the Premises subject to Tenant's rights under this Paragraph. Landlord shall give Tenant notice concurrently with notice to Stanford, and Tenant's election to purchase the Offered Property shall be void if Stanford purchases the Offered Property. Landlord shall give to Tenant written notice of the terms and conditions upon which it would be willing to sell the Offered Property ("Landlord's Offer"). Tenant shall have the right to purchase the Offered Property upon the terms and conditions stated in Landlord's Offer, which Tenant may exercise only by giving written notice to Landlord within sixty (60) days after receipt after receipt of Landlord's Offer. If Tenant timely exercises its right, it shall purchase the Offered Property on the terms and conditions contained in Landlord's Offer within forty-five (45) days after the sixty (60) day period. However, if Tenant does not so accept Landlord's Offer within such sixty (60) day period, then Landlord may sell the Offered Property to any third party on substantially the same terms and conditions contained in Landlord's Offer for a period of twelve (12) months after the expiration of the sixty (60) day period. If, however, the agreement to sell to a third party is substantially more favorable to the third party buyer than the terms contained in Landlord's Offer to Tenant, Landlord shall re-offer the Offered Property to Tenant on such modified terms ("Landlord's Re-Offer"), subject to Stanford's right of reoffer, as above stated. (For purposes of this paragraph, "substantially more favorable" shall mean a price reduction of three percent (3%) or more, or any change in financing or other economic terms of equivalent effect). If Tenant does not accept Landlord's Re-Offer by written notice within fifteen (15) business days of receipt of Landlord's Re-Offer, then Landlord may sell the Offered Property to a third party on substantially the same terms and conditions contained in Landlord's Re-Offer for a period of twelve (12) months after the expiration of the thirty (30) day period. If Tenant does accept Landlord's Re-Offer, Tenant shall purchase the Offered Property upon the terms and conditions contained in Landlord's Re-offer within forty-five (45) days after expiration of the fifteen (15) day period. If an agreement for the purchase and sale of the Offered Property is not fully executed by Landlord and a third party within twelve (12) months after Landlord's Offer or Landlord's Re-Offer, as the case may be, has been delivered to Tenant, then any proposed sale of the Offered Property by Landlord shall be deemed a new determination by Landlord to sell and shall be subject to Tenant's second right of offer in accordance with the terms and conditions of this Paragraph 24. The failure of Tenant to accept Landlord's Offer or Landlord's Re-Offer, as the case may be, in writing within the time period stated in this paragraph shall be deemed a rejection by Tenant but such rejection shall not waive Tenant's rights to the Offered Property on another occasion. Tenant agrees to keep all information set forth in Landlord's Offer or Landlord's Re-Offer confidential except as may be

reasonably required for tax or legal advice or in connection with proposed financing, and further agrees not to interfere with or in any way unreasonably impede Landlord's negotiations with any third party,

25. **FIRST RIGHT TO LEASE**

If, during the original or any additional term hereof any space ("Available Space") in the Complex becomes available for lease due to expiration or termination of then existing leases, then Landlord shall offer the space to Tenant in writing at rates and other terms (including term of the lease and tenant improvement allowance) at which Landlord otherwise would offer the space to other parties. Tenant shall have thirty (30) days to notify Landlord whether Tenant desires to lease the Available Space. If Tenant notifies Landlord it desires to lease the Available Space, but Tenant and Landlord are unable to agree on a rental rate, then the rental rate shall be determined pursuant to the procedures for determining the rental rate for the Premises during an Option Period as set forth in Paragraph 14 (b) of this Lease. Other terms and conditions of the lease for the Available space would be substantially the same terms and conditions as this Lease. If Tenant does not notify Landlord that Tenant elects to lease the Available Space, then Landlord may offer such space to third parties. If at any time Landlord anticipates making or receiving an offer or letter of intent for lease of the Available Space, Landlord may notify Tenant of the identity of the potential tenant ("Notice of Potential Tenant"). Tenant shall have twenty (20) days after receipt of such notice to determine in its reasonable judgment and notify Landlord whether the potential tenant so identified is a competitor of Tenant. If Tenant does not notify Landlord within twenty (20) days after receipt of the Notice of Potential Tenant, that the potential tenant is a competitor, any offer to Landlord from that potential tenant shall not be subject to the right of refusal below. If Tenant notifies Landlord that the potential tenant is a competitor or if Landlord has not provided Tenant with Notice of Potential Tenant (with time to respond as provided above), any offer or letter of intent to or from the potential tenant shall be subject to the following right of refusal. Prior to entering into any lease or rental agreement thereafter for the Available Space, Landlord shall first give Tenant written notice ("Notice of Proposed Lease"), with full particulars of the proposed lease or rental agreement (such as an executed letter of intent) and the identity of the proposed tenant. Tenant shall have five (5) days after receipt of the Notice of Proposed Lease to notify Landlord of the determination by its Real Estate Operations group or its Operations Division whether the potential tenant is a competitor and the recommendation whether to exercise the right of refusal. If the Real Estate Operations group or Operations Division recommends not to exercise the right, the right shall be deemed waived. If the recommendation is to exercise the right, Tenant shall have fifteen (15) days after receipt of the Notice of Proposed Lease to elect to lease the Available Space for the same rent and other economic terms proposed and otherwise on the terms and conditions in this Lease, provided that no term or condition of this Lease shall materially effect the economic terms of the proposed lease. If Tenant fails to exercise its right to lease such space by giving Landlord written notice of acceptance within the stated fifteen (15) day period, or by waiving pursuant to the internal recommendation then Landlord may enter into such lease or rental arrangement with the third party identified in the notice on substantially the terms stated in the Notice of Proposed Lease. Failure by Tenant to lease any Available Space when so offered or notified by Landlord shall not relieve Landlord of its obligation under this Paragraph if, as and when other space or the Available Space again becomes available for lease.

**26. TENANT'S PARTICIPATION**

As a material part of the consideration and as a material inducement for Tenant to enter into this Lease, Landlord hereby agrees that Tenant shall share, at Tenant's election, at any time during the term of this Lease in the "Net Cash Flow", "Net Proceeds of Refinancing", and "Net Proceeds of Sale" (as hereinafter set forth), Tenant's share thereof being ten percent (10%). If Tenant elects to participate in the "Net Cash Flow", "Net Proceeds of Refinancing" and "Net Proceeds of Sale" per this Paragraph 26 then the Tenant will agree to adjust rent by increasing rents in accordance with the provisions of subparagraphs 26(a), 26(b) and 26(c) below.

Landlord shall report the following information to Tenant on a quarterly basis: budget, construction or permanent loan balance, and leasing status. Landlord shall notify Tenant of owners meetings at the time such meetings are scheduled; and Tenant shall be permitted to participate on an information basis at each of the owners meetings, as it relates to those topics which are relevant to Tenant's Participation.

(a). Tenant's Share of Net Cash Flow

1. Net Cash Flow is defined as the total amount of monies received by Landlord in a calendar year, prorated for partial years, for all tenants (including Tenant) and occupants of the Building deriving from so-called base rent, additional rent, escalations (for operating expenses, utilities and real estate taxes), parking or garage rent or other such fees, and any other income of Landlord from the Building, after subtracting therefrom the amounts actually paid by Landlord including, but not limited to operating expenses, real estate taxes and assessments, professional fees, utilities, allocation to capital reserves, and "debt service" (interest and amortization) on Landlord's construction loan or permanent financing, and ground rent and deduction of management fee if any, but excluding depreciation. Landlord may, on an annual basis, contribute to reserves for capital improvements or reserves for additional tenant improvements, leasing commissions, or related releasing costs. Landlord agrees that any and all monies determined by Landlord to be placed in reserves shall actually be transferred to an interest-bearing account set aside for that purpose. In the event Landlord refinances the Building as hereinafter provided, then the "debt service" shall be subject to upward or downward adjustment based on the interest rate or constant as applied to the principal amount of each such refinancing.

On the first day of the twelve months next following the Commencement Date of the Term of this Lease, and each successive twelve month period the Tenant shall elect in writing if it will share in the "Net Cash Flow" for that period. If Tenant elects to participate in the Net Cash Flow:

- (i) During the first five (5) years of the initial lease term, then Tenant agrees to add eight cents (\$0.08) per square foot per month to the then current rent, for the relevant twelve (12) month period.
- (ii) During the final five (5) years of the initial lease term or any extensions provided, subject to this Paragraph 26, then Tenant agrees to add seven cents (\$0.07) per square foot per month to the then current rent, for the relevant twelve (12) month period.

Example:

Base Rent (Xerox)	\$4,112,640	
Additional Rent (Xerox)	141,120	
Base Rent (Others)	936,840	
Operating Expenses, Real Estate Taxes and Utilities	<u>1,030,000</u>	
Total Income	<u>6,220,600</u>	\$6,220,600
Less:		
Operating Expenses	525,000	
Real Estate Taxes	205,000	
Utilities	<u>300,000</u>	
Subtotal	<u>1,030,000</u>	
Allocation to Capital Reserves	138,000	
Debt Service	<u>3,880,000</u>	
Total Expenses	<u>\$5,048,000</u>	<u>5,048,000</u>
Net Income		<u>1,172,600</u>
Tenant's Share		× 10%
Amount Payable to Tenant		<u>\$ 117,260</u>

The twelve month period hereinabove set forth shall be the twelve months next following the Commencement Date of the term of this Lease, and each successive twelve month period. In the event the Net Income should be negative, in no event shall Tenant be liable therefor. Within thirty (30) days after the first anniversary of the Commencement Date and each anniversary thereof, Landlord shall submit to Tenant in Stamford, Connecticut (a) an itemized statement, certified by Landlord, subject to audit by Tenant, setting forth in detail for the period (i) Landlord's total income from the Building, (ii) the Net Income, and (iii) the calculation of Tenant's share or payment to Landlord (b) a copy of the certified balance sheet of Landlord on a cost basis, and (c) a good check to the order of Tenant, if applicable, for the full amount of Tenant's share.



(b). **Tenant's Share of Net Proceeds of Refinancing**

If Tenant elects to participate in the "Net Proceeds of Refinancing" then:

- (i) Rent shall increase by seven (7) cents (\$0.07) per square foot per month for the remaining balance of the then current term, unless rent has previously been increased pursuant to either subparagraph 26 (a) (for the then current twelve (12) month period) or 26 (c); and
- (ii) If fewer than ninety-six (96) months remain in the then current term, the term shall be forthwith extended so that a minimum of ninety-six (96) months remain. Rent for periods after expiration of the then-current term shall be one hundred percent (100%) of the then current fair market rental, determined in accordance with the provisions of Paragraph 14 (b).

For purposes of this paragraph, "Net Proceeds of Refinancing " shall be deemed to include the "Net Proceeds of the First Permanent Loan," the "Net Proceeds of Refinancing the First Permanent Loan," the "Net Proceeds of Subsequent Refinancing the First Permanent Loan," and the "Net Proceeds of Additional or Secondary Financing" (all as hereinafter set forth).

The Building or Complex is being financed by Landlord on an interim basis by a so-called Construction Loan made by lender to be determined by Landlord and Tenant in accordance with the provisions of Paragraph 26 (e), which Construction Loan will be supplanted by a so-called "First Permanent Loan" with a maturity date to be determined.

- 1. The Net Proceeds of the First Permanent Loan shall be computed by subtracting from the principal amount of the First Permanent Loan (a) the actual cost of the land, (for purposes of this calculation the actual cost of the land is \$16,500,000) (b) the cost of constructing the Building, including indirect costs (c) usual customary closing costs and (d) Landlord's actual cash equity balance as determined from the capital accounts of the partners, (The following examples assume that, as of this Lease execution Landlord's actual cash equity balance is zero).

Example:

Original Principal Amount of First Permanent Loan	\$40,900,000
less: (a) Cost of Land	16,500,000
(b) Cost of Building	22,300,000
(c) Closing Costs	100,000
(d) Landlord's Equity Balance	-0-
Net Proceeds of First Permanent Loan	<u>2,000,000</u>
Tenant's Share	× 10%
Amount Payable to Tenant	<u>\$ 200,000</u>

2. The “Net Proceeds of Refinancing the First Permanent Loan” shall be computed by subtracting from the principal amount of the Refinancing the First Permanent Loan (a) the original principal balance of the First Permanent Loan less any amortization of principal thereof, and (b) the usual and customary closing costs and (c) Landlord’s actual cash equity balance, increased or decreased for actual cash contributions and distributions respectively.

Example:

Original Principal Amount of Refinancing First Permanent Loan		\$43,000,000
less:		
(a) Original Principal Amount of First Permanent Loan	\$40,900,000	
Less Amortization	<u>1,000,000</u>	
	\$39,900,000	39,900,000
(b) Closing Costs		100,000
(c) Landlord’s Equity Balance		-0-
Net Proceeds of Refinancing First Permanent Loan		<u>3,000,000</u>
Tenant’s Share		× 10%
Amount Payable to Tenant		<u>\$ 300,000</u>

3. The “Net Proceeds of Subsequent Refinancing the First Permanent Loan” shall be calculated by subtracting from the principal amount of the subsequent Refinancing of the First Permanent Loan (a) the original principal balance of the Refinancing the First Permanent Loan less any amortization of principal thereof, (b) the usual and customary closing costs and (c) Landlord’s actual cash equity balance, increased or decreased for actual cash contributions and distributions respectively. This subparagraph 3 shall apply to any and all subsequent refinancings.

Example:

Original Principal Amount of Subsequent Refinancing of First Permanent Loan		\$45,000,000
less:		
(a) Original Principal Amount of refinancing First Permanent Loan	\$43,000,000	
less Amortizations	<u>1,000,000</u>	
	42,000,000	42,000,000
(b) Closing Costs		100,000
(c) Landlord Equity Balance		-0-
Net Proceeds of Subsequent Refinancing of First Permanent Loan		<u>2,900,000</u>
Tenant’s Share		× 10%
Amount Payable to Tenant		<u>\$ 290,000</u>

4. The “Net Proceeds of Additional or Secondary Financing” shall be calculated by subtracting from the principal amount of the additional or secondary financing the usual and customary closing costs and the Landlord’s actual cash equity balance, increased or decreased for actual cash contributions and distributions respectively. This subparagraph 4 shall apply to any and all additional or secondary refinancings.

Example:

Original Principal Amount of Additional or Secondary Financing	\$1,000,000
less:	
(a) Closing Costs	100,000
(c) Landlord Equity Balance	-0-
Net Proceeds of Additional or Secondary Financing	<u>900,000</u>
Tenant's Share	x 10%
Amount Payable to Tenant	<u>\$ 90,000</u>

In each case above in subparagraphs 1, 2, 3 and 4, Landlord shall notify Tenant at least sixty (60) days in advance of Landlord's intention to finance or refinance. Tenant shall notify Landlord of its election to participate or not to participate within fifteen (15) days after Landlord's notice. If Tenant elects to participate, then within fifteen (15) days after the closing Landlord shall send to Tenant in Stamford, Connecticut a good check for Tenant's share together with copies of the Closing Statement, Promissory Note and Mortgage or Deed of Trust. In the event the Net Proceeds of Refinancing should be negative, in no event shall Tenant be liable therefor.

(c). Tenant's Share of Net Proceeds of Sale

If Tenant elects to participate in the "Net Proceeds of Sale" then:

- (i) Rent shall increase by seven (7) cents (\$0.07) per square foot per month for the remaining balance of the then current term, unless rent has previously been increased pursuant to either subparagraph 26 (a) (for the then current twelve (12) month period) or 26 (b); and
  - (ii) If fewer than ninety-six (96) months remain in the then current term, the term shall be forthwith extended so that a minimum of ninety-six (96) months remain. Rent for periods after expiration of the then-current term shall be one hundred percent (100%) of the then current fair market rental, determined in accordance with the provisions of Paragraph 14 (b).
1. The "Net Proceeds of Sale" shall be computed by deducting from the gross sale price (a) the original principal balance of the then existing primary financing and of the then existing secondary financing, if any, less any amortization of principal of the then existing primary financing and of the then existing secondary financing, if any, (b) the usual and customary closing costs and (c) the Landlord's actual cash equity balance, increased or decreased for actual cash contributions and distributions respectively.

Example:

Gross Sale Price		\$ 50,000,000
Less:		
(a) Original Principal Balance of Primary Financing	\$ 45,000,000	
Less: Amortization	<u>1,000,000</u>	
	44,000,000	44,000,000
(a) Original Principal Balance of Additional or Secondary Financing	1,000,000	
Less: Amortization		<u>500,000</u>
(b) Closing Costs	500,000	100,000
(c) Landlord's Equity Balance	\$ 500,000	-0-
Net Proceeds of Sale		
Secondary Financing		<u>5,400,000</u>
Tenant's Share		× 10%
Amount Payable to Tenant		<u>\$ 540,000</u>

Landlord shall notify Tenant at least sixty (60) days in advance of Landlord's intention to sell and the proposed sale price. Tenant shall notify Landlord of its election to participate or not to participate within fifteen (15) days after Landlord's notice, if Tenant elects to participate, then within fifteen (15) days after the closing, Landlord shall send to Tenant in Stamford, Connecticut a good check for Tenant's share together with Purchase and Sale Agreement and Closing Statement.

In the event the Net Proceeds of Sale should be negative, in no event shall Tenant be liable therefor.

- (d) Upon a sale or transfer of the Complex, Tenant's participation in Net Cash Flow and Refinancing Proceeds shall cease. If Tenant has elected to participate in Refinancing Proceeds or Proceeds of Sale, rent increases shall remain in effect for the remainder of the then current term, including any extension by operation of Paragraphs 26 (b) and 26 (c). If Tenant has elected to participate in Net Cash Flow, but not in Refinancing Proceeds or Proceeds of Sale, any rent increase imposed hereunder shall cease upon sale or transfer of the Complex.

(e) DEVELOPMENT FINANCING

It is the intention of the Landlord to finance the building or complex by a construction loan which will be supplanted by a so-called "Permanent Loan". Landlord agrees to provide Tenant with a "Loan Package" of information covering the proposed financing at the same time Landlord is providing this

information to its other perspective Lenders, but no later than June 1, 1990. Landlord shall notify Tenant of the terms of any specific proposals received from such lenders, and Tenant will then have fifteen (15) days to improve the conditions of the proposed financing. If Tenant is successful in obtaining a more favorable loan with the same maturity, origination fees, amortization schedule and security and other terms and conditions then Tenant shall be entitled to a cash payment or payments equivalent to the savings, provided the Loan with more favorable terms and conditions actually closes. In the case of construction financing, Tenant shall receive a cash payment in the amount of the savings upon completion of construction and repayment of the construction loan. In the case of permanent financing, Tenant shall receive quarterly payments equal to the amount of the savings for that period. This Paragraph shall apply to any and all subsequent financings so long as QTC Venture continues to own the property, unless the loan is assumed by the new owner.

**27. DELIVERY OF EXECUTED LEASE**

Landlord shall deliver to Tenant two (2) fully executed originals of this Lease within fifteen (15) days after delivery to Landlord by Tenant of four (4) duplicate originals of this Lease duly executed by Tenant. In the event Landlord shall fail to deliver the fully executed copies of this Lease as herein required, Tenant may, if Tenant so elects, withdraw its execution and delivery of this Lease by giving Landlord written notice of such withdrawal. Upon such withdrawal neither party shall have any rights against the other either hereunder or otherwise except that Landlord shall forthwith return to Tenant any sums which Tenant shall have paid to Landlord prior to such withdrawal.

**28. DELETED**

(See paragraph 25 - First Right to Lease)

**29. NOTICES**

All notices shall be sent by registered mail, return receipt requested, or recognized private courier service with proof of delivery to the following addresses:

**TO LANDLORD:**

Lovewell Company  
Mr. John B. Lovewell  
General Partner  
700 Emerson  
Palo Alto, Ca 94301

**TO TENANT:**

Xerox Corporation  
Attn: RE/GSD Lease Administration  
800 Long Ridge Road  
P.O. Box 1600  
Stamford, CT 06904

**WITH A COPY TO:**

Xerox Corporation  
Attn: Manager, Real Estate Operations  
1851 East First Street, Suite 460  
Santa Ana, CA 92705

Any notice shall be deemed to have been given on the date set forth on the Registry Receipt given to the sender at the time of mailing, except that for purposes of Paragraph 19 and 21, hereof, such notice shall be deemed to have been received on the earlier of (a) the date set forth on the Return Receipt, (b) the date of delivery as shown on the Post Office records, or (c) the date delivery was refused as shown on the Post Office records.

Except as otherwise provided in this Lease, all correspondence to Tenant with respect to this Lease or any of the provisions hereof shall be sent to the addresses of Tenant set forth above, and any and all correspondence sent to Tenant at the Demised Premises or any location other than as stated herein, and any documents signed by Tenant at the Demised Premises as a result thereof shall be null and void and of no force and effect. Either party, by notice to the other, shall have the right to change the address(es) for notice(s) to be sent to such party, and to add or substitute entities to which a copy of any notice shall be sent by the other party.

**30. BROKERAGE**

Landlord and Tenant acknowledge that no real estate broker was involved in this lease transaction. Landlord hereby indemnifies Tenant against the claims of any other broker arising from Landlord's acts, and Tenant hereby indemnifies Landlord against the claims of any other broker arising from Tenant's acts.

**31. ESTOPPEL CERTIFICATES**

Landlord and Tenant shall, at any time upon not less than twenty (20) days prior written notice, execute and deliver to the Ground Lessor, a prospective new landlord, lender, or assignee or subtenant of Tenant, as the case may be, a statement in writing (i) certifying that this Lease is unmodified and in full force and effect (or if modified, stating the nature of such modification and certifying that this Lease, as so modified, is in full force and effect) and the date to which the rent and other charges are paid in advance, if any, (ii) acknowledging that there are not, to the parties knowledge, any uncured defaults on the part of the other party hereunder, and no circumstances exist that would, with notice or lapse of time, constitute default, or specifying such defaults or circumstances if any are claimed; and (iii) confirming such rental and other information as may be reasonably requested. Failure to respond in a timely manner, or to specify a default, shall be deemed an admission of the matters requested.

**32. INDUSTRIAL DEVELOPMENT BONDS**

Landlord covenants, warrants and represents that tax exempt Industrial Development Bonds, sometimes referred to as Industrial Revenue Bonds ("I.R.B.s") were not used in financing the Complex or the Building. If it is subsequently determined that tax exempt I.R.B.s were used in such financing, Tenant shall have the right and option to terminate this Lease and thereafter be relieved of all further liability hereunder.

In the event Landlord elects to finance the Complex or Building with tax exempt I.R.B.s during the term (or any additional term) of this Lease and Tenant occupies ten percent (10%) or more of the Building or Complex, then Landlord shall promptly so notify Tenant and Landlord hereby indemnifies and holds Tenant harmless from any loss by or claim against Tenant as a result of such tax exempt I.R.B. financing, and Landlord hereby releases Tenant from any liability to Landlord as a result of such tax exempt I.R.B. financing. In addition, Tenant shall have the right and option to terminate this Lease, as hereinabove provided.

**33. ASBESTOS AND CONTAMINATION**

Landlord covenants, warrants, and represents to the best of Landlord's knowledge that (a) the Building (including any transformers adjacent to the Buildings) will be constructed in compliance with all applicable laws and regulations, and will not contain any asbestos or PCB's, and (b) to the best of seller's knowledge, after reasonable inquiry, the land under and adjacent to the Buildings (including any other land underlying the Complex) has no toxic contamination except as described in existing environmental report furnished to Tenant. At any time from and after the date of this Lease and during the term of this Lease or any extension thereof, Tenant shall have the right and option, at Tenant's expense, to investigate the Building for the presence of asbestos and PCB's and to investigate the land for the presence of toxic contamination. Landlord hereby indemnifies and holds Tenant harmless in the event any such asbestos, PCB's or toxic contamination is subsequently found, and in such event Tenant shall also have the right and option to terminate this Lease and thereafter be relieved of all further liability hereunder.

**34. REMEDATION PROGRAM**

(a) Notice to Tenant of Underground Contamination

(i) Tenant acknowledges that the soil and groundwater of the property on which the Complex is located have been previously contaminated by volatile organic compounds (referred to as "Underground Contamination") and that the Complex is subject to orders by the Department of Health Services regarding remediation of the underground contamination. Tenant acknowledges that copies of the following have been made available to Tenant for review prior to execution of this Lease:

- Initial Site Investigation Report (GIC); December 1, 1987 - Levine-Fricke
- Phase II Investigation (GIC) August 4, 1988 - Levine-Fricke
- Remedial Action Order; August 16, 1988; 3400 Hillview Avenue, Palo Alto, California; Docket No. HSA 88-89-005

- Phase III On Site Ground-Water Extraction System; Modeling and Conceptual Treatment System Design, 3400 Hillview Avenue, Palo Alto, California, November 22, 1988 - Levine-Fricke
- Department of Health Services; Remedial Action Order for Hillview Porter Plume Regional Site; December 9, 1988, Docket No. HSA 88/89-016
- Department of Health Services; 3400 Hillview Avenue Site; Fact Sheet No. 1; May 1989
- EMCON Associates; Phase I and Phase II Environmental Assessment of the 3330 Hillview Property In Palo Alto, California, July 13, 1989; Project C25-01-01
- EMCON Associates; Third Party Environmental Review of 3400 Hillview Avenue, Palo Alto, California Site; September 6, 1989; Project C25-03-01
- Monthly Status Report for November 1989 and Results of November 1989 Quarterly Ground-Water Monitoring; 3400 Hillview Avenue, Palo Alto, California; December 15, 1989; Levine-Fricke
- Technical Memorandum On-site Soil Gas Investigation; 3400 Hillview Avenue; Palo Alto, California; April 7, 1989; Levine-Fricke

Tenant represents and warrants that it has reviewed such material. Tenant accepts the Premises with knowledge of the Underground Contamination as described in the specified materials and knowledge of the requirements of the Orders and Remedial Action Plan as described in such documents.

- (ii) Landlord represents to Tenant that Landlord shall require that all work or other activities performed on or about the Complex and the Premises in regard to the Underground Contamination or the Remedial Action Plan shall be performed in a manner which shall not unreasonably interfere with the use of the Complex or the Premises by Tenant, its agents, employees, customers, contractors or subtenants.
- (iii) Tenant, acknowledges that Landlord has notified Tenant that General Instrument Corporation (referred to as "Indemnitor") has agreed to indemnify Landlord and Landlord's Tenants from certain losses, costs, damages or expenses arising from the existing Underground Contamination, subject to certain conditions and limitations, as set forth in an Indemnification Agreement dated March 10, 1988, as amended and supplemented by a letter agreement dated November 18, 1989, between Indemnitor and Landlord.



(b) Landlord's Obligations

- (i) Landlord shall be responsible for all investigation, remediation, and monitoring required by law for (1) the Underground Contamination (and any additional Hazardous Materials existing on the Premises as of the Commencement Date of this Lease, (2) any Hazardous Materials released, emitted, discharged, or stored by Landlord or its agents, employees, or other tenants of the Complex, (3) any Hazardous Materials released, emitted, or discharged on or about the Premises from any other source after the Commencement Date, except to the extent that the Hazardous Materials in question were released, emitted, or discharged by Tenant or its agents, employees, contractors or subtenants. (For purposes of this Lease, "Hazardous Materials" shall mean any substance which has the capacity to cause death, injury or illness to man through ingestion, inhalation, or absorption through any body surface.)
- (ii) Landlord shall indemnify and hold Tenant harmless from any claims or costs, including reasonable attorneys fees, arising from or related to (a) any Hazardous Materials released, emitted, discharged, stored or used by landlord or its agents, employees or contractors, or other tenants of the Complex or (b) any Hazardous Materials present from any cause on or about the Premises on the Commencement Date of the Lease (including, without limitation, the Underground Contamination), except to the extent such Hazardous Materials were released by Tenant.
- (iii) Landlord shall indemnify Tenant as provided above only for out-of-pocket costs and expenses and not for any consequential damages and incidental damages, including loss of profits and loss of rental value of the leasehold; except to the extent such damages result from Landlord's willful failure to fulfill its obligations (specifically excluding good faith disputes with Tenant or government agencies regarding the scope and timing of Landlord's obligation).
- (iv) Any limitation on recovery against Landlord with respect to Hazardous Materials (including the limitation on recovery of consequential damages, loss of profits and loss of rental value) shall not affect Tenant's right to pursue any third parties, including Indemnitor (as defined herein). Upon demand from Tenant, Landlord will assign to Tenant any claims Landlord may have against any third parties, including Indemnitor relating to the losses, costs, expenses, lost profits, liabilities or claims which Tenant may incur or which may be asserted against Tenant with respect to Hazardous Materials.
- (v) Landlord shall impose upon all other tenants restrictions on the use of Hazardous Materials at least as strict as those contained in this Lease.

(c) **Tenant's Obligations**

Tenant has no present intention to use any Hazardous Materials in its operations at the Premises except for such Hazardous Materials as are incidental to normal office and software engineering work. Tenant's use of Hazardous Materials shall be subject to Landlord's approval, which shall not be unreasonably withheld, and shall comply with all applicable laws and regulations and the Ground Lease.

**35. HOLDOVER**

If Tenant shall remain in possession of the Demised Premises after expiration of the original or any additional term hereof, Tenant's occupancy shall be a month-to-month tenancy at 125% of the rental rate applicable to the last month of the unexpired term and under all of the other terms, conditions and provisions hereof except those pertaining to the term of the Lease. Landlord hereby grants to Tenant the right to holdover for up to three (3) months at a rental rate of 105% of the rental rate applicable to the last month of the unexpired term.

**36. SURRENDER**

- (a) Upon any termination or expiration of this Lease, Tenant shall surrender the Demised Premises in the same condition as existed at the commencement of the term, except for normal wear and tear and damage caused by the elements, casualty or any other cause for which Tenant might not be liable, provided, however, that Tenant shall have the option, but not the obligation, to replace or remove any or all of the improvements and alterations made to the Demised Premises by Tenant or at Tenant's expense. Any damage to the Demised Premises resulting from the removal of such improvements or alterations shall be repaired by Tenant at Tenant's expense.
- (b) Tenant shall surrender the Premises to Landlord with all plumbing, electrical and mechanical systems in good working order, normal wear and tear excepted, all carpets cleaned and shampooed, interior wall damage repaired, and damaged ceiling tiles, light fixtures, window blinds and other damaged fixtures replaced.

**37. MODIFICATION OF LEASE**

The terms, covenants and conditions of this Lease may not be changed orally but only by an instrument in writing signed by the party against whom enforcement of the change is sought. The failure of either party hereto to insist in any one or more cases upon the strict performance of any term, covenant or condition of this Lease to be performed or observed by the other party hereto shall not constitute a waiver of relinquishment for the future of any such term, covenant or condition.

**38. MEMORANDUM OF LEASE**

Neither party shall record this Lease or any of the exhibits and/or riders attached hereto, but at the request of either party, Landlord and Tenant shall enter into a "short form" or Memorandum of Lease in recordable form which shall set forth the parties, the legal description of the land underlying the Building, a description of the Demised Premises, the Commencement Date and Expiration Date of the term of the Lease, and any options, rights of refusal and/or restrictions desired to be included by either party.

**39. PARAGRAPH CAPTIONS**

Paragraph captions herein are for Landlord's and Tenant's convenience only, and neither limit nor amplify the provisions of this Lease.

**40. ENTIRE AGREEMENT**

This Lease represents the entire agreement between Landlord and Tenant and supersedes all prior agreements both written and oral. The terms, covenants and conditions of this Lease shall be binding upon and shall inure to the benefit of Landlord and Tenant and their respective executors, administrators, heirs, distributees, legal representatives, successors and assigns. The term "Tenant" as used in this Lease shall include Xerox Corporation and any subsidiary (or any subsidiary of any subsidiary) of Xerox Corporation.

**41. CHOICE OF LAW AND INTERPRETATION**

This Lease shall be governed by the law of the State in which the Complex is situate. Should any provision of this Lease require judicial interpretation, it is agreed that the court interpreting or construing the same shall not apply a presumption that the terms of any such provision shall be more strictly construed against one party or the other by reason of the rule of construction that a document is to be construed most strictly against the party who itself or through its agent prepared the same, it being agreed that the agents of all parties hereto have participated in the preparation of this Lease.

**42. ENTRY BY LANDLORD**

Landlord reserves and shall at any and all times have the right to enter the Premises to inspect the same, with Tenant's approval which will not be unreasonably withheld, to supply any services required hereunder, to submit the Premises to prospective purchasers, tenants or lenders, to post notices of nonresponsibility, to alter, improve or repair the Premises or any portion of the Complex, all without being deemed guilty of an eviction of Tenant and without abatement of rent, and may erect scaffolding and other necessary structures where reasonably required by the character of the work to be performed, provided that the business of the Tenant shall be interfered with as little

as is reasonably practicable. Landlord shall be required to give at least three (3) days written notice, except in an emergency. Landlord shall follow Tenant's reasonable security and or safety regulations, and, if Tenant so requests, shall be accompanied at all times by an employee of Tenant. Tenant hereby waives any claim for damages, for any injury or inconvenience to or interference with Tenant's business, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby, except due to the negligence or willful misconduct of Landlord or its agents or employees or if Landlord violates any of the provisions contained herein.

**43. ATTORNEY'S FEES**

If either party should bring an action at law or in equity or commence arbitration under this Lease to enforce any provision of this Lease or the accompanying Work Agreement, then all costs and expenses, including reasonable attorney's fees, incurred by the prevailing party therein shall be paid by the other party, which obligation on the part of the other party shall be deemed to have accrued on the date of the commencement of such action and shall be enforceable whether or not the action is prosecuted to judgment. All remedies provided herein or at law or in equity shall be cumulative and not exclusive.

**44. NONRECOURSE**

If, as a consequence of a default by Landlord under this Lease, Tenant recovers a money judgment against Landlord, such judgment shall be satisfied only out of the proceeds of sale received upon execution of such judgment and levied thereon against the right, title and interest of Landlord in the Premises and out of Rent or other income from such property received by Landlord or out of consideration received by Landlord from the sale or other disposition of all or any part of Landlord's right, title or interest in the Premises, and neither the Landlord nor its partners shall be liable for any deficiency.

**45. LANDLORD PAYMENT OPTION**

The Property Expenses to be paid by Tenant under the Rider herein are the direct responsibility of Tenant, Landlord may collect Property Expense payments from Tenant and pay the appropriate entities directly. If Landlord elects to do so, the installments of property taxes and special assessments to be paid by Tenant shall be paid to Landlord not later than thirty (30) days from receipt of Landlord's invoice or twenty (20) days prior to the date the installment becomes delinquent whichever is latest and insurance premiums shall be paid to Landlord not later than thirty (30) days from receipt of Landlord's invoice or twenty (20) days prior to the due date whichever is latest. For Common Area Expenses and all other Property Expenses, Tenant shall pay to Landlord monthly, in advance, an amount estimated by Landlord to be Landlord's average monthly expenditures for such Property Expenses items, which estimated amount shall be reconciled once each calendar year, in the month of September, with Landlord's actual expenditures for said Property Expenses items. After reconciliation, Tenant shall pay to Landlord within thirty (30) days after receipt of an invoice from Landlord, the amount of actual expenses expended by Landlord in excess of the estimated amount, or Landlord shall, within thirty (30) days after such reconciliation, refund to Tenant or

credit against the next succeeding installment of Rent (providing Tenant is not in default under this Lease) the amount of estimated payments made by Tenant in excess of Landlord's actual expenditures for said Property Expenses items. Landlord shall maintain complete, accurate records of Property Expenses for at least three (3) years after they are incurred. Landlord shall make such records available to Tenant or its representatives (in accordance to the Rider herein) at reasonable times for inspection, copying and audit. Overpayments or underpayment disclosed by audit shall be adjusted by payment or credit against subsequent rent payments, as appropriate.

**46. DELAYS, LIQUIDATED DAMAGES, TERMINATION**

If Landlord is unable to deliver possession of the Premises or the Premises are not, in Tenant's reasonable judgment, ready for occupancy on or before July 1, 1991, Landlord shall pay liquidated damages to Tenant at the rate of \$1075.00 per day for each day of delay. Liquidated damages shall not be paid to the extent of any delays caused by fire, natural disaster, strikes or other circumstances beyond Landlord's control including inability to obtain government approvals despite diligent efforts to do so (force majeure), provided that Landlord gives Tenant prompt written notice of such circumstances. Liquidated damages shall be payable in cash, upon demand following the Commencement Date or earlier termination, or, at Tenant's option, deducted from amounts due Landlord under this Lease on the accompanying Work Agreement. The parties agree that these provisions liquidating Tenant's damages are reasonable in the circumstances existing at the time of this Lease.

If the Landlord is unable to deliver possession of the Premises or the Premises are not, in Tenant's reasonable judgment, ready for occupancy on or before November 1, 1991, Tenant may terminate this Lease and the accompanying Work Agreement upon written notice to Landlord, except when delays are caused by force majeure, provided that Landlord gives Tenant prompt written notice of such circumstances. However, if for any reason, including force majeure, Landlord is unable to deliver possession of the Premises or the Premises are not, in Tenant's reasonable judgment, ready for occupancy by January 1, 1992 Tenant may terminate this Lease and the accompanying Work Agreement upon written notice to Landlord.

**47. INDEMNIFICATIONS**

(a) Tenant shall indemnify and hold harmless Landlord against and from any and all causes and claims arising from Tenant's use of the Premises or the conduct of its business or from any activity, work done, permitted or suffered by the Tenant in or about the Premises, and shall further indemnify and hold harmless Landlord against and from any and all claims arising from any breach or default in the performance of any obligation of Tenant's part to be performed under the terms of this Lease, or arising from any action, neglect, fault or omission of the Tenant, or of its agents or employees, and from and against all costs, reasonable attorney's fees, expenses and liabilities incurred in or about such claim or any action or proceeding brought thereon, and in case any action or proceeding be brought against Landlord by reason of any such claim, Tenant upon notice from Landlord shall defend the same at Tenant's expense by counsel reasonably satisfactory to Landlord. Tenant, as a material part of the consideration to

Landlord, hereby assumes all risk of damage to property or injury to persons in, upon or about the Premises from any cause whatsoever except to the extent caused by Landlord's negligence, willful misconduct or failure of Landlord to observe any of the terms and conditions to this Lease, or to the extent covered by any indemnity. Landlord shall give Tenant prompt written notice, with full particulars, of all claims subject to this indemnity. Tenant shall have no obligation to pay any amount in connection with any settlement reached without Tenant's consent, which shall not be unreasonably withheld or delayed. Tenant shall indemnify and hold harmless Landlord against and from any and all causes and claims arising from the active neglect or negligence, willful misconduct or intentional failure of Tenant to observe any of the terms and conditions of this Lease.

Without limiting the generality of the foregoing, Tenant shall indemnify and hold Landlord harmless from any claims, third party liabilities or costs arising from, and shall perform (or cause others to perform) all investigation and remediation required by law and the Stanford Ground Lease and remediation required by law and the Stanford Ground Lease with respect to any Hazardous Materials released, emitted, discharged, stored or used by Tenant or its agents, employees, contractors or subtenants. Tenant shall also be responsible for, and shall indemnify and hold Landlord harmless from any claims by any third party relating to the migration of Hazardous Materials from the Premises to other property to the extent that the Hazardous Materials in question were released, emitted, discharged, by Tenant or its agents, employees, contractors or subtenants. (For purposes of this Lease, "Hazardous Materials" shall mean any substance which has the capacity to cause death, injury or illness to man through ingestion, inhalation, or absorption through any body surface.)

Tenant shall indemnify Landlord as provided above only for out-of-pocket costs and expenses and not for any consequential damages and incidental damages, including loss of profits and loss of rental value of the leasehold (other than lost rents during time of clean up), except to the extent such damages result from Tenant's willful failure to fulfill its obligations (specifically excluding good faith disputes with Landlord or government agencies regarding the scope and timing of Tenant's obligations).

- (b) Landlord shall indemnify and hold harmless Tenant against and from any and all causes and claims, subject to the provisions regarding Hazardous Materials which is set forth in Paragraph 34, as provided in this Paragraph 47 (b), arising from the Complex, including all Common Areas, but excluding the Premises, and shall further indemnify and hold harmless Tenant against and from any and all claims arising from any breach or default in the performance of any obligation of Landlord's part to be performed under the terms of this Lease, or arising from any act, neglect, fault or omission of the Landlord, or of its agents or employees, and from and against all costs, reasonable attorneys' fees, expenses and liabilities incurred in or about such claim or any action or proceeding brought thereon, and in case any action or proceeding be brought against Tenant by reason of any such claim, Landlord upon notice from Tenant shall defend the same at Landlord's expense by counsel reasonably satisfactory to Tenant. Landlord's obligations regarding Hazardous Materials are set forth in Paragraph 34 herein. Landlord, as a material part of the consideration to Tenant, hereby assumes all risk of damage

to property or injury to person in, upon or about the Complex, including all Common Areas, but excluding the Premises from any cause whatsoever except to the extent caused by Tenant's negligence, willful misconduct, or failure Tenant to observe any of the terms and conditions to this Lease, or to the extent covered by any indemnity. Landlord shall indemnify and hold harmless Tenant against and from any and all causes and claims arising from the active negligence, neglect or willful misconduct or intentional failure of Landlord to observe any of the terms and conditions of this Lease. Tenant shall give Landlord prompt written notice, with full particulars, of all claims subject to this indemnity. Landlord shall have no obligation to pay any amount in connection with any settlement reached without Landlord's consent, which shall not be unreasonably withheld or delayed.

- (c) Tenant covenants and agrees that Stanford University shall not any time or to any extent whatsoever be liable, responsible or in any way accountable for any loss, injury, death or damage to persons or property or otherwise, whether direct or consequential including without limitation, loss or damage to the Premises and the Building, attorney's fees, which at any time may be suffered or sustained by Tenant or by any person whosoever may at any time be using or occupying or visiting the Premises or be in, on or about the same, whether such loss, injury, death or damage shall be caused by or in any way result from or arise out of any act, omission or negligence of Tenant or of any occupant, subtenant, visitor or user of any portion of the Premises, or shall result from or be caused by any other person, matter or thing whether of the same kind as, or of a different kind than, the persons, matters or things above set forth except to the extent that any loss, injury death or damage may be caused by the negligence or willful misconduct of Stanford University. Tenant shall forever indemnify, defend, hold and save Stanford University free and harmless of, from and against any and all claims, liability, loss or damage whatsoever on account of any such loss, injury, death or damage except to the extent that any loss, injury, death or damage may be caused by the negligence or willful misconduct of Stanford University. Tenant hereby waives all claims against Stanford University for damages to the Premises and to the property of Tenant in, upon or about the Premises, and for injuries to persons or property in or about the Premises, from any cause arising at any time except to the extent that any, injury, death or damage may be caused by the negligence or willful misconduct of Stanford University.

Without limiting the generality of the foregoing, Tenant agrees that the provisions of this Paragraph 47 apply to all Hazardous Materials used, stored, generated, treated, disposed or released ("Used") on, in or under the Premises by Tenant and that Tenant will indemnify, defend, hold and save Stanford University free and harmless from claims, liability, loss or damage on account of such Hazardous Substances used by Tenant and that Tenant will remove such substances used by Tenant that are now or hereafter on, in or under the Premises in a safe and prudent manner and within a reasonable time that is agreed to by Stanford University. The parties hereto recognize and agree that from time to time Stanford University in its reasonable discretion may require the removal of Hazardous Materials or other remediation even though such Stanford University requirements are in excess of or in the absence of applicable governmental requirements. Any dispute with regard to such Sanford University removal or remediation requirements that are in excess of or in the absence or applicable governmental requirements shall be subject to arbitration pursuant to the terms of Paragraph 38 of the Ground Lease provided however that if there is a

contemporaneous dispute with regard to governmental required remediation of Hazardous Substances then Stanford University may join the dispute with regard to its independent requirements with a legal action in court of competent jurisdiction with respect to the government required remediation instead of the arbitration.

As used in this Paragraph 47, Stanford University shall include and be deemed to include The Board of Trustees of the Leland Stanford Junior University and its trustees, directors, officers, employees, faculty, students, agents, and affiliated organizations.

**48. EXHIBITS AND RIDERS**

Attached hereto and made a part hereof are the following:

Rider:	Common Area Maintenance, Real Estate Taxes, Insurance Cost
Exhibit "A":	Complex
Exhibit "B":	Demised Premises
Exhibit "C":	Work Agreement and Allowance
Exhibit "C-1":	Landlord Preparation of Building Shells
Exhibit "C-2":	Building Shell Approved Plans
Exhibit "C-3":	Tenant Improvement Plans and Specifications



IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Lease as of the day and year first above written.

TENANT

Xerox Corporation, a  
New York corporation

By: /s/ Edward L. Maier  
Edward L. Maier

Its: Director, Real Estate Operations

Date: 4/6/90

LANDLORD

QTC Venture, a  
California general partnership

By: Keenan/Lovewell 1. a California  
general partnership, General  
Partner

By: /s/ John B. Lovewell  
John B. Lovewell, General Partner

Date: 4/10/90

By: Kennan QTC L.P. a California  
limited partnership, General  
Partner

By: /s/ Charles J. Keenan III  
Charles J. Keenan III

Trustee of the Kennan  
Declaration of Trust dated  
December 20, 1988

Date: 4/11/90

**RIDER**

This Rider is made a part of Lease dated March 1, 1990 for space at 3400 Hillview Avenue in the City of Palo Alto, State of California and in the event of conflict between this Rider and the printed portion of said Lease, this Rider shall prevail.

**COMMON AREA MAINTENANCE, REAL ESTATE TAXES, INSURANCE COST**

Landlord and Tenant each acknowledge that the rent specified in Paragraph 3 does not provide for Real Estate Taxes, Insurance Costs and Common Area Maintenance which may hereafter pertain to the Premises or the Building. Therefore, Tenant agrees to pay or to reimburse Landlord for the Additional Expenses as hereinafter provided.

- (a) The term "Common Area Maintenance" shall mean the cost of providing water, sewer, parking lot and landscape maintenance (including cleaning, policing, striping of walkways, sidewalks and parking areas, and the keeping of same drained, shrub and flower upkeep and replacement) and trash removal (excluding that trash generated by Tenant), reasonable, actual costs of managing the Common Areas and operating the Complex (which shall exclude Landlord's overhead and shall not exceed the lesser of one percent (1%) of the rent specified by Paragraph 3 or competitive rates for such services), costs of legally mandated programs and capital costs of replacements and legally mandated improvements amortized over their useful lives in accordance with generally accepted accounting principles, plus interest on the unamortized portion of such cost at the Bank of America's reference rate plus two percent (2%). All expenses to be taken into account pursuant to this paragraph shall be "net" only, and for such purpose shall be deemed reduced by the amount of reimbursement, recoupment, payment, discount or allowance received or receivable by Landlord in connection with such expenses.
- (b) During the term of this Lease Tenant agrees to reimburse Landlord for Common Area Maintenance which Landlord agrees to provide in accordance with Paragraph 6 of the Lease. Tenant's prorata share shall be adjusted during the term of said Lease and any renewals thereof by any increases and decreases in the square feet demised to Tenant and by any increases in the square feet in the Building.
- (c) The term "Real Estate Taxes" shall mean the annual ad valorem taxes, special assessments and special taxes levied against the Complex, and imposed by any authority having the direct power so to tax, including any city, county, state, or federal government, or any school, agricultural, transportation or environmental control agency, lighting, drainage or other improvement district thereof. All expenses to be taken into account pursuant to this paragraph shall be "net" only, and for such purpose shall be deemed reduced by the amount of reimbursement, recoupment, payment, discount or allowance received or receivable by Landlord in connection with such expenses. The term "Real Estate Taxes" shall not include any parking surcharge, license fee, penalty, inheritance or estate tax, any tax on Landlord's right to rent or other income from the Building or on Landlord's business of leasing the Buildings, any penalty for delinquent payment of taxes (unless caused by Tenant), increases in taxes

arising from additions or improvements to Buildings not occupied by Tenant, or common areas not used by Tenant, or leasehold improvements made by or for other tenants. In the event the Buildings and/or land or Complex is reassessed (which term includes the current assessment being increased without reassessment) and such reassessment is greater than the prior assessment, then Landlord shall (a) promptly notify Tenant thereof, and (b) if in Tenant's reasonable determination such reassessment is excessive and Tenant so notifies Landlord, Landlord shall diligently protest such reassessment or permit Tenant to do so. In the event Landlord fails so to notify Tenant, or to contest the reassessment or permit Tenant to do so (as the case may be), then Tenant's obligation to pay its share of Real Estate Taxes shall be computed by multiplying the prior assessment by the then current tax rate. Costs of contesting assessments shall be chargeable to Tenant as a property expense.

In the event Landlord's Real Estate Tax bill covers buildings in addition to the Buildings that comprise the Premises or land in excess of that required to support the Buildings, parking and common areas for the Building and Landlord is unable to obtain a separate tax assessment of the Premises, parking and common areas, the Landlord shall make a reasonable allocation for the Building, parking and common areas of the total tax assessment made on the several buildings. Landlord shall submit to Tenant sufficient backup data as to the basis for such allocation to permit Tenant to determine the reasonableness of the allocation. In the event that Tenant disputes the reasonableness of either such allocation, Landlord and Tenant agree to submit the determination of such allocation to arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The arbitrator shall be an independent Certified Public Accountant, an active member of the California bar, or a retired judge.

**NOTICE: BY INITIALLING IN THE SPACE BELOW YOU ARE AGREEING TO HAVE ANY DISPUTE ARISING OUT OF THE MATTERS INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION DECIDED BY NEUTRAL ARBITRATION AS PROVIDED BY CALIFORNIA LAW, AND YOU ARE GIVING UP ANY RIGHTS YOU MIGHT POSSESS TO HAVE THE DISPUTE LITIGATED IN A COURT OR JURY TRIAL. BY INITIALLING IN THE SPACE BELOW, YOU ARE GIVING UP YOUR JUDICIAL RIGHTS TO DISCOVERY AND APPEAL, UNLESS SUCH RIGHTS ARE SPECIFICALLY INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION. IF YOU REFUSE TO SUBMIT TO ARBITRATION AFTER AGREEING TO THIS PROVISION, YOU MAY BE COMPELLED TO ARBITRATE UNDER THE AUTHORITY OF THE CALIFORNIA CODE OF CIVIL PROCEDURE. YOUR AGREEMENT TO THIS ARBITRATION PROVISION IS VOLUNTARY. WE HAVE READ AND UNDERSTAND THE FOREGOING AND AGREE TO SUBMIT DISPUTES ARISING OUT OF THE MATTERS INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION TO NEUTRAL ARBITRATION.**

/s/  
\_\_\_\_\_  
Initialled by Landlord

/s/  
\_\_\_\_\_  
Initialled by Tenant

- (d) The term "Insurance Cost" shall mean premiums for insurance required to be carried by Landlord pursuant to said Lease and the Ground Lease. The term "Insurance Cost" shall specifically exclude increases in premiums for insurance required to be carried by Landlord pursuant to this Lease when such increase is caused by use of the Complex by Landlord or any other tenant of Landlord which is hazardous on account of fire or otherwise, or premiums for any insurance carried by Landlord which is not required to be carried pursuant to this Lease and the Ground Lease. All expenses to be taken into account pursuant to this paragraph shall be "net" only, and for such purpose shall be

deemed reduced by the amount of reimbursement, recoupment, payment, discount or allowance received or receivable by Landlord in connection with such expenses.

- (e) The Tenant's share of Real Estate Taxes and Common Area Maintenance and Insurance Cost shall initially be 81%, which is derived from a fraction using as the numerator the area then under lease by the Tenant, 167,366 square feet, and as the denominator, the total area in the Building(s) projected in the overall project of 206,150 square feet. Tenant's prorata share shall be adjusted when the actual square footages are determined and during the term of said Lease and any renewals thereof by any increases and decreases in the square feet demised to Tenant and by any increases in the square footage in the Building(s).
- (f) The Landlord shall deliver to Tenant in Stamford, Connecticut (Attn: RE/GSD Lease Administration), a statement setting forth the amounts of estimated Common Area Maintenance for the then current year, together with an invoice showing the amounts for which reimbursement is due. Copies of the accounting statements used in the calculations and copies of receipted Real Estate Tax bills shall be furnished with the statements and invoice for reimbursement, and upon request by Tenant, Landlord shall submit additional backup data (including copies of receipted bills) to permit Tenant to review such statement. Tenant or any authorized agent of Tenant, shall have the right, upon prior written notice, to audit Landlord's books at any time with respect to the first full year or any subsequent year. Upon request by Tenant, Landlord shall submit a statement signed by an officer (or partner, as the case may be) of Landlord, setting forth the date on which the Building was assessed as a fully completed building.
- (g) Tenant shall pay its pro rata share of Real Estate Taxes and Insurance Cost due, if any, in the manner set forth in paragraph 45 herein. If Tenant shall dispute, in good faith, any reimbursement item or other sum (other than Rent) claimed by Landlord hereunder and Tenant shall give Landlord written notice specifying in reasonable detail the basis for its dispute. Tenant and Landlord shall proceed diligently to resolve any such dispute by agreement or arbitration in accordance with the commercial arbitration rules of the American Arbitration Association. The arbitrator shall be an independent Certified Public Accountant, an active member of the California bar, or a retired judge.

**NOTICE: BY INITIALLING IN THE SPACE BELOW YOU ARE AGREEING TO HAVE ANY DISPUTE ARISING OUT OF THE MATTERS INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION DECIDED BY NEUTRAL ARBITRATION AS PROVIDED BY CALIFORNIA LAW, AND YOU ARE GIVING UP ANY RIGHTS YOU MIGHT POSSESS TO HAVE THE DISPUTE LITIGATED IN A COURT OR JURY TRIAL. BY INITIALLING IN THE SPACE BELOW, YOU ARE GIVING UP YOUR JUDICIAL RIGHTS TO DISCOVERY AND APPEAL, UNLESS SUCH RIGHTS ARE SPECIFICALLY INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION. IF YOU REFUSE TO SUBMIT TO ARBITRATION AFTER AGREEING TO THIS PROVISION, YOU MAY BE COMPELLED TO ARBITRATE UNDER THE AUTHORITY OF THE CALIFORNIA CODE OF CIVIL PROCEDURE. YOUR AGREEMENT TO THIS ARBITRATION PROVISION IS VOLUNTARY. WE HAVE READ AND UNDERSTAND THE FOREGOING AND AGREE TO SUBMIT DISPUTES ARISING OUT OF THE MATTERS INCLUDED IN THE 'ARBITRATION OF DISPUTES' PROVISION TO NEUTRAL ARBITRATION.**

/s/  
\_\_\_\_\_  
Initialled by Landlord

/s/  
\_\_\_\_\_  
Initialled by Tenant

- (h) If the first or final billing period during the term or any additional term of this Lease for which reimbursement may be due, shall contain less than twelve (12) months, the reimbursement under this Rider shall be prorated.
- (i) Notwithstanding the foregoing provisions of this Rider, it is understood and agreed that in the event Landlord fails to bill Tenant for any amounts which may be due hereunder within nine (9) months after reconciliation date provided in paragraph 45, then Tenant shall have no liability or obligation to make such payment.

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**EXHIBIT A**  
**“COMPLEX”**

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**EXHIBIT B**  
**“DEMISED PREMISES”**

**EXHIBIT C**  
**WORK AGREEMENT AND ALLOWANCES**

This Work Agreement and Allowances ("Work Letter") is attached as EXHIBIT C and made a part of that certain Lease dated March 1, 1990, (the "Lease"), between QTC Venture, a California general partnership ("Landlord") and Xerox Corporation, a New York corporation ("Tenant"). The terms used in this Work Letter that are defined in the Lease shall have the same meaning as provided in the Lease.

The purpose of this Work Letter is to set forth the agreement between Landlord and Tenant with respect to the construction of the Building Shells and the construction of Tenant Improvements to be installed on the Demised Premises by Landlord.

1. Building Shell

Landlord shall pay all costs of design and construction of the Building Shells. The Building Shell and all necessary and required appurtenances thereto is described and defined by EXHIBIT C-1 attached to this Work Letter.

The Building Shell shall be completed in a good and workmanlike manner. All work and materials incorporated into the Building Shell shall conform to all applicable codes, and shall conform to the Building Plans and Specifications approved by Landlord and Tenant. All materials incorporated into the Building Shell shall be new and of first quality. Landlord shall promptly correct and remedy any defective work or materials.

2. Building Shell Plans

Tenant shall have until June 1, 1990 to review and approve the design development drawings for the Building Shells. The final working architectural and engineering plans and specifications for the Building Shells ("Building Plans and Specifications") shall be prepared in accordance with the approved design development drawings. Tenant shall have the right to review and approve the Building Plans and Specifications. Landlord shall build the Building Shells in substantial conformance with the approved Building Plans and Specifications which shall be attached hereto as EXHIBIT C-2 after approval by Landlord and Tenant.



### 3. Tenant Improvements

For purposes of this Work Letter and the Lease, Tenant Improvements shall not include the Building Shell to be provided by Landlord pursuant to Paragraph 1 above. The Tenant Improvements shall include all other improvements to the Premises for Tenant's use and occupancy pursuant to the Lease or this Work Letter. Tenant improvements shall include, but not be limited to, the following:

- (a) Sprinkler drops and heads below drop ceiling;
- (b) Roof mounted VAV HVAC, including main trunk lines to first and second floors with hot water reheat system, secondary distribution lines and controls;
- (c) Ceilings;
- (d) Lighting;
- (e) Building insulation including roof and sound insulation;
- (f) Interior walls and partitions;
- (g) Plumbing;
- (h) Painting and wall coverings;
- (i) Floor covering;
- (j) Suite entry and interior doors;
- (k) All venting;
- (l) Electrical secondary system from transformer (including underground pull section), panels, main switchboard switches, and distribution;
- (m) Gas distribution;
- (n) Telephone switch room, panel, distribution system;
- (o) Lobbies (including lobby stairway), corridors, fire exits;

- (p) Elevators;
- (q) Electrical rooms, phone rooms, and mechanical rooms;
- (r) Restrooms;
- (s) Janitorial closets;
- (t) Window coverings;
- (u) One secondary stairway and finish for each Building;
- (v) Exterior signage;
- (w) Outside landscaped walkway to adjacent property (PARC) and second story bridge walkways between Buildings; and
- (x) Other improvements specific to Tenant's use including shell upgrades (such as additional structural reinforcing) and specialty improvements such as cafeterias, auditoriums and exercise rooms.

All Tenant Improvements shall be completed in a good and workmanlike manner and all materials and equipment incorporated into Tenant Improvements (i) will be new and free of defects, (ii) will conform to all applicable codes, and (iii) will conform to the Tenant Improvement Plans and Specifications (defined in Paragraph 4 below) approved by Landlord and Tenant including all changes or modifications thereto approved by Landlord and Tenant. Landlord shall promptly correct and remedy any defective work or materials. Upon completion of the Tenant Improvements and acceptance of the Demised Premises by Tenant, Landlord shall, if requested by Tenant, furnish Tenant with a complete set of "as built" drawings for the Tenant Improvements to the Demised Premises which drawings shall be furnished at no additional cost to Tenant.

Landlord shall be responsible for obtaining all necessary permits and approvals (including the building and occupancy permits) and other authorizations from governmental agencies or Stanford University needed in connection with the Tenant Improvements. The costs of all such permits and approvals including inspection, mitigation, and other building fees, shall be included as part of the costs of the Tenant improvements.

4. Tenant Improvement Plans and Specifications

Tenant shall retain a licensed architect for the preparation of design development drawings for the Tenant Improvements. Tenant shall submit the design development drawings to Landlord for Landlord's approval no later than October 1, 1990. Landlord shall have fifteen (15) days after receipt of the design development drawings to review and approve the drawings. Landlord shall not unreasonably withhold approval. If Landlord does not approve the drawings, Tenant shall have fifteen (15) days after receipt of Landlord's requested changes to modify the drawings and resubmit the drawings to Landlord for approval. Landlord shall thereafter have ten (10) days to approve the revised drawings. Landlord and Tenant shall submit the approved design development drawings to Landlord's General Contractor for the completion of final working architectural and engineering plans and specifications for the Tenant Improvements ("Tenant Improvement Plans and Specifications"). Landlord's contractor shall prepare estimated cost of the Tenant Improvements based upon the design development drawings. If the estimated cost is not acceptable to Tenant, Tenant shall have twenty (20) days to submit revised design development drawings. If cost of the Core Portion of the Tenant Improvements exceeds Twelve Dollars and Fifty Cents (\$12.50) per square foot or approximately Two Million Ninety-Two Thousand Seventy-Five Dollars (\$2,092,075.00) (167,366 square feet times \$12.50 per square foot), Tenant may require Landlord to redesign the core to meet this figure. The Core Portion shall include one elevator (car, structural improvements to accommodate the car, pit, and shaft), one lobby, four (4) bathrooms, one (1) electrical room per Building and a rooftop mounted double duct HVAC system including primary trunk lines. Building One (1) shall have a ceremonial stairway included as part of the lobby. Upon approval of the estimated costs, Landlord's contractor shall prepare the Tenant Improvement Plans and Specifications based upon the approved design development drawings and cost estimates. Landlord and tenant shall indicate their approval of the Tenant Improvement Final Plans and Specifications by initialing them and attaching a schedule of Tenant Improvement Plans and Specifications hereto as EXHIBIT C-3. Immediately following such approval by Landlord and Tenant, Landlord shall submit the Tenant Improvement Plans and Specifications to the appropriate governmental body for plan checking and a building permit. Landlord, subject to Tenant's approval, agrees to make any reasonable changes to the Tenant Improvement Plans and Specifications required to obtain a building permit for the Tenant Improvements. After final approval of the Tenant Improvement Plans and Specifications, no further changes shall be made without the prior written approval of Landlord and Tenant

5. Construction Contract

The parties agree that the Tenant Improvements shall be constructed by a licensed contractor selected by Landlord and approved by Tenant ("General Contractor") pursuant to a "cost plus" up to guaranteed maximum cost construction contract ("Construction Contract") between Landlord and

General Contractor. The final pricing for the Tenant Improvements shall be subject to Tenant's approval. The Construction Contract shall require that General Contractor provide a minimum warranty of one year with respect to the Tenant Improvements. The General Contractor shall obtain at least three (3) competitive bids for all subcontract work unless Tenant approves in writing a smaller number and all subcontracts awarded shall be based on the lowest bid unless otherwise approved by Tenant.

6. Tenant Improvement Allowance

Landlord shall provide an allowance for the planning and construction of the Tenant Improvements in the amount of Thirty-Five and no/100ths Dollars (\$35.00) per square foot of the Demised Premises ("Tenants Improvements Allowance"). The Tenant Improvements Allowance shall be the maximum contribution by Landlord for the Tenant Improvements Cost, as defined in Paragraph 7, subject to the provisions of Paragraph 8 of this Work Letter. If the Tenant Improvements Cost exceeds the Tenant Improvements Allowance plus the Additional Allowance provided to Tenant, Tenant shall pay any such excess costs.

7. Tenant Improvement Cost

The Tenant Improvements cost ("Tenant Improvements Cost") to be paid from the Tenant Improvements Allowance (or the Additional Allowance) shall include, but not be limited to:

- (a) All costs of preliminary and final architectural and engineering plans and specifications for the Tenant Improvements, and engineering costs associated with completion of the State of California energy utilization calculations under Title 24 legislation;
- (b) All costs of obtaining building permits and other necessary authorizations for the Tenant Improvements from the City of Palo Alto, other governmental agencies, and Stanford University;
- (c) All costs of interior design and finish schedule plans and specifications including as-built drawings;
- (d) All direct and indirect costs of constructing and installing the Tenant Improvements, including, but not limited to, the construction fee for overhead and profit and the cost of all on-site supervisory and administrative staff, office, equipment and temporary services rendered by Landlord's contractor in connection with construction of the Tenant Improvements;

- (e) All fees payable to Tenant's architect, Landlord's General Contractor and/or Landlord's architect if they are required to redesign any portion of the Tenant Improvements following Landlord and Tenant's approval of the Tenant Improvements Plans and Specifications; and
- (f) Sewer, water, or other utility or municipal connection fees not included in the Building Shell costs.

In no event shall the Tenant Improvements Cost include any costs of procuring, constructing or installing in the Premises any of Tenant's personal property or Landlord's general and administrative expense.

8. Additional Allowances

Landlord shall provide Tenant with an additional Tenant Improvements Allowance ("Additional Allowance") of Twenty-Five and no/100ths Dollars (\$25.00) per square foot of the Demised Premises. Tenant shall reimburse Landlord for the Additional Allowance as additional rent at the rate of One and 44/100ths cents (.0144) per month for each One Dollar (\$1.00) of the Additional Allowance expended. Such additional rent is intended to fully amortize the Additional Allowance expended by Landlord over ten (10) years at the rate of twelve percent (12%) per annum. Prior to commencement of construction of the Tenant Improvements, Landlord and Tenant shall enter into a Lease Amortization Affirmation Agreement in the form attached as EXHIBIT C-4, setting forth (a) the precise amount of the Additional Allowance and any other amounts to be expended for the Tenant Improvements, (b) the amount of the monthly payments to be paid as additional rent, and (c) any other amounts owed to Landlord for the Tenant Improvements. In no event shall Landlord commence any work in the Demised Premises for which Tenant may be liable to pay, unless and until Landlord and Tenant have agreed on the amount of the Additional Allowance, and any additional excess costs, to be expended for the construction of the Tenant Improvements as provided herein. If this Lease is terminated prior to the expiration of the initial term, Tenant shall pay within five (5) days after termination any portion of the Additional Allowance not amortized as of the date of termination, without offset, claim, or deduction. In the event of such termination due to Tenant's default or at Tenant's request, Tenant shall also pay any prepayment penalty charged to Landlord by Landlord's lender for prepayment of Landlord's financing of the Additional Allowance.

9. Payment of Allowances

Landlord shall pay Tenant's architect's fees from the Tenant Improvements Allowance after approval of the Tenant Improvement Plans and Specifications and the budget for the Tenant Improvements upon receipt of invoices for the work completed. Landlord's General Contractor, subject to Tenant's approval, shall be paid from the Tenant Improvements Allowance and the Additional Allowance (if utilized by Tenant) on a monthly progress payment basis upon

presentation of invoices evidencing the work completed, lien releases and any other documentation required by Landlord's lender. Progress payments shall be made not more frequently than once every thirty (30) days during the construction of the Tenant Improvements. Landlord shall retain from each progress payment an amount equal to ten percent (10%) of the invoiced amount. Upon submission to Landlord of satisfactory evidence of lien free completion of the Tenant Improvements, Landlord shall pay the balance, including all retainage amounts, provided that the total payments made by Landlord shall not exceed the Tenant Improvements Allowance plus the Additional Allowance made available to Tenant. Tenant shall pay all Tenant Improvement Costs in excess of such amount.

10. Tenant's Representative

Tenant hereby designates Phil Alexander as its representative with authority to approve changes in design or construction, and to inspect and approve workmanship and material. In all cases, his signature shall be final and binding upon Tenant with respect to the authority herein granted to him. All alternates, either of additions or deletions, agreed to between Landlord and Tenant must be in writing and must be agreed to by Tenant's representative to be binding. Tenant reserves the right to designate an alternate representative by written notice to Landlord.

11. Change Requests

No revisions to the approved Tenant Improvement Plans and Specifications shall be made by either Landlord or Tenant unless approved in writing by both parties. Landlord and Tenant agree to make all changes required by any public agency to conform with governmental regulations. Any costs related to such changes shall be added to the Tenant improvements Cost. Costs related to changes shall include, without limitation, any architectural or design fees, and Landlord's General Contractor's price for effecting the change.

12. Construction Guarantee

Landlord hereby guarantees that the Building Shell and the Tenant Improvements shall be free from defects for a period of one (1) year from the date of completion. Landlord shall at Landlord's sole cost and expense promptly correct any construction defects discovered during such one (1) year period, and any damage caused to the Demised Premises in the course of such correction.

13. Termination.

If the Lease is terminated prior to the Commencement Date and prior to completion of the Tenant Improvements for any reason due to the default of Tenant hereunder, Tenant shall pay to Landlord, within thirty (30) days of receipt

of a statement therefor, any costs incurred by Landlord through the date of termination in connection with the Tenant Improvements. Landlord shall return all security deposits, prepaid rent and other monies paid by Tenant under the terms of the Lease within thirty (30) days and neither party shall have further rights or obligations under the terms of the Lease. If the Lease is terminated prior to the Commencement Date and prior to completion of the Tenant Improvements for any reason due to the default of Landlord, or if Landlord for any reason fails to substantially complete the Tenant Improvements by January 1, 1992, Landlord shall also refund all monies paid by Tenant hereunder.

14. Risk of Loss

The risk of Loss of the Premises before the Commence Date (as defined in the Lease) shall be borne by Landlord. After commencement of construction, Landlord at its sole cost and expense, shall maintain contingent liability and broad form "builder's risk" insurance with coverage in an amount equal to the replacement cost of the Building Shell and the Tenant Improvements. Landlord's insurance shall name Tenant as an additional insured, and shall provide that coverage may not be reduced or cancelled without fifteen (15) days' written notice to Tenant.

If the Premises are damaged or destroyed prior to the Commencement Date, and if the Premises, in the reasonable opinion of Landlord, cannot be substantially completed within twelve (12) months after the date of the destructive event, either Tenant or Landlord may terminate the Lease. If the Premises are damaged or destroyed and the Lease is not terminated pursuant to the terms of the Lease, then Landlord shall promptly and diligently complete construction of the Building Shell and Tenant Improvements in accordance with the Lease and this Work Letter.

TENANT

Xerox Corporation, a  
New York corporation

By: /s/ Edward L. Maier  
Edward L. Maier  
Its: Director, Real Estate Operations

Date: 4/6/90

LANDLORD

QTC Venture, a  
California general partnership

By: Keenan/Lovewell 1. a California general partnership, General  
Partner

By: /s/ John B. Lovewell  
John B. Lovewell, General Partner

Date: 4/10/90

By: Kennan QTC L.P. a California limited partnership, General Partner

By: /s/ Charles J. Keenan III  
Charles J. Keenan III  
Trustee of the Kennan  
Declaration of Trust dated  
December 20, 1988

Date: 4/11/90



**EXHIBIT C-1**

**LANDLORD PREPARATION OF BUILDING SHELLS**

The purpose of this Exhibit is to set forth and define the Landlord's obligations with respect to the design, construction and installation of the Building Shells and all necessary and required appurtenances thereto. Landlord shall pay all costs for the design, construction and installation of the Building Shells and all necessary and required appurtenances thereto as provided in the Work Agreement and Allowances ("Work Letter") to which this EXHIBIT C-1 is attached. The term "Building Shell", as used herein shall be deemed to be in the plural and shall, by definition, be considered "Building Shells".

A. Building Shell Plans and Specifications

(See Work Letter)

B. Description of Building Shells

1. Building Structure

- (a) All foundations to include footings, piers, caissons, pilings, grade beams, foundation walls or other building foundation components required to support the entire building structure, or any other additional loads that may be imposed such as, core rest rooms, switchgear, stairs, and any other loads relating to construction that may be imposed on the foundations. Provide and install reinforcing steel in all foundation components as required. Some additional structural reinforcing will be necessary as part of Tenant Improvements as items such as elevators and mechanical equipment are specified and located.
- (b) All columns, beams, joists, headers, or other framing members necessary to support the second (2nd) floors. The live load capacity for all suspended floors shall be not less than 75 P.S.F. Columns shall be steel box or pipe columns.

- (c) All columns, beams, joists, purlins, headers, or other framing member to support the roof and roofing membrane, or other additional loads that may be imposed such as roof top mechanical or electrical equipment, roof penthouses, screens or blinds, or any other loads relating to construction that may be imposed on the roof structure. Columns shall be steel box or pipe columns. Some additional structural reinforcing will be necessary as part of Tenant Improvements as items such as elevators and mechanical equipment are specified and located.
- (d) Five inch (5") thick concrete slab on grade (1st floor) with welded wire mesh and any other reinforcing or structural connections that may be necessary or required.
- (e) Four inch (4") thick concrete suspended floor with actual decking (2nd floor) with welded wire mesh and any other reinforcing or structural connections that may be necessary or required.
- (f) Concrete exterior walls that enclose the perimeter of the buildings, with steel reinforcing and structural connections that may be necessary or required.
- (g) All exterior glass and glazing with painted or anodized aluminum frames. Glass to be clear or tinted as appropriate to the esthetic design of the buildings. All exterior doors with door closer, locking devices and all other hardware necessary or required for proper functioning.
- (h) Wood panel roof system to support the roof membrane and any other loads that may be imposed by the installation of rooftop mechanical or electrical equipment.
- (i) Three (3) ply built up roofing with cap sheet and all flashings by Owens-Corning, John Manville, or equal.
- (j) Exterior painting of all concrete with Tex-Coat or Kel-Tex textural paint. All caulking of exterior concrete in preparation for painting.
- (k) Skylights as shown on shell design development drawings.
- (l) Rooftop penthouses, enclosures or blinds to conceal from view mechanical or other equipment installed on the roofs. Enclosures or blinds shall be constructed so as not to restrict the required airflow necessary for the 100% efficient and proper operation of roof mounted equipment. The cost of penhouses (other than the skylighted penthouse shown on the shell drawings for Buildings 1, 3 and 4) will be shared equally by Landlord and Tenant.

- (m) One (1) secondary stairway per building with second (2nd) floor stair opening framed out and metal pan stair installed complete with concrete fill. Stairwell to be rough framed with no finish.

2. Plumbing

- (a) Underground sanitary sewer laterals connected to the city sewer main in the street and piped into each building and under the concrete slab on grade for the length of the buildings. Main waste lines under the slabs will be in as close proximity as possible to the building restroom locations.
- (b) Domestic water mains connected to the city water main in the street and stubbed up through the slab on grade into the buildings. Stub in locations will be carefully considered to assure concealment of these mains for future routing to rest rooms or other locations. Water mains to each building shall be not less than 3" in size.
- (c) Roof drain leaders piped and connected to the site storm drainage system.
- (d) Gas lines connected to the city or public utility mains and run to gas meters adjacent to, and in close proximity to each building. Gas mains and meters will be sufficiently sized to accommodate each building's heating and hot water requirements.

3. Heating, Ventilating and Air Conditioning

Landlord shall provide the work described in this paragraph 3 during the Shell Construction working closely with the Tenant to avoid reworking the Shell Construction to accommodate the Tenant Improvements. The cost shall be a part of the Tenant Improvement Allowance unless expressly identified otherwise herein.

- (a) All structural requirements to support the conceptually proposed rooftop VAV package unit systems for the heating, ventilating and cooling of the buildings.
- (b) All roof openings, curbs, dunnage, and any other supports or anchors necessary to accept the placement of built up VAV package units on the roof.

- (c) All second (2nd) floor shaftways and floor penetrations to accommodate supply and return ductwork from built up package units on the roof that will be serving the first (1st) floor areas.
- (d) All penhouses, enclosures, or blinds to conceal built up package roof top units from view. Roof top equipment shall not be visible from any location on the building site not shall it be visible from any location on the Xerox Palo Alto Research Center site.

4. Electrical

- (a) All primary electrical service to each building that is complete including underground conduit, wire feeders, transformers, and transformer pads. Underground conduits for secondary feeders from transformer pads into each building's main switchgear electrical room. The electrical characteristics of the secondary side of transformers shall be 277/480 Volt, 3 Phase and the rated capacity of each transformer for each building shall be:

Building No. 1	2400 AMPS*
Building No. 2	1000 AMPS
Building No. 3	1200 AMPS
Building No. 4	1200 AMPS
Building No. 5	1000 AMPS

\* If the service is upgraded, the City of Palo Alto may require bus duct (at this writing we believe the cut off is 3200 AMPS). This cost is not included as a shell cost.

Underground conduit for both primary and secondary feeders and transformer pavs shall be sized to accept wire feeders that would increase the above rated transformer capacities, if transformers were replaced, by 50%.

- (b) Project meter(s), and panel(s) for site lighting and landscaping may be set in conjunction with Tenant electrical service. Include all costs associated with service tie in and distribution.

- (c) Underground conduit from the street to each building via telephone trunk line service by Pacific Telephone. Conduit to each building shall be not less than 4". (Underground loop system.)
- (d) Building conduit interconnections with four 4" conduits to each building at their closest point and rainwater leader location.
- (e) All parking lot and landscape lighting to include fixtures, underground conduit, wire, distribution panel and controller. All exterior lighting shall be a complete and functioning system except for power to building shell exterior lights.
- (f) An electrically operated landscape irrigation controller that is a complete and functioning system.
- (g) Underground conduit from each building to the main fire protection system shut off valve (PIV) for installation of security alarm wiring.
- (h) All other electrical work that may be necessary for site requirements outside the building perimeter walls.

5. Fire Protection (Sprinklers)

A complete and fully functional overhead system distributed throughout the first (1st) and second (2nd) floors of each building. The systems shall be classified ordinary hazard group II, and have a density rating not less than .18/3000.

6. Sitework

- (a) All work outside the building perimeter walls shall be considered site work for the building shells and shall include grading, paving, landscaping, landscape irrigation, storm drainage, utility service laterals, curbs, gutters, sidewalks, specialty paving, retaining walls, planter boxes, parking lot and landscape lighting, other exterior lighting, and any other work necessary on the site to obtain approvals and permits for construction.
- (b) Paving section for automobile parking will be 2 1/2" asphalt over 8" class II aggregate base. Paving for truck access and docks will be 3" asphalt over 10" aggregate base. Subgrade to receive aggregate base and asphalt paving shall be well compacted and properly pitched to assure sub-drainage system.

- (c) All parking lot striping to include handicap space and signage.
- (d) Underground site storm drainage system shall be connected to the city storm system main.

7. Other Shell Work and/or Requirements

- (a) All connection charges, fees, assessment or any other costs to connect any utility serving the site or buildings. Utilities to be connected shall include but not be limited to: Sanitary sewer, storm drainage, gas service, electric service, fire sprinkler mains, domestic water mains, conduit for telephone service, or any other utility or service.
- (b) Landlord in the preparation of its shell plans shall indicate on the plans the preferred location of all building core requirements including but not limited to restrooms with fixtures to meet codes, janitor closets, stairs and stairwells, elevators, main electrical switchgear rooms, rooms for telephone cable entry and equipment, and building main corridor routing to all points of building entry or egress. The selection of preferred locations for the core requirements shall be made on the basis that each building shall have multi-tenant occupancy. Tenant in its space analysis and preparation of the Design Development Drawings for Tenant Improvements will endeavor to design to the Landlords preferred core arrangement. Tenant, in the preparation of its Design Development Drawings for Tenant Improvements may make rearrangements to the Landlords preferred core arrangement in order to maximize its utilization of rented space. Landlord agrees that Tenant has the right to make such rearrangements and further agrees that the final approved Design Development Drawings for Tenant Improvements shall govern the core arrangements and placement during construction.
- (c) Landlord's demolition and removal of the existing building on the site shall be complete to the extent that no debris or obstructions shall be encountered during construction of the tenant improvements. Any debris or obstructions in excess of one half cubic foot that are encountered during tenant improvement construction shall be demolished and/or removed and will be deemed a shell cost.

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**Exhibit B**  
**Subleased Premises**

[Site Plan]

**Exhibit C**  
**Subleased Premises**  
**Maintenance and Janitorial Service Schedule**

Sublandlord shall cause the following maintenance and janitorial tasks to be performed in and to the Subleased Premises and the Building with the following frequency:

<u>Task</u>	<u>Daily</u>	<u>Weekly</u>	<u>Monthly</u>	<u>Annually</u>
Trash Removal	x			
Floor mopping	x			
High/Low dusting		x		
Carpet vacuuming	x			
Interior Glass Cleaning				x
Exterior Glass Cleaning				
Vent/Register Cleaning				x
Light Fixture Cleaning				x
Exterior Policing	x			
Parking Lot Policing		x		
Parking lot sweeping		x		
Parking lot scrubbing				2x
Restroom Detailing	x			
Conference Room Detailing		x		
Carpet spot removal			x	
Carpet Bonnet scrubbing				x
Carpet Extracting				x
Floor Burnishing				x
Shower scrubbing		x		
Floor Finish Restoration				4x
Floor Stripping				x
New Floor Finish				x
Grounds Keeping	x			



**Exhibit D**  
**Initial Alterations**  
**3400 Hillview, Building 2, First Floor**

Sublandlord hereby approves the following initial improvements by Subtenant to be performed, at Subtenant's cost, in and to the Subleased Premises after the Commencement Date:

1. Remove non-load-bearing wall between Room 21132 and Room 21134 to create larger space.
2. Infill door to Room 21132.
3. Install vinyl flooring in Rooms 21132, 21134 and 21204.
4. Replace built-in cabinetry in Room 21204 (kitchen) with new casework.
5. Remove all existing wall-mounted shelving, whiteboards and signage. Patch walls and paint over existing wallpaper.
6. Install carpet over existing vinyl flooring in Rooms 21325 and 21334.
7. Install card readers at front and rear entrances to the Subleased Premises.
8. Exchange doors and door hardware as needed for security purposes. Hardware will be keyed to the Building's master key in the event of an emergency.
9. Add electrical and data outlets as needed within rooms.
10. Pull new data/phone cables where needed.
11. Install electrical and data cabling in Room 21325 over or under the carpet system.
12. Install new interior signage.
13. Replace carpeting in Rooms 21106 and 21218.
14. Clean all existing remaining carpeting.
15. Install freestanding furniture, wall-mounted cabinets, and whiteboards in the Subleased Premises offices.

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**16.** No alterations scheduled for Rooms 21106, 21218, and 21127 at this time. Both entrance doors to the Subleased Premises will be secured for information technology and facility access only.

**Exhibit E**  
**Letter of Credit**

THIS DRAFT IS FOR DISCUSSION PURPOSES ONLY.  
IT WILL BECOME AN INTEGRAL PART OF AND MUST BE ATTACHED TO  
**SILICON VALLEY BANK** APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY  
APPLICANT: **JAZZ PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_  
(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).  
DATED: \_\_\_\_\_, 20\_\_

BENEFICIARY:

**XEROX CORPORATION**  
800 LONG RIDGE ROAD  
STAMFORD, CONNECTICUT 06904

ATTN: **CRE&GS LEASE ADMINISTRATION**

AS "SUBLANDLORD"

APPLICANT:

**JAZZ PHARMACEUTICALS, INC.**  
3180 PORTER DRIVE  
PALO ALTO, CA 94304

AS "SUBTENANT"

AMOUNT: **US\$85,000.00** (EIGHTY-FIVE THOUSAND AND NO/100 U.S. DOLLARS)  
EXPIRATION DATE: **NOVEMBER 1, 2008**  
LOCATION: **SANTA CLARA, CALIFORNIA**

LADIES AND GENTLEMEN:

WE HEREBY ESTABLISH OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_ IN YOUR FAVOR. THIS LETTER OF CREDIT IS AVAILABLE BY SIGHT PAYMENT WITH OURSELVES ONLY AGAINST PRESENTATION AT THIS OFFICE OF THE FOLLOWING DOCUMENTS:

1. THE ORIGINAL OF THIS LETTER OF CREDIT AND ALL AMENDMENT (S), IF ANY.
2. YOUR SIGHT DRAFT DRAWN ON US IN THE FORM ATTACHED HERETO AS **EXHIBIT "A"**.
3. A DATED CERTIFICATION PURPORTEDLY SIGNED BY AN AUTHORIZED OFFICER OR REPRESENTATIVE OF THE BENEFICIARY, FOLLOWED BY HIS/HER PRINTED NAME AND DESIGNATED TITLE, STATING EITHER OF THE FOLLOWING:
  - (A.) ""AN EVENT OF DEFAULT (AS DEFINED IN THE SUBLEASE DATED AS OF FEBRUARY 25, 2007 AND AS AMENDED FROM TIME TO TIME) HAS OCCURRED BY JAZZ PHARMACEUTICALS, INC. AS SUBTENANT UNDER THAT CERTAIN SUBLEASE AGREEMENT BY AND BETWEEN SUBTENANT, AND BENEFICIARY, AS SUBLANDLORD. FURTHERMORE THIS IS TO CERTIFY THAT IF REQUIRED BY THE TERMS OF THE SUBLEASE, SUBLANDLORD HAS GIVEN WRITTEN

PAGE 1

DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust

\_\_\_\_\_  
CLIENT'S SIGNATURE(S)

March 2, 2007

\_\_\_\_\_  
DATE

(NOTE: AN AUTHORIZED SIGNATORY FOR THE CLIENT MUST AFFIX HIS/HER SIGNATURE AND DATE EACH PAGE OF THIS DRAFT. IT MUST THEN BE ATTACHED TO AND FORM PART OF THE LC APPLICATION TO SIGNIFY THEIR AND BENEFICIARY'S AGREEMENT /APPROVAL OF THIS DRAFT.)

THIS DRAFT IS FOR DISCUSSION PURPOSES ONLY.  
IT WILL BECOME AN INTEGRAL PART OF AND MUST BE ATTACHED TO  
**SILICON VALLEY BANK APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY APPLICANT: JAZZ  
PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_

(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).

DATED: \_\_\_\_\_, 20\_\_

NOTICE TO SUBTENANT TO CURE THE DEFAULT AND SUCH DEFAULT HAS NOT BEEN CURED UP TO THIS DATE OF DRAWING UNDER THIS LETTER OF CREDIT AND ALL APPLICABLE CURE PERIODS (IF ANY) HAVE EXPIRED; AND AS A RESULT THEREOF SUBLANDLORD IS AUTHORIZED TO NOW DRAW DOWN ON THE LETTER OF CREDIT."

OR

- (B.) "WITHIN THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE OF THIS LETTER OF CREDIT BENEFICIARY HAS NOT RECEIVED AN EXTENSION AT LEAST FOR ONE YEAR TO THE EXISTING LETTER OF CREDIT OR A REPLACEMENT LETTER OF CREDIT SATISFACTORY TO THE BENEFICIARY."

THE SUBLEASE AGREEMENT MENTIONED ABOVE IS FOR IDENTIFICATION PURPOSES ONLY AND IS NOT INTENDED THAT SAID SUBLEASE AGREEMENT BE INCORPORATED HEREIN OR FORM PART OF THIS LETTER OF CREDIT.

PARTIAL AND MULTIPLE DRAWINGS ARE ALLOWED. IN THE EVENT BENEFICIARY ELECTS TO DRAW UPON THIS LETTER OF CREDIT FOR LESS THAN THE FULL STATED AMOUNT HEREOF. THE AMOUNT AVAILABLE UNDER THIS LETTER OF CREDIT WILL BE REDUCED BY THE AMOUNT OF ANY PARTIAL DRAWINGS HEREUNDER.

THIS LETTER OF CREDIT MUST ACCOMPANY ANY DRAWINGS HEREUNDER FOR ENDORSEMENT OF THE DRAWING AMOUNT AND WILL BE RETURNED TO THE BENEFICIARY UNLESS IT IS FULLY UTILIZED.

WE AGREE THAT WE SHALL HAVE NO DUTY OR RIGHT TO INQUIRE AS TO THE BASIS UPON WHICH BENEFICIARY HAS DETERMINED THAT THE AMOUNT IS DUE AND OWING OR HAS DETERMINED TO PRESENT TO US ANY DRAFT UNDER THIS LETTER OF CREDIT, AND THE PRESENTATION OF SUCH DRAFT IN STRICT COMPLIANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT, SHALL AUTOMATICALLY RESULT IN PAYMENT TO THE BENEFICIARY.

THIS LETTER OF CREDIT SHALL BE AUTOMATICALLY EXTENDED FOR AN ADDITIONAL PERIOD OF ONE YEAR, WITHOUT AMENDMENT, FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE UNLESS AT LEAST **SIXTY (60)** DAYS PRIOR TO THE THEN CURRENT EXPIRATION DATE WE NOTIFY YOU BY REGISTERED MAIL/OVERNIGHT COURIER SERVICE AT THE ABOVE ADDRESS (OR SUCH OTHER ADDRESS AS YOU MAY DESIGNATE TO US IN WRITING FROM TIME TO TIME) THAT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND THE CURRENT EXPIRATION DATE. BUT IN ANY EVENT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND **JUNE 30, 2009**, WHICH SHALL BE THE FINAL EXPIRATION DATE OF THIS LETTER OF CREDIT.

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DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust

CLIENT'S SIGNATURE(S)

March 2, 2007

DATE

(NOTE: AN AUTHORIZED SIGNATORY FOR THE CLIENT MUST AFFIX HIS/HER SIGNATURE AND DATE EACH PAGE OF THIS DRAFT. IT MUST THEN BE ATTACHED TO AND FORM PART OF THE LC APPLICATION TO SIGNIFY THEIR AND BENEFICIARY'S AGREEMENT /APPROVAL OF THIS DRAFT.)

THIS DRAFT IS FOR DISCUSSION PURPOSES ONLY  
IT WILL BECOME AN INTEGRAL PART OF AND MUST BE ATTACHED TO  
**SILICON VALLEY BANK** APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY  
APPLICANT: **JAZZ PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_

(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).

DATED: \_\_\_\_\_, 20\_\_

THE DATE THIS LETTER OF CREDIT EXPIRES IN ACCORDANCE WITH THE ABOVE PROVISION IS THE "FINAL EXPIRATION DATE". UPON THE OCCURRENCE OF THE FINAL EXPIRATION DATE THIS LETTER OF CREDIT SHALL FULLY AND FINALLY EXPIRE AND NO PRESENTATIONS MADE UNDER THIS LETTER OF CREDIT AFTER SUCH DATE WILL BE HONORED.

THIS LETTER OF CREDIT IS TRANSFERABLE ONE OR MORE TIMES, BUT IN EACH INSTANCE ONLY TO A SINGLE BENEFICIARY AS TRANSFEREE AND ONLY UP TO THE THEN AVAILABLE AMOUNT IN FAVOR OF ANY NOMINATED TRANSFEREE THAT IS THE SUCCESSOR IN INTEREST TO BENEFICIARY ("TRANSFEREE"), ASSUMING SUCH TRANSFER TO SUCH TRANSFEREE WOULD BE IN COMPLIANCE WITH THEN APPLICABLE LAW AND REGULATION, INCLUDING BUT NOT LIMITED TO THE REGULATIONS OF THE U.S. DEPARTMENT OF TREASURY AND U.S. DEPARTMENT OF COMMERCE. AT THE TIME OF TRANSFER, THE ORIGINAL LETTER OF CREDIT AND ORIGINAL AMENDMENT(S), IF ANY, MUST BE SURRENDERED TO US AT OUR ADDRESS INDICATED IN THIS LETTER OF CREDIT TOGETHER WITH OUR LETTER OF TRANSFER DOCUMENTATION AS PER ATTACHED **EXHIBIT "B"** DULY EXECUTED AND ACCOMPANIED BY THE ORIGINAL LETTER OF CREDIT AND ALL AMENDMENT(S), IF ANY. BENEFICIARY SHALL PAY OUR TRANSFER FEE OF 1/4% OF 1% OF THE TRANSFER AMOUNT (MINIMUM US\$250.00) UNDER THIS LETTER OF CREDIT. ANY REQUEST FOR TRANSFER WILL BE EFFECTED BY US SUBJECT TO THE ABOVE CONDITIONS. ANY TRANSFER OF THIS LETTER OF CREDIT MAY NOT CHANGE THE PLACE OR DATE OF EXPIRATION OF THE LETTER OF CREDIT FROM OUR ABOVE SPECIFIED OFFICE. EACH TRANSFER SHALL BE EVIDENCED BY OUR ENDORSEMENT ON THE REVERSE OF THE LETTER OF CREDIT AND WE SHALL FORWARD THE ORIGINAL OF THE LETTER OF CREDIT SO ENDORSED TO THE TRANSFEREE.

DRAFT(S) AND DOCUMENTS MUST INDICATE THE NUMBER AND DATE OF THIS LETTER OF CREDIT.

DOCUMENTS MUST BE DELIVERED TO US DURING REGULAR BUSINESS HOURS ON A BUSINESS DAY OR FORWARDED TO US BY OVERNIGHT DELIVERY SERVICE TO: SILICON VALLEY BANK, 3003 TASMAN DRIVE, 2<sup>ND</sup> FLOOR, MAIL SORT HF210, SANTA CLARA, CALIFORNIA 95054, ATTENTION: GLOBAL FINANCIAL SERVICES – STANDBY LETTER OF CREDIT DEPARTMENT (THE "BANK'S OFFICE").

AS USED HEREIN, THE TERM "BUSINESS DAY" MEANS A WEEKDAY OTHER THAN A BANK HOLIDY (I.E. A HOLIDAY OBSERVED BY THE FEDERAL RESERVE SYSTEM OR OTHERWISE GENERALLY OBSERVED BY BANKS IN SANTA CLARA). NOTWITHSTANDING ANY PROVISION TO THE CONTRARY IN THE UCP (AS HEREINAFTER DEFINED), IF THE EXPIRATION DATE OR THE FINAL EXPIRATION DATE IS NOT A BUSINESS DAY THEN SUCH

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DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust

\_\_\_\_\_  
CLIENT'S SIGNATURE(S)

March 2, 2007

\_\_\_\_\_  
DATE

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**SILICON VALLEY BANK** APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY  
APPLICANT: **JAZZ PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_  
(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).  
DATED: \_\_\_\_\_, 20\_\_

DATE SHALL BE AUTOMATICALLY EXTENDED TO THE NEXT SUCCEEDING DATE WHICH IS A BUSINESS DAY.

WE HEREBY ENGAGE WITH YOU THAT DRAFT(S) DRAWN AND/OR DOCUMENTS PRESENTED UNDER AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT SHALL BE DULY HONORED UPON PRESENTATION TO SILICON VALLEY BANK, IF PRESENTED ON OR BEFORE THE EXPIRATION DATE OF THIS CREDIT.

IF ANY INSTRUCTIONS ACCOMPANYING A DRAWING UNDER THIS LETTER OF CREDIT REQUEST THAT PAYMENT IS TO BE MADE BY TRANSFER TO YOUR ACCOUNT WITH ANOTHER BANK, WE WILL ONLY EFFECT SUCH PAYMENT BY FED WIRE TO A U.S. REGULATED BANK, AND WE AND/OR SUCH OTHER BANK MAY RELY ON AN ACCOUNT NUMBER SPECIFIED IN SUCH INSTRUCTIONS EVEN IF THE NUMBER IDENTIFIES A PERSON OR ENTITY DIFFERENT FROM THE INTENDED PAYEE.

THIS LETTER OF CREDIT IS SUBJECT TO THE UNIFORM CUSTOMS AND PRACTICE FOR DOCUMENTARY CREDITS (1993 REVISION), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 500, (THE "UCP").

**SILICON VALLEY BANK,**

\_\_\_\_\_  
AUTHORIZED SIGNATURE

\_\_\_\_\_  
AUTHORIZED SIGNATURE

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DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust

\_\_\_\_\_  
CLIENT'S SIGNATURE(S)

March 2, 2007

\_\_\_\_\_  
DATE

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**SILICON VALLEY BANK** APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY APPLICANT: **JAZZ  
PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_  
(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).  
DATED: \_\_\_\_\_, 20\_\_

**EXHIBIT "A"**

**SIGHT DRAFT/BILL OF EXCHANGE**

DATE: \_\_\_\_\_ REF. NO. \_\_\_\_\_

AT SIGHT OF THIS BILL OF EXCHANGE

PAY TO THE ORDER OF \_\_\_\_\_ US\$ \_\_\_\_\_  
U.S. DOLLARS \_\_\_\_\_

"DRAWN UNDER **SILICON VALLEY BANK**, SANTA CLARA, CALIFORNIA, IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER NO. **SVBSF** \_\_\_\_\_ DATED \_\_\_\_\_, 20\_\_"

TO: **SILICON VALLEY BANK**  
3003 TASMAN DRIVE  
SANTA CLARA, CA 95054

\_\_\_\_\_  
[INSERT NAME OF BENEFICIARY]

\_\_\_\_\_  
**Authorized Signature**

**GUIDELINES TO PREPARE THE SIGHT DRAFT OR BILL OF EXCHANGE:**

1. DATE INSERT ISSUANCE DATE OF DRAFT OR BILL OF EXCHANGE.
2. REF. NO. INSERT YOUR REFERENCE NUMBER IF ANY.
3. PAY TO THE ORDER OF: INSERT NAME OF BENEFICIARY
4. US\$ INSERT AMOUNT OF DRAWING IN NUMERALS/FIGURES.
5. U.S. DOLLARS INSERT AMOUNT OF DRAWING IN WORDS.
6. LETTER OF CREDIT NUMBER INSERT THE LAST DIGITS OF OUR STANDBY L/C NUMBER THAT PERTAINS TO THE DRAWING.
7. DATED INSERT THE ISSUANCE DATE OF OUR STANDBY L/C.

NOTE: BENEFICIARY SHOULD ENDORSE THE BACK OF THE SIGHT DRAFT OR BILL OF EXCHANGE AS YOU WOULD A CHECK.

IF YOU NEED FURTHER ASSISTANCE IN COMPLETING THIS SIGHT DRAFT OR BILL OF EXCHANGE, PLEASE CALL OUR L/C PAYMENT SECTION AND ASK FOR: **EFRAIN TUVILLA** AT (408) 654-6349 OR **ALICE DALUZ** AT (408) 654-7120.

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DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust \_\_\_\_\_  
CLIENT'S SIGNATURE(S)

March 2, 2007  
DATE

(NOTE: AN AUTHORIZED SIGNATORY FOR THE CLIENT MUST AFFIX HIS/HER SIGNATURE AND DATE EACH PAGE OF THIS DRAFT. IT MUST THEN BE ATTACHED TO AND FORM PART OF THE LC APPLICATION TO SIGNIFY THEIR AND BENEFICIARY'S AGREEMENT/APPROVAL OF THIS DRAFT.)

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**SILICON VALLEY BANK** APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY APPLICANT: **JAZZ  
PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_  
(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).  
DATED: \_\_\_\_\_, 20\_\_

**EXHIBIT "B"**

DATE:

TO: **SILICON VALLEY BANK**  
3003 TASMAN DRIVE  
SANTA CLARA, CA 95054

ATTENTION: GLOBAL FINANCIAL SERVICES

RE: SILICON VALLEY BANK, SANTA CLARA, CALIFORNIA  
IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_  
DATED \_\_\_\_\_, 20\_\_ AMOUNT: US\$ \_\_\_\_\_.

GENTLEMEN:

FOR VALUE RECEIVED, THE UNDERSIGNED BEING A DULY AUTHORIZED REPRESENTATIVE OR OFFICER OF THE BENEFICIARY  
("BENEFICIARY") HEREBY IRREVOCABLY TRANSFERS TO:

\_\_\_\_\_  
(NAME OF TRANSFEREE)

\_\_\_\_\_  
(ADDRESS)

("TRANSFEREE") ALL RIGHTS OF THE BENEFICIARY TO DRAW UNDER THE ABOVE LETTER OF CREDIT UP TO ITS AVAILABLE AMOUNT AS  
SHOWN ABOVE AS OF THE DATE OF THIS TRANSFER.

BY THIS TRANSFER, ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY IN SUCH LETTER OF CREDIT ARE TRANSFERRED TO THE  
TRANSFEREE. TRANSFEREE SHALL HAVE THE SOLE RIGHTS AS BENEFICIARY THEREOF, INCLUDING SOLE RIGHTS RELATING TO ANY  
AMENDMENTS, WHETHER INCREASES OR EXTENSIONS OR OTHER AMENDMENTS, AND WHETHER NOW EXISTING OR HEREAFTER  
MADE. ALL AMENDMENTS ARE TO BE ADVISED DIRECTLY TO THE TRANSFEREE WITHOUT NECESSITY OF ANY CONSENT OF OR NOTICE  
TO THE UNDERSIGNED BENEFICIARY.

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DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust

\_\_\_\_\_  
CLIENT'S SIGNATURE(S)

March 2, 2007

\_\_\_\_\_  
DATE

(NOTE: AN AUTHORIZED SIGNATORY FOR THE CLIENT MUST AFFIX HIS/HER SIGNATURE AND DATE EACH PAGE OF THIS DRAFT. IT MUST  
THEN BE ATTACHED TO AND FORM PART OF THE LC APPLICATION TO SIGNIFY THEIR AND BENEFICIARY'S AGREEMENT APPROVAL OF  
THIS DRAFT.)



THIS DRAFT IS FOR DISCUSSION PURPOSES ONLY.  
IT WILL BECOME AN INTEGRAL PART OF AND MUST BE ATTACHED TO  
**SILICON VALLEY BANK** APPLICATION FOR STANDBY LETTER OF CREDIT WHEN APPROVED FOR ISSUANCE BY  
APPLICANT: **JAZZ PHARMACEUTICALS, INC.**

IRREVOCABLE STANDBY LETTER OF CREDIT NO. **SVBSF** \_\_\_\_\_  
(THE LC NO. AND THE ISSUANCE DATE WILL BE INSERTED BY SVB AT TIME OF ISSUANCE OF THE LC).  
DATED: \_\_\_\_\_, 20\_\_

THE ORIGINAL OF SUCH LETTER OF CREDIT IS RETURNED HERewith, AND WE ASK YOU TO ENDORSE THE TRANSFER ON THE REVERSE THEREOF, AND FORWARD IT DIRECTLY TO THE TRANSFEREE WITH YOUR CUSTOMARY NOTICE OF TRANSFER.

SINCERELY,

\_\_\_\_\_  
(BENEFICIARY'S NAME)

\_\_\_\_\_  
(SIGNATURE OF BENEFICIARY)

\_\_\_\_\_  
(PRINTED NAME AND TITLE)

SIGNATURE AUTHENTICATED

THE NAME(S) TITLE(S), AND SIGNATURE(S) CONFORM TO THAT/THOSE ON FILE WITH US FOR THE COMPANY AND THE SIGNATURE(S) IS/ARE AUTHORIZED TO EXECUTE THIS INSTRUMENT.

WE FURTHER CONFIRM THAT THE COMPANY HAS BEEN IDENTIFIED APPLYING THE APPROPRIATE DUE DILIGENCE AND ENHANCED DUE DILIGENCE AS REQUIRED BY THE BANK SECRECY ACT AND ALL ITS SUBSEQUENT AMENDMENTS.

\_\_\_\_\_  
(NAME OF BANK)

\_\_\_\_\_  
(ADDRESS OF BANK)

\_\_\_\_\_  
(CITY, STATE, ZIP CODE)

\_\_\_\_\_  
(AUTHORIZED SIGNATURE)

\_\_\_\_\_  
(PRINTED NAME AND TITLE)

\_\_\_\_\_  
(TELEPHONE NUMBER)

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DRAFT LANGUAGE APPROVED FOR ISSUANCE BY: **JAZZ PHARMACEUTICALS, INC.**

/s/ Matthew K. Fust \_\_\_\_\_

CLIENT'S SIGNATURE(S)

March 2, 2007

DATE

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**Exhibit F**  
**Fitness Center Agreement**

I, \_\_\_\_\_, am a full-time employee of Jazz Pharmaceuticals, Inc. at its offices located at 3400 Hillview Avenue , Palo Alto, CA.

I understand that so long as I am a full-time employee of Jazz Pharmaceuticals and my principal place of employment is at 3400 Hillview Avenue., Palo Alto, and I pay the charges paid by all other members of the Health Club, I may use the Health Club located at 3400 Hillview Building 1, subject to my compliance with the written rules, regulation and hours of operation of the Health Club as they may be established from time to time by Xerox Corporation who is the Health Club operator.

In consideration for being permitted to use the Health Club, I, for myself, my spouse, my heirs, executors, administrators and assigns hereby waive, release and discharge Xerox Corporation, its subsidiaries, affiliated companies, its officers, directors, employees and agents (each such person and entity individually, and all such persons and entities collectively referred to herein as the "Operator") from any and all claims and causes of action of any nature whatsoever including, without limitation, any claims and causes of action related to bodily injury, death or property damage which I have or may ever have against Operator relating to or arising out of my use of the Health Club or on account of first aid, treatment or service rendered to me during my use of the Health Club.

I acknowledge that I fully understand that I should consult my personal physician, before commencing any type of exercise or physical fitness program, and that nothing that has or will be said or done by Operator, my employer or any of their employees or representatives, is meant or intended as a substitute for consultation with my physician.

I expressly agree that this Agreement is intended to be construed as broad and as inclusive as permitted by the applicable laws of the State of California and if any portion of this Agreement is held invalid or unenforceable, I acknowledge and agree that the balance shall, notwithstanding, continue in full legal force and effect.

I HAVE CAREFULLY READ AND FULLY UNDERSTAND THE ABOVE CONDITIONS OF MY PARTICIPATION IN PHYSICAL FITNESS AND RELATED ACTIVITIES AT THE HEALTH CLUB.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_



Chadwick L. Mills  
(650) 843-5654  
cmills@cooley.com

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March 27, 2007

Via EDGAR and Courier

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
100 F Street NE  
Washington, DC 20549  
Attn: Mary K. Fraser, Esq.

**RE: Jazz Pharmaceuticals, Inc.  
Amendment No. 1 to the Registration Statement on Form S-1  
Registration No. 333-141164**

Ladies and Gentlemen:

On behalf of Jazz Pharmaceuticals, Inc. (the "**Registrant**"), we are transmitting for filing Amendment No. 1 (the "**Amendment**") to the Registration Statement on Form S-1, File No. 333-141164 (the "**Registration Statement**"). The Amendment is being filed solely for the purpose of (i) amending "Part II—Item 16. Exhibits and Financial Statement Schedules" and "Part II—Exhibit Index" of the Registration Statement and (ii) filing therewith Exhibits 10.30 through 10.53 (the "**Exhibits**"). In connection with the filing of the Amendment, we have submitted, on behalf of the Registrant, a confidential treatment request in paper format to the U.S. Securities and Exchange Commission (the "**Commission**") with respect to the omitted portions of the Exhibits pursuant to Rule 406 promulgated under the Securities Act of 1933, as amended.

In connection with the filing of the Amendment, we are forwarding a courtesy package in paper format to the staff of the Commission, in care of Ms. Mary K. Fraser, consisting of (i) a copy this letter, (ii) two (2) clean copies, including one set of Exhibits, of the Amendment and (iii) two (2) copies of the Amendment marked to show changes from the initial filing of the Registration Statement with the Commission on March 9, 2007.

Please direct any questions or comments regarding this filing to me at (650) 843-5654 or John M. Geschke at (650) 843-5757.

Sincerely,

/s/ CHADWICK L. MILLS

Chadwick L. Mills

cc: Matthew K. Fust, Jazz Pharmaceuticals, Inc.  
Carol A. Gamble, Esq., Jazz Pharmaceuticals, Inc.  
P.J. Honerkamp, Esq., Jazz Pharmaceuticals, Inc.  
Michael Nordtvedt, Esq., Davis Polk & Wardwell  
John M. Geschke, Esq., Cooley Godward Kronish LLP

FIVE PALO ALTO SQUARE, 3000 EL CAMINO REAL, PALO ALTO, CA 94306-2155 T: (650) 843-5000 F: (650) 849-7400 WWW.COOLEY.COM