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

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**FORM 10-Q**

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(Mark One)

**Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2010

or

**Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from            to

Commission File Number: 001-33500

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**JAZZ PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

05-0563787  
(I.R.S. Employer  
Identification No.)

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)

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

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

As of April 30, 2010, 31,539,444 shares of the registrant's Common Stock, \$.0001 par value, were outstanding.

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**JAZZ PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2010**  
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In this report, “Jazz Pharmaceuticals,” “we,” “us,” and “our” refer to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries.

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Xyrem® (sodium oxybate) oral solution; Luvox CR® (fluvoxamine maleate) Extended-Release Capsules; and Luvox® (fluvoxamine). This report also includes other trademarks, service marks, and trade names of other companies.

## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements.

**JAZZ PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(In thousands)**  
**(Unaudited)**

	<u>March 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,998	\$ 15,595
Restricted cash	951	2,988
Accounts receivable, net of allowances of \$278 and \$288 at March 31, 2010 and December 31, 2009, respectively	11,955	12,313
Inventories	3,522	3,426
Prepaid expenses	2,324	1,653
Other current assets	992	979
Total current assets	<u>38,742</u>	<u>36,954</u>
Property and equipment, net	909	1,124
Intangible assets, net	27,802	29,858
Goodwill	38,213	38,213
Other long-term assets	1,040	1,247
Total assets	<u>\$ 106,706</u>	<u>\$ 107,396</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Line of credit	\$ 7,840	\$ 9,399
Accounts payable	3,885	2,158
Accrued liabilities	15,368	14,296
Senior secured notes (including \$1,876 and \$1,355 pertaining to a related party at March 31, 2010 and December 31, 2009, respectively)	32,891	23,759
Purchased product rights liability	4,125	4,000
Liability under government settlement	2,594	2,954
Deferred revenue	3,208	2,675
Total current liabilities	<u>69,911</u>	<u>59,241</u>
Deferred rent	51	29
Deferred revenue, non-current	9,907	10,191
Purchased product rights liability, non-current	7,875	9,000
Liability under government settlement, non-current	8,142	10,658
Senior secured notes (including \$4,553 and \$5,196 pertaining to a related party at March 31, 2010 and December 31, 2009, respectively)	79,818	91,107
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Common stock	3	3
Additional paid-in capital	437,179	434,811
Accumulated deficit	<u>(506,180)</u>	<u>(507,644)</u>
Total stockholders' deficit	<u>(68,998)</u>	<u>(72,830)</u>
Total liabilities and stockholders' deficit	<u>\$ 106,706</u>	<u>\$ 107,396</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**JAZZ PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except per share amounts)**  
**(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Revenues:</b>		
Product sales, net	\$ 34,283	\$ 21,319
Royalties	605	472
Contract revenues	285	285
Total revenues	<u>35,173</u>	<u>22,076</u>
<b>Operating expenses:</b>		
Cost of product sales (excluding amortization of acquired developed technology)	2,882	1,943
Research and development	6,215	11,408
Selling, general and administrative	16,790	14,216
Intangible asset amortization	2,057	1,732
Total operating expenses	<u>27,944</u>	<u>29,299</u>
Income (loss) from operations	7,229	(7,223)
Interest income	2	21
Interest expense (including \$315 and \$320 for the three months ended March 31, 2010 and 2009, respectively, pertaining to a related party)	(5,767)	(5,794)
Other income	—	8
Net income (loss)	<u>\$ 1,464</u>	<u>\$ (12,988)</u>
<b>Net income (loss) per share:</b>		
Basic	<u>\$ 0.05</u>	<u>\$ (0.45)</u>
Diluted	<u>\$ 0.04</u>	<u>\$ (0.45)</u>
<b>Weighted-average common shares used in computing net income (loss) per share:</b>		
Basic	<u>31,412</u>	<u>28,968</u>
Diluted	<u>34,926</u>	<u>28,968</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**JAZZ PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**  
**(Unaudited)**

	Three Months Ended	
	March 31,	
	2010	2009
<b>Operating activities</b>		
Net income (loss)	\$ 1,464	\$(12,988)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	301	370
Amortization of intangible assets	2,057	1,732
Loss on disposal of property and equipment	—	9
Stock-based compensation expense	1,832	1,082
Senior secured notes, non-cash interest expense	1,050	535
Changes in assets and liabilities:		
Accounts receivable	358	(369)
Inventories	(71)	566
Prepaid expenses and other current assets	(685)	51
Other assets	—	(4)
Accounts payable	1,727	(1,182)
Accrued liabilities	1,072	(90)
Senior secured notes, accrued and unpaid interest	—	5,078
Deferred revenue	249	(2)
Deferred rent	22	—
Liability under government settlement	(2,876)	62
Net cash provided by (used in) operating activities	6,500	(5,150)
<b>Investing activities</b>		
Purchases of property and equipment	(86)	(5)
Purchase of product rights	(1,000)	(1,000)
Decrease in restricted cash and investments	2,037	1,138
Proceeds from maturities of marketable securities	—	1,004
Net cash provided by investing activities	951	1,137
<b>Financing activities</b>		
Repayment of senior secured notes	(3,000)	—
Proceeds from exercise of employee stock options	511	—
Net repayment of revolving line of credit	(1,559)	(3,875)
Net cash used in financing activities	(4,048)	(3,875)
Net increase (decrease) in cash and cash equivalents	3,403	(7,888)
Cash and cash equivalents, at beginning of period	15,595	24,903
Cash and cash equivalents, at end of period	<u>\$18,998</u>	<u>\$ 17,015</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Liability for purchase of product rights	\$ —	\$ 5,000

The accompanying notes are an integral part of these condensed consolidated financial statements.

**JAZZ PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**1. Summary of Significant Accounting Policies**

***Basis of Presentation***

These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2009. In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. Certain amounts related to deferred cost of goods sold in the condensed consolidated statements of cash flows for the three months ended March 31, 2009 have been reclassified to conform to the presentation for the three months ended March 31, 2010. The results for the three months ended March 31, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010 or for any other interim period or for any future period. The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. and our wholly-owned subsidiaries, Orphan Medical, LLC, or Orphan Medical, and JPI Commercial, LLC, or JPIC, after elimination of intercompany transactions and balances.

***Significant Risks and Uncertainties***

Although we generated a profit during the three months ended March 31, 2010, we have incurred significant losses since our inception and our accumulated deficit is \$506.2 million. As of March 31, 2010, we had cash and cash equivalents of \$19.0 million.

As of March 31, 2010, \$116.5 million principal amount of our senior secured notes, or Senior Notes, was outstanding. Pursuant to the agreement with the holders of our Senior Notes, we repaid principal of \$3.0 million on March 31, 2010 and are required to repay principal of \$6.0 million, \$9.0 million and \$10.0 million on June 30, 2010, September 30, 2010 and December 31, 2010, respectively. On March 31, 2011, a \$12.0 million principal payment is due on the Senior Notes, and the remaining balance on the Senior Notes (approximately \$79.5 million assuming no principal repayments in addition to those described above) is due in full on June 24, 2011. We believe our existing cash balances, cash we expect to generate from operations, and cash we expect to have available under our revolving bank line of credit, which was amended in April 2010 to extend the maturity date to May 2011, will be sufficient to fund our operations and meet all of our obligations through March 31, 2011. We do not expect our cash resources to be sufficient to cover all of the costs associated with the launch of our JZP-6 product candidate if approved by the U.S. Food and Drug Administration, or FDA, the cost of our Luvox CR Phase IV clinical trial commitments (if we are not released by the FDA from that commitment), any significant additional costs related to the development of our product candidates, and the repayment of the Senior Notes at maturity on June 24, 2011. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility with Kingsbridge Capital Limited. Our ability to raise additional funds and/or partner or license one or more of our product candidates will depend, among other things, on the capital markets and our financial condition and prospects at such time, with respect to partnering or licensing, and the interest of third parties in acquiring rights to our product candidates.

***Concentration of Credit Risks***

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents, restricted cash, marketable securities and accounts receivable. Our investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents and issuers of investments to the extent recorded on the balance sheet.

We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, and to international distributors in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, we have not experienced significant credit losses on our accounts receivable. Our five largest customers accounted for an aggregate of approximately 98% and 99% of gross accounts receivable as of March 31, 2010 and December 31, 2009, respectively.

**JAZZ PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**(Unaudited)**

**Concentration of Supply Risk**

We rely on certain sole suppliers for drug substance and certain sole manufacturing partners for each of our marketed products and certain of our product candidates. Earlier this year, Lonza, Inc., or Lonza, our current sole supplier of sodium oxybate, the active ingredient in both Xyrem and JZP-6, announced its intention to close the plant where it manufactures sodium oxybate and formally notified us in March 2010 that our agreement for the supply of sodium oxybate will terminate on December 31, 2011, at the end of its current term. Lonza is contractually obligated to supply our requirements of sodium oxybate through December 31, 2011. We recently entered into an agreement with a new supplier in order to help ensure that we have an uninterrupted supply of sodium oxybate. The FDA must approve our new supplier as a new supplier of sodium oxybate and our new supplier will need to obtain quota from the U.S. Drug Enforcement Administration, or DEA, in order to manufacture sodium oxybate for us. Lonza will also need to obtain additional DEA quota in 2010 in order to manufacture additional supplies for us for 2011. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our suppliers cannot obtain as much quota as is needed on a timely basis, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, intangible assets, inventory reserves, accrued expenses, and stock-based compensation. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

**Net Income (Loss) Per Common Share**

Basic and diluted net income (loss) per common share is computed using the weighted-average number of shares of common stock outstanding as follows (in thousands, except per share amounts):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Numerator:</b>		
Net income (loss)	\$ 1,464	\$ (12,988)
<b>Denominator:</b>		
Weighted-average common shares outstanding—basic	31,412	28,968
Dilutive effect of employee equity incentive and purchase plans	2,290	—
Dilutive effect of warrants	1,224	—
Weighted-average common shares outstanding—diluted	34,926	28,968
<b>Net income (loss) per share:</b>		
Basic	\$ 0.05	\$ (0.45)
Diluted	\$ 0.04	\$ (0.45)

Potentially dilutive common shares from employee stock plans and warrants are determined by applying the treasury stock method to the assumed exercise of warrants and stock options, the assumed vesting of outstanding restricted stock units, and the assumed issuance of common stock under our employee stock purchase plan. The following table represents the weighted-average shares of our common stock that were excluded from the computation of diluted net loss per share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Warrants to purchase common stock	—	3,300
Options to purchase common stock	2,590	5,186
Restricted stock units	—	48
Total	2,590	8,534

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**(Unaudited)**

**Recent Accounting Pronouncements**

In March 2010, the Financial Accounting Standards Board, or FASB, ratified authoritative guidance which amends the revenue recognition guidance related to milestone payments. The FASB concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Under the guidance, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. This guidance will not have an impact on our results of operations and financial position as we have applied the milestone method to previously received milestone payments as this method is an acceptable alternative applied in practice.

In October 2009, the FASB issued authoritative guidance which amends the revenue recognition guidance to require companies to allocate revenue in multiple-element arrangements based on an element's estimated selling price if vendor-specific or other third-party evidence is not available. The guidance is effective beginning January 1, 2011. Earlier adoption is permitted. We are currently evaluating the effect that the adoption of this guidance will have on our results of operations and financial position.

**2. Inventories**

The components of inventories were as follows (in thousands):

	March 31, 2010	December 31, 2009
Raw materials	\$ 863	\$ 1,245
Work in process	921	676
Finished goods	1,738	1,505
Total inventories	<u>\$ 3,522</u>	<u>\$ 3,426</u>

**3. Goodwill and Intangible Assets**

The gross carrying amount of goodwill was \$38.2 million at both March 31, 2010 and December 31, 2009. The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	March 31, 2010			December 31, 2009		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology—Xyrem	\$39,700	\$ (19,885)	\$19,815	\$39,700	\$ (18,842)	\$20,858
Developed technology—Luvox CR	9,700	(3,193)	6,507	9,700	(2,443)	7,257
Agreements not to compete	3,900	(3,718)	182	3,900	(3,523)	377
Trademarks	2,600	(1,302)	1,298	2,600	(1,234)	1,366
Total	<u>\$55,900</u>	<u>\$ (28,098)</u>	<u>\$27,802</u>	<u>\$55,900</u>	<u>\$ (26,042)</u>	<u>\$29,858</u>

Based on intangible assets recorded as of March 31, 2010, and assuming the underlying assets will not be impaired in the future and that we will not change the expected lives of the assets, future amortization costs per year for our existing intangible assets other than goodwill as of March 31, 2010 were estimated as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Estimated Amortization Expense</u>
2010 (remaining portion)	\$ 5,768
2011	7,448
2012	5,696
2013	4,445
2014	4,445



**JAZZ PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**(Unaudited)**

**4. Fair Value Measurement**

Available-for-sale investments consisted of the following as of March 31, 2010 and December 31, 2009 (in thousands):

	March 31, 2010			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Money market funds	\$ 5,073	\$ —	\$ —	\$ 5,073
Total	\$ 5,073	\$ —	\$ —	\$ 5,073
				<b>March 31, 2010</b>
Available-for-sale investments				\$ 5,073
Cash				13,925
Restricted cash				951
Total				\$ 19,949
				<b>March 31, 2010</b>
<u>Reported as</u>				
Amounts classified as cash and cash equivalents				\$ 18,998
Amounts classified as restricted cash				951
Total				\$ 19,949

	December 31, 2009			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Money market funds	\$ 5,072	\$ —	\$ —	\$ 5,072
Total	\$ 5,072	\$ —	\$ —	\$ 5,072
				<b>December 31, 2009</b>
Available-for-sale investments				\$ 5,072
Cash				10,523
Restricted cash				2,988
Total				\$ 18,583
				<b>December 31, 2009</b>
<u>Reported as</u>				
Amounts classified as cash and cash equivalents				\$ 15,595
Amounts classified as restricted cash				2,988
Total				\$ 18,583

Since inception, there have been no significant realized gains or losses on cash equivalents or marketable securities.

## JAZZ PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)  
(Unaudited)

The following table summarizes, by major security type, our available-for-sale investments that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	March 31, 2010		December 31, 2009	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Estimated Fair Value
Money market funds	\$ 5,073	\$ 5,073	\$ 5,072	\$ 5,072
Total	\$ 5,073	\$ 5,073	\$ 5,072	\$ 5,072

As of March 31, 2010, the carrying amount of the \$116.5 million principal amount of Senior Notes was \$112.7 million and the estimated fair value was \$120.5 million. As of December 31, 2009, the carrying amount of the \$119.5 million principal amount of Senior Notes was \$114.9 million and the estimated fair value was \$123.6 million. The fair value was estimated using a discounted cash flow analysis based on our estimated incremental borrowing rates for similar types of borrowing arrangements.

## 5. Debt and Financing Obligations

### Senior Secured Notes

We refer to the agreement governing all of the Senior Notes as the Senior Note Agreement, which we amended in November 2009. Under the terms of the amended Senior Note Agreement we repaid principal of \$3.0 million on March 31, 2010 and are required to repay principal of \$6.0 million, \$9.0 million, \$10.0 million and \$12.0 million on June 30, 2010, September 30, 2010, December 31, 2010 and March 31, 2011, respectively, without a prepayment penalty. The principal amount of \$79.5 million remaining after giving effect to the required quarterly payments is due on June 24, 2011 if not paid earlier. Under the terms of the amended Senior Note Agreement, we are also required to pay a \$500,000 fee on the maturity date or upon earlier repayment in full of the Senior Notes. Under the amended Senior Note Agreement, in the event of default or if we prepay the Senior Notes before they are due or upon acceleration of the Senior Notes following a change in control, we are obligated to pay a prepayment penalty, which was 8.3% as of March 31, 2010 and reduces ratably to zero through June 24, 2011.

The \$116.5 million principal amount of Senior Notes was recorded net of a debt discount of \$3.8 million as of March 31, 2010. The current portion of the carrying amount of the Senior Notes was \$32.9 million as of March 31, 2010. Interest expense associated with the Senior Notes is recorded using the interest method and includes non-cash interest related to the debt discount and debt issuance costs. The effective interest rate on the Senior Notes subsequent to the amendment of the Senior Note Agreement in November 2009 was 21.2%.

### Revolving Bank Line of Credit

Under our revolving bank line of credit agreement, subject to certain limitations, we may borrow up to 75% of eligible accounts receivable with a maximum borrowing of \$15.0 million. Borrowings under the revolving bank line of credit are secured by a first priority security interest in our accounts receivable and inventory and bear interest at a variable rate. As of March 31, 2010 and December 31, 2009, \$7.8 million and \$9.4 million, respectively, were outstanding under the revolving bank line of credit. These amounts bore interest at 6.5% of the eligible accounts receivable financed at both March 31, 2010 and December 31, 2009, respectively. The amended agreement provides for a minimum monthly interest payment of \$14,000 and a collateral monitoring fee up to 0.15% per month on the outstanding principal amount. In April 2010, we amended our revolving bank line of credit agreement to extend the maturity date to May 2011.

## 6. Common Stock

### Stock Option Exercises

We issued 283,273 shares of common stock as a result of stock option exercises during the three months ended March 31, 2010 for proceeds of \$511,000.

**JAZZ PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**(Unaudited)**

**7. Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) and all changes in stockholders' deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. For the three months ended March 31, 2010, comprehensive income was equal to net income. The difference between comprehensive loss and net loss during the three months ended March 31, 2009 represented the change in unrealized gains/losses on available-for-sale securities and was not significant.

**8. Segment Information**

We have determined that we operate in one business segment, which is the development and commercialization of pharmaceutical products.

The following table presents a summary of product sales, net (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Xyrem	\$ 28,745	\$ 17,719
Luvox CR	5,538	3,600
Total	<u>\$ 34,283</u>	<u>\$ 21,319</u>

The following table presents a summary of total revenues including net product sales, royalties and contract revenues attributed to domestic and foreign sources (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
United States	\$ 34,062	\$ 21,321
Europe	1,106	750
All other	5	5
Total	<u>\$ 35,173</u>	<u>\$ 22,076</u>

The following table presents a summary of total revenues from significant customers as a percentage of our total revenues:

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Express Scripts	81%	80%

**9. Stock-Based Compensation**

Stock-based compensation expense related to stock options, restricted stock units, shares of common stock credited to each director's phantom stock account under our directors deferred compensation plan, and stock awards under our employee stock purchase plan was as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Selling, general and administrative	\$ 1,321	\$ 732
Research and development	465	314
Cost of product sales	46	36
Total stock-based compensation expense	<u>\$ 1,832</u>	<u>\$ 1,082</u>

Employee stock-based compensation costs of \$71,000 and \$46,000 as of March 31, 2010 and December 31, 2009, respectively, were capitalized as a component of inventory and included in the condensed consolidated balance sheets.

**JAZZ PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**(Unaudited)**

**Stock Options**

During the three months ended March 31, 2010 and 2009, we granted options to employees to purchase 1,258,000 and 2,453,000 shares of common stock, respectively. The weighted-average grant date fair value per share of options granted during the three months ended March 31, 2010 and 2009 was \$8.29 and \$0.95, respectively. The fair value of options granted was estimated at the grant date using the Black–Scholes option pricing model with the following assumptions:

	<u>Three Months Ended March 31,</u>	
	<u>2010</u>	<u>2009</u>
Weighted-average volatility	84%	92%
Weighted-average expected term (years)	6.1	6.1
Range of risk-free rates	2.8%	1.8-2.3%
Expected dividend yield	0.0%	0.0%

**10. Income Tax Expense**

During the three months ended March 31, 2010, our effective income tax rate was 0%. This rate was lower than the federal statutory rate of 35% due to our application of federal net operating loss carryforwards to offset both regular taxable income and alternative minimum taxable income, and reflects our utilization of deferred state tax benefits.

**11. Commitments and Contingencies****Indemnification**

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations.

We have agreed to indemnify our officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we have not recognized any liabilities relating to these obligations as of March 31, 2010 and December 31, 2009. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

**Legal Proceedings**

In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated new drug application, or ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. We have not been informed as to the timing or status of the FDA's review of either party's filing, or whether either filer has complied with FDA requirements for proving bioequivalence. Actavis' Paragraph IV Certification alleges that U.S. Patent No. 7,465,462, or the 462 patent, which is owned by Elan Pharma International Limited, or Elan, and licensed to us, is invalid on the basis that the inventions claimed therein were obvious. Anchen's Paragraph IV Certification alleges that the 462 patent will not be infringed by Anchen's manufacture, use or sale of the generic product for which the ANDA was submitted and that the 462 patent is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, we and Elan, as plaintiffs, filed a lawsuit against Actavis, Anchen, and Anchen Incorporated, the parent of Anchen, in the United States District Court for the District of Delaware claiming infringement of the 462 patent by the defendants in response to the Paragraph IV Certifications filed by Actavis and Anchen. We are seeking a permanent injunction that prevents Actavis and Anchen from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. On October 27, 2009, Anchen and Anchen Incorporated filed a motion to dismiss for lack of jurisdiction. On November 16, 2009, we and Elan filed our response. On January 14, 2010, we and Elan filed a motion to enjoin the later-filed duplicative proceeding in the United States District Court for the Central District of California referenced below. On February 1, 2010, Anchen and Anchen Incorporated responded. The court has not ruled on either motion and no hearing dates are scheduled. We cannot predict or determine the outcome of this matter.

**JAZZ PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**(Unaudited)**

On October 14, 2009, we and Elan, as plaintiffs, also filed a lawsuit in the United States District Court for the Central District of California against Anchen and Anchen Incorporated claiming infringement of the 462 patent based upon Anchen's Paragraph IV Certification. The plaintiffs are seeking a permanent injunction that prevents Anchen from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. Since Anchen is incorporated in California, the additional protective lawsuit was filed in California in an effort to both ensure jurisdiction over Anchen in the event that the United States District Court for the District of Delaware finds that it does not have jurisdiction over Anchen in Delaware, and to prevent the FDA from approving the ANDA filed by Anchen until the earliest of 30 months following the filing of the lawsuit, expiration of the 462 patent, settlement of the lawsuit or a decision in the infringement case that is favorable to Anchen in California. On December 14, 2009, the court in the United States District Court for the Central District of California held a scheduling conference to discuss the status of the case and the Delaware case. Following the conference and submission of scheduling proposals by both parties, the court scheduled a patent claim construction or *Markman* hearing for June 1, 2010. Following a ruling in that hearing, the court indicated that it will set the remaining schedule following consultation with both parties. We cannot predict or determine the outcome of this matter.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

***Phase IV Clinical Trials***

The FDA approval of Luvox CR included a commitment for two Phase IV clinical trials, one in adolescent patients with social anxiety disorder, or SAD, and one a long-term duration of effect study in patients with SAD. The cost of these Phase IV clinical trials is significant. We have been in discussions with the FDA concerning our Phase IV commitment, and as a result of these discussions, in April 2010, we submitted a labeling supplement to the new drug application, or NDA, for Luvox CR to remove the SAD indication from the label. We expect that the FDA's review of this supplement could take up to six months or more. Based upon our discussions with the FDA, we believe that if the labeling supplement is approved by the FDA, we would then be released from the Phase IV clinical study commitment.

**Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described in Part II Item 1A “Risk Factors” included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations—see “Cautionary Note Regarding Forward-Looking Statements” that appears at the end of this discussion. These statements, like all statements in this report, speak only as of their date (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.*

**Overview**

We are a specialty pharmaceutical company that, since our inception, has focused on the development and commercialization of pharmaceutical products to meet important unmet medical needs in neurology and psychiatry. With our JZP-6 product candidate for the treatment of fibromyalgia, for which we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in December 2009, and which NDA was filed by the FDA in February 2010, we expanded our development activities to include rheumatology and pain management. We currently market two products: Xyrem (sodium oxybate) and Luvox CR (fluvoxamine maleate). We are building a portfolio of products through a combination of internal development, acquisition and in-licensing activities, and we utilize our specialty sales force to promote our products in our target markets. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes our two marketed products, our late-stage JZP-6 product candidate, and several product candidates in various stages of clinical development.

Our marketed products and late-stage product candidate are:

- *Xyrem® (sodium oxybate) oral solution.* Xyrem is the only product approved by the FDA for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. We promote Xyrem in the United States for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 14 countries in Europe.
- *Luvox CR® (fluvoxamine maleate) Extended-Release Capsules.* Once-daily Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder, or OCD, and social anxiety disorder, or SAD, in February 2008. We began promoting Luvox CR through our specialty sales force in April 2008. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the United States.
- *JZP-6 (sodium oxybate).* We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. Our development program includes two completed Phase III pivotal clinical trials and a long-term safety trial that is expected to be completed in mid-2010. In November 2008 and June 2009, we announced positive top-line results from our first and second Phase III pivotal clinical trials, respectively. The two randomized, double-blind, placebo-controlled studies demonstrated that sodium oxybate significantly decreased pain and fatigue, and improved daily function and patient global impression of change, in patients with fibromyalgia. We submitted an NDA for JZP-6 in December 2009 and the NDA was filed by the FDA in February 2010 with a Prescription Drug User Fee Act action date of October 11, 2010. If our NDA is approved by the FDA, we expect to market JZP-6 in the United States to physicians who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnership with third parties. We have licensed to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States in exchange for development funding, commercial milestones and royalties.

Our other product candidates in clinical development are oral tablet forms of sodium oxybate; JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens; JZP-4 (elpetrigine), being developed for the treatment of epilepsy and bipolar disorder; and JZP-7 (ropinirole gel), being developed for the treatment of restless legs syndrome. We are seeking development partners for JZP-4, JZP-7 and JZP-8, and we do not anticipate significant spending on these programs in the near term unless and until we partner a program or otherwise obtain additional funding.

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Although we have incurred significant net losses since our inception, we reported both net income and cash generated from operations in our two most recent quarters. This improvement in our operating performance was due to a significant increase in revenue from product sales and a decrease in operating expenses. The increase in revenue from product sales was due primarily to increased product sales resulting primarily from price increases taken in 2009 and, to a lesser extent, increases in prescriptions. In May 2010, we increased the price of Xyrem by approximately 15%.

We believe our existing cash balances, cash we expect to generate from operations, and cash we expect to have available under our revolving bank line of credit, which was amended in April 2010 to extend the maturity date to May 2011, will be sufficient to fund our operations and meet all of our obligations through March 31, 2011. We do not expect our cash resources to be sufficient to cover all of the costs associated with the launch of our JZP-6 product candidate if approved by the FDA, the cost of our Luvox CR Phase IV clinical trial commitments (if we are not released by the FDA from that commitment), any significant additional costs related to the development of our product candidates and repayment of our senior secured notes, or Senior Notes, at maturity on June 24, 2011. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility with Kingsbridge Capital Limited, or Kingsbridge. Our ability to raise additional funds and/or partner or license one or more of our product candidates will depend, among other things, on the capital markets and our financial condition and prospects at such time and, with respect to partnering or licensing, the interest of third parties in acquiring rights to our product candidates. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses as well as other factors set forth in Part II Item 1A of this Quarterly Report on Form 10-Q under the heading “*We have a history of net losses, and, if we are to grow our business in the future, we will need to commit substantial resources, which could result in future losses*”. Our assumptions may prove to be wrong or other factors may adversely affect our business, and we could exhaust our available cash resources or be forced to reduce our expenses, which could have a material adverse effect on our business.

In July 2009, Xyrem’s orphan drug exclusivity for the treatment of cataplexy in patients with narcolepsy expired, and Xyrem’s orphan exclusivity for the excessive daytime sleepiness indication in patients with narcolepsy will expire in November 2012. We are currently involved in litigation relating to abbreviated new drug applications filed by two companies seeking to market generic versions of Luvox CR. If generic products were to be introduced for either or both of our products, our revenue from product sales would decline.

The FDA approval of Luvox CR included a commitment for two Phase IV clinical trials, one in adolescent patients with SAD and one a long-term duration of effect study in patients with SAD. The cost of these Phase IV clinical trials is significant. We have been in discussions with the FDA concerning the Phase IV commitment, and as a result of these discussions, in April 2010 we submitted a labeling supplement to the NDA for Luvox CR to remove the SAD indication from the label. We expect that the FDA’s review of this supplement could take up to six months or more. Based upon our discussions with the FDA, we believe that if the labeling supplement is approved by the FDA, we would be released from the Phase IV clinical study commitment. Based upon third party data available to us, we believe that the removal of the SAD indication from the label, if it occurs, will not have a significant negative impact on Luvox CR product sales.

Our discussions with the FDA, and our decision to submit a labeling supplement to the FDA, did not result from any new safety or efficacy issues for Luvox CR. Rather, in light of the small number of SAD patients being treated with Luvox CR, we were concerned that we would not be able to enroll a sufficient number of patients to complete the studies in a timely or reasonable fashion, if at all.

Lonza, Inc., or Lonza, our current sole supplier of sodium oxybate, the active ingredient in both Xyrem and JZP-6, formally notified us in March 2010 that our agreement for the supply of sodium oxybate will terminate on December 31, 2011, at the end of its current term, and that Lonza’s plan is to close the plant in which sodium oxybate is currently produced by the end of 2010. In April 2010, we entered into an agreement with a new supplier in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve our new supplier as a new supplier of sodium oxybate and our new supplier will need to obtain quota from the U.S. Drug Enforcement Administration, or DEA, in order to manufacture sodium oxybate for us. Lonza will also need to obtain additional DEA quota in 2010 in order to manufacture additional supplies for us for 2011. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process.

On March 24, 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Healthcare Reform Act, was signed into law. As a result of this new law, we expect to incur approximately \$1.0 million of additional rebates for Medicare and Medicaid patients for the remainder of 2010 which will reduce our net product sales in 2010. The Healthcare Reform Act contains a number of additional provisions that are expected to impact our business and operations. In general, it is too early to predict specifically all of the effects this recently enacted Health Reform Act and its implementation will have on our business. We will continue to evaluate the effect of this new law on our business and operations.

### **Critical Accounting Policies and Significant Estimates**

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with United States generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition, in particular related to our agreement with UCB, sales deductions for estimated specialty distributor and wholesaler fees, prompt payment discounts, Medicaid and TRICARE rebates, chargebacks, customer rebates, and royalties. Significant estimates and assumptions are also required to determine whether to capitalize intangible assets, the amortization periods for identifiable intangible assets, the potential impairment of goodwill and other intangible assets, the determination of excess and obsolete inventory reserves, stock-based compensation and accrued expenses. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. Although we believe our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2009. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.



**Results of Operations****Comparison of Three Months Ended March 31, 2010 and 2009**

	Three Months Ended March 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2010	2009 (In thousands)		
Product sales, net	\$34,283	\$ 21,319	\$ 12,964	61%
Xyrem	28,745	17,719	11,026	62%
Luvox CR	5,538	3,600	1,938	54%
Royalties	605	472	133	28%
Contract revenues	285	285	—	0%
Cost of product sales (excluding amortization of acquired developed technology)	2,882	1,943	939	48%
Research and development	6,215	11,408	(5,193)	(46)%
Selling, general and administrative	16,790	14,216	2,574	18%
Intangible asset amortization	2,057	1,732	325	19%
Interest income	2	21	(19)	(90)%
Interest expense	5,767	5,794	(27)	0%
Other income	—	8	(8)	N/A(1)

(1) Comparison to prior period is not meaningful.

**Product Sales, Net**

The increase in Xyrem product sales in the three months ended March 31, 2010 compared to the same period in 2009 was primarily due to the impact of price increases taken in 2009 and, to a lesser extent, a 5% increase in volume. Although Xyrem product sales increased in the three months ended March 31, 2010 compared to the same period in 2009, the rate of increase was lower than the rate of increase in the 2009 period. We expect Xyrem product sales in 2010 to be higher than in 2009 due primarily to price increases. Total Xyrem volume growth in 2009 compared to 2008 was 10%, and we expect to see continued volume growth in 2010 as compared to 2009 though at a more modest single digit rate.

The increase in Luvox CR product sales in the three months ended March 31, 2010 compared to the same period in 2009, was primarily due to increases in volume and, to a lesser extent, due to price increases. We market Luvox CR for the treatment of both OCD and SAD. In April 2010, we submitted to the FDA a labeling supplement to the NDA for Luvox CR to remove the SAD indication from the Luvox CR label. We believe that the removal of the SAD indication from the label, if it occurs, will not have a significant negative impact on Luvox CR product sales. We expect Luvox CR product sales in 2010 to be higher than in 2009 due primarily to increases in volume.

We are currently evaluating the impact of the recent Healthcare Reform Act. As a result of this new law, we expect to incur approximately \$1.0 million of additional rebates for Medicare and Medicaid patients for the remainder of 2010 which will reduce our net product sales in 2010.

**Royalties**

The increase in royalties in the three months ended March 31, 2010 compared to the same period in 2009 was entirely due to the increase in royalties we received under our agreement with UCB related to UCB's sales of Xyrem in territories outside of North America. We expect modest growth in royalty income in 2010 over 2009.

**Contract Revenues**

We recognized contract revenues of \$285,000 in both the three months ended March 31, 2010 and 2009 primarily related to previously deferred upfront payments under our agreement with UCB which are being recognized as contract revenues ratably through 2019, the expected performance period under our agreement with UCB.

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### *Cost of Product Sales*

The increase in cost of product sales in the three months ended March 31, 2010 compared to the same period in 2009 was due to our increased sales volumes. As a percentage of product sales, costs were 8.4% versus 9.1% for the same period in 2009. This improvement resulted primarily from price increases during 2009.

### *Research and Development Expenses*

Research and development costs were 46% lower in the three months ended March 31, 2010 compared to the same period in 2009 as we focused on the prosecution of our NDA for our JZP-6 product candidate, our ongoing safety study for JZP-6 which we expect to complete mid-year 2010, and development work on potential oral tablet forms of sodium oxybate, the active pharmaceutical ingredient in both Xyrem and JZP-6. As a result, our direct development costs decreased \$5.9 million in the three months ended March 31, 2010 compared to the same period in 2009 when we were actively conducting our second JZP-6 Phase III clinical trial and enrolling patients in the long-term safety study. Our direct development costs consist primarily of out-sourced study costs, including investigator payments and consulting fees, and do not include salaries and benefits or general administrative costs related to maintaining a research and development organization. Salaries and benefits expenses including stock-based compensation incurred in the research and development organization increased \$752,000 in the three months ended March 31, 2010 compared to the same period in 2009. We expect research and development spending in 2010 to be lower than 2009 and to continue to be focused primarily on prosecution of the JZP-6 NDA, completion of the JZP-6 safety study and development work on potential oral tablet forms of sodium oxybate. We do not anticipate significant development spending on our other pipeline programs in the near term unless and until we partner a program or otherwise obtain additional funding.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were 18% higher in the three months ended March 31, 2010 compared to the same period in 2009, due to pre-launch planning and preparation activities in the 2010 period related to our JZP-6 product candidate and to increases in salaries and benefits expenses including stock-based compensation. We expect that selling, general and administrative expenses will be higher in 2010 than in 2009, primarily as a result of pre-launch planning and preparation activities related to our JZP-6 product candidate.

### *Amortization of Intangible Assets*

Our intangible assets consist primarily of developed technology related to Xyrem and Luvox CR which are amortized on a straight-line basis over their estimated useful lives. Amortization costs in the three months ended March 31, 2010 were higher compared to the same period in 2009, primarily due to our reduction in the estimated useful life of the Luvox CR intangible asset in response to the filings in the third quarter of 2009 of two abbreviated new drug applications with the FDA by third parties seeking to market generic versions of Luvox CR.

### *Interest Income*

Interest income was not significant in the three months ended March 31, 2010 and 2009.

### *Interest Expense*

Interest expense relates primarily to interest on our Senior Notes and, to a small extent, interest on our liability under a government settlement. Interest on the Senior Notes is comprised of quarterly cash payments for interest, amortization of a debt discount related to warrants that were issued in conjunction with the Senior Notes and amortization of debt issuance costs. In 2010, we expect interest expense to decrease slightly compared with 2009 as we make required quarterly principal payments on the Senior Notes.

### **Liquidity and Capital Resources**

As of March 31, 2010, we had \$19.0 million of cash and cash equivalents, \$7.8 million borrowed under our revolving bank line of credit (the maximum amount available at that time) and \$116.5 million principal amount of Senior Notes outstanding. In the three months ended March 31, 2010, we reported both net income and cash generated from operations.

Under the terms of the amended agreement governing our Senior Notes we made a principal payment of \$3.0 million on March 31, 2010 and are required to make principal payments of \$6.0 million, \$9.0 million, \$10.0 million and \$12.0 million on June 30, 2010, September 30, 2010, December 31, 2010 and March 31, 2011, respectively, without a prepayment penalty. The remaining principal amount of \$79.5 million is due on June 24, 2011 unless it is earlier paid. We are also required to pay a \$500,000 fee to the holders of the Senior Notes on the maturity date of the Senior Notes, or upon earlier repayment in full of the Senior Notes. In the event of default or if we prepay the Senior Notes before they are due, we are obligated to pay a prepayment penalty which was 8.3% of the principal amount prepaid as of March 31, 2010 and reduces to zero ratably through June 24, 2011. Upon a change in control, the holders of the Senior Notes could accelerate payment of the Senior Notes and if accelerated, a prepayment penalty would be due. The holders of the Senior Notes have a security interest in all of our assets other than accounts receivable and inventory. The amended agreement also provides for certain restrictions on working capital borrowings, dividends and certain other payments and for certain minimum restricted cash balance requirements if our total net sales in any quarter are less than \$25.0 million.

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We believe our existing cash balances, cash we expect to generate from operations, and cash we expect to have available under our revolving bank line of credit, which was amended in April 2010 to extend the maturity date to May 2011, will be sufficient to fund our operations and meet all of our obligations through March 31, 2011. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses as well as the other factors set forth in Part II Item 1A of this Quarterly Report on Form 10-Q under the heading “*We have a history of net losses, and, if we are to grow our business in the future, we will need to commit substantial resources, which could result in future losses*”. Our assumptions may prove to be wrong or other factors may adversely affect our business, and we could exhaust our available cash resources or be forced to reduce our expenses, which could have a material adverse effect on our business. We do not expect our cash resources to be sufficient to cover all of the costs associated with the launch of our JZP-6 product candidate if approved by the FDA, the cost of our Luvox CR Phase IV clinical trial commitments (if we are not released by the FDA from that commitment), any significant additional costs related to the development of our product candidates and the repayment of the Senior Notes at maturity on June 24, 2011. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility with Kingsbridge. Our ability to raise additional funds and/or partner or license one or more of our product candidates will depend, among other things, on the capital markets and our financial condition and prospects at such time and, with respect to partnering or licensing, the interest of third parties in acquiring rights to our product candidates. We have an effective shelf registration statement on file with the Securities and Exchange Commission, or SEC, pursuant to which we could, subject to market conditions, publicly offer and sell approximately \$61.2 million of our debt and/or equity securities, provided that we continue to meet applicable SEC eligibility requirements to sell securities under the registration statement and subject to compliance with certain NASDAQ Stock Market rules relating to securities offerings.

We may seek to refinance our existing debt before it is due to lower the interest rate, extend the maturity date, or for other reasons. We may also seek to raise additional funds for general corporate purposes, including licensing or acquiring potential new product candidates, spending on our existing product candidates or spending related to launching JZP-6, if approved by the FDA. Refinancing or raising additional capital may be accomplished through one or more public or private debt or equity financings, collaborations, partnering arrangements or development financings. If we were to seek to incur new secured debt without repaying the Senior Notes in full, the consent of the holders of our Senior Notes would be required. Because the holders of the Senior Notes currently have a first priority security interest in all of our assets other than accounts receivable and inventory, they may be unwilling to consent to any transaction that limits their rights or impacts their security interest. If we raise funds through the issuance of debt securities, these securities would have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any equity financing would be dilutive to our stockholders. In addition, if we raise funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. If we raise funds through collaborations, partnering arrangements, or development financings, we may be required to relinquish, on terms that are not favorable to us, rights to some of our products or product candidates that we could have otherwise sought to develop or commercialize ourselves. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization of our products or product candidates. Our need to raise capital soon may require us to accept terms that may harm our business or be disadvantageous to our current stockholders.

The following table shows a summary of our cash flows for the periods indicated:

	Three Months Ended	
	March 31,	
	2010	2009
	(In thousands)	
Net cash provided by (used in) operating activities	\$ 6,500	\$(5,150)
Net cash provided by investing activities	951	1,137
Net cash used in financing activities	(4,048)	(3,875)
Net increase (decrease) in cash and cash equivalents	<u>\$ 3,403</u>	<u>\$(7,888)</u>

Net cash provided by (used in) operating activities during the three months ended March 31, 2010 and 2009, primarily reflected the net income (loss), adjusted for non-cash items including depreciation and amortization and stock-based compensation expense in addition to the change in working capital. Net cash provided by investing activities during the three months ended March 31, 2010 primarily related to the release of restricted cash partially offset by a payment for the purchase of rights to Luvox CR. Net cash provided by investing activities during the three months ended March 31, 2009 primarily related to the release of restricted cash and the maturity of an investment in a marketable security partially offset by a payment for the purchase of rights to Luvox CR. Net cash used in financing activities during the three months ended March 31, 2010 was attributable to a principal payment of \$3.0 million of our Senior Notes and a net repayment of our revolving bank line of credit, partially offset by proceeds from employee stock option exercises. Net cash used in financing activities during the three months ended March 31, 2009 was attributable to the repayment of our revolving bank line of credit.

### **Off-Balance Sheet Arrangements**

Since our inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

### **Cautionary Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q (including documents incorporated by reference) and other written and oral statements we make from time to time contain certain “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact they use words such as “should”, “expect”, “anticipate”, “estimate”, “target”, “may”, “project”, “guidance”, “intend”, “plan”, “believe” and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our goals, plans and projections regarding our financial position, results of operations, cash flows, market position, product development, clinical trials, product approvals, sales efforts, expenses, performance or results of current and anticipated products, the outcome of contingencies such as legal proceedings, and financial results, all of which are based on current expectations that involve inherent risks and uncertainties, including internal or external factors that could delay, divert or change any of them from time to time. We have included important factors in the cautionary statements included in this report, particularly under Part II Item 1A “Risk Factors”, that we believe could cause actual results to differ materially from any forward-looking statement.

Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved, and you are cautioned not to place undue reliance on such statements, which speak only as of the date made. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

During the three months ended March 31, 2010, there were no material changes to our market risk disclosures as set forth in “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2009.

**Item 4. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures.* We have carried out an evaluation, under the supervision, and with the participation of, management including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2010.

*Limitations on the Effectiveness of Controls.* A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

*Changes in Internal Control over Financial Reporting.* No changes in our internal control over financial reporting occurred during the three months ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1A. Risk Factors.

*We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes.*

*We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC.*

#### Risks Relating to Our Business

***We depend on sales of Xyrem and Luvox CR to generate the cash necessary to operate our business and to meet all of our ongoing financial obligations, and, if we are not able to maintain or increase sales of our products, it would have a material adverse effect on our business, financial condition, results of operations and growth prospects. \****

We depend on sales of Xyrem and Luvox CR to generate the cash necessary to operate our business and to meet all of our ongoing financial obligations, and our future plans assume that sales of our products will increase. Sales and prescriptions of Xyrem increased in 2008 and 2009; however, sales and prescriptions of Xyrem for the first quarter of 2010 were lower than sales and prescriptions for the fourth quarter of 2009. In addition, while Xyrem product sales increased in the three months ended March 31, 2010 compared to the same period in 2009, the rate of increase was lower than the rate of increase in the 2009 period. We expect the Xyrem sales volume growth rate in 2010 to be at a more modest rate than in 2009; however, we cannot assure you that Xyrem sales volume will grow. We increased the price of Xyrem during 2009, and we further increased the price in May 2010 by approximately 15%. We cannot assure you that these or future price increases have not or will not negatively affect Xyrem sales volumes. In July 2009, our orphan drug exclusivity for Xyrem for cataplexy in patients with narcolepsy expired and we cannot assure you that a generic equivalent will not be introduced for that indication.

If sales of Luvox CR do not increase as expected, they may not cover the payments due to Solvay under our license agreement for Luvox CR plus the cost to manufacture, market and sell the product. While we have been in discussions with the U.S. Food and Drug Administration, or FDA, concerning our Phase IV clinical study commitment, and as a result of these discussions, in April 2010 we submitted a labeling supplement to the new drug application, or NDA, for Luvox CR to remove the social anxiety disorder, or SAD, indication from the label, we cannot assure you that if the labeling supplement is approved by the FDA, we would be released from the Phase IV clinical study commitment. In addition, while we believe that the removal of the SAD indication from the Luvox CR label, if it occurs, will not have a significant negative impact on our Luvox CR product sales, such removal could nonetheless have a significant negative impact on our Luvox CR product sales. The cost of the Phase IV studies is significant, and we do not have sufficient funds to fulfill our Phase IV clinical trial commitment, repay our Senior Notes, fund our ongoing operations and launch JZP-6, if it is approved.

If prescriptions and revenue from sales of Xyrem and Luvox CR do not increase as expected, we may be required to reduce our operating expenses, decrease our efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***Our only product candidate currently in late-stage development is JZP-6 for the treatment of fibromyalgia, for which we submitted an NDA to the FDA in December 2009. Although we believe our completed Phase III pivotal clinical trials have shown JZP-6 to be safe and effective for the treatment of fibromyalgia, the FDA may not approve JZP-6 for marketing or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We are currently seeking approval from the FDA of JZP-6 for the treatment of fibromyalgia. Our development program for JZP-6 includes two completed Phase III pivotal clinical trials and a long-term safety trial that is expected to be completed in mid-2010. Although we received statistically significant positive results from both of our Phase III pivotal clinical trials and believe the results show JZP-6 to be safe and effective for the treatment of fibromyalgia, we do not know if the FDA will agree with our interpretation of the results of these trials or whether the FDA and other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia. Although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this active pharmaceutical ingredient for the treatment of fibromyalgia. Lyrica (pregabalin), marketed by Pfizer, Cymbalta (duloxetine), marketed by Eli Lilly, and Savella (milnacipran), marketed by Forest Laboratories, were approved by the FDA in June 2007, June 2008, and January 2009, respectively, for the treatment of fibromyalgia. With treatments for fibromyalgia already approved, the FDA may be less willing to approve JZP-6 for the treatment of fibromyalgia. None of these products has been approved by the European Medicines Agency, or EMA, for the treatment of fibromyalgia. A failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia patients could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA will likely require us to have a Risk Evaluation and Mitigation Strategy program, or REMS, which may be similar to the one we use for Xyrem. Under the current Xyrem REMS, Xyrem is distributed through a single central pharmacy. The central pharmacy maintains physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient receives materials concerning the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and obtains additional information by contacting the patient. The central pharmacy also speaks with the patient before it ships any Xyrem to the patient. The central pharmacy ships the product directly to the patient by a courier service, and the patient or his/her designee signs for the package. The initial shipment may only be for a one-month supply, and physicians may only prescribe up to six months of supply of Xyrem at one time.

The Xyrem REMS is labor intensive, complex and expensive to operate. Since Xyrem is currently prescribed for a relatively small number of patients, the Xyrem REMS does not prevent us from effectively supplying Xyrem to narcolepsy patients. However, significantly more patients are diagnosed with fibromyalgia, and if the same or a similar REMS is required for JZP-6, scale-up of the REMS could make it difficult for us to timely supply all of the patients who may be prescribed JZP-6 for the treatment of fibromyalgia. This could make JZP-6 less attractive to physicians and patients than other products that are currently, or that in the future may be, approved for the treatment of fibromyalgia, which could limit potential sales of JZP-6.

***We depend upon UCB Pharma Limited, or UCB, to market and promote Xyrem outside the United States, and we are dependent upon our collaboration with UCB for the development and potential commercialization of JZP-6 for the treatment of fibromyalgia in major markets outside of the United States.***

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the United States. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames we expect, or at all, our revenues would be adversely affected. In addition, under the terms of our collaboration with UCB, we granted UCB the exclusive right to commercialize JZP-6 for the treatment of fibromyalgia in the same territories in which UCB has the right to market and promote Xyrem for patients with narcolepsy. There are currently no approved fibromyalgia treatments in the European Union. In October 2008, April 2009 and July 2009 panels of European regulators recommended against approving Cymbalta, Lyrica and Savella, respectively, as treatments for fibromyalgia. We cannot be sure that the EMA will approve any treatment, or JZP-6 in particular, for fibromyalgia.

UCB has the right to terminate our collaboration on 12-months' notice (or less in certain circumstances), and UCB may terminate its rights to JZP-6 for the fibromyalgia indication on six-months' notice at any time prior to the receipt of marketing approval of JZP-6 for fibromyalgia in the European Union. If UCB terminates our collaboration or terminates its rights to JZP-6 for the fibromyalgia indication, we would need to find another party or parties to commercialize Xyrem and JZP-6 in UCB's territories. We may be unable to do this on acceptable terms, or at all, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

***We depend on one central pharmacy distributor for Xyrem sales in the United States, and the loss of that distributor or its failure to distribute Xyrem effectively would adversely affect sales of Xyrem.***

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under the Xyrem REMS is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, or Express Scripts, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem, and our sales, would be adversely affected. Changing central pharmacy distributors could take a significant amount of time. In addition, sodium oxybate, the active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. Any new central pharmacy would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem under the REMS approved by the FDA. If we change central pharmacies, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, and/or result in additional costs and expenses for us, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

***Our current and new suppliers of sodium oxybate and our product manufacturer for Xyrem and JZP-6 must obtain DEA quotas in order to supply us with Xyrem, JZP-6 and sodium oxybate, and these quotas may not be sufficient to satisfy our clinical and commercial needs.\****



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The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our current and new suppliers of sodium oxybate and our product manufacturer must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our suppliers' and product manufacturer's DEA quotas, our suppliers and product manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. The DEA has issued a quota for 2010 that is substantially the same as that issued for 2009 but that is less than the quota that we believe we will need to provide commercial supplies of Xyrem, support our development needs and prepare for the potential commercial launch of JZP-6. We and our suppliers have requested additional quota from the DEA for 2010, which, if it is not granted in a timely manner, could delay the potential commercial launch of JZP-6.

Lonza, Inc., or Lonza, currently our sole supplier of sodium oxybate, announced earlier this year that it is closing its U.S. facility where it manufactures sodium oxybate, and Lonza formally notified us in March 2010 that our agreement for the supply of sodium oxybate will terminate on December 31, 2011, at the end of its current term. As a result, we recently entered into an agreement with a new supplier of sodium oxybate. However, the FDA must approve our new supplier as a new supplier of sodium oxybate and our new supplier will need quota from the DEA in order to manufacture sodium oxybate. Lonza will also need to obtain additional DEA quota in 2010 in order to manufacture additional supplies for us for 2011. If we and our suppliers cannot obtain as much quota as is needed on a timely basis, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

***We depend on single source suppliers and manufacturers for each of our products and product candidates. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects.\****

We do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. Accordingly, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. The deterioration in worldwide economic conditions and the disruption to the credit and financial markets in the United States and worldwide may materially and adversely impact the financial position of our single source suppliers and manufacturers. If our suppliers and contract manufacturers are unable to obtain the necessary capital to operate their respective businesses or for other reasons, our suppliers and contract manufacturers may not be able to manufacture our products or product candidates without interruption, or may not comply with their obligations to us under our supply and manufacturing arrangements. We may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale depends upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a "prior approval supplement" and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem, JZP-6 or sodium oxybate, any new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem, sodium oxybate or, if approved, JZP-6 for the marketplace or for use in our clinical studies, or both.

Lonza is currently our sole supplier of sodium oxybate, the active pharmaceutical ingredient in Xyrem and, through Solvay Pharmaceuticals, Inc., or Solvay, our sole supplier of fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. We will need Lonza to build significant additional supplies of sodium oxybate before Lonza closes its plant, and, even if Lonza is able to obtain sufficient and timely DEA quota to manufacture additional inventory, we cannot assure you that Lonza will have the capacity to timely meet our requirements. We cannot assure you that we and any new suppliers or manufacturers, including our new supplier for sodium oxybate, will be able to complete all of the necessary validation and other activities prior to the time at which Lonza ceases manufacturing sodium oxybate for us or we run out of inventory. Any failure to obtain sufficient commercial and clinical quantities of sodium oxybate could have a material adverse effect on our business, financial condition, results of operations and growth prospects.



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Elan Pharma International Limited, or Elan, has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. In June 2001, Solvay's NDA for Luvox CR was withdrawn due to manufacturing difficulties. We cannot assure you that Elan will be able to continue to supply in a timely manner or at all our ongoing commercial needs of Luvox CR. Any failure of Elan to supply necessary quantities of Luvox CR could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's current Good Manufacturing Practices, or cGMP, requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. DEA regulations also govern facilities where controlled substances such as sodium oxybate are manufactured. Manufacturing facilities are subject to periodic unannounced inspection by the FDA, the DEA and other regulatory authorities, including state authorities. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

Due to FDA-mandated dating requirements, the limited market size for our approved products and DEA quotas relating to sodium oxybate, Xyrem and JZP-6, we are subject to complex manufacturing logistics and minimum order quantities that could result in excess inventory as determined under our accounting policy, unsalable inventory as a result of product expiring prior to use, and competition with others for manufacturing services when needed or expected. We have adopted a production planning program to assess and manage manufacturing logistics among the vendors supplying our requirements of active pharmaceutical ingredient, drug product and packaging; however, unexpected market requirements or problems with vendors' facilities, among other things, could result in shortages of one or more of our products for the marketplace or product candidates for use in our clinical studies, or both.

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. In addition, under our agreement with UCB, we are responsible for the supply of Xyrem and, if approved, JZP-6 to UCB. Our failure to meet our contractual obligations to supply UCB with adequate quantities of Xyrem and JZP-6 would result in lost revenues to us and, if material, could result in termination of our agreements by UCB.

***The commercial success of our products depends upon attaining market acceptance by physicians, patients, third party payors and the medical community.***

Even if our product candidates are approved for sale by the appropriate regulatory authorities, physicians may not prescribe our products, in which case we would not generate the revenues we anticipate. Market acceptance of any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved, including any potential additional restrictions placed upon the product in connection with its approval;
- prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

***A failure to prove that our product candidates are safe and effective in clinical trials would require us to discontinue their development, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.***

Significant additional research and development, financial resources and additional personnel will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. As a condition to regulatory approval, each product candidate must undergo extensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The clinical trials for a product candidate can cost between \$40 million and \$100 million, and potentially even more. If a product candidate fails at any stage of development, we will not be able to commercialize it and we will not receive any return on our investment from that product candidate.

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Clinical testing can take many years to complete, and failure can occur any time during the clinical trial process. In addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials. The completion of clinical trials for our product candidates may be delayed or halted for many reasons, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- regulators or institutional review boards may not authorize us to commence or continue a clinical trial;
- our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;
- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, including adverse events associated with product candidates;
- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- governmental or regulatory delays or changes in regulatory requirements, policies and guidelines;
- varying interpretation of data by the FDA or foreign regulatory agencies; and
- insufficient funds to complete the trials.

In addition, our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. Many of these companies have far greater financial and human resources than we do.

The FDA or foreign regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additional expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

***We rely on third parties to conduct clinical trials for our product candidates, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We design the clinical trials for our product candidates, but rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays.

Although we rely on third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. The FDA enforces good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our contract research organizations or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations. Our failure, or the failure of our contract manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

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If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates.

***We could be materially adversely affected if we or our products are subject to negative publicity. For example, sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of gamma hydroxybutyrate, or GHB, which has been a drug of abuse and may not be sold legally in the United States. If physicians and patients perceive Xyrem and JZP-6 to be the same as or similar to GHB, or if adverse effects become associated with our products, sales of our products could be adversely affected.***

From time to time, there is negative publicity about illicit GHB and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of GHB, Xyrem sometimes also receives (and it can be expected that JZP-6, if approved, could receive) negative mention in publicity relating to GHB. For the same reason, patients, physicians and regulators may view Xyrem and JZP-6 as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally (and may oppose the prescription and use of JZP-6) because of its connection to GHB. Xyrem's label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

***The investigation by the U.S. Attorney's Office for the Eastern District of New York concerning the sales and marketing of Xyrem creates additional compliance-related operating costs and could result in additional fines, penalties or other adverse consequences.***

In April 2006, we and our subsidiary, Orphan Medical, received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. We and Orphan Medical have settled this matter with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately \$20 million in civil and criminal payments is required to be paid in connection with this matter, of which \$1 million was paid in July 2007, \$2 million was paid in January 2008, \$2.5 million was paid in October 2009, and \$3 million was paid in January 2010; the remaining amount will be due over the next two years.

While we were not prosecuted, as part of the settlement, we entered into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services. That agreement requires us to maintain a comprehensive compliance program, and we will have additional ongoing compliance-related operating costs related to this compliance program and the corporate integrity agreement. In the event of an uncured material breach or deliberate violation, as the case may be, of the corporate integrity agreement or the other definitive settlement agreements we entered into, we could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

In addition, there is no assurance that we will not be subject to future investigations. Many pharmaceutical companies have announced government investigations of their sales and marketing practices for many of their products. Even with compliance training and a company culture of compliance, our current or future practices may nonetheless become the subject of an investigation. A number of laws, often referred to as "whistleblower" statutes, provide for financial rewards to employees and others for bringing to the attention of the government sales and marketing practices that the government views as illegal or fraudulent. The costs of investigating any claims, responding to subpoenas of investigators, and any resulting fines, can be significant and could divert the attention of our management from operating our business.

***Xyrem cannot be advertised in the same manner as competing products, which could limit sales.***

The FDA has required that Xyrem's label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, ads which mention the pharmaceutical brand name but not the indication or medical condition it treats. Provigil (modafinil) and Nuvigil (armodafinil), the only other products approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, do not have a boxed warning and can be advertised with reminder ads. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Unlike Xyrem, Provigil and Nuvigil were not approved under the FDA's Subpart H regulations and are not subject to the pre-review requirements. Accordingly, promotional materials for Provigil and Nuvigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

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Because JZP-6 contains the same active pharmaceutical ingredient as Xyrem, we anticipate that the label for JZP-6, if approved by the FDA, will also include a boxed warning. One of the products already approved by the FDA for the treatment of fibromyalgia is not, and future competing products may not be, subject to this restriction, and the boxed warning may negatively affect potential JZP-6 sales if competing products can be advertised directly to consumers.

### ***We face substantial competition from companies with greater resources than we have.***

With respect to all of our existing and future products, we may compete with companies selling or working to develop products that may be more effective, safer or less costly than our products. The markets for which we are developing products are competitive and include generic and branded products, some of which are marketed by major pharmaceutical companies that have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing and selling approved products than we do. While Xyrem is the only product approved by the FDA for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, or SSRIs, although none of these compounds has been approved by the FDA for the treatment of cataplexy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil and Nuvigil, the only other FDA-approved products for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Luvox CR is an SSRI, and SSRIs are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Six other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, and most of these products have generic equivalents. Generic products are generally sold at significantly lower prices than non-generic branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Four other products are currently approved by the FDA for the treatment of social anxiety disorder, and each of these products has generic equivalents.

We are seeking FDA approval of JZP-6 for the treatment of fibromyalgia. The FDA has approved Lyrica, marketed by Pfizer, Cymbalta, marketed by Eli Lilly, and Savella, marketed by Forest Laboratories, for the treatment of fibromyalgia. In clinical practice, a variety of other drugs are often prescribed to address individual symptoms of fibromyalgia, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants, even though those products are not specifically approved by the FDA for the treatment of fibromyalgia. These treatments, as well as other product candidates that may be approved for the treatment of fibromyalgia may be better accepted by physicians and patients. Thus, even if we are able to obtain and maintain FDA approval of JZP-6 for the treatment of fibromyalgia, JZP-6 may not result in significant commercial revenues for us.

JZP-6 contains the same active pharmaceutical ingredient as Xyrem. While we have not established the price we will charge for JZP-6 if it is approved by the FDA and launched, Xyrem is substantially more expensive than the products currently approved by the FDA for the treatment of fibromyalgia. If the price we charge for JZP-6 is substantially higher than the price of other products that are now or that may in the future be approved for the treatment of fibromyalgia, we cannot assure you that JZP-6 will be included on formularies, or at what level it might be included on formularies, or that there will not be managed care, government or insurance restrictions on its use. Any such restrictions could negatively affect the commercial potential of JZP-6.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with other large, established companies. Our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize generic or branded products that are safer or more effective, have fewer side effects or are less expensive than our products.

Many of our competitors have far greater financial resources and a larger number of personnel to market and sell their products than we do. Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from the sales of our products.

### ***If generic products that compete with any of our products are approved, sales of our products may be adversely affected.***

Our products are or may become subject to competition from generic equivalents if there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA had previously granted Xyrem orphan drug exclusivity in the United States for the treatment of cataplexy in patients with narcolepsy, but this exclusivity expired in July 2009, and other companies could possibly introduce generic equivalents of Xyrem for the cataplexy indication if they do not infringe our existing patents covering Xyrem. Although the FDA has granted orphan drug exclusivity for Xyrem until November 2012 for the treatment of excessive daytime sleepiness in patients with narcolepsy, prescriptions for Xyrem for the excessive daytime sleepiness in patients with narcolepsy indication, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that are granted approval for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or fibromyalgia.

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Although Xyrem, Luvox CR and JZP-6 are covered by patents that we own or license, it is possible that other companies could manufacture generic equivalents of Xyrem, JZP-6 and Luvox CR in ways that are not covered by the claims of our patents. In addition, patent protection is not available for the active pharmaceutical ingredient in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6.

In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated new drug application, or ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA for a generic version of Luvox CR. We and Elan have filed lawsuits in response to the Paragraph IV certifications. We cannot assure you that these lawsuits will prevent the introduction of generic products for any particular length of time, or at all.

After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product generally may be filled with the generic version at the pharmacy, resulting in a loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Generic competition often results in decreases in the prices at which branded products can be sold. In addition, legislation enacted in the United States allows for and, in a few instances in the absence of specific instructions from the prescribing physician, mandates the dispensing of generic products rather than branded products where a generic equivalent is available. Generic competition for our products earlier than expected, including as a result of FDA approval of ANDAs for generic versions of our products, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***We may not be able to successfully acquire, in-license or develop additional products or product candidates to grow our business.***

In order to grow our business, we will need to acquire, in-license or develop additional products and product candidates that we believe have significant commercial potential. Any growth through acquisitions or in-licensing will depend upon the continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions, and any growth through development will depend upon our obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development, obtain regulatory approval of and commercialize these product candidates. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition, in-licensing or development, or we may not have the financial resources necessary to pursue opportunities. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.

***We currently have a relatively small sales organization compared with most other pharmaceutical companies with marketed products. If our specialty sales force and sales organization is not appropriately sized to adequately promote our current and potential future products, the commercial opportunity for our products may be diminished.***

We have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. Our potential future commercial products, including JZP-6, may require expansion of our sales force and sales support organization, and we will need to commit significant additional funds, management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel.

Turnover in our sales force could also negatively affect sales of our products. If we elect to rely on third parties to sell our products in the United States, we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately size our sales force or collaborate with third parties to sell our products, our ability to generate revenues would be adversely affected.

***If we fail to retain key personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products.***

Our success depends in part on our continued ability to retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team and other key personnel. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry "key person" insurance. Any member of our executive management team and any other key employees may terminate his or her employment at any time without notice and without cause or good reason. For example, in early 2009, our then chief executive officer left the company.

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Competition for qualified personnel in the life sciences industry has historically been intense. If we need to hire additional personnel to expand our development, clinical and commercial activities, or to support those activities, we may not be able to attract and retain quality personnel on acceptable terms. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage our personnel resources effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

***Our offices are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could damage our facilities, which could adversely affect our operations.***

Our offices are located in the San Francisco Bay Area, near known earthquake fault zones and are therefore vulnerable to damage from earthquake. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. We are also vulnerable to damage from other disasters such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

### **Risks Related to Our Intellectual Property**

***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. In the case of Luvox CR, for example, Actavis' Paragraph IV Certification alleges that Elan's U.S. Patent No. 7,465,462, listed in the Orange Book, is invalid on the basis that the inventions claimed therein were obvious; Anchen's Paragraph IV Certification alleges that Elan's U.S. Patent No. 7,465,462, listed in the Orange Book, will not be infringed by Anchen's manufacture, use or sale of the generic product for which the ANDA was submitted and that the patent is invalid on the basis that the inventions claimed therein were obvious. The expiration date for the patent at issue is May 10, 2020. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.



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We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or commercialize, our products.***

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and foreign counterparts, and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. In October 2009, we and Elan filed lawsuits in response to the Paragraph IV certifications that we received from Actavis and Anchen. We cannot assure you that these lawsuits will be successful in stopping the infringement of our related patents, that the litigation will be cost effective, or that the litigation will have a satisfactory result for us.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Patent infringement lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing third party patent rights. In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;
- expend significant resources to redesign our products so they do not infringe others' patent rights, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

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The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the United States.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

### **Risks Related to Our Industry**

***The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates.***

The research, testing, manufacturing, selling and marketing of pharmaceutical products are subject to extensive regulation by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, generally of an NDA. An NDA must contain, among other things, data to demonstrate that the drug is safe and effective for its intended uses and that it will be manufactured to appropriate quality standards. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, untitled letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

In 2008, the FDA announced that, in light of staffing issues, it has given its managers discretion to miss Prescription Drug User Fee Act, or PDUFA, deadlines for completing reviews of NDAs. Although the FDA has since publicly expressed a recommitment to meeting PDUFA deadlines, it remains unclear whether and to what extent the FDA will adhere to PDUFA deadlines in the future. If the FDA were to miss a PDUFA deadline for JZP-6 or one of our other product candidates, delaying the approval and launch, the delay could have a material adverse effect on our business.

***Healthcare law and policy changes, including those based on recently enacted legislation, may impact our business in ways that we cannot currently predict and these changes could have a material adverse effect on our business and financial condition.\****

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the "Healthcare Reform Act. This law substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which become effective in 2011, may negatively affect our revenues and prospects for continued profitability in the future. For example, the Healthcare Reform Act imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will also be required to provide a 50% discount on branded prescription drugs sold to beneficiaries who fall within the donut hole. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and our ability to maintain or increase our product sales or successfully commercialize our product candidates, including JZP-6, or could limit or eliminate our future spending on development projects.



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In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep these costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on pharmaceutical companies such as ours. While in general it is too early to predict specifically what effect the recently enacted Health Reform Act and its implementation or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

***We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.***

We are subject to significant ongoing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products are, and any of our product candidates that may be approved by the FDA will be, subject to extensive and ongoing regulatory requirements. If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of previously unknown problems with any of our products in the United States or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers' facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits, including class action suits. The FDA and other governmental authorities also actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

We are also subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government health care programs. Our manufacturing partners are subject to many of the same requirements, which include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate, Xyrem and JZP-6. These statutes and regulations include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting identified common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid.

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Many pharmaceutical and other health care companies have been prosecuted under these laws for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government health care programs. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other health care companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we or any of our partners fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our or our partners' ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

***If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.\****

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. The minimum amount of the rebate for each unit of product is set by law at 23.1% of the average manufacturing price of that product, or if it is greater, the difference between the average manufacturing price and the best price we make available to any non-federal customer. The rebate also includes an additional amount if price increases exceed the rate of inflation. Under the Healthcare Reform Act enacted in March 2010, the Medicaid rebate increased to 23.1% from 15.0%, effective retroactively to January 1, 2010, and we cannot assure that there will not be additional increases in rebates or other costs and charges from government agencies.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services of our current average manufacturing price and best prices for the quarter. If we become aware that our reporting for prior quarters was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected average manufacturing price or best price for that quarter. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. In addition to retroactive rebates (and interest, if any), if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service's pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Service pricing program extends discounts comparable to the Medicaid rebates to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of poor patients and children.

***Reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.***

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR is competing in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products.

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. For example, a final rule published by the Department of Defense, or DoD, in March 2009 under the National Defense Authorization Act of 2008, established a program under which DoD requires rebates from pharmaceutical manufacturers on all prescriptions of covered prescription drugs filled under the TRICARE retail pharmacy program from January 28, 2008 forward, unless DoD agrees to a waiver or compromise of amounts due. Additionally, under the final rule, to remain eligible for inclusion on the DoD Uniform Formulary, a pharmaceutical manufacturer must enter into a pricing agreement under which it agrees to pay rebates to DoD on TRICARE retail pharmacy utilization on a prospective basis, and, in compliance with this rule, we entered into a pricing agreement with DoD in July 2009. These legislative and regulatory changes, including our entering into the pricing agreement with DoD, could impact our ability to maximize revenues in the Federal marketplace. Some of the proposals that have been made for additional legislative and regulatory changes include expanding the 340B drug pricing program to allow additional types of health care providers to purchase drugs at significant discounts and to require those discounts on inpatient drugs as well, increasing the minimum Medicaid drug rebate percentage, expanding Medicaid rebate liability to drugs purchased under Medicaid managed care contracts, increasing the Medicaid rebate on new formulations of existing drugs, and requiring Medicaid rebates to be paid on drugs provided to certain enrollees in the Medicare Part D prescription drug benefit.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

***Prescription drug importation from Canada and other countries could increase pricing pressure on our products and could decrease our revenues and profit margins.***

Under current U.S. law, there is a general prohibition on imports of unapproved drug products. The FDA has published internal guidance that sets forth the agency's enforcement priorities for imported drugs. Under this policy, the FDA allows its personnel to use their discretion in permitting entry into the United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permits pharmacists and wholesalers to import prescription drugs into the United States from Canada under specified circumstances. These additional import provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the United States to be imported or reimported to the United States from Canada, Europe and other countries. In addition, there have been indications that the current presidential administration is considering changing certain rules to make it easier to import drugs from other countries, and we cannot predict what, if any changes will happen. If these provisions or changes in the rules take effect, the volume of prescription drug imports from Canada and elsewhere could increase significantly and our products could face competition from lower priced imports.

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Even if these provisions do not take effect and alter current law, the volume of prescription drug imports from Canada and elsewhere could increase due to a variety of factors, including the further spread of internet pharmacies and actions by a number of state and local governments to facilitate Canadian and other imports. These imports may harm our business.

### ***Product liability and product recalls could harm our business.***

The development, manufacture, testing, marketing and sale of pharmaceutical products entail significant risk of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient's condition, serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. For example, studies and publications suggest that SSRIs, including the active pharmaceutical ingredient in Luvox CR and its immediate release formulation Luvox, may increase the risk of suicidal behavior in adults and adolescents. In addition, the current SSRI products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Side effects associated with SSRIs include sexual dysfunction, adverse drug interaction and risk of hypertension. Claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical companies to obtain. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation.

### ***Risks Relating to Our Financial Condition***

#### ***We have a substantial amount of secured debt, which matures in June 2011 and may adversely affect our ability to operate our business.***

As of March 31, 2010, our total consolidated indebtedness was \$124.3 million, \$116.5 million of which constituted secured indebtedness under our senior secured notes due in June 2011, or the Senior Notes, and \$7.8 million of which constituted secured indebtedness under our revolving line of credit with Silicon Valley Bank, or SVB. Pursuant to our revolving line of credit with SVB, we currently may borrow up to the lesser of 75% of eligible accounts receivable or \$15 million. Our substantial debt, combined with our other financial obligations and contractual commitments, could have important consequences. For example, it could:

- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, capital expenditures and acquisitions;
- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a competitive disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, in the event of a default under the agreement governing the Senior Notes, or the Senior Note Agreement, the holders of our Senior Notes could accelerate, or demand immediate repayment of, all or a portion of our indebtedness under the Senior Notes. Any such acceleration would have a material adverse effect on our business, financial condition and results of operations.

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We did not timely make the quarterly interest payments on the Senior Notes due on December 31, 2008, March 31, 2009 and June 30, 2009. In addition, we failed to comply with a covenant to establish and maintain a minimum cash balance in an account pledged to the collateral agent for the Senior Notes, which became applicable in May 2009 because our annualized aggregate net product sales did not exceed \$100 million for the three months ended March 31, 2009. The failure to make the quarterly interest payments when due and the failure to establish the required restricted cash balance account in May 2009 constituted events of default under the Senior Note Agreement, which then permitted the holders of more than 50% in principal amount of the Senior Notes to accelerate payment of the Senior Notes.

In July 2009, we paid the overdue interest and, because our annualized aggregate net product sales exceeded \$100 million for the three months ended June 30, 2009, we were no longer required to maintain the minimum cash balance. In November 2009, we amended the Senior Note Agreement to provide, among other things, for amortization of a portion of the principal amount of the Senior Notes. In connection with that amendment, the holders of the Senior Notes have waived the prior events of default described above. However, our failure to comply with the terms of the Senior Note Agreement on an ongoing basis could result in the holders of our Senior Notes attempting to accelerate our indebtedness under the Senior Notes. We do not currently expect to be able to repay the Senior Notes in full at maturity without new financing or additional cash resources.

If we do not have sufficient funds to pay all remaining principal on our Senior Notes when it is due in June 2011, service our indebtedness under the Senior Notes, or to restrict cash if required under the Senior Note Agreement, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or obtain additional equity capital, including on terms that may be onerous or highly dilutive, none of which we can assure you that we would be able to do in a timely manner or at all. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. In addition, our ability to refinance any amounts that may become accelerated under the Senior Notes or to secure future waivers from the holders of the Senior Notes with respect to compliance with the Senior Note Agreement covenants may be adversely affected by our prior defaults under the Senior Notes. The holders of the Senior Notes currently have a first priority security interest in all of our assets other than inventory and accounts receivable, on which SVB has a lien and first priority security interest.

***We have a history of net losses, and, if we are to grow our business in the future, we will need to commit substantial resources, which could result in future losses.\****

We have incurred significant net losses since our inception in 2003, and although we reported both net income and cash generated from operations in our two most recent quarters, we may incur net losses in the future. To grow our business in the future, we will need to commit substantial resources to costly and time-consuming product development and clinical trials of our product candidates and significant funds to our commercial operations. Our future capital requirements will depend on many factors, including:

- the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;
- market acceptance of and the number of prescriptions written for our products;
- selling and marketing costs associated with Xyrem and Luvox CR in the United States;
- the timing of potential receipt of FDA approval of JZP-6 and its potential commercialization;
- revenues from current and potential future development and/or commercial collaboration partners, in particular our current partnership with UCB;
- the scope, rate of progress, results and costs of our preclinical studies and clinical trials, including our Phase IV clinical trial commitment to the FDA for Luvox CR (if we are not released by the FDA from that commitment), and other research and development activities;
- the number and characteristics of product candidates that we pursue;
- the cost and timing of establishing clinical and commercial supplies of our product candidates and products, including the cost and timing of new arrangements for the supply of sodium oxybate;
- the cost and timing of obtaining regulatory approval;
- payments of milestones to third parties;
- increased expenses associated with our current employees and new employees hired to support our continued growth;
- the cost of investigations, litigation and/or settlements related to regulatory activities;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the extent to which we acquire, in-license or invest in new businesses, products or product candidates;
- changes in laws and regulations, including, for example, the recently enacted comprehensive health care reform legislation; and

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- our ability to utilize our net operating loss carryforwards to offset potential future taxable income and related income taxes.

Although we reported both net income and cash generated from operations in our two most recent quarters, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to sustain or increase profitability, the market value of our common stock will likely decline.

***Our operations have, until very recently, generated negative cash flows, and, if our cash flow estimates are incorrect, we may be required to secure additional funding, significantly scale back our operations, significantly reduce our headcount, and/or discontinue many of our activities which could negatively affect our business and prospects.\****

We believe our existing cash balances, cash we expect to generate from operations, and cash we expect to have under our revolving bank line of credit will be sufficient to fund our operations and meet all of our obligations through March 31, 2011. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses. Our assumptions may prove to be wrong or other factors may adversely affect our business, and we could exhaust our available cash resources or be forced to reduce our expenses, which could have a material adverse effect on our business. We do not expect our cash resources to be sufficient to cover all of the costs associated with the launch of our JZP-6 product candidate if approved by the FDA, the cost of our Luvox CR Phase IV clinical trial commitments (if we are not released by the FDA from that commitment), any significant additional costs related to the development of our product candidates and repayment of our Senior Notes at maturity on June 24, 2011. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge. Our ability to raise additional funds and/or partner or license one or more of our product candidates will depend, among other things, on the capital markets and our financial condition at such time and, with respect to partnering or licensing, the interest of third parties in acquiring rights to our product candidates. If we are unable to raise sufficient additional funds when or if needed, we would be required to further reduce operating expenses. Furthermore, any additional funds we may raise could be on terms that are not favorable to us and may be dilutive to existing stockholders.

We cannot predict with certainty the level of our product sales. If product sales do not meet our expectations and/or we do not raise additional funds, we will need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we may take may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and prospects.

***The terms of our Senior Notes could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.***

The terms of our Senior Notes currently contain, and any future indebtedness may contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. The terms of the Senior Notes include covenants restricting, among other things, our ability to:

- incur additional debt;
- dispose of certain assets;
- repurchase our capital stock or make distributions to our stockholders;
- impair our lenders' security interests in our assets; and
- voluntarily prepay our debt prior to the repayment of the Senior Notes.

In addition, the terms of the Senior Notes require us to maintain restricted cash balances under certain circumstances.

***Our ability to use our net operating losses to offset potential future taxable income and related income taxes that would otherwise be due could be limited or lost entirely, which could materially and adversely affect our business, financial condition, and results of operations if we generate taxable income, if we do not generate taxable income in a timely manner or if an "ownership change" pursuant to Section 382 of the Internal Revenue Code is triggered.***

We have significant net operating loss carryforwards, or NOLs. Our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, if ever, we will be able to generate future taxable income. In addition, even if we generate taxable income, realization of our NOLs to offset potential future taxable income and related income taxes that would otherwise be due could be restricted by annual limitations on use of NOLs triggered by an "ownership change" under Section 382 of the Internal Revenue Code and similar state provisions. An "ownership change" may occur if, during a three-year period, the percentage ownership of our company by our 5% shareholders increases by 50% or more. If we generate taxable income, the loss of some or all of our NOLs could materially and adversely affect our business, financial condition, results of operations and growth prospects.



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Effective July 7, 2009, we entered into an NOL preservation lock-up agreement with most of our significant stockholders that restricts transferability of shares of our common stock by the stockholders who entered into the agreement until June 2011, unless terminated earlier under certain circumstances, in order to minimize the risk that we will undergo an “ownership change” within the meaning of Section 382(g) of the Internal Revenue Code prior to that time. Section 382 of the Internal Revenue Code is an extremely complex provision with respect to which there are many uncertainties. Although the NOL preservation lock-up agreement and 5% shareholder limitation are intended to minimize the risk of such an “ownership change,” we cannot assure you that such an ownership change will not occur. In addition, we have not requested a ruling from the Internal Revenue Service, or IRS, regarding whether we have effectively preserved our NOLs, and, therefore, we have not established whether the IRS agrees with us that our NOLs have been effectively preserved for purposes of Section 382 of the Internal Revenue Code.

### **Risks Relating to Our Common Stock**

*The market price of our common stock may be volatile, and the value of your investment could decline significantly.*

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. Our common stock has historically had a very low average trading volume, and our stockholders may not be able to sell any or all of their holdings quickly or at all. The price of our stock has also fluctuated significantly since the beginning of 2009 and we cannot predict if it will continue to do so. In addition, the stock market in general, and the market for life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

- the success of Xyrem and Luvox CR in the United States;
- conditions or trends in the pharmaceutical industry, the credit and financial markets or the United States and worldwide economy in general;
- the failure or delay by the DEA in providing sufficient quotas for sodium oxybate, Xyrem or JZP-6;
- the success of our development efforts and clinical trials;
- announcement of FDA approval or non-approval of our product candidates, including JZP-6, or specific label indications for their use, or delays in the FDA review process;
- the review, evaluation and recommendations of any FDA advisory committee regarding the potential approval of JZP-6;
- our ability to successfully market JZP-6 in the United States if approved by the FDA for the treatment of fibromyalgia, or any delays in the potential commercial launch of JZP-6;
- our ability to obtain adequate clinical and commercial supplies of our product candidates and products from our single source suppliers and manufacturers, including our ability to effectively transition to our new supplier of sodium oxybate;
- the ability of Elan to provide us with sufficient commercial supply of Luvox CR;
- our financial situation, including our ability or inability to raise additional capital when needed and the terms on which we raise it;
- actual or expected fluctuations in our operating results, including as a result of fluctuating demand for our commercial products as a result of purchases by wholesalers in connection with product launches, stockpiling or inventory drawdowns by our customers, or otherwise;
- hedging or arbitrage trading activity that may develop involving our common stock;
- changes in the prices for our products;
- the success of our efforts to acquire or in-license additional products or product candidates;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- the filing of, and thereafter the possible FDA approval of, ANDAs for generic forms of Xyrem, Luvox CR and, if approved by the FDA, JZP-6;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

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- announcements of product innovations by us, our partners or our competitors;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements and changes as a result of the recently enacted Healthcare Reform Act;
- actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- actual or expected changes in our growth rates or our competitors' growth rates;
- changes in the market valuation of similar companies;
- trading volume of our common stock; and
- sales of our common stock by us or our stockholders.

### ***Future sales of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock, and could impair our ability to raise capital through the sale of additional equity securities. As of April 30, 2010, we had 31,539,444 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144 and the restrictions under our NOL preservation lock-up agreement. We have an effective shelf registration statement on file with the Securities and Exchange Commission pursuant to which we could, offer and sell up to \$61.2 million of debt and/or equity securities.

As of April 30, 2010, the holders of up to approximately 18,312,159 shares of common stock, based on shares outstanding as of that date, including 785,728 shares underlying outstanding warrants, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, under an amended and restated investor rights agreement that we entered into with these holders. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights under the amended and restated investor rights agreement with respect to registration of the shares of common stock acquired on exercise. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital. We also entered into a registration rights agreement pursuant to which we filed a registration statement covering the resale of the 562,192 shares underlying the warrants that we issued in connection with the issuance of the Senior Notes. In addition, we have filed registration statements on Form S-8 under the Securities Act to register the shares of our common stock reserved for issuance under our stock option and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

We entered into the CEFF in May 2008 with Kingsbridge and amended the CEFF in November 2009. The perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. The registration rights agreement entered into in connection with the CEFF, as amended, requires that we use commercially reasonable efforts to ensure that the registration statement we filed in connection with the CEFF, and any additional registration statements that we file with the SEC to cover the resale of the shares issuable under the CEFF, remain effective for up to one year following the termination of the CEFF. We have not drawn down funds and have not issued shares of our common stock under the CEFF with Kingsbridge. Our ability to draw down funds and sell shares under the CEFF requires that the registration statement we filed in connection with the CEFF continue to be effective. In addition, the registration statement that we filed in connection with the CEFF registers approximately 76% of the 4,922,064 total shares of our common stock issuable under the CEFF, or 3,726,727 shares, and our ability to access the CEFF to sell the 1,195,337 remaining shares issuable under the CEFF is subject to our ability to prepare and file one or more additional registration statements registering the resale of these shares, which we may not file until the later of 60 days after Kingsbridge and its affiliates have resold substantially all of the common stock registered for resale under the registration statement that we have filed in connection with the CEFF, or six months after the effective date of such registration statement. These subsequent registration statements may be subject to review and comment by the Staff of the SEC, and will require the consent of our independent registered public accounting firm. Therefore, the timing of effectiveness of these subsequent registration statements cannot be assured. The effectiveness of these subsequent registration statements is a condition precedent to our ability to sell the shares of common stock subject to these subsequent registration statements to Kingsbridge under the CEFF. In addition, we will not be able to sell shares under the CEFF unless certain other conditions are met, including a minimum average price of our common stock of at least \$2.50 per share. Because our ability to draw down amounts under the CEFF is subject to a number of conditions, there is no guarantee that we will be able to draw down any portion or all of the \$75 million available to us under the CEFF. In addition, although the CEFF provides for our ability to draw down amounts of up to \$75 million, the maximum number of shares of common stock that we can issue to Kingsbridge under the CEFF is limited to 4,922,064 shares. As a result, since we will issue shares of our common stock at a discount of up to 9.5% from the then average price of our common stock if we draw down amounts under the CEFF, even if we are able to issue the maximum number of shares provided for under the CEFF to Kingsbridge, the aggregate proceeds to us could be substantially less than \$75 million. Once Kingsbridge acquires shares in connection with a drawdown there are no restrictions on its ability to sell those shares or engage in other transactions that could put downward pressure on the price of our common stock.



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Pursuant to the terms of an investor rights agreement dated July 7, 2009 we entered into in connection with a private placement completed on July 7, 2009, we filed a registration statement under the Securities Act registering the resale of the 1,895,734 shares of common stock we issued to the investors pursuant to a securities purchase agreement we entered into with the investors on July 6, 2009, as well as the 947,867 shares of common stock underlying the warrants we issued to the investors pursuant to the securities purchase agreement. In addition, if we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the investors are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.

### ***The CEFF and/or sales made pursuant to our shelf registration may result in dilution to our stockholders.***

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of \$75 million of our common stock or 4,922,064 shares of our common stock over a three-year period beginning in December 2009. If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment as described below, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to 9.5% from the average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price. In addition, we are entitled in certain circumstances to deliver a “blackout” notice to Kingsbridge to suspend the use of the registration statements that we have filed or may in the future file with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant we issued to Kingsbridge. If we deliver a blackout notice during a certain number of trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge, or issue Kingsbridge additional shares of our common stock in lieu of this payment.

We have an effective shelf registration statement on file with the Securities and Exchange Commission pursuant to which we could offer and sell approximately \$61.2 million of our equity securities. If we sell shares under our shelf registration statement it will have, and if we sell other equity securities it could have, a dilutive effect on the holdings of our current stockholders and may result in downward pressure on the price of our common stock.

### ***Our executive officers and directors, together with their respective affiliates, own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

As of April 30, 2010, our executive officers and directors, together with the stockholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 65.0% of our capital stock, of which approximately 5.4% was beneficially owned by our executive officers. Accordingly, our executive officers and directors, together with their respective affiliates or associates, are able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

### ***We incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules of the Securities and Exchange Commission and The NASDAQ Stock Market LLC have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel must continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may incur substantial costs to maintain the same or similar coverage

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The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. For example, we were required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our Annual Report on Form 10-K for the year ended December 31, 2008, and to allow our independent registered public accounting firm to issue a report on the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2010. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new, operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, or for a change in the composition of our board of directors or management to occur, even if doing so would benefit our stockholders. These provisions include:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- dividing our board of directors into three classes;
- limiting the removal of directors by the stockholders;
- eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless, among other exceptions, such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, because some corporate takeovers occur through an acquirer’s purchase, in the public market or otherwise, of sufficient stock to give it control of a company, the NOL preservation lock-up agreement, which restricts the transferability of our securities, could have the effect of delaying or discouraging such a takeover of us.

***We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.***

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently plan to invest all available funds and future earnings in the development and growth of our business and in the payment of our obligations. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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### **Item 6. Exhibits.**

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to exhibit 3.1 in the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
3.2	Amended and Restated Bylaws (incorporated herein by reference to exhibit 3.4 in the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate (incorporated herein by reference to exhibit 4.2 in the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.3A in the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.3B in the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.3C in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008)
4.3D	Waiver and Amendment Agreement, dated as of July 6, 2009 by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.3D in the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant (incorporated by reference to exhibit 4.6 to the Registrant's registration statement on Form S-1 (File No. 333-141164), as filed with the SEC on March 9, 2007)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended (incorporated herein by reference to exhibit 4.4B in the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008)
4.5A†	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein (incorporated herein by reference to exhibit 4.5A in the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC (incorporated herein by reference to exhibit 4.5B in the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008)
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4.5E†	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.5E in the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008)

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4.5F	Amendment and Waiver Agreement, dated as of November 10, 2009, by and among the Registrant, JPI Commercial, LLC and the other parties named therein (incorporated by reference to exhibit 4.5F in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on November 10, 2009)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008 (incorporated herein by reference to exhibit 4.6A in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited (incorporated herein by reference to exhibit 4.6B in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008)
4.6C	Amendment Agreement No. 1, dated as of November 20, 2009, by and between the Registrant and Kingsbridge Capital Limited (incorporated by reference to exhibit 4.6C in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on November 23, 2009)
4.7	Form of Registered Direct Common Stock Warrant (incorporated herein by reference to exhibit 4.7 in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008)
4.8	NOL Preservation Lock-Up Agreement, effective as of July 7, 2009, by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.8 in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009)
4.9A	Form of Common Stock Warrant of the Registrant issued on July 7, 2009 (incorporated herein by reference to exhibit 4.9A in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009)
4.9B	Investor Rights Agreement, dated July 7, 2009 by and between the Registrant and the other parties named therein (incorporated herein by reference to exhibit 4.9B in the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009)
10.13#	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.54#	Supply Agreement, dated as of April 1, 2010, by and between the Registrant and Siegfried (USA) Inc.
10.55	2010 Executive Officer Compensation Arrangements.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
*	The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
#	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.
†	Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

**SIGNATURES**

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

Dated: May 6, 2010

**Jazz Pharmaceuticals, Inc.**  
(Registrant)

/s/ BRUCE C. COZADD

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**Bruce C. Cozadd**  
*Chairman and Chief Executive Officer and Director*  
*(Principal Executive Officer)*

/s/ KATHRYN E. FALBERG

---

**Kathryn E. Falberg**  
*Senior Vice President and Chief Financial Officer*  
*(Principal Financial Officer)*

**EXHIBIT INDEX**

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*	The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
#	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.
†	Confidential treatment has been granted for 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.

**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.

[ \* ] = 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.

1.3 “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.”

**[ \* ] = 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.**

1.14 “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®-IR (fluvoxamine maleate) will be referred to individually as “LUVOX-IR” and LUVOX®-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.

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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 [\*].

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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.

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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 fifteen (15) days of the First Commercial Sale of LUVOX-IR, supplied by or on behalf of Solvay, by Jazz Pharmaceuticals;

(c) Ten million (\$10,000,000.00) dollars within fifteen (15) days of receipt of FDA approval of the first indication for the LUVOX-ER NDA (which is either an indication for the treatment of obsessive compulsive disorder ("OCD") or an indication for the treatment of generalized social anxiety disorder ("SAD"));

(d) Five million (\$5,000,000.00) dollars within fifteen (15) days of receipt of FDA approval of a second indication for the LUVOX-ER NDA (which is either an indication for the treatment of OCD or an indication for the treatment of SAD);

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- (e) Five million (\$5,000,000.00) dollars within fifteen (15) days of receipt of FDA approval of LUVOX-ER for OCD or SAD with a label that includes expiration dating of at least eighteen (18) months;
- (f) Thirteen million (\$13,000,000.00) dollars within fifteen (15) days of the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals after FDA approval of the first indication for LUVOX-ER (which is either an indication for the treatment of OCD or an indication for the treatment of SAD); provided, however, if the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals occurs more than sixty (60) days following approval of the first indication due to Solvay's failure to supply API or Elan's failure to supply Product, the milestone payment payable pursuant to this Section 3.1(f) shall be reduced to [\*] (\$[\*]) dollars;
- (g) Eight million (\$8,000,000.00) dollars within fifteen (15) days of the First Commercial Sale of LUVOX-ER (regardless of indication) by Jazz Pharmaceuticals after FDA approval of the second indication for LUVOX-ER (which is either an indication for the treatment of OCD or an indication for the treatment of SAD); provided, however, if the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals after the FDA approval of the second indication for LUVOX-ER (which is either an indication for the treatment of OCD or an indication for the treatment of SAD) occurs more than sixty (60) days following approval of the second indication, due to Solvay's failure to supply API or Elan's failure to supply Product, the milestone payment payable pursuant to this Section 3.1(g) shall be reduced to [\*] (\$[\*]) dollars;
- (h) Five million (\$5,000,000.00) dollars payable as set forth in Section 3.5 after twelve (12) months of uninterrupted supply of Jazz Pharmaceuticals' requirements of LUVOX-ER by Elan to Jazz Pharmaceuticals in accordance with the terms and conditions of the Elan Agreement as measured from the date of the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals;
- (i) Twenty million (\$20,000,000.00) dollars payable as set forth in Section 3.5 when Net Sales of LUVOX-ER first reach one hundred million (\$100,000,000.00) dollars in a single twelve month period;
- (j) Thirty million (\$30,000,000.00) dollars payable as set forth in Section 3.5 when Net Sales of LUVOX-ER first reach two hundred million (\$200,000,000.00) dollars in a single twelve month period; and
- (k) Forty million (\$40,000,000.00) dollars payable as set forth in Section 3.5 when Net Sales of LUVOX-ER first reach four hundred million (\$400,000,000.00) dollars in a single twelve month period.

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.

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For the sake of clarity, it is acknowledged and understood that in the event both OCD and SAD indications are approved by the FDA at the same time, 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) two and one-half (2.5%) percent of LUVOX-ER Net Sales up to and including two hundred fifty million (\$250,000,000.00) dollars in such calendar year, and (b) five (5%) percent of LUVOX-ER Net Sales in excess of two hundred fifty million (\$250,000,000.00) 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 infringing 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.

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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.

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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.

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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.

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**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.

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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.

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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 fifty percent (50%) 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, up to a maximum aggregate amount of two million (\$2,000,000.00) dollars.

## 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.

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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.

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(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;

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- (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 [\*] after the Time of Closing. The covenants and agreements of the parties hereto contained in this Agreement will survive and remain in full force for [\*]. 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.

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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:

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;

any breach by Solvay of any of its covenants contained in this Agreement;

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;

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;

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;

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(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.

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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 sixty (60) days following written notice of such breach; provided, however, that if the breach is of such a nature that it can not be cured within sixty (60) days, 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 six (6) months 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 six (6) months 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.

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11.4 Termination by Jazz Pharmaceuticals. If either (a) the FDA has not approved the LUVOX-IR NDA by April 1, 2008 or (b) the FDA has not approved the LUVOX-ER NDA by April 1, 2008, 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 [\*].

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### 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.

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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

[ \* ] = 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.

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.

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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

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**Exhibit A**  
**Elan Agreement**

{This Exhibit A has been filed separately as an exhibit to the Registrant's Registration Statement on  
Form S-1 in executed form.}

**[ \* ] = 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 Registrant's Registration Statement  
on Form S-1 in executed form.}

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**Exhibit C**  
**Form of Supply Agreement**

{This Exhibit C has been filed separately as an exhibit to the Registrant's Registration Statement  
on Form S-1 in executed form.}

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**Exhibit D**  
**Assignment and Assumption Agreement**

{This Exhibit D has been filed separately as an exhibit to the Registrant's Registration Statement  
on Form S-1 in executed form.}

[ \* ] = 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 1.13**

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)

**[ \* ] = 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 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**

between

**Jazz Pharmaceuticals, Inc.**, 3180 Porter Drive, Palo Alto, CA 94304  
(hereinafter "**JAZZ PHARMACEUTICALS**")

and

**Siegfried (USA) Inc.**, 33 Industrial Park Road, Pennsville, NJ, 08070,  
(hereinafter "**SIEGFRIED**")

---

***Recitals***

*WHEREAS*, SIEGFRIED is engaged in the business of, among other things, manufacturing pharmaceutical products for the pharmaceutical industry;

*WHEREAS*, JAZZ PHARMACEUTICALS now desires to have SIEGFRIED manufacture for, and supply to, JAZZ PHARMACEUTICALS the Active Material (as herein below defined) in accordance with the terms of this Agreement (as herein below defined);

*WHEREAS*, JAZZ PHARMACEUTICALS desires SIEGFRIED to supply to JAZZ PHARMACEUTICALS the Active Material in accordance with the terms of this Agreement; and

*WHEREAS*, SIEGFRIED, subject to the terms and conditions of this Agreement, desires to so supply the Active Material to JAZZ PHARMACEUTICALS in accordance with the terms of this Agreement.

**NOW, THEREFORE**, in consideration of the mutual covenants and promises contained in this Agreement the Parties agree as follows:

## **1. DEFINITIONS**

Each of the capitalized terms used in this Agreement (other than the names of the Parties and the headings of the Articles and Sections) shall have the meanings indicated below. Such meanings shall apply equally to all forms of such terms, including singular and plural forms, unless otherwise clearly indicated.

“**Act**” shall mean the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

“**Active Material**” shall mean the active pharmaceutical ingredient (API) listed on Schedule 1, hereto.

“**Affiliate**” shall mean with respect to any Party any person or entity controlling, controlled by, or under common control with a Party at any time during the term of this Agreement. For purposes of this definition, the term “control” shall mean the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting stock, by contract or otherwise. In the case of a corporation, the term “control” shall mean the direct or indirect ownership of at least fifty percent (50%) of the outstanding voting stock.

“**Agreement**” shall mean this Agreement including its Schedules (and Appendices, if applicable), as may be amended from time to time.

“**Batch**” means a specific quantity of Active Material that is intended to have uniform character and quality, within specified limits, and is produced during the same cycle of manufacture.

“**Business Day**” shall mean a day (not being a Saturday or Sunday) on which banks are open for business in New York.

“**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
- (d) the latest Health Canada, Ministry of Health, Labour, and Welfare, 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.

“**Confidential Information**” shall mean any information of whatever kind (including without limitation, data, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies and techniques), and all tangible and intangible embodiments thereof of any kind whatsoever (including without limitation, samples, apparatus, compositions, documents, drawings, machinery, patent applications, records and reports) which has been or will be disclosed by one Party (“**Disclosing Party**”) to the other Party (“**Receiving Party**”) in connection with this Agreement, and which is confidential or proprietary to the Disclosing Party or an Affiliate thereof, including, without limitation, any and all information pertaining to the Active Material and information which relates to the business of either Party, including business plans, strategies, operations policies, procedures, techniques, accounts, marketing plans, financial plans and status, and personnel of either Party.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

“**DEA**” means the United States Drug Enforcement Administration or, if applicable, its international counterparts.

“**Effective Date**” means April 1, 2010 unless revised by mutual written agreement of the parties in accordance with this Agreement.

“**EMEA**” 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.

“**Finished Dosage Form**” shall mean a final form of a drug product containing any Active Material.

“**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.

“**Hidden Defects**” shall mean any instance where a Batch of Active Material fails to conform to the Specifications, such failure not being discoverable upon Inspection or standard testing of Active Material in accordance with Section 3.2 or at any point in the production of the Finished Dosage Form.

“**Inspection**” shall mean any reasonable activity other than testing to determine the condition of the Product, including without limitation, visual inspection of the packaging condition, visual inspection of the label, visual inspection of Active Material condition, and review of Active Material documentation, and “Inspect” shall mean to conduct an Inspection.

“**Intellectual Property**” includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions (as herein defined below), copyright and industrial designs.

“**Laws**” means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Regulatory Authority applicable to the activities hereunder.

“**Manufacture**” shall mean all activities with respect to the manufacturing of the Active Material, including, without limitation, production, quality control, packaging and release for shipment.

“**Manufacturing Commencement Date**” means the date when SIEGFRIED will commence Manufacturing Services to manufacture and package Active Material hereunder.

“**Manufacturing Services**” means 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 and related services as contemplated in this Agreement.

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“**Manufacturing Site**” means the facility owned and operated by SIEGFRIED that is located at 33 Industrial Park Road, Pennsville, NJ, 08070 or such other facility located in the United States that is owned by SIEGFRIED and approved by JAZZ PHARMACEUTICALS pursuant to Section .2.5 of this Agreement.

“**Ministry of Health, Labour, and Welfare**” means the Japanese regulatory authority responsible for promulgating regulations for the good manufacturing practices related to the manufacture of the Active Material.

“**Party/ies**” shall mean either JAZZ PHARMACEUTICALS or SIEGFRIED, or both, as the context may require.

“**Quality Agreement**” shall mean the agreement between JAZZ PHARMACEUTICALS and SIEGFRIED which defines the responsibilities of each Party with respect to the practices to be followed to ensure Active Material quality and compliance under cGMP and applicable Laws, as same may be amended from time to time by written agreement between the Parties. Upon execution, such agreement will be attached to and incorporated by reference in this Agreement.

“**Quota**” means the manufacturing quota quantity of Active Material allotted by the DEA to SIEGFRIED in order for SIEGFRIED to perform the Manufacturing Services.

“**Regulatory Authority**” shall mean the FDA, EMEA, Ministry of Health, Labour, and Welfare, Health Canada and any other national or supranational authorities which are responsible for approving the conduct of clinical trials, marketing and sale of pharmaceutical products in their respective markets.

“**Specifications**” shall mean the detailed description of the technical requirements for the Active Material set out in detail in Schedule 1 attached hereto, as may be updated, amended and revised from time to time in accordance with Section 6.3 of this Agreement.

“**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.

“**Year**” means in the first year of this Agreement, the period from the Manufacturing Commencement Date up to and including December 31 of the same calendar year, and thereafter shall mean a calendar year.

## **2. TECHNOLOGY TRANSFER, MANUFACTURE AND SUPPLY OF ACTIVE MATERIAL**

**2.1** SIEGFRIED hereby agrees to conduct the technology transfer of the Active Material to the Manufacturing Site in accordance with the plan agreed upon in writing by the Parties (“**Technology Transfer Plan**”), the goal of which is to transfer the current process for commercial manufacture of the Active Material, develop protocols for testing the Active material, and finalize Specifications. SIEGFRIED and JAZZ PHARMACEUTICALS 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. SIEGFRIED shall perform validations for the Active Material at its Manufacturing Site, provide stability samples, and prepare the chemical manufacturing section for JAZZ PHARMACEUTICALS to file with FDA. A more detailed description, including the time schedule for completion of all transfer activities will be set forth in the Technology Transfer Plan to be attached hereto and made a part hereof. A preliminary baseline for the Technology Transfer Plan and the compensation to be paid to SIEGFRIED thereunder is attached as Schedule 2.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

2.2 Promptly upon completion of each development milestone by SIEGFRIED, as set forth in the Technology Transfer Plan, SIEGFRIED shall deliver to JAZZ PHARMACEUTICALS a complete written report or reports. A detailed description of such reports, as well as other reports to be provided by SIEGFRIED will be set forth in the Technology Transfer Plan. Within [ \* ] after the delivery to JAZZ PHARMACEUTICALS of each report, JAZZ PHARMACEUTICALS shall either (a) accept such report and notify SIEGFRIED to proceed with the Technology Transfer Plan or (b) send SIEGFRIED written notice of SIEGFRIED's failure to conduct such activities in accordance with the requirements set forth in the Technology Transfer Plan. SIEGFRIED agrees to take such corrective actions and to conduct such additional work required to satisfy the requirements set forth in the Technology Transfer Plan.

2.3 In consideration of SIEGFRIED's conduct of the Technology Transfer Plan, JAZZ PHARMACEUTICALS agrees to pay SIEGFRIED the amounts set forth in the Technology Transfer Plan. JAZZ PHARMACEUTICALS shall only pay SIEGFRIED for milestones which are completed. A breakdown of costs for each milestone will be set forth in the Technology Transfer Plan. Payments for each milestone will be made within [ \* ] of satisfactory completion, as determined by JAZZ PHARMACEUTICALS after review of the associated milestone completion summary reports discussed in Section 2.2 above and any other data generated through execution of the Technology Transfer Plan. SIEGFRIED shall not incur any costs in excess of the amounts set forth in the Technology Transfer Plan without the prior written consent of JAZZ PHARMACEUTICALS.

2.4 Upon completion of the Technology Transfer Plan and subject to Section 2.5 below, SIEGFRIED shall Manufacture the Active Material in accordance with the Specifications, cGMP, the Quality Agreement and all applicable Laws. All work specified hereunder shall be carried out by SIEGFRIED, or a subcontractor designated by SIEGFRIED in accordance with Section 10.2.

2.5 JAZZ PHARMACEUTICALS shall specify the Manufacturing Commencement Date by written notice to SIEGFRIED within [ \* ] following (i) the approval of SIEGFRIED as a manufacturer of the Active Material, including approval of the Manufacturing Site by the FDA, DEA and any other applicable Regulatory Authority, and (ii) receipt of appropriate Quota. SIEGFRIED will provide all Manufacturing Services at the Manufacturing Site; provided, however, SIEGFRIED may transfer the Manufacturing Services to another facility located in the United States and owned by Siegfried (the "**New Manufacturing Site**") upon the written approval of JAZZ PHARMACEUTICALS, such approval not to be unreasonably withheld. If SIEGFRIED wishes to transfer the Manufacturing Services to a New Manufacturing Site, it will provide JAZZ PHARMACEUTICALS with a written request that indicates the location of the New Manufacturing Site and the proposed timeline for the transfer of Manufacturing Services to the New Manufacturing Site. All costs associated with the transfer of the Manufacturing Services to the New Manufacturing Site, including any costs incurred by JAZZ PHARMACEUTICALS, will be the sole responsibility of SIEGFRIED. SIEGFRIED will not be allowed to transfer the Manufacturing Services to the New Manufacturing Site and JAZZ PHARMACEUTICALS will not have to approve the transfer to the New Manufacturing Site until (a) approval of the New Manufacturing Site by the FDA, DEA and any other applicable Regulatory Authority to manufacture the Active Material and (b) receipt of appropriate Quota for the New Manufacturing Site.

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**2.6** From and after the Manufacturing Commencement Date, SIEGFRIED shall perform the Manufacturing Services set forth on Schedule 3 attached hereto. JAZZ PHARMACEUTICALS shall purchase at least sixty percent (60%) of its requirements of Active Material for the Territory from SIEGFRIED. JAZZ PHARMACEUTICALS may establish other suppliers as additional manufacturers of up to forty percent (40%) of its requirements of Active Material. If SIEGFRIED, for reasons within its control, does not, or cannot, meet all of the JAZZ PHARMACEUTICALS' Firm Orders (as herein below defined) for the Active Material submitted pursuant to the terms and conditions of this Agreement, JAZZ PHARMACEUTICALS may purchase more than forty percent (40%) of its requirements from such manufacturers, but only to the extent, and only for so long as, SIEGFRIED does not, or cannot, meet all of the JAZZ PHARMACEUTICALS' Firm Orders; provided, however, if SIEGFRIED cannot meet JAZZ PHARMACEUTICALS' Firm Orders for a period of more than [ \* ] for any reason or reasons not constituting a Force Majeure Event as defined in Article 13, JAZZ PHARMACEUTICALS will not be obligated to return any portion of its requirements that it has transferred to another manufacturer back to SIEGFRIED.

**2.7** No later than the [ \* ] of each calendar month during the term of the Agreement, JAZZ PHARMACEUTICALS shall furnish to SIEGFRIED a written rolling [ \* ] forecast of JAZZ PHARMACEUTICALS' anticipated purchases, including shipment dates, of the Active Material (the "**Forecast**"). The first [ \* ] covered in each [ \* ] Forecast provided shall constitute a firm order (each, a "**Firm Order**"); the remaining [ \* ] covered by each Forecast shall be a non-binding estimate only. Each Forecast shall cover a [ \* ] forecast period starting the first (1st) day of the calendar month that is [ \* ] in which JAZZ PHARMACEUTICALS provided such Forecast to SIEGFRIED. By way of example, the Forecast which JAZZ PHARMACEUTICALS provides by [ \* ] shall cover the period from [ \* ]. For amounts of the Active Material set forth in the Forecast, JAZZ PHARMACEUTICALS and SIEGFRIED realize that the Quota may restrict manufacturing and hence delivery of shipments throughout the calendar year for which such Quota applies. If the Quota restricts, or is anticipated to restrict, SIEGFRIED's ability to meet the manufacturing requirements set forth in the Forecast, SIEGFRIED will promptly notify JAZZ PHARMACEUTICALS and the parties will meet and agree on a plan to resolve the anticipated shortfall in requested Active Material within [ \* ]. Each Firm Order shall be in writing and shall specify the Active Material ordered, the quantity ordered, the price pursuant to Schedule 4 and the required delivery date, giving SIEGFRIED a lead time of [ \* ]. Shorter lead times for Active Material deliveries, if deemed necessary by JAZZ PHARMACEUTICALS, may be agreed upon between the Parties in good faith.

**2.8** Firm Orders placed with SIEGFRIED by JAZZ PHARMACEUTICALS pursuant to the provisions of Section 2.7 shall be acknowledged by SIEGFRIED in writing within [ \* ] of receipt thereof. SIEGFRIED will use commercially reasonable efforts to ensure that all Active Material ordered by the JAZZ PHARMACEUTICALS in accordance with this Agreement will be shipped in accordance with the delivery dates specified in the JAZZ PHARMACEUTICALS' Firm Order but in no event shall the actual delivery date be [ \* ] from the date of delivery specified in the JAZZ PHARMACEUTICALS' Firm Order, and SIEGFRIED will notify the JAZZ PHARMACEUTICALS promptly of any significant anticipated delay no later than [ \* ] prior to such delivery date.

**2.9** The Parties acknowledge that the Active Material is scheduled under the Federal Controlled Substances Act. SIEGFRIED is required to obtain a Quota from the DEA before producing the Active Material. In that regard, throughout the term hereof, SIEGFRIED will submit to DEA in a timely manner all documents required by the DEA to obtain a Quota sufficient to meet JAZZ PHARMACEUTICALS' Forecasts made pursuant to Section 2.7. Additional request(s) will be submitted by SIEGFRIED to DEA in a timely manner as necessary to reflect changes in JAZZ PHARMACEUTICALS' Forecasts of Active Material. SIEGFRIED further agrees to use its commercially reasonable efforts to obtain a Quota from the DEA that allows SIEGFRIED to manufacture all Forecasts for the Active Material including cooperating with the JAZZ PHARMACEUTICALS in connection with any discussions with the DEA regarding a Quota. SIEGFRIED ACKNOWLEDGES THAT TIME IS OF THE ESSENCE IN PERFORMING ITS OBLIGATIONS UNDER THIS SECTION.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**2.10** SIEGFRIED will use its commercially reasonable efforts to avoid any loss of Active Material. If and to the extent that Active Material is spilled, scrapped or otherwise unusable hereunder, SIEGFRIED 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, SIEGFRIED will prepare all required diversion reports and will provide a copy to JAZZ PHARMACEUTICALS, if legally permissible, at least [ \* ] prior to the filing thereof with the DEA in accordance with applicable regulations.

**2.11** The Active Material ordered by JAZZ PHARMACEUTICALS pursuant to Firm Orders shall be delivered [ \* ] (as per INCOTERMS 2000, made a part hereof by reference). Risk of loss or of damage to the Active Material ordered by JAZZ PHARMACEUTICALS pursuant to Firm Orders shall remain with SIEGFRIED until the Active Material is made available for loading onto the carrier's vehicle by SIEGFRIED for shipment at the shipping point at which time risk of loss or damage shall transfer to JAZZ PHARMACEUTICALS. SIEGFRIED shall, in accordance with the JAZZ PHARMACEUTICALS' instructions and as agent for JAZZ PHARMACEUTICALS, arrange for shipping to be paid by JAZZ PHARMACEUTICALS. JAZZ PHARMACEUTICALS shall arrange for insurance and shall select the freight carrier used by SIEGFRIED to ship the Active Material and may monitor SIEGFRIED's shipping and freight practices as they pertain to this Agreement. The Active Material shall be transported in accordance with the Specifications and all applicable Laws. Notwithstanding the foregoing, there will be no additional charge by SIEGFRIED for storage for a period of up to [ \* ] from the date of invoice of Firm Orders paid for by JAZZ PHARMACEUTICALS but held for shipment which Firm Orders do not exceed at any given time [ \* ] of the then-current Forecast; provided however that in no event will such stored Firm Orders exceed [ \* ]. The storage quantities of Active Material in excess of the amounts provided for in the preceding sentence must be mutually agreed-upon by the Parties.

**2.12** During the term of this Agreement, JAZZ PHARMACEUTICALS shall disclose and deliver to SIEGFRIED all material information in JAZZ PHARMACEUTICALS' possession relating to the Manufacture, which may reasonably assist SIEGFRIED in performing its obligations hereunder.

**2.13** In connection with obtaining approval to manufacture the Active Material and Quota from the DEA, SIEGFRIED will deliver a letter to the DEA authorizing the DEA to release to JAZZ PHARMACEUTICALS any and all information with respect to the Active Material that SIEGFRIED has provided directly to the DEA for the purposes of allowing DEA to communicate with SIEGFRIED regarding Quota in its capacity as a contract manufacturer for JAZZ PHARMACEUTICALS and to allow DEA to provide SIEGFRIED with preliminary estimates of the Quota to be issued to SIEGFRIED. SIEGFRIED will also authorize JAZZ PHARMACEUTICALS to interact directly with the DEA on SIEGFRIED's behalf on all matters pertaining to the Quota and represent the Parties in all meetings with the DEA provided that SIEGFRIED will be allowed to participate in such meetings if it so desires.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

### **3. PRODUCT QUALITY**

**3.1** SIEGFRIED shall take reasonable best precautions and institute effective procedures to ensure that the Manufacture is and remains fully compliant with the Quality Agreement, cGMP, the Specifications and all applicable Laws.

**3.2** JAZZ PHARMACEUTICALS or its designee shall examine the Active Material produced by Siegfried within [ \* ] of JAZZ PHARMACEUTICALS' or its designee's receipt thereof in order to determine compliance with the Specifications and cGMP. If, in JAZZ PHARMACEUTICALS' or its designee's opinion, the Active Material delivered does not comply with the Specifications or cGMP, JAZZ PHARMACEUTICALS shall notify SIEGFRIED within [ \* ] after JAZZ PHARMACEUTICALS' or its designee's determination made within the aforesaid [ \* ] period that the Active Material delivered does not comply with the Specifications or cGMP (or, in the case of any Hidden Defects, within [ \* ] after discovery by JAZZ PHARMACEUTICALS) in writing thereof. If JAZZ PHARMACEUTICALS does not notify SIEGFRIED accordingly within the specified time set forth above, the Active Material is deemed accepted, provided that JAZZ PHARMACEUTICALS retains the right to reject the Active Material at a later time in case of Hidden Defects, in which case JAZZ PHARMACEUTICALS shall inform SIEGFRIED within [ \* ] in writing thereof. Any claims by JAZZ PHARMACEUTICALS regarding Active Material delivered shall specify in reasonable detail the nature and basis for the claim and cite SIEGFRIED's relevant batch numbers or other information to enable specific identification of the Active Material involved. SIEGFRIED agrees to review any written claim made by JAZZ PHARMACEUTICALS regarding the quality of the Active Material and to provide JAZZ PHARMACEUTICALS with the results of such review in writing within [ \* ] of receiving JAZZ PHARMACEUTICALS' claim. If such review and testing by SIEGFRIED confirms that a certain quantity of Active Material did not meet the Specifications, JAZZ PHARMACEUTICALS shall have the right to reject such Batch of Active Material.

**3.3** If the Parties fail to agree as to whether a delivered quantity of Active Material complies with cGMP and the Specifications at the time of delivery, the Parties agree to have the Batch in dispute tested and further analysed by an independent testing laboratory selected by agreement between the Parties. The decision of the independent testing laboratory shall be deemed final as to any dispute over Active Material quality. Should the laboratory's testing determine that delivered Active Material does not comply with the Specifications or cGMP, SIEGFRIED shall bear all costs for the independent laboratory testing and JAZZ PHARMACEUTICALS shall have the right to reject such Batch of Active Material. If said quantity of Active Material is determined by the independent laboratory to have met the Specifications and cGMP, then JAZZ PHARMACEUTICALS shall bear all costs of the independent laboratory testing and compensate SIEGFRIED for the Batch in question as set out in this Agreement.

**3.4** In the event JAZZ PHARMACEUTICALS rejects Product in accordance with Section 3.2 above and SIEGFRIED does not dispute such rejection, or if the independent testing laboratory selected by agreement between the Parties in accordance with Section 3.2 above determines that delivered Active Material does not comply with the Specifications or cGMP, and the deviation is determined to arise from SIEGFRIED's failure to provide the Manufacturing Services in accordance with Specifications or cGMPs, SIEGFRIED shall promptly, at JAZZ PHARMACEUTICALS' election, either: (i) offset such amount against other amounts due to SIEGFRIED hereunder; or (ii) replace such Active Material with conforming Active material without JAZZ PHARMACEUTICALS being liable for payment therefor under Section 6.1 below. Such credit or replacement will be JAZZ PHARMACEUTICALS' sole remedy for such rejected Active Material provided SIEGFRIED provides replacement or credit within [ \* ] of notice of rejection or, in the event of a dispute regarding compliance, within [ \* ] of notice the independent testing laboratory selected by agreement between the Parties in accordance with Section 3.2 has determined that delivered Active Material did not comply with the Specifications or cGMP.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

3.5 Each Party shall promptly notify the other party if any Batch of the Active Material 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, JAZZ PHARMACEUTICALS' decision shall prevail. JAZZ PHARMACEUTICALS shall bear all the costs of any such recall, market withdrawal or correction unless such recall, market withdrawal or correction was the result of SIEGFRIED'S breach of any of its representations and warranties set forth in Article 11 below, in which case SIEGFRIED shall bear all costs of such recall, market withdrawal, or correction subject to the limitations set forth in Article 12. If SIEGFRIED asks for a recall and provides written detail regarding the specific reasons for the request that would be sufficient to justify it to an individual familiar with the pharmaceutical industry, and JAZZ PHARMACEUTICALS declines to initiate a recall, SIEGFRIED shall not be liable for any consequences or damages arising after JAZZ PHARMACEUTICALS has had a period of time reasonable under the circumstances (which period shall in no event exceed [ \* ], and is referred to as the "Evaluation Period") to assess the requested recall, and JAZZ PHARMACEUTICALS shall defend, indemnify and hold SIEGFRIED harmless with respect to any liability arising after the end of the Evaluation Period and resulting from JAZZ PHARMACEUTICALS' decision not to initiate a recall, regardless of any other provisions of this Agreement.

#### 4. AUDITS AND INSPECTIONS

4.1 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 Active Material is being produced and anticipated shut downs of such site, and manage any issues that have arisen.

4.2 SIEGFRIED shall keep records of the manufacture, testing and shipping of the Active Material, and retain samples of such Active Material as are necessary to comply with the Specifications and all manufacturing regulatory requirements and Laws applicable to SIEGFRIED, as well as to assist with resolving Active Material complaints and other similar investigations. Copies of such records and samples shall be retained for a period of seven (7) years, or longer if required by Law, after which SIEGFRIED may destroy such records unless JAZZ PHARMACEUTICALS specifies otherwise in advance.

4.3 JAZZ PHARMACEUTICALS may inspect SIEGFRIED reports and records relating to this Agreement during normal business hours and with reasonable advance notice, provided a SIEGFRIED representative is present during any such inspection. Furthermore, JAZZ PHARMACEUTICALS shall have the right, if JAZZ PHARMACEUTICALS reasonably deems it necessary, to request additional documentation from SIEGFRIED to verify SIEGFRIED's calculation of any pass-through costs and cost increases.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**4.4** SIEGFRIED shall provide JAZZ PHARMACEUTICALS and its licensees with reasonable access at mutually agreeable times to its Manufacturing Site in which the Active Material is manufactured, stored, handled or shipped in order to permit the JAZZ PHARMACEUTICALS' and its licensees verification of SIEGFRIED's compliance with the Agreement and with all applicable Laws. SIEGFRIED agrees to permit JAZZ PHARMACEUTICALS or its licensee to review SIEGFRIED's standard operating procedures for the manufacture of the Active Material and those associated with the general facilities, equipment, or procedures required for compliance with cGMPs or DEA requirements. SIEGFRIED shall use commercially reasonable efforts to obtain the right for JAZZ PHARMACEUTICALS and its licensees to have similar inspection rights with respect to all third party suppliers used by SIEGFRIED to provide components to manufacture the Active Material. If deficiencies are found by JAZZ PHARMACEUTICALS or its licensees during the course of such inspections, the Parties will promptly meet to discuss and resolve them, and JAZZ PHARMACEUTICALS and its licensees will be entitled to make reasonable follow up inspections to monitor correction of the deficiencies. SIEGFRIED shall notify JAZZ PHARMACEUTICALS of any inspections by, or communications with, any governmental agency involving the Active Material. SIEGFRIED 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 the Active Material, or the ability of SIEGFRIED to supply such Active Material, within [ \* ] of their receipt of such information or delivery of such information, as the case may be. SIEGFRIED will promptly correct any deficiencies noted by governmental agencies in any such inspections. Any licensee of JAZZ PHARMACEUTICALS permitted access to SIEGFRIED's Manufacturing Site and records pursuant to this Section 4.4 will be bound by obligations of confidentiality at least as stringent as those set forth in Article 7 of this Agreement.

**4.5** SIEGFRIED will supply on an annual basis an annual Manufacturing Services review which includes release test results, complaint test results, investigations in manufacturing, testing and storage, and the like, that JAZZ PHARMACEUTICALS reasonably requires in order to complete any filing under any applicable Law, including any annual product report that the JAZZ PHARMACEUTICALS is required to file with the FDA. SIEGFRIED will supply JAZZ PHARMACEUTICALS, no later than [ \* ] 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 JAZZ PHARMACEUTICALS, in order that JAZZ PHARMACEUTICALS may properly account for the Active Material held by SIEGFRIED pursuant to this Agreement. At the JAZZ PHARMACEUTICALS' request, SIEGFRIED will prepare on behalf of JAZZ PHARMACEUTICALS additional specialized annual product reports in accordance with the JAZZ PHARMACEUTICALS' instructions. At the JAZZ PHARMACEUTICALS' request and expense, SIEGFRIED will provide the data described in this Section 4.5 on a quarterly basis.

## **5. REGULATORY**

**5.1** SIEGFRIED shall have the sole responsibility to obtain and maintain any required local, federal or other permits or approvals, including DEA approval, to allow SIEGFRIED to perform Manufacturing Services hereunder. JAZZ PHARMACEUTICALS shall use commercially reasonable efforts to assist SIEGFRIED, to the extent consistent with JAZZ PHARMACEUTICALS' obligations under this Agreement, to obtain FDA and other regulatory approval for the manufacture of the Active Material by SIEGFRIED 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 SIEGFRIED by JAZZ PHARMACEUTICALS.

**5.2** Prior to filing any CMC-related documents with the FDA or other Regulatory Authority that incorporate data generated by SIEGFRIED, JAZZ PHARMACEUTICALS shall provide SIEGFRIED with a copy of the documents incorporating such data so as to give SIEGFRIED a reasonable opportunity to verify the accuracy and regulatory validity of such documents as they relate to the SIEGFRIED generated data.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

5.3 At least [ \* ] prior to filing with the FDA the CMC section of a NDA covering manufacture of the Active Material by SIEGFRIED, JAZZ PHARMACEUTICALS shall provide SIEGFRIED with a copy of the CMC portion as well as all supporting documents which have been relied upon to prepare the CMC portion so as to permit SIEGFRIED to verify that the CMC portion accurately describes the work that SIEGFRIED has performed and the manufacturing processes that SIEGFRIED will perform pursuant to this Agreement.

5.4 Subject to Section 5.5 below, if JAZZ PHARMACEUTICALS does not provide SIEGFRIED with the documentation requested under paragraph (c) above within the time stipulated in these paragraphs and if SIEGFRIED reasonably believes that SIEGFRIED's standing with the FDA may be jeopardized, SIEGFRIED may, in its reasonable, good faith discretion, delay or postpone the FDA pre-approval inspection ("PAI") until such time SIEGFRIED has reviewed the requested documentation and is satisfied with its contents provided that such review will be completed within [ \* ] of SIEGFRIED's receipt of such documentation from JAZZ PHARMACEUTICALS.

5.5 If in SIEGFRIED's good faith discretion, acting reasonably, SIEGFRIED determines that any of the information provided by JAZZ PHARMACEUTICALS in accordance with Sections 5.2 and 5.3 above is inaccurate or deficient in any material manner (the "Deficiencies"), SIEGFRIED shall notify JAZZ PHARMACEUTICALS in writing of such Deficiencies within [ \* ] of receipt of such information from JAZZ PHARMACEUTICALS. Failure to notify JAZZ PHARMACEUTICALS within the applicable period set forth above will constitute SIEGFRIED's acceptance of the documentation provided in accordance with Sections 5.2 and 5.3 above. Until such Deficiencies have been resolved or agreement has been reached with JAZZ PHARMACEUTICALS, SIEGFRIED reserves the right not to participate in the PAI. In such event, SIEGFRIED's non-participation in the PAI shall not be construed as a breach of any of its obligations under this Agreement. Any such PAI that is delayed shall be rescheduled as soon as reasonably practicable.

## 6. **COMPENSATION AND TERMS OF PAYMENT**

6.1 In consideration for the supply of the Active Material by SIEGFRIED to JAZZ PHARMACEUTICALS under the terms of this Agreement, JAZZ PHARMACEUTICALS shall pay SIEGFRIED the amounts as set out in Schedule 4, subject to such adjustments as set forth in Section 6.2 below. The fees that are payable by JAZZ PHARMACEUTICALS for the Active Material as set forth on Schedule 4 are based on the actual annual volume of Active Material ordered by JAZZ PHARMACEUTICALS in any Year ("Actual Ordered Product"). The Parties shall estimate the fees payable by JAZZ PHARMACEUTICALS in any Year based on the Forecasts provided by JAZZ PHARMACEUTICALS under Section 2.7 above. Within [ \* ] of the end of the each Year, the Parties shall reconcile the difference which may be payable by either Party based on the Actual Ordered Product for such Year. If the Actual Ordered Product for such Year is in a tier with a higher cost than that used to calculate the fees for such Year, JAZZ PHARMACEUTICALS shall pay SIEGFRIED the difference owed in accordance with Section 6.4 below. If the Actual Ordered Product for such Year is in a tier with a lower cost than that used by the Parties to estimate the fees for such Year, SIEGFRIED shall credit or refund, at JAZZ PHARMACEUTICALS' option, JAZZ PHARMACEUTICALS for such overpayment.

6.2 On the first day of the applicable Year during the term of this Agreement, SIEGFRIED shall be entitled to an adjustment to the fees set forth on Schedule 4 (i) for Manufacturing Services in respect of the Active Material other than raw materials costs ("Conversion Costs") to reflect increases in manufacturing costs, which adjustment shall not exceed the increase in the Producers' Price Index, Pharmaceuticals Preparations, NAICS 325412 ("PPI") of the immediately preceding month compared to the same month of the preceding Year, unless the parties otherwise agree in writing; and (ii) for raw material costs to pass on the actual documented amount of any increase or decrease in such costs. SIEGFRIED will use commercially reasonable efforts to minimize raw material costs. Notwithstanding the foregoing, if at any time market conditions result in SIEGFRIED's cost of raw materials being materially greater than or less than the raw material costs anticipated for the current Year when pricing was determined in January of such year, then there shall be an adjustment to the raw material costs used in the calculation of the fees set forth on Schedule 4 to reflect such increase or decrease in costs for the period of such material increase or decrease in costs. For the purpose of this Section 6.2, the threshold for materially greater than or less than shall be defined as [ \* ] for the Active Material in the relevant Year.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**6.3** For changes to the Specifications or manufacturing processes that are required by applicable Laws (“**Required Manufacturing Changes**”), SIEGFRIED and the 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 the Active Material meeting Specifications. All costs associated with Required Manufacturing Changes directly related to the Manufacturing Site that are not required solely to permit SIEGFRIED to Manufacture the Active Material shall be borne by SIEGFRIED. All other costs associated with Required Manufacturing Changes under this Agreement, including, without limitation, obsolete raw material, regulatory filings, work in process, equipment and Active Material shall be borne by JAZZ PHARMACEUTICALS. Amendments to the Specifications or the Quality Agreement requested by JAZZ PHARMACEUTICALS that are not Required Manufacturing Changes (“**JAZZ PHARMACEUTICALS Requested Changes**”) will only be implemented following a technical and cost review by SIEGFRIED and are subject to JAZZ PHARMACEUTICALS and SIEGFRIED reaching agreement as to revisions, if any, to the fees specified in Schedules 4 necessitated by any such amendment. Amendments to the Specifications, the Quality Agreement or the Manufacturing Site requested by SIEGFRIED that are not Required Manufacturing Changes (“**SIEGFRIED Requested Changes**”) will only be implemented following the approval of JAZZ PHARMACEUTICALS, such approval not to be unreasonably withheld, and the costs of the SIEGFRIED Requested Changes will be borne by SIEGFRIED. If JAZZ PHARMACEUTICALS 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 Active Material that are manufactured in accordance with the revised Specifications. In addition, with respect to JAZZ PHARMACEUTICALS Requested Changes, JAZZ PHARMACEUTICALS agrees to purchase, at SIEGFRIED’s cost therefor (including all costs incurred by SIEGFRIED in connection with the purchase and handling of such inventory), all Inventory utilized under the “old” Specifications and purchased or maintained by SIEGFRIED in order to fill Firm Orders or in accordance with Section 2.7 above, to the extent that such inventory can no longer be utilized under the revised Specifications. Open purchase orders for raw materials no longer required under any revised Specifications that were placed by SIEGFRIED in accordance with this Agreement with suppliers in order to fill Firm Orders or in accordance with Section 2.7 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by JAZZ PHARMACEUTICALS.

**6.4** Invoices will be issued by SIEGFRIED and sent to JAZZ PHARMACEUTICALS upon shipment of the Active Material in accordance with Section 2.11 of this Agreement. Each such invoice shall, to the extent applicable, identify the JAZZ PHARMACEUTICALS purchase order number, Active Material quantities, unit price, freight charges and the total amount to be remitted by JAZZ PHARMACEUTICALS. JAZZ PHARMACEUTICALS shall pay all such invoices within [ \* ] of the date thereof by wire transfer. Notwithstanding the foregoing, JAZZ PHARMACEUTICALS may withhold any amounts invoiced by SIEGFRIED that it disputes in good faith. If JAZZ PHARMACEUTICALS disputes any invoice, JAZZ PHARMACEUTICALS shall within [ \* ] after such invoice is furnished to it notify SIEGFRIED 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 SIEGFRIED will 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.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

6.5 The Parties agree that, unless set out otherwise in this Agreement, all payments made to SIEGFRIED pursuant to this Agreement shall be non-refundable and that the expiration or termination of this Agreement shall not relieve JAZZ PHARMACEUTICALS of its obligation to pay any outstanding balances due.

## 7. **CONFIDENTIAL INFORMATION**

7.1 Each Party agrees to retain in strict confidence and not to disclose, divulge or otherwise communicate to any third party or entity any Confidential Information of the other Party (or its Affiliate), whether disclosed prior to, or after the date of signature of this Agreement or of prior secrecy agreements. The Parties further agree not to use any such Confidential Information for any other purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, except that each Party may disclose Confidential Information of the other Party to its (or its Affiliate's) officers, directors, employees, agents, consultants, subcontractors or representatives (the "Entitled Persons"), who, in each case, need to know such information for purposes of the implementation and performance by the Receiving Party of this Agreement, who will use the Information only for such limited purposes and who are bound by obligations of confidentiality at least as stringent as those set forth in this Agreement.

7.2 Each Party agrees to use with respect to Confidential Information of the other Party at least the same standard of care as it uses to protect proprietary or confidential information of its own of comparable sensitivity and to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Entitled Persons.

7.3 Each Party warrants that each of its Entitled Persons to whom any Confidential Information is revealed shall previously have been informed of the confidential nature of the Confidential Information and shall be under professional secrecy or shall have agreed to be bound by the terms and conditions of this Article 6 or by confidentiality obligations equal to this Article 6.

7.4 The provisions of this Article 7 shall not apply to any Confidential Information disclosed hereunder which was either (a) independently developed or known by the Receiving Party prior to its disclosure to the Receiving Party by the Disclosing Party, as evidenced by written records; or (b) before or after the date of disclosure to the Receiving Party by the Disclosing Party is in the public domain or lawfully disclosed to the Receiving Party by an independent, unaffiliated third party rightfully in possession of the Confidential Information and not under any confidentiality obligation towards the Disclosing Party with regard to such Confidential Information; or (c) is required to be disclosed by the Receiving Party to the officials of a Regulatory Authority or to comply with applicable laws, to defend or prosecute litigation or to comply with governmental laws or regulations, judicial orders or valid subpoenas, provided that the Receiving Party provides prior written notice of such intended disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure. The burden of proof lies with the Party alleging one of the above exceptions. Nonetheless, such Party shall not disclose that the same Confidential Information was also acquired from the other Party.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.



7.5 Except as otherwise provided for under this Agreement, nothing herein shall be construed as giving either Party any right, title or interest in or ownership of the Confidential Information of the other Party. For the purposes of this Agreement, specific information disclosed as part of the Confidential Information shall not be deemed to be in the public domain or in prior possession of the Receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the Receiving Party.

7.6 Except as may be required by law or regulation, or in response to a valid subpoena or other judicial order, neither Party shall disclose the terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that the Parties may disclose the terms of this Agreement to the Parties' or third parties' accountants and attorneys, provided any such attorney or accountant receiving information concerning the terms of this Agreement is either bound by professional secrecy or agrees to be bound by confidentiality obligations equal to this Article 7 with respect to such information.

7.7 The confidentiality obligations of the Parties contained in this Article 7 shall remain binding upon both Parties during the term of this Agreement and for a period of ten (10) years after the termination or expiry of this Agreement, regardless of the cause of such termination. The Parties acknowledge that any breach of this Article 7 will constitute irreparable harm, and that the non-breaching Party shall be entitled to specific performance or injunctive relief to enforce this Article 6 in addition to whatever remedies such Party may otherwise be entitled to at law or in equity.

7.8 The confidentiality provisions of this Agreement extend to the Parties and their Affiliates.

## **8. INTELLECTUAL PROPERTY**

8.1 SIEGFRIED hereby assigns, releases, and transfers to JAZZ PHARMACEUTICALS its entire right, title and interest in and to any invention, discovery or improvement to the extent it is specific to the development, manufacture and use of the Active Material that is the subject of the Manufacturing Services (whether patentable or not) made or conceived by SIEGFRIED's employees or contractors, including, without limitation, manufacturing, manufacturing processes and procedures, analytical process, procedure or method, analytical results, and any route(s) of synthesis provided, however, JAZZ PHARMACEUTICALS hereby grants to SIEGFRIED a paid-up, worldwide, nonexclusive, nontransferable license to use patented inventions, discoveries, or improvements solely for purposes of providing Manufacturing Services pursuant to this Agreement.

8.2 JAZZ PHARMACEUTICALS shall own all right, title and interest in and to any Intellectual Property specific to the development, manufacture and use of the Active Material (whether patentable or not) made or conceived by JAZZ PHARMACEUTICALS employees or by any JAZZ PHARMACEUTICALS contractor, including, without limitation, any manufacturing or analytical process, procedure or method or any source of synthesis given to SIEGFRIED.

8.3 All Intellectual Property generated or derived by SIEGFRIED in the course of performing the Manufacturing Services which are not related to or derived from the JAZZ PHARMACEUTICALS' Intellectual Property or specific to, or dependent upon, the Active Material and which have general application to manufacturing processes or formulation development of drug product or drug delivery systems shall be the exclusive property of SIEGFRIED (the "SIEGFRIED Intellectual Property Rights"). SIEGFRIED hereby grants to JAZZ PHARMACEUTICALS, a non-exclusive, paid-up, royalty-free, transferable license of the SIEGFRIED Intellectual Property Rights which JAZZ PHARMACEUTICALS may use for the manufacture of the Active Material pursuant to this Agreement.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

8.4 SIEGFRIED shall promptly disclose to JAZZ PHARMACEUTICALS any and all inventions, discoveries and improvements specific to the development, manufacture and use of the Active Material (collectively “**Inventions**”), by SIEGFRIED’s employees or contractors, either alone or together with JAZZ PHARMACEUTICALS’ employees or contractors, and shall assign all its interests to JAZZ PHARMACEUTICALS or its designee in accordance with Section 8.1. SIEGFRIED shall execute at JAZZ PHARMACEUTICALS’ expense any assignments, applications or other instruments or documents reasonably requested by JAZZ PHARMACEUTICALS in accordance with this Article 8 and, at JAZZ PHARMACEUTICALS’ 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 JAZZ PHARMACEUTICALS’ interest therein. SIEGFRIED’s and JAZZ PHARMACEUTICALS’ obligations hereunder shall survive termination of this Agreement.

**9. TERM AND TERMINATION**

9.1 Subject to earlier termination pursuant to this Article 9 or as stipulated for elsewhere in this Agreement, this Agreement shall become effective on the date when signed by the second Party and continue in full force and effect for an initial period of five (5) years (hereinafter “**Initial Period**”), to be automatically renewed for three (3) year periods at a time, subject to the right of either Party to terminate this Agreement at any time at the end of the Initial Period or any subsequent three (3) year period with at least eighteen (18) months prior written notice to the other Party.

9.2 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.

9.3 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 [ \* ] following receipt of a written notice (the “**Remediation Period**”) of said breach that expressly states that it is a notice under this Section 9.3 (a “**Breach Notice**”). The aggrieved Party’s right to terminate this Agreement pursuant to this Section 9.3 may only be exercised for a period of [ \* ] 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; provided, however, that such waiver shall only apply to the specific occurrence of the breach described in the Breach Notice.

9.4 JAZZ PHARMACEUTICALS may terminate this Agreement at any time on or after December 31, 2011 upon [ \* ] notice if SIEGFRIED has not (i) obtained approval as a manufacturer of the Active Material, including approval of SIEGFRIED’s facility by the FDA, DEA and any other applicable Regulatory Authority or (ii) obtained a Quota for the Active Material for calendar year 2011.

9.5 JAZZ PHARMACEUTICALS may terminate this Agreement upon [ \* ] prior written notice if it intends to no longer order the Active Material due to its decision to discontinue the use of the Active Material in its commercial pharmaceutical products.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**9.6** If this Agreement expires or is terminated for any reason (including a termination in the event of a Force Majeure Event), then (in addition to any other remedies either Party may have in the event of default by the other Party):

- (a) subject to the terms of the Agreement, the JAZZ PHARMACEUTICALS shall take delivery of and pay for all undelivered Active Material (i) (A) that is manufactured pursuant to a Firm Order and (B) that meets the Specifications and (C) was manufactured in accordance with the Quality Agreement and cGMPs at the price in effect at the time the Firm Order was placed and (ii) all raw materials identified to the Active Material acquired or produced by SIEGFRIED in good faith reliance on the Forecasts delivered by JAZZ PHARMACEUTICALS hereunder;
- (b) SIEGFRIED shall continue to provide manufacturing and quality assurance support and support of the stability studies for the Active Material until the expiration date of the last production Batch of the Active Material purchased by JAZZ PHARMACEUTICALS hereunder or the date required by any applicable Law or Regulatory Authority in the Territory, whichever is later, provided, however, if JAZZ PHARMACEUTICALS terminates this Agreement other than pursuant to Section 9.2 or 9.3, JAZZ PHARMACEUTICALS shall reimburse SIEGFRIED for the actual costs of any required support of the stability studies;
- (c) SIEGFRIED shall take all steps reasonably requested by JAZZ PHARMACEUTICALS to confirm the assignment to JAZZ PHARMACEUTICALS all of SIEGFRIED'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 JAZZ PHARMACEUTICALS to vest all such right, title and interest in such Inventions in JAZZ PHARMACEUTICALS, provided JAZZ PHARMACEUTICALS shall pay all reasonable expenses, including any of time and travel of SIEGFRIED's employees, in connection with steps; and
- (d) Each Party shall return to the other party any Confidential 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 Regulatory Authority in the Territory.

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.

**9.7** The provisions of Articles 1, 7, 8, 11, 12, 16, 18, 19 and 20, and Sections 4.2, 9.6 and 9.7 shall survive the termination of this Agreement for any reason.

## **10. ASSIGNMENT AND SUBCONTRACTING**

**10.1** This Agreement is binding upon and shall inure to the benefit of the Parties hereto and their successors and permitted assigns. This Agreement and any rights or obligations hereunder may be assigned or delegated only (i) with the consent of the other Party, or (ii) to the successor to all or substantially all of the business of a Party (whether by merger, consolidation, asset transfer or similar transaction) to which this Agreement relates, or (iii) to an Affiliate of either Party. Any other assignment or delegation by either Party without the prior written consent of the other Party is void.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**10.2** SIEGFRIED is not entitled to engage any subcontractor for conducting the work under this Agreement without the prior written consent of JAZZ PHARMACEUTICALS provided such subcontractor agrees in writing to all the terms and conditions of this agreement including the terms of Article 16 below. If a subcontractor is appointed, SIEGFRIED shall be responsible for all work performed by such subcontractor as if performed by itself.

## **11. REPRESENTATIONS AND WARRANTIES**

**11.1** Warranties by Each Party. Each of JAZZ PHARMACEUTICALS and SIEGFRIED hereby represents, warrants and covenants to the other Party as follows:

- (a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction in which it is incorporated;
- (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;
- (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
- (d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms hereof does not and will not conflict with or result in a breach of any term of, or constitute a default under (i) any agreement or instrument binding or affecting it or its property; (ii) its charter documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;
- (e) subject in the case of SIEGFRIED to the receipt of the Quota, it has obtained any consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental or Regulatory Authorities required for the execution, delivery and performance of this Agreement by such Party, and the execution, delivery and performance of this Agreement will not violate any law, rule or regulation applicable to such Party;
- (f) this Agreement has been duly executed and delivered and constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles; and
- (g) it shall comply with all applicable Laws, rules and regulations relating to its activities under this Agreement.

**11.2** Warranties by SIEGFRIED. SIEGFRIED represents, warrants and covenants to JAZZ PHARMACEUTICALS that:

- (a) all Active Material delivered to JAZZ PHARMACEUTICALS or its designated Affiliates pursuant to this Agreement shall conform at the time of delivery with cGMP, applicable Laws and the Specifications and that such Active Material shall be manufactured in accordance with Article 2 hereof and the Quality Agreement;

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

- (b) to its knowledge, no third party patents, copyrights, trademarks, trade secrets or other third party intellectual property rights will be infringed by SIEGFRIED's performance of its obligations under this Agreement;
- (c) it will not use in any capacity, in connection with the Manufacturing Services to be performed under this Agreement, the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). SIEGFRIED 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; and
- (d) at the time of its delivery at the Manufacturing Site, each Batch of the Active Material manufactured by SIEGFRIED will: (i) have an expiration date at the time of shipment equal to that approved by the FDA, (ii) conform to the Specifications and will be stored under proper conditions; and (iii) not be adulterated or misbranded by SIEGFRIED within the meaning of the Act, or be an article which may not be introduced into interstate commerce under Sections 404 or 505 of such Act.

**11.3 EXCEPT AS EXPRESSLY WARRANTED IN THIS AGREEMENT, SIEGFRIED EXTENDS NO OTHER WARRANTIES OR REPRESENTATIONS COVERING THE PRODUCT, EXPRESS OR IMPLIED, AND SIEGFRIED EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. SIEGFRIED'S LIABILITY UNDER THESE WARRANTY PROVISIONS SHALL BE STRICTLY LIMITED TO THE REMEDIES PROVIDED FOR UNDER THIS AGREEMENT.**

## **12. LIABILITY AND INDEMNITY**

**12.1 Indemnification by JAZZ PHARMACEUTICALS.** Subject to SIEGFRIED's compliance with its obligations in Section 12.3 hereof, JAZZ PHARMACEUTICALS hereby indemnifies, defends, and holds SIEGFRIED 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 SIEGFRIED may be subject with respect to the Active Material or any Finished Dosage Form, (b) arising out of or resulting from any Finished Dosage Form or any other subsequent formulation, repackaging, distribution or other use of the Active Material supplied hereunder, including third party liability claims relating thereto, or (c) relating to or arising from any claim that the Manufacturing Services infringed a patent, copyright, trademark, trade secret or other intellectual property right of a third party, except to the extent that such losses, damages, expenses, fees, settlement costs or judgments result from (i) the breach by SIEGFRIED of its representations or warranties under Article 11 or (ii) the gross negligence or willful misconduct of SIEGFRIED, its employees or agents.

**12.2 Indemnification by SIEGFRIED.** Subject to JAZZ PHARMACEUTICALS' compliance with its obligations in Section 12.3 hereof, SIEGFRIED hereby indemnifies, defends, and holds JAZZ PHARMACEUTICALS 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 (a) SIEGFRIED's breach of any of its representations or warranties under Article 11 above, including, but not limited to, development, manufacture, testing, shipping, storage, delivery and/or other handling or processing of the Active Material (except for a breach arising from the noncompliance of Active Material with the Specifications or cGMP, for which case the sole remedy shall be as prescribed in Section 3.4), (b) SIEGFRIED's gross negligence or willful misconduct or (c) any injuries or claims of injuries which occur at the Manufacturing Site in connection with the Manufacturing Services, except to the extent that such losses, damages, expenses, fees, settlement costs or judgments result from (i) the breach by JAZZ PHARMACEUTICALS of its representations or warranties under Article 11 or (ii) the gross negligence or willful misconduct of JAZZ PHARMACEUTICALS, its employees or agents.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**12.3 Conditions to Indemnification.** The indemnified Party shall give the indemnifying Party prompt written notice of any claim or the institution of any suit against the indemnified Party for which it may seek indemnification under this Article 12. The failure to give such notice shall not relieve the indemnifying Party from any liability that it may have to the indemnified Party under this Article 12, except to the extent that the indemnifying Party's ability to defend such claim or suit is materially prejudiced by such failure to give notice. The indemnifying Party shall be entitled to participate in the defense of such claim or suit and to assume the control of such defense; provided, however, that the indemnified Party may elect to participate in, but not control, the defense of such claim or suit and to be represented by counsel, at its own expense, in connection therewith. The indemnifying Party shall not enter into any settlement agreement, which would materially adversely affect the rights or obligations of the indemnified Party under this Agreement without the indemnified Party's prior written consent.

**12.4 Limitation of Liability.** Except in the case of SIEGFRIED's gross negligence or wilful misconduct, SIEGFRIED's total liability for any damages of any kind or nature (including any liability relating to a recall, market withdrawal or correction) shall not exceed in a Year the amount equal to [ \* ].

**12.5 EXCEPT WITH RESPECT TO AMOUNTS PAYABLE TO THIRD PARTIES, NEITHER PARTY SHALL BE RESPONSIBLE TO THE OTHER PARTY FOR SUCH OTHER PARTY'S LOST PROFITS OR INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OR DAMAGE TO GOODWILL OR REPUTATION.**

**12.6 Debarment Certification.** In accordance with the requirements of the Act, SIEGFRIED certifies that, to the best of its knowledge, SIEGFRIED is not and will not be using any person presently under investigation by the FDA for debarment action, or debarred under 21 U.S.C § 335a, in any capacity, in connection with the manufacture of Active Material. SIEGFRIED also certifies that, to the best of its knowledge, SIEGFRIED is not and will not be using any person or Affiliate for whom convictions subject to debarment have occurred in the last five (5) years in any capacity in connection with the manufacture of Active Material. If, at any time after execution of this Agreement, SIEGFRIED becomes aware that SIEGFRIED is using any person or any Affiliate that has been or is in the process of being debarred, SIEGFRIED hereby certifies that it will promptly notify JAZZ PHARMACEUTICALS of such.

**12.7** Without limiting their obligations hereunder, both Parties shall maintain at their individual sole expense, commencing with the Effective Date and continuing throughout the term and any renewals thereof, sufficient insurance coverage to satisfy their obligations hereunder. Without derogating from the foregoing, this shall include, at minimum, the following insurance: (i) commercial general liability insurance, including broad form contractual liability and personal/ advertising injury coverage, with limits of not less than US \$5,000,000 per occurrence and US \$5,000,000 annual aggregate; (ii) product liability insurance with a coverage limit of not less than US \$5,000,000 per occurrence and US \$ 10,000,000 annual aggregate (iii) with respect to SIEGFRIED, workers compensation insurance with not less than minimum coverage limit as required by law; employers liability insurance of not less than \$1,000,000 per accident/injury. The required limits for general liability and product liability may be satisfied through a combination of primary and umbrella coverage. Both Parties agree to endeavor to provide [ \* ] notice of cancellation or non-renewal of required insurance. Prior to the performance of any activities under this Agreement, each Party shall provide the other with a certificate of insurance evidencing its respective insurance coverage. Required insurance shall be placed with carriers having a minimum A.M. Best rating of A- or better. If any required insurance is written on a claims-made basis, the policy holder/named insured shall be responsible for ensuring continuity of cover for claims which may be presented following policy expiry or cancellation.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

### **13. FORCE MAJEURE**

Either Party shall be excused from performing its obligations under this Agreement if its performance is delayed or prevented by any cause beyond such Party's control, including but not limited to, act of God, fire, explosion, weather, disease, war, insurrection, civil strike, riots, labor strike, slow-downs or similar labor disturbances, power failure or energy shortages ("**Force Majeure Event**") or a Force Majeure Event affecting a raw material supplier. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement that falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. SIEGFRIED shall immediately notify JAZZ PHARMACEUTICALS if, by reason of any Force Majeure Event referred to herein, SIEGFRIED is unable to meet any deadline or time for performance specified in this Agreement. In the event that such Force Majeure Event cannot be removed or overcome within [ \* ] (or such other period as the Parties jointly shall determine) from the date the Party affected first became affected, then either Party may, at any time after the expiration of such period, and for so long as such Force Majeure Event continues to exist, by written notice to the other Party, suspend or terminate this Agreement.

### **14. INDEPENDENT PARTIES**

Nothing herein, or in any attachments hereto, shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. Neither of the Parties shall be responsible for the acts or omissions of the other Party, and neither Party will have authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

### **15. ENTIRE AGREEMENT AND LEGAL AUTHORITY**

**15.1** This Agreement and the Schedules attached hereto (which Schedules are deemed to be an integral part of this Agreement for all purposes) contain the full understanding of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties.

**15.2** Each Party represents and warrants to the other that it has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein. This Agreement has been duly executed and delivered by each Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**15.3** If any portion of this Agreement is held invalid by a court of competent jurisdiction, such portion shall be deemed to be of no force and effect and the Agreement shall be construed as if such portion had not been included herein, provided however, if the deletion of such provision materially impairs the commercial value of this Agreement to either Party, the Parties shall attempt to renegotiate such provision in good faith. The fact that any provision of this Agreement shall be prohibited or unenforceable in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the Parties to this Agreement waive any provision of law that renders any provision of this Agreement prohibited or unenforceable in any respect.

**15.4** This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute but one and the same Agreement.

**16 EXCLUSIVITY**

During the term of this Agreement and, except in the case of a termination by SIEGFRIED pursuant to Sections 9.2 or 9.3 or a termination by JAZZ PHARMACEUTICALS pursuant to Sections 9.4 or 9.5, for eighteen (18) months thereafter, SIEGFRIED 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 Active Material other than JAZZ PHARMACEUTICALS pursuant to this Agreement.

**17. PRECEDENCE OF AGREEMENT, WAIVERS AND FURTHER ASSURANCES**

**17.1** Unless expressly agreed otherwise in writing the terms outlined in this Agreement shall prevail over any terms and conditions outlined in any Firm Order or Firm Order confirmation for Active Material or any general terms and conditions of either Party, and such terms and conditions are hereby expressly excluded.

**17.2** In case of conflicts between this Agreement and a Schedule hereto the provisions of this Agreement shall prevail. In case of conflicts between this Agreement and the Quality Agreement the provisions of this Agreement shall prevail.

**17.3** The failure by either Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute or be construed to constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. No waiver of any term, provision or condition of this Agreement shall be effective unless it is in writing and signed by duly authorised persons on behalf of the waiving Party.

**17.4** Each Party agrees to execute, acknowledge and deliver such further instruments, and to take such further actions, as may be necessary or appropriate in order to carry out the purpose and intent of this Agreement.

**18. NO PUBLICITY**

Neither JAZZ PHARMACEUTICALS nor SIEGFRIED shall use the name of the other Party in any advertising or press release without the prior consent of the other Party; provided that this Article 18 shall not restrict JAZZ PHARMACEUTICALS from identifying SIEGFRIED and its work in connection with this Agreement to any Regulatory Authority or as required by law or regulation.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.



## **19. NOTICES**

Any notice required under this Agreement shall be effective only if it is in writing and (i) delivered in person or (ii) deposited with a nationally recognized overnight delivery service, or (iii) sent by registered mail or (iv) dispatched by fax with copy of receipt, in which case such notice is to be confirmed by registered mail within [ \* ]; in either case any notice is to be addressed to the applicable address set forth below or any other address as designated by either Party.

All notices or demands to be given between the Parties under this Agreement shall be addressed as follows:

if to SIEGFRIED:

Siegfried (USA) Inc  
33 Industrial Park Road  
Pennsville, NJ 08070  
Attention: [ \* ]  
(Fax): [ \* ]

if to JAZZ PHARMACEUTICALS:

Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
Attention: President  
(Fax): [ \* ]

With a copy to:

Jazz Pharmaceuticals, Inc.  
3180 Porter Drive  
Palo Alto, CA 94304  
Attention: General Counsel  
(Fax): [ \* ]

Either Party may change the above addresses, but no such change shall have any effect until the other Party has been properly notified of the change as set out hereinabove.

## **20. GOVERNING LAW AND DISPUTE RESOLUTION**

**20.1 Governing Law.** This Agreement is to be governed by and construed in accordance with the laws of the State of New York, without giving effect to conflict of law principles. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**20.2 Formal Dispute Resolution.** In the event a dispute arises under this Agreement that can not be resolved by those with direct responsibility for the matter in dispute, such dispute shall be resolved by way of the following process:

(a) Management from JAZZ PHARMACEUTICALS and from SIEGFRIED shall meet to discuss the basis for the dispute and shall use their best efforts to reach a reasonable resolution to the dispute.

(b) If management fails to resolve the dispute within [ \* ] of its receipt of written notice of the dispute, the matter in dispute shall be brought to the attention of senior management at JAZZ PHARMACEUTICALS and SIEGFRIED. Said management shall meet in person to negotiate a good faith resolution to the dispute within [ \* ] of their receipt of written notice of the dispute.

(c) If such negotiations are unsuccessful, the matter may promptly be submitted by either party to and settled exclusively by arbitration in accordance with the Commercial Arbitration Rules, then in effect, of the American Arbitration Association (“AAA”), except to the extent modified herein or by agreement of the parties. Judgment on the award rendered may be entered in any court having jurisdiction thereof.

(d) Each Party shall, within [ \* ] of receipt of notice that the matter has been referred to arbitration, appoint one arbitrator pursuant to a procedure to be agreed upon by the parties and shall commence arbitration as soon as practicable thereafter. Such appointed arbitrators shall jointly select a third arbitrator. The arbitrators shall not be empowered to award punitive or exemplary damages.

(e) Notwithstanding any provision to the contrary in the Rules, the Parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules: (i) the arbitrators may require either Party to specifically perform its obligations under this Agreement and (ii) each Party shall bear its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrators, 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.

(f) Notwithstanding any other provision of this Agreement, each Party shall still be entitled to access the courts to obtain appropriate injunctive relief.

(h) During the pendency of any dispute resolution procedure pursuant to this Section, the effectiveness of any notice of termination given pursuant to Section 9 shall be suspended.

(i) All mediations and arbitrations pursuant to this Agreement shall take place in the City of New York, New York, U.S.A. in the English Language.

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives.

**SIEGFRIED (USA) INC.**

Date: April 1, 2010

By: /s/ Walter Kittl  
Name: Walter Kittl  
Title: General Manager

April 5, 2010

By: /s/ Sandra Cernick  
Name: Sandra Cernick  
Title: Director, Business Development

**JAZZ PHARMACEUTICALS, INC.**

Date: April 8, 2010

By: /s/ Janne Wissel  
Name: Janne Wissel  
Title: SVP, Chief Regulatory 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 24b-2 of the Securities Exchange Act of 1934, as amended.

## List of Schedules

<b>Schedule</b>	<b>Description</b>	<b>Content</b>
<b>1</b>	Specifications	Details and technical description of Active Material
<b>2</b>	Baseline Technology Transfer Plan	Milestones, Cost, Assumptions, Timeline, Payment Terms
<b>3</b>	Manufacturing Services	Description of services to be provided by SIEGFRIED
<b>4</b>	Commercial Pricing	Purchase prices for Active Material

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

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**SCHEDULE 1**

Specifications

[ \* ]

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**SCHEDULE 2**

Baseline Technology Transfer Plan

[ \* ]

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

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**SCHEDULE 3**

Manufacturing Services

[ \* ]

[ \* ] = 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 24b-2 of the Securities Exchange Act of 1934, as amended.

**SCHEDULE 4 – COMMERCIAL PRICING**

[ \* ]

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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 24b-2 of the Securities Exchange Act of 1934, as amended.



2010 Executive Officer Compensation Arrangements

<u>Executive Officer</u>	<u>2010 Base Salary Rate</u>	<u>2010 Target Bonus as % of Annual Base Salary Rate</u>
Bruce C. Cozadd Chairman and Chief Executive Officer	\$ 500,000.00	60
Robert M. Myers President	\$ 448,000.00	50
Kathryn E. Falberg Senior Vice President and Chief Financial Officer	\$ 365,000.00	40
Carol A. Gamble Senior Vice President, General Counsel and Corporate Secretary	\$ 361,000.00	40
Joan E. Colligan Controller and Principal Accounting Officer	\$ 217,250.00	10 -30

## CERTIFICATION

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2010

By: \_\_\_\_\_ /s/ Bruce C. Cozadd  
Bruce C. Cozadd  
Chairman and Chief Executive Officer



**CERTIFICATION (1)**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Bruce C. Cozadd, Chief Executive Officer of Jazz Pharmaceuticals, Inc. (the "Company"), and Kathryn E. Falberg, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of May 6, 2010.

/s/ Bruce C. Cozadd

\_\_\_\_\_  
**Bruce C. Cozadd**  
**Chairman and Chief Executive Officer**

/s/ Kathryn E. Falberg

\_\_\_\_\_  
**Kathryn E. Falberg**  
**Senior Vice President and Chief Financial Officer**

- (1) This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Jazz Pharmaceuticals, Inc. and will be retained by Jazz Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.