JAZZ PHARMACEUTICALS INC
Form 10-Q
May 09, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2011

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	**(I.R.S. Employer**
incorporation or organization)	**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	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

As of April 29, 2011, 40,741,809 shares of the registrant s Common Stock, $0.0001 par value, were outstanding.

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JAZZ PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2011

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In this report, Jazz Pharmaceuticals, we, us, and our refer to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries.

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

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	March 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,061	$ 44,794
Restricted cash	400	400
Accounts receivable, net of allowances of $486 and $482 at March 31, 2011 and December 31, 2010, respectively	21,383	22,081
Inventories	5,017	5,046
Prepaid expenses	2,577	1,858
Other current assets	402	279
Total current assets	94,840	74,458
Property and equipment, net	652	690
Intangible assets, net	20,171	22,033
Goodwill	38,213	38,213
Other long-term assets	302	335
Total assets	$ 154,178	$ 135,729
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Revolving credit facility	$ 4,000	$ 7,350
Accounts payable	3,648	3,049
Accrued liabilities	23,274	23,572
Current portion of long-term debt	16,131	16,064
Purchased product rights liability	4,625	4,500
Liability under government settlement	8,202	4,128
Deferred revenue	1,561	1,273
Total current liabilities	61,441	59,936
Deferred rent	77	82
Deferred revenue, non-current	8,768	9,053
Purchased product rights liability, non-current	3,250	4,500
Liability under government settlement, non-current		6,978
Long-term debt, less current portion	20,569	24,629
Commitments and contingencies (Note 10)		
Stockholders equity:		
Common stock	4	4

Additional paid-in capital	513,108	505,413
Accumulated deficit	(453,039)	(474,866)
Total stockholders equity	60,073	30,551
Total liabilities and stockholders equity	$ 154,178	$ 135,729

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31, 2011	2010
Revenues:		
Product sales, net	$ 49,903	$ 34,283
Royalties	693	605
Contract revenues	285	285
Total revenues	50,881	35,173
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technology)	2,809	2,882
Selling, general and administrative	19,911	16,790
Research and development	3,695	6,215
Intangible asset amortization	1,862	2,057
Total operating expenses	28,277	27,944
Income from operations	22,604	7,229
Interest income	1	2
Interest expense (including $315 for the three months ended March 31, 2010 pertaining to a related party)	(777)	(5,767)
Other expense	(1)	
Net income	$ 21,827	$ 1,464
Net income per share:		
Basic	$ 0.54	$ 0.05
Diluted	$ 0.48	$ 0.04
Weighted-average common shares used in computing net income per share:		
Basic	40,362	31,412
Diluted	45,697	34,926

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31, 2011	2010
Operating activities		
Net income	$ 21,827	$ 1,464
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	104	301
Amortization of intangible assets	1,862	2,057
Stock-based compensation expense	3,148	1,832
Long-term debt, non-cash interest expense	206	1,050
Changes in assets and liabilities:		
Accounts receivable	698	358
Inventories	50	(71)
Prepaid expenses and other current assets	(842)	(685)
Accounts payable	599	1,727
Accrued liabilities	(298)	1,072
Deferred revenue	3	249
Deferred rent	(5)	22
Liability under government settlement	(2,904)	(2,876)
Net cash provided by operating activities	24,448	6,500
Investing activities		
Purchases of property and equipment	(66)	(86)
Purchase of product rights	(1,125)	(1,000)
Decrease in restricted cash and investments		2,037
Net cash (used in) provided by investing activities	(1,191)	951
Financing activities		
Repayment of senior secured notes (including $171 for the three months ended March 31, 2010 paid to a related party)		(3,000)
Repayment of term loan	(4,166)	
Proceeds from exercise of stock options and warrants	4,526	511
Net repayments under revolving credit facilities	(3,350)	(1,559)
Net cash used in financing activities	(2,990)	(4,048)
Net increase in cash and cash equivalents	20,267	3,403
Cash and cash equivalents, at beginning of period	44,794	15,595
Cash and cash equivalents, at end of period	$ 65,061	$ 18,998

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, 2010. 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. The results for the three months ended March 31, 2011 are not necessarily indicative of the results to be expected for the year ending December 31, 2011 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

Most of our revenues are derived from sales of one product, Xyrem. Xyrem and its active pharmaceutical ingredient, sodium oxybate, are highly regulated by the U.S. Food and Drug Administration, or FDA, and the U.S. Drug Enforcement Agency, or DEA, and actions by either or both of these agencies could adversely affect sales of Xyrem. Xyrem has a black box warning, which is the strongest safety warning required by the FDA, and in recent years there has been increasing focus on the safety of pharmaceutical products. During 2010, an abbreviated new drug application, or ANDA, was filed with the FDA by a third party seeking to market a generic form of Xyrem. We have sued that third party for infringement of our patents, and the litigation is ongoing. We cannot predict the timing or outcome of this litigation. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected.

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, dependence on key customers and sole source suppliers and protection of intellectual property rights.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents and restricted cash, 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. Customer creditworthiness is monitored and collateral is not usually required. Historically, we have not experienced significant credit losses on our accounts receivable. One customer, Express Scripts Specialty Distribution Services, Inc. and its affiliate Curascript, Inc., or Express Scripts, accounted for 80% and 79% of gross accounts receivable as of March 31, 2011 and December 31, 2010, respectively.

We rely on certain sole suppliers for drug substance and certain sole manufacturing partners for each of our marketed products and product candidates.

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, stock-based compensation and income taxes. 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.

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Net Income Per Common Share

Basic net income per common share is based upon the weighted-average number of shares of common stock outstanding. Diluted net income per common share is based on the weighted-average number of shares of common stock outstanding and potentially dilutive common shares outstanding. Basic and diluted net income per common share is computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31, 2011	2010
Numerator:		
Net income	$ 21,827	$ 1,464
Denominator:		
Weighted-average common shares outstanding - basic	40,362	31,412
Dilutive effect of employee equity incentive and purchase plans	2,867	2,290
Dilutive effect of warrants	2,468	1,224
Weighted-average common shares outstanding - diluted	45,697	34,926
Net income per share:		
Basic	$ 0.54	$ 0.05
Diluted	$ 0.48	$ 0.04

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

	Three Months Ended March 31, 2011	2010
Options to purchase common stock	660	2,590

2. Inventories

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

	March 31, 2011	December 31, 2010
Raw materials	$ 2,669	$ 2,986
Work in process	991	705
Finished goods	1,357	1,355
Total inventories	$ 5,017	$ 5,046

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3. Fair Value Measurement

Available-for-sale investments consisted of the following (in thousands):

	March 31, 2011		December 31, 2010	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Money market funds	$ 37,047	$ 37,047	$ 25,046	$ 25,046

	March 31, 2011	December 31, 2010
Available-for-sale investments	$ 37,047	$ 25,046
Cash	28,014	19,748
Restricted cash	400	400
Total	$ 65,461	$ 45,194

Reported as	March 31, 2011	December 31, 2010
Amounts classified as cash and cash equivalents	$ 65,061	$ 44,794
Amounts classified as restricted cash	400	400
Total	$ 65,461	$ 45,194

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

	March 31, 2011		December 31, 2010	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Estimated Fair Value
Money market funds	$ 37,047	$ 37,047	$ 25,046	$ 25,046

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

	March 31, 2011	December 31, 2010

	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt	$ 36,700	$ 36,974	$ 40,693	$ 40,864

The fair value of our long-term debt was estimated using a discounted cash flow analysis based on our estimated incremental borrowing rates for similar types of borrowing arrangements.

4. Goodwill and Intangible Assets

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

	March 31, 2011	December 31, 2010
Goodwill	$ 38,213	$ 38,213

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

	March 31, 2011			December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology - Xyrem	$ 39,700	$ 24,056	$ 15,644	$ 39,700	$ 23,014	$ 16,686
Developed technology - Luvox CR	9,700	6,197	3,503	9,700	5,446	4,254
Trademarks	2,600	1,576	1,024	2,600	1,507	1,093
Total	$ 52,000	$ 31,829	$ 20,171	$ 52,000	$ 29,967	$ 22,033

Based on intangible assets recorded as of March 31, 2011, 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
2011 (remaining portion)	$ 5,586
2012	5,696
2013	4,445
2014	4,444
Total	$ 20,171

5. Stock-Based Compensation

Stock-based compensation expense related to stock options, restricted stock units, shares of common stock credited to the directors phantom stock accounts and grants under our employee stock purchase plan was as follows (in thousands):

	Three Months Ended March 31,	
	2011	2010
Selling, general and administrative	$ 2,412	$ 1,321
Research and development	656	465
Cost of product sales	80	46
Total stock-based compensation expense	$ 3,148	$ 1,832

Selling, general and administrative expenses for the three months ended March 31, 2011 included $0.6 million of stock-based compensation related to an executive severance agreement.

Employee stock-based compensation costs of $43,000 and $22,000 as of March 31, 2011 and December 31, 2010, respectively, were capitalized as a component of inventory and included in the condensed consolidated balance sheets.

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Stock Options

The table below shows the number of shares underlying options to purchase shares of our common stock granted to employees, the weighted-average grant date fair value per share of those stock options and certain information about the assumptions used in the Black-Scholes option pricing model which was used to estimate the grant date fair value per share:

	Three Months Ended March 31,	
	2011	2010
Shares	1,170,350	1,258,000
Weighted-average grant date fair value	$ 17.58	$ 8.29
Black-Scholes option pricing model assumption information:		
Weighted-average volatility	74%	84%
Weighted-average expected term (years)	5.6	6.1
Range of risk-free rates	2.4-2.7%	2.8%
Expected dividend yield	0.0%	0.0%

6. Common Stock

The following table presents a summary of shares of our common stock issued and proceeds received (dollars in thousands):

	Three Months Ended March 31, 2011	
	Shares issued	Proceeds
Option exercises	257,033	$ 1,908
Warrant exercises	337,776	2,618
Cashless warrant exercises	118,662	
Totals	713,471	$ 4,526

7. Comprehensive Income

Comprehensive income includes net income and all changes in stockholders equity during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. For the three months ended March 31, 2011 and 2010, comprehensive income was equal to net income.

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 total revenues (in thousands):

	Three Months Ended March 31,	
	2011	2010
Xyrem	$ 42,778	$ 28,745
Luvox CR	7,125	5,538

Product sales, net	49,903	34,283
Royalties	693	605
Contract revenues	285	285
Total revenues	$ 50,881	$ 35,173

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The following table presents a summary of total revenues attributed to domestic and foreign sources (in thousands):

	Three Months Ended March 31,	
	2011	2010
United States	$ 49,899	$ 34,062
Europe	977	1,106
All other	5	5
Total	$ 50,881	$ 35,173

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

	Three Months Ended March 31,	
	2011	2010
Express Scripts	84%	81%

9. Income Tax Expense

During the three months ended March 31, 2011, 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.

10. Commitments and Contingencies

Indemnification

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

We have agreed to indemnify our officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we have not recognized any liabilities relating to these obligations as of March 31, 2011 and December 31, 2010. 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

On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it filed an ANDA with the FDA requesting approval to market a generic version of Xyrem. Roxane s Paragraph IV Certification alleges that all five patents listed for Xyrem in the FDA s approved drug products with therapeutic equivalence evaluation documents, or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane s proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane s Paragraph IV Certification in the United States District Court for the District of New Jersey. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane s ANDA will be stayed until the earlier of (i) 30 months from our October 18, 2010 receipt of Roxane s Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. An additional method of use patent covering the distribution system for Xyrem issued in December 2010 and is listed in the Orange Book, and we amended our lawsuit against Roxane on February 4, 2011 to include the additional patent in the litigation in response to Roxane s Paragraph IV Certification against this patent. An additional method of use patent covering the distribution system for Xyrem issued in February 2011 and is listed in the Orange Book, and we amended our lawsuit on May 2, 2011 to include this additional patent in response to Roxane s Paragraph IV Certification against it. We cannot predict the outcome of this litigation.

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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.

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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 focused on the identification, development and commercialization of pharmaceutical products to meet important unmet medical needs. Since we were founded in 2003, we have built a commercial and development organization. We currently market two products, which generated net product sales of $49.9 million in the first quarter of 2011: Xyrem (sodium oxybate) is the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy; and Luvox CR (fluvoxamine maleate) is marketed for the treatment of obsessive compulsive disorder. We promote these products in the United States through our experienced specialty sales force targeting sleep specialists, neurologists, pulmonologists and psychiatrists.

In the three months ended March 31, 2011, net income was $21.8 million which resulted in operating cash flows of $24.4 million. We continue to be dependent on sales of Xyrem, which accounted for 86% of our net product sales in the first quarter of 2011. During 2010, an abbreviated new drug application, or ANDA, was filed with the FDA by a third party seeking to market a generic form of Xyrem. We have sued that third party for infringement of our patents, and the litigation is ongoing. We cannot predict the timing or outcome of this litigation. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected.

As of March 31, 2011, we had $65.1 million of cash and cash equivalents and $37.5 million principal amount of long-term debt outstanding. Because of our history of losses prior to 2010, we have significant net operating losses with which to offset current and potential future taxable income.

In October 2010, we received a Complete Response Letter, or CRL, from the FDA relating to our JZP-6 product candidate, sodium oxybate for the treatment of fibromyalgia, in which the FDA stated, among other things, that additional clinical trials of JZP-6 would be required. Since we received the CRL, we have had discussions with the FDA, and with our consultants and advisors, about the best way to proceed in response to the CRL. While we continue to believe that sodium oxybate could be an important treatment option for fibromyalgia patients, we believe that the additional clinical trials requested by the FDA in the CRL could take several years to complete and would require a significant investment. We also believe that there could still be significant regulatory uncertainty as to whether JZP-6 would be approved by the FDA. Therefore, unless or until we are able to significantly reduce or eliminate the requirement for pre-approval clinical trials and/or otherwise gain additional certainty as to FDA approval, we do not intend to move forward with additional JZP-6 clinical studies.

Recently, we have had important input from outside advisors with respect to our JZP-8 intranasal clonazepam product candidate. We and our advisors believe that JZP-8 could meet an important unmet medical need; however, some recent input has led us to conclude that the cost of the program and the time to FDA approval may be significantly greater than we previously anticipated. Given this input, along with the competitive landscape, we will determine in the next several months whether or how the program should be continued.

We are actively looking for appropriate opportunities to in-license or acquire additional products and product candidates to leverage our existing commercial and development capabilities.

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Results of Operations

Comparison of Three Months Ended March 31, 2011 and 2010

	Three Months Ended March 31, 2011	2010	Increase/ (Decrease)	Increase/ (Decrease)
	(In thousands)			
Product sales, net	$ 49,903	$ 34,283	$ 15,620	46%
Xyrem	42,778	28,745	14,033	49%
Luvox CR	7,125	5,538	1,587	29%
Royalties	693	605	88	15%
Contract revenues	285	285		0%
Cost of product sales (excluding amortization of acquired developed technology)	2,809	2,882	(73)	(3%)
Selling, general and administrative	19,911	16,790	3,121	19%
Research and development	3,695	6,215	(2,520)	(41%)
Intangible asset amortization	1,862	2,057	(195)	(9%)
Interest income	1	2	(1)	(50%)
Interest expense	777	5,767	(4,990)	(87%)
Other expense	1		1	N/A(1)

(1) Comparison to prior period is not meaningful.

Product Sales, Net

Xyrem product sales increased in the three months ended March 31, 2011 compared to the same period in 2010, primarily due to price increases and to a lesser extent a 12% increase in sales volume. Luvox CR product sales increased in the three months ended March 31, 2011 compared to the same period in 2010, primarily due to sales volume increases and to a lesser extent price increases. While we expect total product sales to increase in 2011 over 2010, the rate of growth of product sales or sales volumes, or both could be less than that experienced in 2010.

Royalties

Royalties increased in the three months ended March 31, 2011 compared to the same period in 2010 due to an increase in sales of Xyrem in Europe by UCB Pharma Limited, or UCB, under a license agreement. We expect modest growth in royalty income in 2011 as compared with 2010.

Contract Revenues

Contract revenues in the three months ended March 31, 2011 and 2010 include the recognition of previously deferred upfront payments under our agreement with UCB. These payments 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 in the three months ended March 31, 2011 as compared the same period in 2010 was approximately the same. As a percentage of product sales, costs were 6% and 8% in the three months ended March 31, 2011 and 2010, respectively. This decrease in cost of product sales as a percentage of product sales was primarily due to increases in average selling prices. We expect cost of product sales as a percentage of sales in 2011 to be consistent with the first quarter of 2011.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three months ended March 31, 2011 compared to the same period in 2010, due to $1.1 million recorded as a result of an executive severance agreement, of which $0.6 million was related to stock-based compensation, and increases in headcount-related, legal and information technology expenses. We expect that selling, general and administrative expenses will be higher in 2011 than in 2010 due to increases in headcount related expenses, legal expenses associated with protecting our sodium oxybate business, Xyrem marketing and promotional investments and stock-based compensation expense.

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Research and Development Expenses

Research and development costs were lower in the three months ended March 31, 2011 compared to the same period in 2010, primarily due to lower spending on JZP-6. We expect research and development spending in 2011 to be significantly lower than spending in 2010 and to consist primarily of expenses associated with research and development headcount.

Intangible Asset Amortization

Our intangible assets consist primarily of acquired developed technology related to Xyrem and Luvox CR. These assets are amortized on a straight-line basis over their estimated useful lives. We expect that intangible asset amortization expense will be slightly less in 2011 than in 2010.

Interest Income

Interest income was insignificant in both the three months ended March 31, 2011 and 2010 due to low interest rates.

Interest Expense

Interest expense relates primarily to interest on our long-term debt and, to a small extent, interest on our liability under a 2007 government litigation settlement. As of March 31, 2011 we had long-term debt of $37.5 million which bore interest at a variable rate of 3.75% compared to long-term debt of $116.5 million on March 31, 2010 which bore interest at a fixed rate of 15%. As a result, interest expense for 2011 is expected to be significantly lower than in 2010.

Non-GAAP Financial Measures

To supplement our financial results presented on a U.S. generally accepted accounting principles, or GAAP, basis, we use the non-GAAP measures adjusted net income and adjusted net income per diluted share as shown in the table below. These measures exclude the following: revenue related to upfront and milestone payments, amortization of intangible assets, stock-based compensation and non-cash interest expense associated with a debt discount and debt issuance costs. We believe these non-GAAP financial measures are helpful in understanding our past financial performance and our potential future results. They 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. Adjusted net income and adjusted net income 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.

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

	Three Months Ended March 31, 2011	2010
	(In thousands, except per share amounts)	
GAAP net income	$ 21,827	$ 1,464
Add:		
Intangible asset amortization	1,862	2,057
Stock-based compensation expense	3,148	1,832
Non-cash interest expense	206	1,050
Deduct:		
Contract revenues	(285)	(285)
Adjusted net income	$ 26,758	$ 6,118
GAAP net income per diluted share	$ 0.48	$ 0.04
Adjusted net income per diluted share	$ 0.59	$ 0.18
Shares used in computing GAAP and adjusted net income per diluted share amounts	45,697	34,926

Liquidity and Capital Resources

In the first quarter of 2011, we generated cash flows from operations of $24.4 million, and as of March 31, 2011, we had cash and cash equivalents of $65.1 million. 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 for the foreseeable future. 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 To grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. 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 March 31, 2011, $37.5 million principal amount was outstanding on our term loan, which is repayable in quarterly installments of $4.2 million, and $4.0 million was outstanding under our revolving credit facility. The average daily amount outstanding under our revolving credit facility during the three months ended March 31, 2011 was $1.0 million. Interest on the term loan and the revolving credit facility is payable at a variable rate which was 3.75% for most of the three months ended March 31, 2011. Borrowing availability under the revolving credit facility is currently $14.4 million. The facility has a commitment fee payable on the undrawn amount which is currently 0.5% per annum.

Our 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 liquidity, each as defined in the credit agreement. 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 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 are currently in compliance with all material covenants under the credit agreement. We have sufficient cash to repay the borrowings under the credit agreement in full, if that were necessary.

To grow our business over the longer-term, 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 that we choose to develop,

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and to expanding our commercial operations. We may need to raise additional funds to license or acquire additional products, product candidates or companies or seek to raise additional funds for general corporate purposes. 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 which expires in December 2012. Under the CEFF, we have the ability to draw down amounts up to $75.0 million, subject to certain conditions and limitations. Any equity financing would be dilutive to our stockholders, and 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:

	Three Months Ended March 31, 2011	2010
	(In thousands)	
Net cash provided by operating activities	$ 24,448	$ 6,500
Net cash (used in) provided by investing activities	(1,191)	951
Net cash used in financing activities	(2,990)	(4,048)
Net increase in cash and cash equivalents	$ 20,267	$ 3,403

Net cash provided by operating activities during the three months ended March 31, 2011 and 2010 primarily reflected net income, adjusted for non-cash items including depreciation, amortization, non-cash interest expense and stock-based compensation expense in addition to the change in working capital and a payment related to the settlement of government litigation.

Net cash used in investing activities during the three months ended March 31, 2011 primarily related to a scheduled payment under our agreement for the rights to market Luvox CR. Net cash provided by investing activities during the three months ended March 31, 2010 primarily related to the release of restricted cash partially offset by a scheduled payment under our agreement for the rights to market Luvox CR.

Net cash used in financing activities during the three months ended March 31, 2011 included a scheduled principal repayment of our term loan and a net repayment of our revolving credit facility, partially offset by proceeds from warrant exercises and employee stock option exercises. Net cash used in financing activities during the three months ended March 31, 2010 was attributable to a principal payment of $3.0 million of the then outstanding senior secured debt and a net repayment of a revolving credit facility, partially offset by proceeds from employee stock option exercises.

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 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 determining the amounts to be deducted from gross revenues, in particular estimates of government rebates, which include Medicaid and TRICARE rebates, and estimated returns of Luvox CR. 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, accrued expenses and income taxes. 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, 2010. 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, 2010.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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

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words such as should, expect, anticipate, estimate, target, may, project, guidance, intend, plan, believe and other words and meaning and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our goals, plans, expectations and projections regarding our financial position, results of operations, cash flows, market position, product candidate development, product approvals and other regulatory matters, sales efforts, expenses, performance or results of current products, the outcome of contingencies such as legal proceedings, and future 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, expectation or plan set forth in forward-looking statements can be achieved, and you are cautioned not to place undue reliance on such statements, which speak only as of the date made. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2011, there were no material changes to our market risk disclosures as set forth in Part II Item 7A. Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2010.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We have carried out an evaluation, under the supervision, and with the participation of, management including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2011.

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

Changes in Internal Control over Financial Reporting. No changes in our internal control over financial reporting occurred during the three months ended March 31, 2011 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

On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane s Paragraph IV Certification alleges that all five patents listed for Xyrem in the FDA s approved drug products with therapeutic equivalence evaluation documents, or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane s proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane s Paragraph IV Certification in the United States District Court for the District of New Jersey. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane s ANDA will be stayed until the earlier of (i) 30 months from our October 18, 2010 receipt of Roxane s Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. An additional method of use patent covering the distribution system for Xyrem issued in December 2010 and is listed in the Orange Book, and we amended our lawsuit against Roxane on February 4, 2011 to include the additional patent in the litigation in response to Roxane s Paragraph IV Certification against this patent. An additional method of use patent covering the distribution system for Xyrem issued in February 2011 and is listed in the Orange Book, and we amended our lawsuit on May 2, 2011 to include this additional patent in response to Roxane s Paragraph IV Certification against it. 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, 2010.

Risks Relating to Our Business

We are dependent on sales of Xyrem 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 Xyrem, it would have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

We are dependent on sales of Xyrem to generate the cash necessary to operate our business and to meet our ongoing financial obligations, and our future plans assume that sales of Xyrem will increase. While Xyrem product sales increased in the year ended December 31, 2010 compared to the same period in 2009, and we expect Xyrem sales growth for 2011 compared to 2010, we cannot assure you that this will occur. We have periodically significantly increased the price of Xyrem, most recently in April 2011, and we cannot assure you that price increases we have taken or may take in the future have not, or will not in the future, negatively affect Xyrem sales volumes.

In addition to other risks described herein, our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, the most important of which are discussed below, including those related to:

- the potential introduction of a generic version of Xyrem;

our manufacturing partners ability to obtain sufficient quota from the U.S. Drug Enforcement Agency, or DEA, to satisfy our needs for Xyrem;

any supply or distribution problems arising with any of our manufacturing and distribution partners, all of whom are sole source providers for us;

changed or increased regulatory restrictions, including changes to our risk management program for Xyrem;

changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;

changes to our label, including our black box warning, that further restrict how we market and sell Xyrem; and

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continued acceptance of Xyrem as safe and effective by physicians and patients.

These and the other risks described in these risk factors related to Xyrem s product sales could have a material adverse effect on our ability to maintain or increase sales of Xyrem.

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

If generic products that compete with Xyrem are approved, sales of Xyrem would be adversely affected.*

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, 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 patents covering Xyrem or can demonstrate that our patents are invalid or unenforceable.

On October 18, 2010, we received notice from Roxane Laboratories, Inc, or Roxane, that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. If the application is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. 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 would further decrease.

Roxane has sent us Paragraph IV certifications with respect to our patents listed in the FDA s approved drug products with therapeutic equivalence evaluation documents, or Orange Book, covering Xyrem for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy. 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. We have filed a lawsuit against Roxane, but we cannot assure you that the lawsuit will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all.

After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product generally may be filled with the generic version, 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 Xyrem could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture, distribution and sale of Xyrem are subject to significant restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.*

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, 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 and Xyrem. 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 or Xyrem 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. We cannot assure you that our suppliers will receive sufficient quota from the DEA to meet our needs, and 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.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem. The risk management plan includes unique features that provide information about adverse events, including deaths, that is generally not available for other products that are not subject to a similar risk management plan. Information concerning adverse events that may not be related to the use of Xyrem is likely to be collected under the risk management plan. This information, which we are required to report regularly to the FDA, could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse affect on Xyrem s commercial success.

Under the risk management plan, all of the Xyrem that we sell in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under the Xyrem risk management program is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, Inc. or Express Scripts, through June 2015, 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. If we change our central pharmacy, new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under the risk management plan approved by the FDA. 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, and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We depend on Express Scripts to conduct many required activities under the Xyrem risk management plan, including making regular contacts, generally by telephone, with Xyrem patients and physicians offices. Among other requirements, Express Scripts is required to report to us, under a standard procedure, information related to any adverse events of which it becomes aware. We recently learned that Express Scripts had not reported to us in accordance with that procedure a total of 74 deaths from all causes, occurring between 2003 and 2010, of patients who had been prescribed Xyrem. As a result, these cases were not reported to the FDA as required. Most of the cases occurred between 2003 and 2007; in each of 2008, 2009 and 2010 there were four unreported cases. In May 2011, we reported all of these cases to the FDA, within 15 days after we learned of them. We cannot be certain that additional cases have not been reported. The information provided to us does not specify the cause of death in most cases, and as a result we cannot be certain whether any, or how many, of the cases are related to Xyrem, and we may not be able to obtain such information.

Following a recent inspection by the FDA of our adverse event reporting system, we received on May 6, 2011 a Form 483 which included the inspector s observations concerning our adverse event reporting system. That document discussed the failure to report the cases discussed above, and also noted deficiencies in certain of our drug safety procedures. We have taken specific steps to correct certain deficiencies noted in the Form 483, and we intend to take additional corrective actions to address all of the matters covered in the Form 483.

As a result of our review to date of the cases recently reported to us, we believe that the adjusted annual all-cause mortality rate does not constitute a new safety signal for Xyrem. However, we cannot assure you that additional information will not modify our current assessment, that the FDA will agree with this assessment or that the FDA will not issue a warning letter, open an evaluation based on the FDA s Adverse Event Reporting System database, require changes to Xyrem s label or take or require us to take other actions that could be costly or time-consuming and/or negatively affect the commercial success of Xyrem. We cannot assure you that regulatory authorities in other countries where Xyrem is sold will not take similar actions.

The Xyrem risk management plan adopted with the approval of the product in 2002 is not in the same form as required under the current Risk Evaluation and Mitigation Strategy, or REMS, as it is structured today by the FDA. The FDA has required that pre-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 converting our current risk management plan for Xyrem to a REMS under the new 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 or could adversely affect our sales or make competition easier.

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. 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.

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If we are not able to maintain or increase sales of Luvox CR in the near term, it could have an adverse effect on our results of operations.

While Luvox CR product sales increased in 2010 compared to 2009, and we expect Luvox CR sales growth in 2011 as compared to 2010, we cannot assure you that Luvox CR sales will continue to grow.

We have been in discussions with the FDA concerning our remaining 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 have not been promoting Luvox CR for social anxiety disorder since April 2010; however, we cannot assure you that the removal of the SAD indication from the Luvox CR label, if it occurs, will not have a negative impact on our Luvox CR product sales.

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 ended in February 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. We and Elan entered into settlement agreements with Anchen granting Anchen a sublicense of our rights to have manufactured, market and sell a generic version of Luvox CR commencing on February 15, 2013 or earlier upon the occurrence of certain events. The lawsuit against Actavis is pending in the United States District Court for the District of Delaware, but, we cannot assure you that this lawsuit will prevent the introduction of an additional generic form of Luvox CR for any particular length of time, or at all.

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. In part due to the limited market size for our approved products, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. If our suppliers and contract manufacturers do not manufacture our products or product candidates without interruption or do not comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale depends upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a prior approval supplement and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem 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. For example, in 2010 we entered into an agreement with a new supplier for sodium oxybate, Siegfried (USA) Inc., or Siegfried. While we expect Siegfried to be approved by the FDA as a supplier in the second half of 2011, we cannot be certain this will occur. 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 and sodium oxybate for the marketplace or for use in clinical studies, or both.

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.

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 in the United States and our partners needs outside the United States, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

We may not be able to successfully identify and acquire, in-license or develop additional products or product candidates to grow our business, and, even if we are able to do so, we may not be able to successfully identify and manage the risks associated with integrating acquisitions, including acquisitions of a company or business unit, or other new products or product candidates.

We intend to grow our business over the long-term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. Any growth through acquisition or in-licensing will depend upon the availability of suitable acquisition or in-license products and product candidates on acceptable prices, terms and conditions, and any growth through development will depend upon our identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize these product candidates. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities.

In addition, integrating an acquisition, including the acquisition of a company or business unit, or an in-licensed product or product candidate, may create unforeseen operating difficulties and expenses for us, including:

- the diversion of management time and focus from operating our current business;

unanticipated liabilities for activities of or related to an acquired company or product before the acquisition;

failure to retain employees or to smoothly integrate related departments; and

failure to successfully develop and commercialize acquired products and product candidates.

We cannot assure you that we will be able to successfully manage these risks or other anticipated and unanticipated problems in connection with integrating an acquisition, including the acquisition of a company or business unit, or in-licensed product or product

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candidate, and, if we are not successful in identifying and managing these risks and uncertainties effectively, it could have a material adverse effect on our business.

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

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.

From time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Patients, physicians and regulators may therefore view Xyrem 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 because of its connection to GHB. Xyrem s label includes information about adverse events from GHB. 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 patients.

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. Negative publicity resulting from our recent receipt of a 483 observation from the FDA or other related regulatory actions could adversely affect sales of Xyrem.

We face substantial competition from other companies, including 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.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with 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.

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 any potential future products, the commercial opportunity for our potential future 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. Future commercial products may require expansion of our sales force and sales support organization, and we may 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 any necessary growth in a timely or 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, and turnover in our sales force and marketing personnel could negatively affect sales of our products.

We depend upon UCB to market and promote Xyrem in many countries outside the United States.*

We have exclusively licensed to UCB Pharma Limited, or UCB, the rights to market and promote Xyrem in 54 countries outside of the United States. In addition, under the terms of our collaboration with UCB, we granted UCB the exclusive right to commercialize JZP-6, which UCB would market under the Xyrem trade name if approved, 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 the European Medicines Agency, or EMA, will not approve JZP-6 for fibromyalgia at this time. UCB is currently assessing how to proceed with respect to Xyrem 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.

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 and expensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. 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, especially for product candidates that are in Phase II, or earlier, clinical trials, 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. 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.

To grow our sodium oxybate business, we have and may in the future conduct additional studies in different diseases or conditions or with additional or different doses or dosage forms. We cannot assure you that adverse events or other information obtained during the course of any of these studies will not result in action by the FDA or otherwise that could have a material adverse effect on the Xyrem commercial product as well as the candidate we are studying.

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. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA s and foreign regulatory agencies requirements, 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. 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 are a small company and our employees must work on many important and diverse matters at the same time. If we fail to attract, retain and motivate 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 attract, 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 employee 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.

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 nine patents covering Xyrem, with expiration dates between 2019 and 2024, and seven 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 have received notices from the company that filed the ANDA stating that the ANDA included Paragraph IV certifications with respect to our patents listed in the FDA s Orange Book. In the case of Luvox CR, 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.

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 consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party s activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. We have filed and are prosecuting a lawsuit against Roxane related to the Paragraph IV certifications delivered to us with respect to Xyrem. We and Elan are prosecuting a lawsuit against Actavis related to the Paragraph IV certification delivered to us with respect to Luvox CR. 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 which could be very costly to us and have a material adverse effect on our business.

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.

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. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process.

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, untitled letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

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 became effective in 2011, may negatively affect our revenues in the future. For example, 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 are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. In addition, under the Healthcare Reform Act, the minimum Medicaid rebate has been increased from 15.1% to 23.1% of the average manufacturer price for our products. 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 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.

To help patients afford our products, we have various programs to assist them, including a patient assistance program, a Xyrem voucher program and coupon programs for both of our products. Coupon programs, including our program for Xyrem, have recently received some negative publicity, and it is possible that new legislation could be enacted to restrict or otherwise negatively affect these programs. The enactment and implementation of any future healthcare reform legislation or policies could have a material adverse effect on our sales, 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. In such an instance, we could 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.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. For example, our predecessor company was investigated for off-label promotion of Xyrem, and, 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 through mid-2012. The investigation resulted in significant fines and penalties, which we guaranteed and have been paying; the final payment is due in 2012. The corporate integrity agreement requires us to maintain a comprehensive compliance program. 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.

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

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. 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.

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.

Under the Healthcare Reform Act, the minimum Medicaid rebate for branded prescription drugs has increased. There is also an additional rebate amount above the minimum rebate 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 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 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 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.

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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.

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. Both Xyrem and Luvox CR have boxed warnings in their labels.

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. 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. A recall could also result in product liability claims.

Risks Relating to Our Financial Condition

To grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.

To grow our business over the longer-term, we will need to commit substantial resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We will also need to continue to invest in our commercial operations. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

- the revenues from our commercial products and the costs of our commercial operations;
- whether or not there is generic competition for our products;
- the acquisition and/or licensing cost for any new products and product candidates;
- the scope, rate of progress, results and costs of our development and clinical activities;

- the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost of investigations, litigation and/or settlements related to regulatory activities; and
- changes in laws and regulations, including, for example, health care reform legislation.

One of our corporate goals is to expand our business through the licensing, acquisition and/or development of additional products and product candidates. We cannot assure you that our funds will be sufficient to fund these activities if opportunities arise, and we may be unable to expand our business if we do not have sufficient capital or cannot borrow or raise additional capital on attractive terms. In addition, if we use a substantial amount of borrowings or our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

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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 our 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 enter into transactions with affiliates. In addition, the terms of our 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 liquidity. 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. Although we currently have sufficient funds to repay our debt, if our outstanding borrowings were to be accelerated and we have used significant amounts of our cash or intend to use significant amounts of our cash for other purposes, we might not have sufficient funds to repay those borrowings and conduct all of our operations in the manner we would otherwise choose, and any such acceleration could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating losses to offset potential taxable income and related income taxes that would otherwise be due could be limited if we do not generate taxable income in a timely manner or if an ownership change pursuant to Section 382 of the Internal Revenue Code is triggered.*

We have significant net operating loss carryforwards, or NOLs. Our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs. In addition, 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, based on a calculation related to our market capitalization. An ownership change may occur if, during a three-year period, there is a change of 50% or more in the percentage ownership of our company by 5% shareholders or shareholder groups, as defined in the Code.

In July 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, which expires in July 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. We have the right to grant waivers under the agreement if requested by one or more parties and if the conditions set forth in the agreement are met, and we have done so. 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 is intended to reduce the risk of such an ownership change before July 2011, 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. The price of our stock has fluctuated significantly from time to time and has increased substantially in the past year, and we cannot predict if it will continue to do so. The risk factors described above relating to our business and products could cause the price of our common stock to fluctuate significantly. 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 addition, our stock price may be dependent upon the valuations and recommendations of the analysts who cover our business, and if our results do not meet our analysts forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise. 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.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock, and could impair our ability to raise capital through the sale of additional equity securities. As of April 29, 2011, we had 40,741,809 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 which expires in July 2011.

As of April 29, 2011, the holders of up to approximately 13,161,817 shares of common stock, based on shares outstanding as of that date, 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 or otherwise, 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 or otherwise, 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. 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. 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 April 29, 2011, our executive officers and directors, together with the stockholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 50% of our capital stock. Accordingly, our executive officers and directors, together with their respective affiliates or associates, are able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 8, 2011, we issued 20,221 shares of our common stock pursuant to the net exercise of warrants originally issued to certain investors in our Series BB preferred stock financing in 2005. Those warrants were exercisable for an aggregate of 33,756 shares of common stock and each had an exercise price of $9.34 per share. The number of shares issued upon the exercise of those warrants was reduced by an aggregate of 13,535 shares to effect the net exercise of the warrants in accordance with their terms.

On March 11, 2011, we issued 51,847 shares of our common stock pursuant to the net exercise of a warrant originally issued to an investor in our Series BB preferred stock financing in 2005. This warrant was exercisable for an aggregate of 78,573 shares of common stock and had an exercise price of $9.34 per share. The number of shares issued upon the exercise of this warrant was reduced by an aggregate of 26,726 shares to effect the net exercise of the warrant in accordance with its terms.

In issuing the above-mentioned shares, we relied on the exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering.

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Item 6. Exhibits.

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

Exhibit Number	Description of Document
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 4.9 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 10.88 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	2011 Executive Officer Compensation Arrangements.
10.2#	Master Services Agreement, dated April 15, 2011, by and between the Registrant, CuraScript, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.3	Separation Agreement, dated January 6, 2011, by and between the Registrant and Robert Myers (incorporated herein by reference to exhibit 10.53 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
10.4	Jazz Pharmaceuticals, Inc. Cash Bonus Plan, as amended as of February 8, 2011 (incorporated herein by reference to exhibit 10.55 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

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

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

Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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SIGNATURES

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

Dated: May 9, 2011

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)

/s/ Karen J. Wilson

Karen J. Wilson
Vice President, Finance

(Principal Accounting 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).

Exhibit Number	Description of Document
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 4.9 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 10.88 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	2011 Executive Officer Compensation Arrangements.
10.2#	Master Services Agreement, dated April 15, 2011, by and between the Registrant, CuraScript, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.3	Separation Agreement, dated January 6, 2011, by and between the Registrant and Robert Myers (incorporated herein by reference to exhibit 10.53 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
10.4	Jazz Pharmaceuticals, Inc. Cash Bonus Plan, as amended as of February 8, 2011 (incorporated herein by reference to exhibit 10.55 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

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

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

Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.