JAZZ PHARMACEUTICALS INC
Form 10-Q
May 06, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x 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

JAZZ PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**05-0563787**
(State or other jurisdiction of incorporation or organization)	**(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)

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 x 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 ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

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.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	March 31, 2010	December 31, 2009
ASSETS		
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	38,742	36,954
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	$ 106,706	$ 107,396
LIABILITIES AND STOCKHOLDERS DEFICIT		
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	69,911	59,241
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	(506,180)	(507,644)
Total stockholders deficit	(68,998)	(72,830)
Total liabilities and stockholders deficit	$ 106,706	$ 107,396

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2010	2009
Revenues:		
Product sales, net	$ 34,283	$ 21,319
Royalties	605	472
Contract revenues	285	285
Total revenues	35,173	22,076
Operating expenses:		
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	27,944	29,299
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)	$ 1,464	$ (12,988)
Net income (loss) per share:		
Basic	$ 0.05	$ (0.45)
Diluted	$ 0.04	$ (0.45)
Weighted-average common shares used in computing net income (loss) per share:		
Basic	31,412	28,968
Diluted	34,926	28,968

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2010	**2009**
Operating activities		
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)
Investing activities		
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
Financing activities		
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	$ 18,998	$ 17,015
Supplemental disclosure of non-cash investing and financing activities:		

Liability for purchase of product rights	$	$ 5,000

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

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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.

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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):

	Three Months Ended March 31,	
	2010	2009
Numerator:		
Net income (loss)	$ 1,464	$ (12,988)
Denominator:		
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
Net income (loss) per share:		
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):

	Three Months Ended March 31,	
	2010	**2009**
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

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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	$ 3,522	$ 3,426

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	$ 55,900	$ (28,098)	$ 27,802	$ 55,900	$ (26,042)	$ 29,858

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):

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

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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			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 5,073	$	$	$ 5,073
Total	$ 5,073	$	$	$ 5,073

	March 31, 2010
Available-for-sale investments	$ 5,073
Cash	13,925
Restricted cash	951
Total	$ 19,949

Reported as	March 31, 2010
Amounts classified as cash and cash equivalents	$ 18,998
Amounts classified as restricted cash	951
Total	$ 19,949

	December 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 5,072	$	$	$ 5,072
Total	$ 5,072	$	$	$ 5,072

	December 31, 2009

Available-for-sale investments	$	5,072
Cash		10,523
Restricted cash		2,988
Total	$	18,583

Reported as		**December 31, 2009**
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.

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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.

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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):

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

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):

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

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

	Three Months Ended March 31,	
	2010	2009
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):

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

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.

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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:

	Three Months Ended March 31,	
	2010	2009
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.

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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.

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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.

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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.

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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	$ 3,403	$ (7,888)

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.

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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 expre 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.

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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.

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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.

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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.

Exhibit Number	Description of Document
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)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC (incorporated herein by reference to exhibit 4.5C 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)
4.5D	Form of Common Stock Warrant of the Registrant (incorporated herein by reference to exhibit 4.5D 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)
4.5E	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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Exhibit Number	Description of Document
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.
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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
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)

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