JAZZ PHARMACEUTICALS INC
Form 10-Q
November 05, 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 September 30, 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 November 1, 2010, 38,918,545 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 SEPTEMBER 30, 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)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,853	$ 15,595
Restricted cash	400	2,988
Accounts receivable, net of allowances of $322 and $288 at September 30, 2010 and December 31, 2009, respectively	14,114	12,313
Inventories	4,476	3,426
Prepaid expenses	1,992	1,653
Other current assets	962	979
Total current assets	44,797	36,954
Property and equipment, net	716	1,124
Intangible assets, net	23,895	29,858
Goodwill	38,213	38,213
Other long-term assets	371	1,247
Total assets	$ 107,992	$ 107,396
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Revolving credit facility	$ 7,350	$ 9,399
Accounts payable	3,891	2,158
Accrued liabilities	19,075	14,296
Current portion of long-term debt (including $1,355 pertaining to a related party at December 31, 2009)	15,995	23,759
Purchased product rights liability	4,375	4,000
Liability under government settlement	4,002	2,954
Deferred revenue	3,412	2,675
Total current liabilities	58,100	59,241
Deferred rent	86	29
Deferred revenue, non-current	9,338	10,191
Purchased product rights liability, non-current	5,625	9,000
Liability under government settlement, non-current	6,978	10,658
Long-term debt, less current portion (including $5,196 pertaining to a related party at December 31, 2009)	28,670	91,107

Commitments and contingencies (Note 12)		
Stockholders deficit:		
Common stock	4	3
Additional paid-in capital	498,516	434,811
Accumulated deficit	(499,325)	(507,644)
Total stockholders deficit	(805)	(72,830)
Total liabilities and stockholders deficit	$ 107,992	$ 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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Product sales, net	$ 43,838	$ 29,992	$ 117,649	$ 77,789
Royalties	630	532	1,909	1,522
Contract revenues	285	285	854	10,854
Total revenues	44,753	30,809	120,412	90,165
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technology)	3,091	2,338	8,775	6,856
Research and development	7,317	7,644	21,494	30,244
Selling, general and administrative	18,040	15,061	51,926	42,934
Intangible asset amortization	1,862	2,057	5,963	5,611
Total operating expenses	30,310	27,100	88,158	85,645
Income from operations	14,443	3,709	32,254	4,520
Interest income	1	2	5	29
Interest expense (including $0 and $296 for the three months ended September 30, 2010 and 2009, respectively, and $570 and $937 for the nine months ended September 30, 2010 and 2009, respectively, pertaining to a related party)	(1,197)	(5,384)	(11,651)	(17,034)
Other (expense) income	(4)	1	(2)	(4)
Loss on extinguishment of debt			(12,287)	
Net income (loss)	$ 13,243	$ (1,672)	$ 8,319	$ (12,489)
Net income (loss) per share:				
Basic	$ 0.34	$ (0.05)	$ 0.24	$ (0.42)
Diluted	$ 0.32	$ (0.05)	$ 0.22	$ (0.42)
Weighted-average common shares used in computing net income (loss) per share:				
Basic	38,965	30,895	35,294	29,635
Diluted	41,737	30,895	38,233	29,635

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)

	Nine Months Ended September 30,	
	2010	2009
Operating activities		
Net income (loss)	$ 8,319	$ (12,489)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	713	1,103
Amortization of intangible assets	5,963	5,611
Loss on disposal of property and equipment	313	14
Stock-based compensation expense	5,969	3,509
Long-term debt, non-cash interest expense	2,175	1,849
Loss on extinguishment of debt, non-cash portion	3,803	
Changes in assets and liabilities:		
Accounts receivable	(1,801)	(2,559)
Inventories	(1,031)	133
Prepaid expenses and other current assets	(391)	1,158
Other assets	(260)	(274)
Accounts payable	1,733	(496)
Accrued liabilities	4,779	(4,902)
Deferred revenue	(116)	(10,676)
Deferred rent	57	7
Liability under government settlement	(2,632)	362
Net cash provided by (used in) operating activities	27,593	(17,650)
Investing activities		
Purchases of property and equipment	(618)	(47)
Purchase of product rights	(3,000)	(3,000)
Decrease in restricted cash and investments	2,588	963
Proceeds from maturities of marketable securities		1,004
Net cash used in investing activities	(1,030)	(1,080)
Financing activities		
Repayment of senior secured notes (including $6,816 paid to a related party)	(119,496)	
Proceeds from offering of common stock, net of issuance costs	56,817	
Proceeds from term loan, net	48,688	
Repayment of term loan	(4,166)	
Proceeds from private offerings, net of issuance costs		6,780
Proceeds from employee stock purchases and exercise of stock options	901	152
Net repayment of revolving credit facilities	(2,049)	(875)
Net cash (used in) provided by financing activities	(19,305)	6,057
Net increase (decrease) in cash and cash equivalents	7,258	(12,673)

Cash and cash equivalents, at beginning of period	15,595	24,903
Cash and cash equivalents, at end of period	$ 22,853	$ 12,230
Supplemental disclosure of non-cash investing and financing activities:		
Liability for purchase of product rights	$	$ 5,000
Warrants to purchase common stock issued in conjunction with unregistered sales of equity securities	$	$ 2,700

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 nine months ended September 30, 2009 have been reclassified to conform to the presentation for the nine months ended September 30, 2010. The results for the three and nine months ended September 30, 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 and JPI Commercial, LLC after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

Although we reported net income for the three and nine months ended September 30, 2010, we have incurred significant cumulative losses since our inception in 2003 and we may incur net losses in the future. As of September 30, 2010, our accumulated deficit was $499.3 million, the principal amount outstanding on our long-term debt was $45.8 million and we had cash and cash equivalents of $22.9 million. We believe our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and meet all of our existing obligations through at least 2011. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses. Our assumptions concerning our product sales and expenses may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, any of which could have a material adverse effect on our business.

We are subject to risks common to companies in the pharmaceutical industry with development and commercial operations including, but not limited to, risks and uncertainties related to commercial success and acceptance of our products by patients, physicians and payors, competition from branded and generic products, regulatory approvals, regulatory requirements, including those of the U.S. Food and Drug Administration, or FDA, and the U.S. Drug Enforcement Administration, or DEA, dependence on key customers and sole source suppliers and protection of intellectual property rights. In addition, most of our revenues are derived from sales of one product, Xyrem, as to which an Abbreviated New Drug Application, or ANDA, has been filed with the FDA by a party seeking to market a generic form of Xyrem. We have only one product candidate in late stage development, JZP-6, and we recently received a complete response letter, or CRL, from the FDA with respect to that product candidate stating that the FDA cannot approve our new drug application, or NDA, in its present form. We plan to meet with the FDA to discuss and clarify the letter, in order to determine the appropriate course of action for us with respect to JZP-6. We cannot assure you when, or whether, we will receive sufficient clarification from the FDA, or of the timing or cost of the continued development of JZP-6, or if its development will be continued, or whether our NDA for JZP-6 will be approved by the FDA.

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. Five customers accounted for 99% of gross accounts receivable as of both September 30, 2010 and December 31, 2009.

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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. In addition, certain of our sole suppliers themselves rely on sole suppliers. Lonza, Inc., or Lonza, our sole supplier of sodium oxybate, 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. Under the agreement, Lonza has an obligation to meet our sodium oxybate supply needs through 2011. Recently, the DEA increased the aggregate quota, and Lonza manufactured additional sodium oxybate for us.

In April 2010, we entered into an agreement with a new supplier, Siegfried (USA) Inc., or Siegfried, in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve Siegfried as a new supplier of sodium oxybate. Siegfried is conducting the necessary activities and plans to seek FDA approval as a supplier of sodium oxybate as soon as possible. We expect Siegfried to be approved by the FDA as a supplier by the second half of 2011 but we cannot be certain that this will occur.

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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Numerator:				
Net income (loss)	$ 13,243	$ (1,672)	$ 8,319	$ (12,489)
Denominator:				
Weighted-average common shares outstanding basic	38,965	30,895	35,294	29,635
Dilutive effect of employee equity incentive and purchase plans	1,864		1,948	
Dilutive effect of warrants	908		991	
Weighted-average common shares outstanding diluted	41,737	30,895	38,233	29,635
Net income (loss) per share:				
Basic	$ 0.34	$ (0.05)	$ 0.24	$ (0.42)
Diluted	$ 0.32	$ (0.05)	$ 0.22	$ (0.42)

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

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shares of our common stock that were excluded from the computation of diluted net income per share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Warrants to purchase common stock	1,348	3,300		3,595
Options to purchase common stock	3,675	2,559	3,268	2,904
Restricted stock units		35		42
Total	5,023	5,894	3,268	6,541

As of September 30, 2010, we had options to purchase 6,075,402 shares of common stock outstanding with a weighted average exercise price of $9.91 and a weighted average remaining contractual term of 7.7 years and 13,220 restricted stock units outstanding with a weighted average remaining contractual term of 0.9 years which had been granted to employees and members of our board of directors. As of September 30, 2010, we also had warrants to purchase common stock outstanding as follows:

Warrants issued in conjuction with:	Shares	Expiration Date	Exercise Price
$80.0 million senior secured notes	785,728	June 2012	$ 9.34
$40.0 million senior secured notes	562,192	March 2013	$ 9.34
Equity financing facility	220,000	November 2013	$ 9.20
Public offering	1,731,724	July 2014	$ 7.37
Private offering	947,867	July 2016	$ 4.00

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, if any.

2. Inventories

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

	September 30, 2010	December 31, 2009
Raw materials	$ 1,561	$ 1,245
Work in process	1,199	676
Finished goods	1,716	1,505

Total inventories	$ 4,476	$ 3,426

3. Goodwill and Intangible Assets

The gross carrying amount of goodwill was as follows (in thousands):

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	September 30, 2010	December 31, 2009
Goodwill	$ 38,213	$ 38,213

The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	September 30, 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	$ (21,971)	$ 17,729	$ 39,700	$ (18,842)	$ 20,858
Developed technology Luvox CR	9,700	(4,695)	5,005	9,700	(2,443)	7,257
Agreements not to compete				3,900	(3,523)	377
Trademarks	2,600	(1,439)	1,161	2,600	(1,234)	1,366
Total	$ 52,000	$ (28,105)	$ 23,895	$ 55,900	$ (26,042)	$ 29,858

Based on intangible assets recorded as of September 30, 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 were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2010 (remaining portion)	$ 1,862
2011	7,448
2012	5,696
2013	4,445
2014	4,444

4. Fair Value Measurement

Available-for-sale investments consisted of the following as of September 30, 2010 and December 31, 2009 (in thousands):

	September 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 46	$	$	$ 46

	September 30, 2010
Available-for-sale investments	$ 46
Cash	22,807
Restricted cash	400
Total	$ 23,253

Reported as	September 30, 2010
Amounts classified as cash and cash equivalents	$ 22,853
Amounts classified as restricted cash	400
Total	$ 23,253

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	December 31, 2009		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 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 our inception, there have been no significant realized gains or losses on cash equivalents or marketable securities.

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):

	September 30, 2010		December 31, 2009	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Estimated Fair Value
Money market funds	$ 46	$ 46	$ 5,072	$ 5,072

The carrying amount and the estimated fair value of our long-term debt were as follows (in thousands):

	September 30, 2010		December 31, 2009	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt	$ 44,665	$ 45,156	$ 114,866	$ 123,628

We used a discounted cash flow analysis based on our estimated incremental borrowing rates for similar types of borrowing arrangements to calculate the fair value of our long-term debt.

5. Debt and Financing Obligations

Retired Senior Secured Notes

In March, May and June 2010 we repaid $3.0 million, $53.0 million and $63.5 million principal amount of our previously-outstanding senior secured notes, respectively. In addition to the principal repayments in May and June 2010, we paid prepayment penalties and fees totaling $8.5 million in accordance with our agreement with the holders of the senior secured notes, and recorded non-cash charges related to unamortized debt discount and debt issuance costs of $3.8 million during the nine months ended September 30, 2010. As of June 30, 2010, the senior secured notes were repaid in full.

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Term Loan and Revolving Credit Facility

In June 2010, we entered into a credit agreement with a lender which provides for a term loan in an aggregate principal amount of $50.0 million and a $15.0 million revolving credit facility, both of which mature in June 2013. On June 30, 2010, we borrowed $57.4 million under the credit agreement, consisting of the term loan of $50.0 million and $7.4 million under the revolving credit facility, and we used all of the borrowed funds, together with cash on hand, to repay all of the remaining outstanding senior secured notes, which otherwise had a final maturity of June 2011. We also terminated our previous revolving line of credit. Borrowings under the term loan and revolving credit facility bear interest at a variable rate based on the higher of the prime rate or the federal funds rate plus 0.5% plus, in each case, a margin ranging from 1% to 2.5% or, at our option, the Eurodollar rate plus a margin ranging from 3% to 5%. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.5% to 0.75% per annum. The interest rate margins and the commitment fee will vary based on our consolidated leverage ratio, as defined in the credit agreement.

The borrowing availability under the revolving credit facility will vary according to the levels of our eligible accounts receivable and other terms and conditions described in the credit agreement and is limited to $8.0 million until January 1, 2011 and $15.0 million thereafter. Borrowings under the revolving credit facility and the term loan are secured by substantially all of our assets. The term loan is repayable in twelve equal quarterly installments of $4.2 million beginning with the first payment of $4.2 million we made on September 30, 2010. If we prepay the term loan (in whole or in part), or if we terminate or reduce the lender s commitments to make loans under the revolving credit facility, we must pay a prepayment fee equal to (a) 2% of the aggregate amount of the term loan prepaid or commitments terminated or reduced during the first year of the credit agreement, and (b) 1% of the aggregate amount of the term loan prepaid or commitments terminated or reduced during the second year of the credit agreement.

The credit agreement contains customary operating covenants, including covenants that restrict our ability to: incur indebtedness and liens; effect mergers, consolidations and other fundamental changes; dispose of significant assets or enter into sale-leaseback transactions; pay dividends or make other restricted payments; make loans, advances or certain investments including acquisitions of companies and products; or enter into transactions with affiliates. The credit agreement also requires us to comply with financial covenants requiring us to maintain a minimum consolidated fixed charge coverage ratio, a maximum consolidated leverage ratio and minimum monthly liquidity, each as defined in the credit agreement. The minimum monthly liquidity covenant requires us to maintain cash and availability under the revolving line of credit of not less than $10.0 million combined beginning October 1, 2010 through March 31, 2011 and not less than $20.0 million combined thereafter. As of September 30, 2010, we were in compliance with all material covenants under the credit agreement.

The $45.8 million principal amount of the term loan was recorded net of a debt discount of $1.2 million related to fees paid to the lender under the credit agreement as of September 30, 2010. As of September 30, 2010, the interest rate on the term loan was 5.75%. Interest expense associated with the term loan 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 term loan is 8.1%. The current portion of the carrying amount of the term loan was $16.0 million as of September 30, 2010.

As of September 30, 2010, $7.4 million was outstanding under the revolving credit facility which bore interest at 5.75%. As of December 31, 2009, $9.4 million was outstanding under our previous revolving bank line of credit which bore interest at 6.5%. Our previous revolving bank line of credit was terminated effective June 30, 2010.

6. Common Stock

Common Stock Offering

In May 2010, we issued 7,000,000 shares of our common stock in an underwritten public offering for net proceeds of $56.8 million, after deducting underwriting discounts, commissions and offering expenses.

Stock Option Exercises, Vested Restricted Stock Units and Employee Stock Purchase Plan (ESPP)

During the nine months ended September 30, 2010, we issued 402,839 shares of common stock as a result of the vesting of restricted stock units and stock option exercises for proceeds of $646,000.

In May 2010, we issued 259,906 shares of our common stock under our ESPP for proceeds of $255,000.

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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. During the three and nine months ended September 30, 2010, comprehensive income was equal to net income. During the three and nine months ended September 30, 2009, the difference between comprehensive loss and net loss 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 specialty pharmaceutical products.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Xyrem	$ 37,231	$ 25,038	$ 99,699	$ 65,119
Luvox CR	6,607	4,954	17,950	12,670
Total	$ 43,838	$ 29,992	$ 117,649	$ 77,789

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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
United States	$ 43,564	$ 29,761	$ 117,172	$ 76,746
Europe	907	1,044	2,950	13,066
All other	282	4	290	353
Total	$ 44,753	$ 30,809	$ 120,412	$ 90,165

The following table presents a summary of total revenues from customers that represent more than 10% of our total revenues:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Express Scripts	83%	81%	82%	71%
UCB Pharma Limited (1)	*	*	*	14%

(1) In April 2009, we recognized as revenue a $10.0 million nonrefundable milestone payment received from UCB Pharma Limited, or UCB, in July 2008. See Note 9 for additional information.

* Represented less than 10% of our total revenues.

9. Collaboration and License Agreements

Under the terms of our agreement with UCB, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. In April 2009, upon the completion of the last patient in our second Phase III pivotal clinical trial of sodium oxybate for the treatment of fibromyalgia, we recognized as revenue a $10.0 million nonrefundable milestone payment we received from UCB in July 2008 that was previously recorded as deferred revenue. In addition, we recognized contract revenues of $280,000 in each of the three months ended September 30, 2010 and 2009, and $840,000 in each of the nine months ended September 30, 2010 and 2009 related to previously deferred upfront payments which are being recognized as contract revenue ratably through 2019, the expected performance period under the agreement.

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10. 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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Selling, general and administrative	$ 1,632	$ 1,039	$ 4,297	$ 2,545
Research and development	478	262	1,488	875
Cost of product sales	67	12	184	89
Total	$ 2,177	$ 1,313	$ 5,969	$ 3,509

Employee stock-based compensation costs of $65,000 and $46,000 as of September 30, 2010 and December 31, 2009, respectively, were capitalized as a component of inventories and included in the condensed consolidated balance sheets.

Stock Options

We granted options to employees and to members of our board of directors to purchase shares of our common stock as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Options granted	274,875	109,900	1,623,800	2,679,000
Weighted-average grant date fair value	$ 6.14	$ 4.02	$ 7.83	$ 1.06

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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Weighted-average volatility	88%	85%	85%	92%
Weighted-average expected term (years)	5.8	5.7	6.0	6.1
Range of risk-free rates	1.7-2.1%	2.6-3.1%	1.7-3.1%	1.8-3.1%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

Phantom Shares

In August 2010, certain directors elected to defer receipt of their retainer fees to be paid in our common stock under our Directors Deferred Compensation Plan, and we recorded phantom shares equivalent to 24,166 shares of our common stock with a market value per share of $8.21 under that plan. In August 2009, we recorded phantom shares equivalent to 38,432 shares of our common stock with a market value per share of $6.33. Total compensation cost related to phantom shares of our common stock credited to the directors phantom stock accounts was approximately $198,000 for the three and nine months ended September 30, 2010 and $243,000 for the three and nine months ended September 30, 2009.

11. Income Tax Expense

During the three and nine months ended September 30, 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.

12. 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.

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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 September 30, 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 and September 2009, we received Paragraph IV certification notices from Actavis Elizabeth, LLC, or Actavis, and from Anchen Pharmaceuticals, Inc., or Anchen, advising that each 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, or which party was first to file its ANDA with the FDA. Actavis Paragraph IV certification alleged that the United States patent covering Luvox CR, 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 alleged that the Elan patent would not be infringed by Anchen s manufacture, use or sale of the generic product for which the ANDA was submitted and that the Elan 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 patent by the defendants. 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 Elan patent.

On August 25, 2010, we and Elan entered into settlement agreements with Anchen. Under the agreements, we, Elan and Anchen have agreed to dismiss all of the claims brought in the litigation without prejudice, Anchen has agreed not to contest the validity or enforceability of the Elan patent in the United States, and we, Elan and Anchen have agreed to release each other from all claims arising in the litigation or relating to the product Anchen intends to market under its ANDA. Settlement agreements of ANDA litigation can be reviewed by the Federal Trade Commission and the U.S. Department of Justice at their discretion. In addition, we have granted a sublicense to Anchen of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicense is non-transferable, non-sublicensable and royalty-free and is exclusive even as to us and Elan (except with respect to Luvox CR) for a period of time. The sublicense will commence on February 15, 2013 or earlier upon the occurrence of certain events. On October 5, 2010, the United States District Court for the Central District of California dismissed the case against Anchen without prejudice. On the same date, the United States District Court for the District of Delaware also dismissed the case against Anchen without prejudice.

The lawsuit against Actavis is still pending in Delaware. We cannot predict the outcome of this litigation.

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 Study Commitment

The FDA approval of Luvox CR included a commitment for two Phase IV clinical studies, one in adolescent patients with social anxiety disorder, or SAD, and one a long-term duration of effect study in patients with SAD. If they were to be performed, the cost of these Phase IV studies would likely be significant. We have been in discussions with the 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 NDA for Luvox CR to remove the SAD indication from the label. This supplement is under active review by the FDA. 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, currently in neurology and psychiatry. We currently market two products: Xyrem (sodium oxybate) oral solution and Luvox CR (fluvoxamine maleate) Extended-Release Capsules. 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, Xyrem and Luvox CR. Our development pipeline includes: our JZP-6 product candidate, sodium oxybate for the treatment of fibromyalgia, for which we recently received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, as discussed below; our solid oral dosage forms of sodium oxybate; our JZP-8 product candidate in development for the treatment of recurrent acute repetitive seizures in epilepsy patients; and our JZP-4 product candidate for the treatment of epilepsy and bipolar disorder, which we are seeking to partner or out-license.

Xyrem

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. UCB currently markets Xyrem in 15 countries in Europe. We have three issued patents covering our formulation for Xyrem, one of which expires in 2019, and two of which expire in 2020, in the United States. We have four issued U.S. patents covering our distribution system for Xyrem which expire in 2024. Two of the formulation patents and three of the distribution system patents are listed in the FDA s approved drug products with therapeutic equivalence evaluation documents, or Orange Book. In addition, we have orphan drug exclusivity for the excessive daytime sleepiness in narcolepsy indication for Xyrem until November 2012; all narcolepsy patients suffer from excessive daytime sleepiness.

On October 5, 2010, the FDA s website indicated that an abbreviated new drug application, or ANDA, was submitted to the FDA on July 8, 2010 by a party seeking to market a generic form of Xyrem. On October 18, 2010, we received notice from Roxane Laboratories, Inc, or Roxane, that it filed an ANDA with the FDA seeking to market a generic form of Xyrem. We believe that the ANDA noticed to us by Roxane is the ANDA filed with the FDA on July 8, 2010. We are currently reviewing the details of Roxane s notice. Under the Hatch-Waxman Act, we have 45 days from receipt of the notice to determine if we will file a patent infringement suit. If we bring such a suit, a stay of approval of up to 30 months from our receipt of Roxane s notice will be imposed by the FDA on Roxane s ANDA. We intend to vigorously enforce our intellectual property rights. If generic products were to be introduced, our revenue from Xyrem product sales would decline.

Luvox CR

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 (which was recently acquired by Abbott Laboratories) retained the rights to market and distribute Luvox CR outside of the United States. Luvox CR is covered by a product-specific patent issued to Elan, which manufactures the product for us. In 2009, two companies filed ANDAs, seeking to market generic forms of Luvox CR and sent us certifications as required by the FDA that their products did not infringe the Elan patent, or that the patent is invalid. We filed suit against both

companies; one of the suits was settled during the third quarter of 2010 and the other is pending in Delaware. If generic products were to be introduced, our revenue from Luvox CR product sales would decline.

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In July 2010 we received a warning letter from the FDA concerning our promotional materials for Luvox CR. We have proposed a plan to the FDA and have taken actions to address the FDA s concerns. We have agreed with the FDA on a corrective action plan and we intend to complete our actions promptly.

JZP-6

We are developing and seeking FDA approval for 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. 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 a new drug application, or 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.

The FDA s Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee reviewed JZP-6 at a joint meeting on August 20, 2010 and voted 20-2 against approval of the NDA as submitted. On October 8, 2010, the FDA sent us a CRL regarding our NDA for JZP-6. The CRL states that the FDA cannot approve the NDA in its present form. In the letter, the FDA discusses a number of topics, including the need for additional clinical studies, the appropriate patient population, methods for ensuring safe use, and the proposed Risk Evaluation and Mitigation Strategy, or REMS, program, concentration of the formulation and the trade name for the product. We plan to meet with the FDA to discuss and clarify the letter, in order to determine the appropriate course of action for us with respect to JZP-6. We cannot assure you when, or whether, we will receive sufficient clarification from the FDA, or of the timing or cost of the continued development of JZP-6, or if its development will be continued, or whether the NDA for JZP-6 will be approved by the FDA.

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 that expire in 2024. In August 2010, UCB announced that it had filed an application with the European Medicines Agency, or EMA, for the approval of JZP-6, which UCB intends to market under the Xyrem trade name if it is approved in Europe. Currently, there are no approved treatments for fibromyalgia in the European Union. Under the terms of our agreement with UCB, we are entitled to a milestone payment of up to $25 million upon EMA approval of JZP-6, royalties on UCB s sales and additional commercial milestone payments of up to $100 million on sales of sodium oxybate. UCB has announced that it expects feedback from the European authorities during the first half of 2011.

Our JZP-6 product candidate is covered by one or more of our formulation patents covering Xyrem, and we expect that its distribution system, if the product is approved by the FDA, will be covered by one or more of our distribution system patents. JZP-6 is also covered by a patent covering the use of sodium oxybate to treat fibromyalgia that expires in 2017.

Other Product Candidates

Our other product candidates in clinical development are solid oral dosage forms of sodium oxybate and 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. We are seeking a partner to continue development of JZP-4 (elpetrigine), our product candidate for the treatment of epilepsy and bipolar disorder.

Financial Outlook

Until 2010, we incurred significant net losses in our business. Our net loss was $6.8 million for the year ended December 31, 2009, and $184.3 million for 2008. For the first nine months of 2010, we had net income of $13.2 million, and, although we expect to have significant net income for the full years 2010 and 2011, we may incur net losses in the future. The improvements for 2010 have been due to a significant increase in our product sales and a decrease in our expenses, as discussed below. However, our estimates of product sales and expenses for the full years 2010 and 2011 may prove to be wrong or other factors may adversely affect our business, and our net income could be lower than we expect .

We depend primarily on sales of Xyrem, and to a lesser extent Luvox CR, to fund our operations and generate our net income. The increase in our Xyrem revenues for 2010 resulted primarily from price increases, and to a lesser extent from increasing sales volume. On November 1, 2010, we implemented a price increase of approximately 20% for Xyrem. We cannot be certain that this or any future price increases will not cause a disruption in Xyrem sales and any decrease in sales would have a negative effect on our revenues.

We believe our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and meet all of our existing obligations through at least 2011. We have an active business development effort, and we may seek to in-license or acquire products and/or companies. If the FDA approves

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our NDA for JZP-6, we would incur significant expenses to launch the product, and we cannot predict its commercial success, if launched. If significant additional studies are required by the FDA with respect to JZP-6, we could expend significant resources if we were to choose to conduct the studies. To in-license products or acquire products or other companies, launch JZP-6 or conduct significant additional clinical trials, we may need to raise additional funds, and we do not know if such funds would be available to us on terms we would find acceptable, or at all.

Quota from the U.S. Drug Enforcement Agency, or DEA, is required in order to manufacture Xyrem and its active ingredient, sodium oxybate. Obtaining quota from the DEA is a difficult and time-consuming process, and the DEA has historically not given our suppliers the amounts of quota requested to meet our needs although we have never had a supply disruption. Insufficient quota could result in shortages of our commercial product or delays in our development and clinical activities.

We depend on single source suppliers for sodium oxybate, the active ingredient in both Xyrem and JZP-6. Lonza, Inc., or Lonza, our sole supplier of sodium oxybate, 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. Under the agreement, Lonza has an obligation to meet our sodium oxybate supply needs through 2011. Recently, the DEA increased the aggregate quota, and Lonza manufactured additional sodium oxybate for us.

In April 2010, we entered into an agreement with a new supplier, Siegfried (USA) Inc., or Siegfried, in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve Siegfried as a new supplier of sodium oxybate. As part of the transition to Siegfried, we are also expecting to transition to a new supplier for the precursor of sodium oxybate. Siegfried is conducting the necessary activities and plans to seek FDA approval as a supplier of sodium oxybate as soon as possible. We expect Siegfried to be approved by the FDA as a supplier by the second half of 2011 but we cannot be certain that this will occur.

Lonza has advised us that it is selling its plant to a third party that intends to operate the plant as a manufacturing facility. We have had initial discussions with the third party concerning the possibility of the plant being a source of supply of sodium oxybate for us, but no agreement has been reached.

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, or GAAP, 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, 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 and Nine Months Ended September 30, 2010 and 2009

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	Increase/ (Decrease)	Increase/ (Decrease)	2010	2009	Increase/ (Decrease)	Increase/ (Decrease)
	(In thousands)				(In thousands)			
Product sales, net	$ 43,838	$ 29,992	$ 13,846	46%	$ 117,649	$ 77,789	$ 39,860	51%
Xyrem	37,231	25,038	12,193	49%	99,699	65,119	34,580	53%
Luvox CR	6,607	4,954	1,653	33%	17,950	12,670	5,280	42%
Royalties, net	630	532	98	18%	1,909	1,522	387	25%
Contract revenues	285	285		0%	854	10,854	(10,000)	N/A (1)
Cost of product sales (excluding amortization of acquired developed technology)	3,091	2,338	753	32%	8,775	6,856	1,919	28%
Research and development	7,317	7,644	(327)	(4%)	21,494	30,244	(8,750)	(29%)
Selling, general and administrative	18,040	15,061	2,979	20%	51,926	42,934	8,992	21%
Amortization of intangible assets	1,862	2,057	(195)	(9%)	5,963	5,611	352	6%
Interest income	1	2	(1)	(50%)	5	29	(24)	(83%)
Interest expense	1,197	5,384	(4,187)	(78%)	11,651	17,034	(5,383)	(32%)
Other (expense) income	(4)	1	(5)	N/A (1)	(2)	(4)	2	N/A (1)
Loss on extinguishment of debt				N/A (1)	12,287		12,287	N/A (1)

(1) Comparison to prior period is not meaningful.

Product Sales, Net

Xyrem product sales increased in the three and nine months ended September 30, 2010 compared to the same periods in 2009 primarily due to price increases taken in 2009 and 2010 and, to a lesser extent, increases in volume. Domestic Xyrem sales volumes increased approximately 8% and 6% during the three and nine months ended September 30, 2010, respectively. We expect domestic Xyrem product sales in 2010 to increase compared to 2009 due primarily to the impact of price increases and to a lesser extent increases in volume. We also expect 2011 domestic Xyrem product sales to increase over 2010 due to the combined impact of price increases and, to a lesser extent, volume growth.

Luvox CR product sales increased in the three and nine months ended September 30, 2010 compared to the same periods in 2009 primarily due to increases in volume and, to a lesser extent, price increases. Luvox CR is approved by the FDA for the treatment of 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 and have stopped promoting Luvox CR for the SAD indication. We believe that the removal of the SAD indication from the label, if it occurs, will not have a significant negative impact on our Luvox CR product sales. We expect Luvox CR product sales in 2010 to be higher than in 2009, due primarily to increases in volume. For 2011, we expect sales of Luvox CR to increase over 2010 due to continued growth in volume and the impact of price increases.

Royalties

Royalties increased in the three and nine months ended September 30, 2010 compared to the same periods in 2009 due to increased royalties 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 as compared with 2009.

Contract Revenues

Except for a $10.0 million milestone payment which we recognized as revenue in the nine months ended September 30, 2009, contract revenues consist primarily of 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.

Cost of Product Sales

Cost of product sales increased in the three and nine months ended September 30, 2010 compared to the same periods in 2009 primarily due to our increased sales and sales volumes. As a percentage of product sales, costs were 7.1% and 7.5% in the three and nine months ended September 30, 2010, respectively, compared to 7.8% and 8.8%, respectively, for the same periods in 2009. This improvement in cost of product sales as a percentage of product sales was due primarily to price increases taken in 2009 and 2010.

Research and Development Expenses

Research and development costs were lower in the three and nine months ended September 30, 2010 compared to the same periods in 2009 primarily due to lower spending on JZP-6 as we focused on the prosecution of our NDA for our JZP-6 product candidate and our safety study for JZP-6, partially offset by higher spending on solid oral dosage forms of sodium oxybate, the active

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pharmaceutical ingredient in both Xyrem and JZP-6. As a result, our direct development costs decreased $553,000 and $10.6 million in the three and nine months ended September 30, 2010, respectively compared to the same periods 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 consisted 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 and accrued incentive compensation incurred in the research and development organization increased $317,000 and $2.0 million in the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009. We expect research and development spending in 2010 to be lower than 2009 and to continue to include development work on solid oral dosage forms of sodium oxybate and JZP-8 activities. As a result of the CRL we recently received from the FDA, we cannot predict the amount or timing of any additional spending on JZP-6 development work.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three and nine months ended September 30, 2010 compared to the same periods in 2009, due primarily to pre-launch planning and preparation activities in the 2010 periods related to our JZP-6 product candidate and to increases in salaries and benefits expenses including stock-based compensation and incentive compensation. We expect that selling, general and administrative expenses will be higher in 2010 than in 2009.

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. Higher amortization costs in the nine months ended September 30, 2010 compared to the prior year reflect our reduction in the estimated useful life of our Luvox CR intangible asset in connection with the two ANDA filings in 2009. Amortization costs for the three months ended September 30, 2010 were lower than the prior year due to the expiration of a non-compete agreement related to our 2005 acquisition of Orphan Medical, Inc. We believe the filing with the FDA of an ANDA seeking to market a generic form of Xyrem will not have an impact on the useful lives of our Xyrem intangible assets.

Interest Expense

In 2010, we reduced the principal amount of our long-term debt outstanding from $119.5 million to $45.8 million, extended the final maturity date of our debt from June 2011 to June 2013 and reduced the rate at which we pay interest on our debt from a fixed rate of 15% to a variable rate that was 5.75% as of September 30, 2010 by repaying our senior secured notes in full and entering into a bank credit agreement. As a result, interest expense was lower in the three and nine months ended September 30, 2010 compared to the same periods in 2009.

Loss on Extinguishment of Debt

The loss on extinguishment of debt relates to the early repayment of our senior secured notes in May and June 2010 and is comprised of $8.5 million of prepayment premiums and fees, and $3.8 million of non-cash expense related to the write-off of unamortized debt discount and debt issuance costs.

Non-GAAP Financial Measures

To supplement our financial results and financial guidance presented on a GAAP basis, we use the non-GAAP measures adjusted net income (loss) and adjusted net income (loss) per diluted share as shown in the table below. These measures exclude (1) revenue related to upfront and milestone payments, and (2) certain expenses related to the loss on extinguishment of debt, amortization of intangible assets, stock-based compensation and non-cash interest expense associated with debt discount and debt issuance costs. We believe these non-GAAP financial measures are helpful in understanding our past financial performance and our future results, are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Our management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate our business and make operating decisions. Compensation of our executives is based in part on the performance of our business based on these non-GAAP measures. In addition, we believe that the use of these non-GAAP measures enhances the ability of investors to compare our results both from period to period and with those of other companies. Adjusted net income (loss) and adjusted net income (loss) per diluted share, as used by us, may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by our competitors and other companies.

A reconciliation of GAAP net income (loss) to adjusted net income (loss), a non-GAAP financial measure, and related per share amounts follows:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands, except per share amounts)			
GAAP net income (loss)	$ 13,243	$ (1,672)	$ 8,319	$ (12,489)
Add:				
Intangible asset amortization	1,862	2,057	5,963	5,611
Stock-based compensation expense	2,177	1,313	5,969	3,509
Non-cash interest expense	252	701	2,175	1,849
Loss on extinguishment of debt			12,287	
Deduct:				
Contract revenues	(285)	(285)	(854)	(10,854)
Adjusted net income (loss)	$ 17,249	$ 2,114	$ 33,859	$ (12,374)
GAAP net income (loss) per diluted share	$ 0.32	$ (0.05)	$ 0.22	$ (0.42)
Adjusted net income (loss) per diluted share	$ 0.41	$ 0.06	$ 0.89	$ (0.42)
Shares used in computing GAAP net income (loss) per diluted share	41,737	30,895	38,233	29,635
Shares used in computing adjusted net income (loss) per diluted share	41,737	32,790(1)	38,233	29,635

(1) Shares used in computing adjusted net income per diluted share are greater than shares used in computing GAAP net loss per diluted share due to the potentially dilutive effect of common shares from employee stock plans and warrants.

Liquidity and Capital Resources

During 2010 we have taken a number of measures designed to strengthen our balance sheet and improve our liquidity and financial condition. The primary factor that allowed us to do this was a substantial improvement in cash generated from operations. During the nine months ended September 30, 2010, we generated operating cash flows of $27.6 million, reduced the principal amount of our long-term debt outstanding from $119.5 million to $45.8 million, and by repaying our former senior secured notes in full and entering into a new credit agreement, extended the final maturity date of our long-term debt from June 2011 to June 2013 and reduced the rate at which we pay interest on our debt from a fixed rate of 15% to a variable rate that was 5.75% as of September 30, 2010.

We believe that our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and to meet our existing obligations through at least 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 as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business. As of September 30, 2010, we had cash and cash equivalents of $22.9 million.

In May 2010, we issued 7,000,000 shares of our common stock in an underwritten public offering for net proceeds of $56.8 million. With the proceeds of this offering we prepaid $53.0 million principal amount of our then existing senior secured notes. In June 2010, we entered into a credit agreement which provides for a term loan in an aggregate principal amount of $50.0 million and a $15.0 million revolving credit facility both of which mature in June 2013, the proceeds from which we used to prepay in full all of the remaining outstanding senior secured notes. As of September 30, 2010, $45.8 million principal amount was outstanding on the term loan and $7.4 million was outstanding under the revolving credit facility. The average amount outstanding under the revolving credit facility during the three months ended September 30, 2010 was $2.8 million. Borrowings under the term loan and revolving credit facility bear interest at a variable rate based on the higher of the prime rate or the federal funds rate plus 0.5% plus, in each case, a margin ranging from 1% to 2.5% or, at our option, the Eurodollar rate plus a margin ranging from 3% to 5%. The interest rate was 5.75% at September 30, 2010. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.5% to 0.75% per annum. The interest rate margins and the commitment fee will vary based on our consolidated leverage ratio, as defined in the credit agreement.

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The borrowing availability under the revolving credit facility will vary according to the levels of our eligible accounts receivable and other terms and conditions described in the credit agreement and is limited to $8.0 million until January 1, 2011 and $15.0 million thereafter. Borrowings under the revolving credit facility and the term loan are secured by substantially all of our assets. At such times as our cash, cash equivalents and amounts available under the revolving credit facility, in total, are less than $25.0 million, our borrowings under the revolving credit facility are automatically paid with our cash receipts, although we are able to reborrow based on our eligible accounts receivable and other terms and conditions described in the credit agreements. The term loan is repayable in twelve equal quarterly installments of $4.2 million beginning with the first payment of $4.2 million we made on September 30, 2010. If we prepay the term loan (in whole or in part) or if we terminate or reduce the lender s commitments to make loans under the revolving credit facility we must pay a prepayment fee equal to (a) 2% of the aggregate amount of the term loan prepaid or commitments terminated or reduced during the first year of the credit agreement, and (b) 1% of the aggregate amount of the term loan prepaid or commitments terminated or reduced during the second year of the credit agreement.

The credit agreement contains customary operating covenants, including covenants that restrict our ability to: incur indebtedness and liens; effect mergers, consolidations and other fundamental changes; dispose of significant assets or enter into sale-leaseback transactions; pay dividends or make other restricted payments; make loans, advances or certain investments, including acquisitions of companies and products; or enter into transactions with affiliates. The credit agreement also requires us to comply with financial covenants requiring us to maintain a minimum consolidated fixed charge coverage ratio, a maximum consolidated leverage ratio and minimum monthly liquidity, each as defined in the credit agreement. The minimum monthly liquidity covenant requires us to maintain at any time during any month daily cash balances and availability under the revolving line of credit of not less than $10.0 million combined from October 1, 2010 through to March 31, 2011 and not less than $20.0 million combined thereafter. Our failure to comply with any of the operating and financial covenants contained in the credit agreement would constitute an event of default under the credit agreement. The credit agreement contains other customary events of default. Upon the occurrence of one or more events of default, including our failure to comply with all operating and financial covenants, all or part of the obligations under the credit agreement may be declared immediately due and payable and borrowings under the credit agreement may be stopped. We do not currently have the cash resources necessary to satisfy our obligations under the credit agreement in full if our obligations were accelerated. As of September 30, 2010, we were in compliance with all material covenants under the credit agreement.

To grow our business in the future, we will need to commit substantial resources to product acquisition and in-licensing costs, to expensive and time-consuming product development and clinical trials of our product candidates (including potentially JZP-6), and to expanding our commercial operations. We may seek to raise additional funds for general corporate purposes, including licensing or acquiring additional products, product candidates or companies. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations, partnering arrangements or development financings or a draw down of funds under our committed equity financing facility, or CEFF, with Kingsbridge Capital Limited. Under the CEFF, we have the ability to draw down amounts up to $75.0 million, subject to certain conditions. The CEFF expires in December 2012. Any equity financing would be dilutive to our stockholders, and a debt issuance could be prohibited or difficult, or the consent of the lender under our credit agreement could be required.

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

	Nine Months Ended September 30,	
	2010	2009
	(In thousands)	
Net cash provided by (used in) operating activities	$ 27,593	$ (17,650)
Net cash used in investing activities	(1,030)	(1,080)
Net cash (used in) provided by financing activities	(19,305)	6,057
Net increase (decrease) in cash and cash equivalents	$ 7,258	$ (12,673)

Net cash provided by operating activities during the nine months ended September 30, 2010 primarily reflected net income, adjusted for non-cash items including depreciation and amortization, stock-based compensation expense and a portion of the loss on the extinguishment of the senior secured notes in addition to the change in working capital. Net cash used in operating activities during the nine months ended September 30, 2009 primarily reflected the net 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 used in investing activities during the nine months ended September 30, 2010 primarily related to $3.0 million paid for the purchase of rights to Luvox CR and purchases of property, plant and equipment partially offset by the release of restricted cash. Net cash used in investing activities during the nine months ended September 30,

2009 primarily related to $3.0 million paid for the purchase of rights to Luvox CR partially offset by the release of restricted cash and the maturity of an investment in a marketable security. Net cash used in financing activities during the nine months ended September 30, 2010 was attributable to the repayment of $119.5 million principal amount of senior secured notes, a repayment of $4.2 million under our credit agreement and a net repayment of $2.0 million under our

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revolving credit facilities offset by net proceeds of $56.8 million from an underwritten public offering of shares of our common stock and borrowings of $48.7 million under our term loan. Net cash provided by financing activities during the nine months ended September 30, 2009 was primarily attributable to net proceeds of $6.8 million from our private placement in July 2009 offset by our net repayment of our line of credit.

Contractual Obligations

In addition to our contractual obligations set forth in our Annual Report on Form 10-K for the year ended December 31, 2009, the following table reflects a summary of material contractual obligations that have been modified or have been incurred during the first nine months of 2010 and remain outstanding as of September 30, 2010:

		Payments due by period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 years**
			(In thousands)		
Term loan - principal (1)	$ 45,834	$ 16,664	$ 29,170	$	$
Term loan - interest (2)	3,957	2,276	1,681		
Revolving credit facility (1)	7,350	7,350			
Liability under government settlement (3)	11,500	4,164	7,336		
Total	$ 68,641	$ 30,454	$ 38,187	$	$

(1) In June 2010, we entered into a credit agreement which provides for a term loan in an aggregate principal amount of $50.0 million and a $15.0 million revolving credit facility both of which mature in June 2013. On June 30, 2010, we borrowed $57.4 million under the credit agreement, consisting of a term loan of $50.0 million and $7.4 million under the revolving credit facility. Borrowings under the term loan and revolving credit facility bear interest at a variable rate based on the higher of the prime rate or the federal funds rate plus 0.5% plus, in each case, a margin ranging from 1% to 2.5% or, at our option, the Eurodollar rate plus a margin ranging from 3% to 5%. The interest rate was 5.75% at September 30, 2010. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.5% to 0.75% per annum. The interest rate margins and the commitment fee will vary based on our consolidated leverage ratio, as defined in the credit agreement. The borrowing availability under the revolving credit facility will vary according to the levels of our eligible accounts receivable and other terms and conditions described in the credit agreement and is limited to $8.0 million until January 1, 2011 and $15.0 million thereafter. Borrowings under the revolving credit facility and the term loan are secured by substantially all of our assets. The term loan is repayable in twelve equal quarterly installments of $4.2 million beginning on September 30, 2010. On September 30, 2010, we repaid $4.2 million under the term loan and borrowed $7.4 million under the revolving credit facility.

(2) Borrowings under the term loan bear interest at a variable rate which was 5.75% at September 30, 2010. We estimated future interest payments by applying the currently applicable interest rate, which may not represent actual interest payments made.

(3) We believe that we will report net income for the year ended December 31, 2010 and as a result, $1.2 million of the liability which would have been due in January 2012 will be due in April 2011.

The FDA approval of Luvox CR included a commitment for two Phase IV clinical studies, one in adolescent patients with SAD and one a long-term duration of effect study in patients with SAD. If they were to be performed, the cost of the Phase IV studies would likely be significant. The cost of the Phase IV studies is not included in the table above and it was not included in our contractual obligations table as set forth in our Annual Report on Form 10-K for the year ended December 31, 2009. We have been in discussions with the 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 NDA for Luvox CR to remove the SAD indication from the label. This supplement is under active review by the FDA. 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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Related Party

As of December 31, 2009, an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder, held senior secured notes with an aggregate principal amount of $6.8 million and warrants to purchase 70,156 shares of our common stock exercisable at $9.34 per share. In 2010, we repaid the entire principal balance of all of our senior secured notes, including the $6.8 million of the senior secured notes held by the entity affiliated with KKR, and cash paid for interest and prepayment penalties with respect to those senior secured notes held by the entity affiliated with KKR was $461,000 and $484,000, respectively.

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.

In addition to the market risk disclosures 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, effective June 30, 2010, we were exposed to risks associated with changes in interest rates as a result of borrowings under the $45.8 million principal amount of our term loan. As of September 30, 2010 the $45.8 million principal amount of the term loan bore interest at a variable rate that was 5.75%. We are required to make quarterly principal payments of $4.2 million on the term loan over the next 2.75 years and therefore our exposure to risks associated with changes in interest rates will decrease over time. If the variable interest rate on the term loan changed by 1% our interest expense would change by a total of $688,000 over the remaining term of the term loan. Actual interest expense in the future may differ materially.

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 September 30, 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 September 30, 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 1. Legal Proceedings.

In August and September 2009, we received Paragraph IV certification notices from Actavis Elizabeth, LLC, or Actavis, and from Anchen Pharmaceuticals, Inc., or Anchen, advising that each has filed an abbreviated new drug application, or 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, or which party was first to file its ANDA with the FDA. On October 6, 2009, we and Elan Pharma International Limited, or 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 patent, owned by Elan, covering Luvox CR by the defendants. 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 Elan patent.

On August 25, 2010, we and Elan entered into settlement agreements with Anchen. Under the agreements, we, Elan and Anchen agreed to dismiss all of the claims brought in the litigation without prejudice, Anchen agreed not to contest the validity or enforceability of the Elan patent in the United States, and we, Elan and Anchen agreed to release each other from all claims arising in the litigation or relating to the product Anchen intends to market under its ANDA. Settlement agreements of ANDA litigation can be reviewed by the Federal Trade Commission and the U.S. Department of Justice at their discretion. In addition, we have granted a sublicense to Anchen of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicense is non-transferable, non-sublicensable and royalty-free and is exclusive even as to us and Elan (except with respect to Luvox CR) for a period of time. The sublicense will commence on February 15, 2013 or earlier upon the occurrence of certain events.

On October 5, 2010, the United States District Court for the Central District of California dismissed the case against Anchen without prejudice. On the same date, the United States District Court for the District of Delaware also dismissed the case against Anchen without prejudice.

The lawsuit against Actavis is still pending in Delaware. Actavis Paragraph IV certification alleged that the Elan patent, which is licensed to us, is invalid on the basis that the inventions claimed therein were obvious. 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.

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.

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 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 our ongoing financial obligations, and our future plans assume that sales of our products will increase. While Xyrem product sales increased in the nine month period

ended September 30, 2010 compared to the same period in 2009, and we expect Xyrem sales volume growth for 2010 compared to 2009, we cannot assure you that Xyrem sales volume will continue to grow. We have periodically increased the price of Xyrem, most recently on November 1, 2010, and we cannot assure you that price increases we have taken or may take in the future have not affected or will not negatively affect Xyrem sales volumes.

Xyrem was approved in 2002 with a risk management plan that is not under the current Risk Evaluation and Mitigation Strategy, or REMS, formulation as it is structured today by the U.S. Food and Drug Administration, or FDA. The FDA has required that existing risk management programs be converted to the newer REMS structure under the Food and Drug Administration Amendments Act of 2007. While we have been in discussions with the FDA about adopting a REMS for Xyrem under the new

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structure, those discussions have not been completed. We cannot assure you that the FDA will not impose new and onerous requirements under the new REMS structure that could make it more difficult or expensive for us to distribute Xyrem.

While we have been in discussions with the FDA concerning our Phase IV clinical study commitment related to social anxiety disorder, or SAD, 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 cannot assure you that the labeling supplement will be approved by the FDA, or that if the labeling supplement is approved by the FDA, we would be released from the Phase IV clinical study commitment. If the Phase IV studies were to be performed, it is likely that their cost would be significant. 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, our belief could be incorrect and sales of Luvox CR could decrease.

In July 2010 we received a warning letter from the FDA concerning our promotional materials for Luvox CR. We have agreed with the FDA on the actions we have taken and intend to take that will address the FDA s concerns, and we continue to emphasize compliance in our promotion of Luvox CR and all of our products. We cannot assure you that any actions we have taken and intend to take in response to the FDA warning letter will not have a negative effect on Luvox CR sales.

If prescriptions and revenue from sales of Xyrem and Luvox CR do not continue 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.

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. Although Xyrem is covered by three issued U.S. patents covering its formulation expiring in 2019 and 2020, and four U.S. patents covering its distribution system expiring in 2024, we cannot assure you that third parties will not attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable and introduce generic equivalents of Xyrem. Once orphan drug exclusivity for Xyrem in the United States for the treatment of excessive daytime sleepiness in patients with narcolepsy expires in November 2012, other companies could possibly introduce generic equivalents of Xyrem if they do not infringe our existing patents covering for Xyrem.

We recently learned from the FDA s website that an ANDA was filed with the FDA on July 8, 2010 requesting approval to market a generic version of Xyrem. On October 18, 2010, we received notice from Roxane Laboratories, Inc, or Roxane, that it filed an ANDA with the FDA requesting approval to market a generic version of Xyrem. We believe that the ANDA noticed to us by Roxane is the ANDA filed with the FDA on July 8, 2010. If the application is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. If a generic product were approved by the FDA for excessive daytime sleepiness or cataplexy in narcolepsy patients, or both, it is possible that prescriptions for other indications, such as fibromyalgia, if our JZP-6 product candidate is approved by the FDA, could be filled with a generic equivalent approved only for cataplexy or excessive daytime sleepiness, even if the patient is diagnosed with fibromyalgia. Additional ANDAs could also be filed requesting approval to market generic forms of Xyrem; if those applications for generics were approved and the generics were launched, sales of Xyrem could further decrease.

The notice from Roxane included a Paragraph IV certification with respect to all of our patents listed in the FDA s approved drug products with therapeutic equivalence evaluation documents, or Orange Book, for Xyrem on the date of our receipt of the notice. A Paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. The FDA will not approve an ANDA for a generic form of a product unless the submitting manufacturer either files a Paragraph IV certification with respect to the patents listed in the FDA s Orange Book for that product or all of those patents expire.

Although Luvox CR is covered by a product-specific patent issued to Elan Pharma International Limited, or Elan, expiring in 2020, other companies could manufacture and sell generic equivalents of Luvox CR in ways that are not covered by the claims of the patent after the expiration of three years of marketing exclusivity, which ends on February 28, 2011. In August 2009, we received a Paragraph IV certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received a Paragraph IV 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 filed lawsuits against both companies after receipt of their certifications. While we and Elan have settled our lawsuit with Anchen, the settlement agreement permits Anchen s entry into the market in early 2013, or earlier under certain circumstances. We are prosecuting the lawsuit against Actavis, but, we cannot assure you that this lawsuit will prevent the introduction of generic products for any particular length of time, or at all.

Although our JZP-6 product candidate is covered by one or more of our formulation patents and a patent covering the use of sodium oxybate to treat fibromyalgia expiring in 2017, and we expect that JZP-6 will also be covered by one or more of our distribution system patents expiring in 2024, we cannot assure you that this will prevent generic competition for JZP-6, if it is approved by the FDA and commercially launched.

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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, particularly when there is more than one generic available in the marketplace. 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.

Our only product candidate currently in late-stage development is JZP-6 for the treatment of fibromyalgia, for which we received a complete response letter on October 8, 2010. Although we believe our completed Phase III pivotal clinical trials have shown JZP-6 to be safe and effective for the treatment of fibromyalgia, we may decide to not continue development of JZP-6, the FDA may not approve JZP-6 for marketing or, if the FDA approves it for marketing, they may do so with restrictions that could adversely affect its commercial prospects, all of which could have a material adverse effect on our growth prospects.*

We are seeking approval from the FDA for 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. 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 when, or if, the FDA and other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia. The FDA s Arthritis Committee and Drug Safety and Risk Management Advisory Committee, or the Advisory Committees, reviewed JZP-6 at a joint meeting on August 20, 2010. At the meeting, Advisory Committee members raised concerns about various aspects of the JZP-6 program and product and made suggestions to the FDA on a wide variety of maters concerning the product. The members of the Advisory Committee were asked to vote on whether JZP-6 should be approved as submitted in our New Drug Application, or NDA, without any of the changes or suggestions discussed at the meeting. The vote was 20-2 against such an approval.

On October 8, 2010 we received a complete response letter, or CRL, from the FDA regarding our NDA for JZP-6. The CRL states that the FDA cannot approve the NDA in its present form. In the CRL, the FDA discusses a number of topics, including the need for additional clinical studies, the appropriate patient population, methods for ensuring safe use, and the proposed REMS for JZP-6, the formulation concentration and the trade name for the product. We plan to meet with the FDA to discuss and clarify the letter, in order to determine the appropriate course of action for us with respect to JZP-6. We cannot assure you when, or whether, we will receive sufficient clarification from the FDA, or of the timing or cost of the continued development of JZP-6, or if its development will be continued, or whether our NDA for JZP-6 will be approved by the FDA.

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. As with all product candidates, the benefits to patients must outweigh the risks. We cannot assure you that in the fibromyalgia population, which is larger than the narcolepsy population, the FDA will ultimately decide that the benefits of JZP-6 outweigh the risks, including the risks that the product will not be used safely or will be diverted or abused. 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 growth prospects.

The FDA requires us to have a REMS for JZP-6, if it is approved. The FDA may also require us to incorporate JZP-6 into the new Xyrem REMS, once it is finalized. The Xyrem risk management program is labor intensive, complex and expensive to operate. Since Xyrem is currently prescribed for a relatively small number of patients, the Xyrem risk management program 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 program, or a REMS with even more requirements, 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. To effectively manage a REMS for JZP-6, we may need to alter the Xyrem risk management program, or its REMS when one is finalized, and we cannot assure you that the FDA will allow us to do so, or will allow us to do so quickly enough for a smooth launch of JZP-6, if it is approved. The REMS 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 on one central pharmacy distributor for Xyrem sales in the United States, and the loss of that distributor, its failure to distribute Xyrem effectively or a decision by us to transfer our distribution to a new central pharmacy could adversely affect sales of Xyrem and, if it is approved, JZP-6.*

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

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which patients receive Xyrem under the Xyrem risk management program is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, or Express Scripts, through June 2011, 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 risk management program or 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.

Because there is a potential for more patients to use our JZP-6 product, if it is approved by the FDA for the treatment of fibromyalgia, we may wish to use a different central pharmacy or a different system under a REMS for JZP-6. It would take time and significant effort to develop such a system, and we would need to identify and enter into an arrangement with an appropriate central pharmacy to provide the necessary services under the REMS. Any such third party would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute JZP-6 under the REMS approved by the FDA. New or additional contracts might also be required with government and other insurers who would pay for JZP-6. Transitioning to a new system could result in product shortages, which would adversely affect sales of JZP-6, if it were approved, 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.*

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.

Lonza, Inc., or Lonza, currently our sole supplier of sodium oxybate, 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. In April 2010, we entered into an agreement with a new supplier, Siegfried (USA) Inc., or Siegfried, in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve Siegfried as a new supplier of sodium oxybate and Siegfried will need to obtain quota from the DEA each year in order to manufacture sodium oxybate for us. We cannot assure you that Siegfried will receive sufficient quota from the DEA to meet our needs.

If we and our suppliers cannot obtain as much quota as is needed, on a timely basis, or at all, 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

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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. (acquired earlier this year by Abbott Laboratories, or Abbott,), or Solvay, our sole supplier of fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. 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. Lonza has an obligation to meet our sodium oxybate supply needs through 2011. Recently, the DEA increased the aggregate quota, and Lonza manufactured additional sodium oxybate for us. In April 2010, we entered into an agreement with a new supplier, Siegfried (USA) Inc., or Siegfried, in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve Siegfried as a new supplier of sodium oxybate. In connection with the transition to Siegfried, we are also expecting to transition to a new supplier for the precursor of sodium oxybate. While we believe that we will be able to identify and qualify a new supplier of the immediate precursor and obtain the necessary supplies, we may not be able to do so on a timely basis, or at all. Siegfried is conducting the necessary activities and plans to seek FDA approval as a supplier of sodium oxybate as soon as possible. We expect Siegfried to be approved by the FDA as a supplier by the second half of 2011, but we cannot assure you that this will occur. If we need additional supplies of sodium oxybate, we cannot assure you that we will be able to obtain additional supplies in a timely manner, if at all.

Lonza has advised us that it is selling its plant to a third party that intends to operate the plant as a manufacturing facility. We have had initial discussions with the third party concerning the possibility of the plant being a source of supply of sodium oxybate for us, but no agreement has been reached, and we cannot assure you that we can or will enter into such an agreement on terms that would be acceptable to us.

Abbott has an ongoing obligation to supply us with fluvoxamine maleate, and as a result of Lonza selling its plant, Abbott will need to manufacture the material itself, or find a new supplier, to meet our needs. Other than through Lonza, Abbott has not supplied us with fluvoxamine maleate to date, and we cannot assure you that Abbott will be able to do so. We believe we have sufficient supplies to last until the end of 2011, but we cannot assure you that this will be the case. Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. 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 Abbott or Elan to supply necessary quantities of fluvoxamine maleate or 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.

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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 Pharma Limited, or 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.

We depend upon 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. UCB has announced that it has filed for EMA approval of JZP-6 for fibromyalgia, which UCB intends to market in Europe under the Xyrem trade name if JZP-6 is approved in Europe. However, there are currently no approved fibromyalgia treatments in the European Union, and we cannot assure you that the EMA will approve JZP-6 for fibromyalgia. For example, in October 2008, April 2009 and July 2009 panels of European regulators recommended against approving Cymbalta, Lyrica and Savella, respectively, as treatments 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/or JZP-6 in UCB s territories. We may be unable to do this on acceptable terms, or at all.

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 restrictions placed upon the product in connection with its approval, such as a REMS or labeling restrictions;
- 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 current and any future 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

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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.

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. For example, we recently received a CRL from the FDA concerning our JZP-6 product candidate, which may require additional clinical studies in order for JZP-6 to be approved for the treatment of fibromyalgia, and we do not know whether we would undertake additional studies, if they are required. 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 example, negative comments related to sodium oxybate being a derivative of GHB were made at the recent JZP-6 Advisory Committee meeting, which were publicized in news articles and on the internet. 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, LLC, or 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 $8.5 million has been paid to date; the remaining amount will be due in 2011 and 2012.

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.

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.

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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.

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.

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

Because we do not perform discovery research, we intend to grow our business by acquiring or in-licensing 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 of, 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. In addition, the terms of our credit agreement may restrict our ability to pursue certain 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.

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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.

We are a small company and our employees must work on many important and diverse matters at the same time. If we fail to retain key personnel, or to retain our executive management team, or if we cannot provide additional resources to perform important tasks, we may be unable to successfully sustain or grow our business.*

Our success and our ability to grow depend 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. As a small company, we are highly dependent upon our executive management team and other key personnel, all of whom work on many complex matters that are critical to our success. 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.

To grow our company we will need additional personnel. Competition for qualified personnel in the life sciences industry has historically been intense. If we cannot timely attract and retain quality personnel on acceptable terms, 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 products and product candidates, their use and the methods used to manufacture and, in some cases, distribute them, as well as successfully defending these patents against third party challenges. Our ability to protect our products and 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. For example, even though we have seven patents covering Xyrem, with expiration dates between 2019 and 2024, and five of the patents are listed in the FDA s Orange Book, an ANDA was filed requesting permission from the FDA to market a generic form of Xyrem. We received a notice from a company that we believe filed the ANDA stating that the ANDA included a Paragraph IV certification with respect to all of our patents listed in the FDA s Orange Book on the date we received the notice of the filing. In the case of Luvox CR, for example, Actavis Paragraph IV certification alleges that the Elan patent, which is listed in the Orange Book for Luvox CR, is invalid. The expiration date for the Elan patent at issue is May 10, 2020.

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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.

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, our licensed patents or our partners patents, 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

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rights to these patents or that it is in the public interest to permit the infringing activity. We and Elan have filed and are prosecuting a lawsuit in response to the Paragraph IV certification that we received from Actavis. As a result of our receipt of a Paragraph IV certification with respect to Xyrem, we may choose to file and prosecute a lawsuit. We cannot assure you that these, or other lawsuits we may file in the future, will be successful in stopping the infringement of our patents, that any such 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.

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. For example, we have spent significant time and money developing our JZP-6 product candidate, and although we believe our clinical studies have shown the product candidate to be safe and effective, we recently received a CRL from the FDA related to our JZP-6 that states the FDA cannot approve the NDA in its present form.

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

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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.

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, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes 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 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 that we believe will impact our revenues from 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 dispensed to beneficiaries within this 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 on 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.

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 healthcare 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. The enactment and implementation of any future healthcare reform legislation or 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

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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 certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the exemptions and safe harbors whenever possible, but 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.

Many pharmaceutical and other health care companies have been investigated and have reached substantial financial settlements with the federal government 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 marketing of their products 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. 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 various federal and state laws is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company s products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government s ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and, beginning in March 2013 for payments made in 2012, public reporting of payments by pharmaceutical manufacturers to physicians and teaching hospitals nationwide. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and 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.

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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 covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under a fee-for-service arrangement, as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the Centers for Medicare and Medicare Services, or CMS, the federal agency which administers the Medicaid drug rebate program. These data include the average manufacturer price, or AMP, and in the case of innovator products, the best price for each drug. As a result of the enactment of the Healthcare Reform Act, rebates now also are due on the utilization of Medicaid managed care organizations, effective March 23, 2010.

Pursuant to the Healthcare Reform Act, and effective for rebate periods beginning the first quarter 2010, the minimum amount of the Medicaid rebate for each unit of a drug has been increased. For innovator products, in general a drug marketed under an NDA the minimum rebate has been increased from 15.1% to 23.1% of the AMP for that product, or if it is greater, the difference between the AMP and the best price for the product. The 23.1% rebate amount is lowered to 17.1% for certain clotting factor and pediatric drug products. For noninnovator products, in general a drug marketed under an ANDA, the rebate amount has been increased from 11% to 13.1% of the AMP for drug. The Medicaid rebate for innovator products also includes an additional rebate amount if price increases for the drug exceed the rate of inflation since the product s launch. The Healthcare Reform Act changes this additional rebate formula for certain products that qualify as line extensions of existing drugs, effective for rebate periods beginning with drugs paid for by a state as of the first quarter 2010, so that the rebate for these products can be increased and based on the additional rebate for the original drug. It also caps the total rebate amount for innovator drugs at 100% of the AMP for the drug. In addition, the Healthcare Reform Act changes the definition of AMP, effective for AMP prices reported for the fourth quarter of 2010, and additional legislation is currently pending that would further amend the AMP definition. CMS has yet to issue regulations to implement any of the enacted statutory changes.

We cannot assure that there will not be additional increases in rebates or other costs and charges from government agencies. Regulations continue to be issued and coverage expanded by various governmental agencies relating to these programs, increasing the cost and complexity of compliance.

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 CMS of our current AMP 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 AMP 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 as well as changes in the 340B ceiling prices based on those rebate calculations, as discussed below, such that refunds to covered entities that purchased at the earlier prices may be due. In addition to retroactive rebates and the potential for 340B ceiling price refunds, 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, and, in September 2010, CMS and the Office of the Inspector General indicated that they intend to more aggressively pursue companies who fail to report this data to the government in a timely manner. 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. CMS recently published information stating that many companies monthly and quarterly submissions are incomplete or incorrect. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service s 340B pharmaceutical pricing program in order for federal funds to be available for the manufacturer s drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B ceiling price for the manufacturer s covered outpatient drugs. These covered entities include 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. The 340B ceiling price is calculated using a statutory formula which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid drug rebate program. This means that to the extent the Healthcare Reform Act, as discussed above, changes the statutory and regulatory definitions of AMP and the Medicaid rebate amount, these changes also will affect the 340B ceiling price. The Healthcare Reform Act expands the 340B drug pricing program to include new covered entity types, effective for drugs purchased on or after January 1, 2010, although drugs that have received an orphan drug designation under section 526 of the Federal Food Drug and Cosmetic Act are exempt from the ceiling price requirement for the new categories of covered entities. The Healthcare Reform Act also obligates the

Secretary of the

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Department of Health and Human Services to create regulations and processes to improve the integrity of the program and to update the agreement that manufacturers must sign to participate in the program to obligate manufacturers to sell to covered entities if they sell to any other purchaser and to report to the government the ceiling prices for its drugs. In addition, Congress is currently

considering legislation that, if passed, would further expand the 340B program to require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting by certain covered entity hospitals, where those drugs are used for the covered entity s uninsured inpatients.

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, implementing the terms of the National Defense Authorization Act of 2008, established a program under which DoD expects rebates from pharmaceutical manufacturers on all prescriptions of covered prescription drugs (including innovator drugs and biologics) 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. These rebates are meant to enable DoD to access pricing that is either close to or equal to Federal Ceiling Prices, defined under the Veterans Health Care Act of 1992. Per the process set forth in this rule, we entered into a retail rebate agreement with DoD in July 2009. These legislative and regulatory changes, including our entering into the retail rebate agreement with DoD, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid drug rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues.

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

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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.

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. Xyrem is contraindicated in patients being treated with sedative hypnotic agents and in patients with succinic semialdehyde dehydrogenase deficiency. It should not be used with alcohol or other central nervous system depressants. Its label includes many adverse events associated with illicit GHB and with the use of sodium oxybate. In addition, both Xyrem and Luvox CR have boxed warnings in their labels. We expect that the label for JZP-6, if it is approved by the FDA, will also have a boxed warning, and will include adverse events seen in narcolepsy and fibromyalgia trials, as well as post-marketing safety information.

Product liability 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. If our JZP-6 product candidate is approved by the FDA, sales of that product could be significantly higher than those of Xyrem or Luvox CR, or both, which makes product liability claims more likely. 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 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 for the three and nine months ended September 30, 2010, 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, and whether or not there is generic competition;

- market acceptance of and the number of prescriptions written for our products and competition;

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selling and marketing costs associated with our products in the United States;

whether we obtain FDA approval of JZP-6, the timing of any such approval of JZP-6 and its potential commercialization, as well as the costs of any additional activities we may need to undertake in order to obtain regulatory approval of JZP-6, including any pre- or post-approval clinical studies;

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 and maintaining clinical and commercial supplies of our product candidates and products and our reliance on sole source suppliers;

the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;

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

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

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, scale back our operations, reduce our headcount, and/or discontinue some of our activities, which could negatively affect our business and prospects.*

Although we have generated cash from our operations in recent quarters, we may not be able to sustain or increase our cash from operations on a quarterly or annual basis. While we believe that our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and meet all of our existing obligations through at least 2011, we cannot assure you that this belief is correct. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses. We cannot predict with certainty the level of our product sales. We may also need additional cash resources to continue our development and clinical activities for JZP-6, if they are significant, and to in-license or acquire products, product candidates or companies. Our assumptions concerning our product sales and expenses may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

Our ability to raise additional funds will depend, among other things, on the capital markets and our financial condition at such time. Any additional funds we may raise could be on terms that are not favorable to us and may be dilutive to existing stockholders. If future product sales and expenses do not meet our expectations and we cannot raise additional funds, we may need to reduce our expenditures, which could negatively affect our business and prospects.

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

The terms of our credit agreement include, and any future indebtedness may include, 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 credit agreement include operating covenants restricting, among other things, our ability to:

incur additional indebtedness and liens;

effect mergers, consolidations and other fundamental changes

dispose of significant assets or enter into sale-leaseback transactions;

pay dividends or make other restricted payments;

make loans, advances or other investments including acquisitions of companies and products; and

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enter into transactions with affiliates.

In addition, the terms of the credit agreement include financial covenants requiring us, among other things, to

maintain a certain consolidated fixed charge coverage ratio;

maintain a certain leverage ratio; and

maintain minimum monthly liquidity from October 1, 2010 through the duration of the credit agreement.

Our failure to comply with any of these covenants could result in a default under the terms of the credit agreement, which could permit the lenders to declare all or part of the outstanding borrowings to be immediately due and payable. If our outstanding borrowings were to be accelerated, we may not have sufficient funds to repay those borrowings, and any such acceleration would have a material adverse effect on our business, financial condition and results of operations.

We have a substantial amount of secured debt, which matures in June 2013.*

Although we have significantly reduced the total amount of our outstanding debt through the repayment of our senior secured notes and the execution of our credit agreement, as of September 30, 2010, we had outstanding $53.2 million under our credit agreement, all of which is secured by a first lien and security interest in substantially all of our assets. These borrowings, 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.

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 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 whether or when, we will generate sufficient taxable income to use our NOLs. 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 5% shareholders or shareholder groups, as defined in the Code, 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.

Effective July 7, 2009, we entered into an NOL preservation lock-up agreement with most of our significant stockholders that restricts transferability of all of the shares of our common stock held by the stockholders who entered into the agreement until June 2011, unless terminated earlier under certain circumstances, in order to reduce 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 reduce 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 not experienced an ownership change since 2005, 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

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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, including the market for life sciences companies, 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 level of Xyrem and Luvox CR sales 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;
- our ability to successfully market JZP-6 in the United States if approved by the FDA for the treatment of fibromyalgia;
- 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;
- 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, product candidates and companies;

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;

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 comprehensive healthcare reform legislation;

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

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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 November 1, 2010, we had 38,918,545 shares of common stock outstanding, all of which shares are 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.

As of November 1, 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 June 2007. 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 in the future 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 senior secured notes that were repaid in June 2010. 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 a committed equity financing facility, or CEFF, in May 2008 with Kingsbridge Capital Limited, or Kingsbridge, which we amended in November 2009. The perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF in the future 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. We have not drawn down funds and have not issued shares of our common stock under the CEFF with Kingsbridge. 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, there is a limit on the maximum number of shares of common stock we can issue to Kingsbridge. Since we would 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 were to draw down amounts under the CEFF, even if we were 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. If we were to draw down funds under the CEFF and 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. If we sell shares to Kingsbridge under the CEFF, they will be issued at a discount from the average price of our common stock. This 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 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 could further decrease our share price. The CEFF expires in December 2012.

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.

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 November 1, 2010, our executive officers and directors, together with the stockholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 56.3% of our capital stock, of which approximately 5.0% 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

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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 devotes 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 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.

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 are 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, and, beginning with our annual report on Form10-K for the fiscal year ending December 31, 2010, to allow our independent registered public accounting firm to issue a report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. 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.

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 terms of our credit agreement include, and any future indebtedness may include, a covenant restricting our ability to pay dividends. 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 5. Other Information.

On August 31, 2010, we extended the term by six months and amended the pricing of Xyrem under our master services agreement for Xyrem with CuraScript, Inc., or CuraScript, and Express Scripts through June 30, 2011, subject to automatic one-year extensions thereafter. Additional information about our master services agreement for Xyrem with CuraScript and Express Scripts is included in Item. 1. Business in our Annual Report on Form 10-K for the year ended December 31, 2009 under the heading Marketed Products and Late-Stage Product Candidate Xyrem (sodium oxybate) oral solution Commercialization. We have no material relationship with CuraScript and Express Scripts other than in respect of the master services agreement.

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	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)
4.5B	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)
4.5C	

	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)

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Exhibit Number	Description of Document
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)
10.1+	Form of Option Agreement and Form of Option Grant Notice under the Amended and Restated 2007 Equity Incentive Plan.
10.2+	Amended and Restated 2007 Non-Employee Directors Stock Option Plan.
10.3+	Amended and Restated 2007 Employee Stock Purchase Plan.
10.4+	Amended and Restated Form of 2007 Employee Stock Purchase Plan Offering Document.
10.5+	Amended and Restated Directors Deferred Compensation Plan.
10.6+	Amended and Restated Non-Employee Director Compensation Arrangements.
10.7	Amendment No. 1 to Master Services Agreement, dated as of August 31, 2010, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and CuraScript, Inc.
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.*

\+ Indicates management contract or compensatory plan.

* 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 granted for 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: November 5, 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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EXHIBIT INDEX

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	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)
4.5B	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)
4.5C	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)

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