JAZZ PHARMACEUTICALS INC
Form 10-Q
November 08, 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 September 30, 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 incorporation or organization)	**(I.R.S. Employer Identification No.)**

3180 Porter Drive

Palo Alto, CA 94304

(650) 496-3777

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 October 24, 2011, 42,157,349 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 SEPTEMBER 30, 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)

	September 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 101,215	$ 44,794
Marketable securities	12,133	-
Restricted cash	-	400
Accounts receivable, net of allowances of $354 and $482 at September 30, 2011 and December 31, 2010, respectively	31,428	22,081
Inventories	4,297	5,046
Prepaid expenses	2,535	1,858
Other current assets	532	279
Total current assets	152,140	74,458
Property and equipment, net	930	690
Intangible assets, net	16,447	22,033
Goodwill	38,213	38,213
Other long-term assets	83	335
Total assets	$ 207,813	$ 135,729
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 8,463	$ 3,049
Accrued liabilities	35,834	23,572
Purchased product rights liability	4,875	4,500
Liability under government settlement	7,225	4,128
Revolving credit facility	-	7,350
Current portion of long-term debt	-	16,064
Deferred revenue	1,138	1,273
Total current liabilities	57,535	59,936
Purchased product rights liability, non-current	750	4,500
Liability under government settlement, non-current	-	6,978
Long-term debt, less current portion	-	24,629
Deferred rent	-	82
Deferred revenue, non-current	8,199	9,053
Commitments and contingencies (Note 10)		
Stockholders equity:		

Common stock	4	4
Additional paid-in capital	528,682	505,413
Accumulated other comprehensive loss	(2)	-
Accumulated deficit	(387,355)	(474,866)
Total stockholders equity	141,329	30,551
Total liabilities and stockholders equity	$ 207,813	$ 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 INCOME

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Product sales, net	$ 72,216	$ 43,838	$ 185,583	$ 117,649
Royalties	792	630	2,304	1,909
Contract revenues	285	285	854	854
Total revenues	73,293	44,753	188,741	120,412
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technology)	3,901	3,091	10,080	8,775
Selling, general and administrative	30,547	18,040	72,552	51,926
Research and development	3,279	7,317	10,356	21,494
Intangible asset amortization	1,862	1,862	5,586	5,963
Total operating expenses	39,589	30,310	98,574	88,158
Income from operations	33,704	14,443	90,167	32,254
Interest income and other, net	4	(3)	6	3
Interest expense (including $570 for the nine months ended September 30, 2010 pertaining to a related party)	(129)	(1,197)	(1,565)	(11,651)
Loss on extinguishment of debt (including $701 for the nine months ended September 30, 2010 pertaining to a related party)	(1,097)	-	(1,097)	(12,287)
Net income	$ 32,482	$ 13,243	$ 87,511	$ 8,319
Net income per share:				
Basic	$ 0.77	$ 0.34	$ 2.12	$ 0.24
Diluted	$ 0.69	$ 0.32	$ 1.88	$ 0.22
Weighted-average common shares used in computing net income per share:				
Basic	42,028	38,965	41,206	35,294
Diluted	47,241	41,737	46,577	38,233

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)

	0000	0000
	Nine Months Ended September 30,	
	2011	**2010**
Operating activities		
Net income	$ 87,511	$ 8,319
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	268	713
Amortization of intangible assets	5,586	5,963
Loss on disposal of property and equipment	15	313
Stock-based compensation expense	9,758	5,969
Long-term debt, non-cash interest expense	394	2,175
Loss on extinguishment of debt	1,097	12,287
Changes in assets and liabilities:		
Accounts receivable	(9,347)	(1,801)
Inventories	792	(1,031)
Prepaid expenses and other current assets	(1,051)	(391)
Other assets	190	(260)
Accounts payable	5,414	1,733
Accrued liabilities	12,262	4,779
Deferred revenue	(989)	(116)
Deferred rent	(82)	57
Liability under government settlement	(3,881)	(2,632)
Net cash provided by operating activities	107,937	36,077
Investing activities		
Purchases of property and equipment	(523)	(618)
Purchase of product rights	(3,375)	(3,000)
Decrease in restricted cash	400	2,588
Purchases of marketable securities	(12,135)	-
Net cash used in investing activities	(15,633)	(1,030)
Financing activities		
Repayment of long-term debt (including $6,816 for the nine months ended September 30, 2010 paid to a related party)	(41,668)	(123,662)
Payments of debt extinguishment costs (including $484 for the nine months ended September 30, 2010 paid to a related party)	(333)	(8,484)
Proceeds from offerings of common stock, net of issuance costs	-	56,817
Proceeds from issuance of long-term debt, net	-	48,688
Proceeds from employee stock purchases, exercise of stock options and warrants	13,468	901
Net repayments under revolving credit facilities	(7,350)	(2,049)
Net cash used in financing activities	(35,883)	(27,789)
Net increase in cash and cash equivalents	56,421	7,258

Cash and cash equivalents, at beginning of period	44,794	15,595
Cash and cash equivalents, at end of period	$ 101,215	$ 22,853

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 and nine months ended September 30, 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.

On September 19, 2011, we and Azur Pharma Public Limited Company (formerly Azur Pharma Limited), a public limited company formed under the laws of Ireland, or Azur Pharma, announced the signing of an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, pursuant to which we and Azur Pharma will combine our businesses in a stock transaction in which (a) Azur Pharma will effectuate a reorganization described in the Merger Agreement and (b) a wholly owned subsidiary of Azur Pharma will merge with and into our company, and as a result of this merger, our company will survive as a wholly owned subsidiary of Azur Pharma. At or prior to the completion of the merger, Azur Pharma will change its name to Jazz Pharmaceuticals plc, or New Jazz. Following the completion of the merger, our former stockholders will own slightly less than 80% of New Jazz, and Azur Pharma s shareholders will own the remainder, slightly over 20%. The New Jazz ordinary shares will be registered with the SEC and are expected to be listed on the NASDAQ Global Stock Market under the symbol JAZZ, the same trading symbol currently used by us. We anticipate the closing of the merger will be in the first quarter of 2012, at which time New Jazz s capitalization is estimated to be approximately 60 million shares fully diluted. Pursuant to the Merger Agreement, effective as of the closing of the merger, directors of our company and the chief executive officer of Azur Pharma are expected to be the directors of New Jazz. This transaction, which has been approved by our board of directors and the board of directors of Azur Pharma, is subject to customary closing conditions including approval of our stockholders and Azur Pharma s shareholders and regulatory approvals. Certain affiliates of ours who hold approximately 43% of our common stock have agreed to vote in favor of the merger.

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 Administration, or DEA, and actions by either or both of these agencies could adversely affect sales of Xyrem. Xyrem has a boxed 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.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or the FASB, issued guidance which changes certain fair value measurement principles and increases disclosure requirements, particularly for fair value measurements subject to significant judgment and is effective for fiscal years beginning after December 15, 2011. We are currently evaluating the effect that the adoption of this guidance will have on our results of

operations and financial position.

In June 2011, the FASB issued amended guidance on the presentation of comprehensive income in financial statements. The amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The amendment eliminates the option

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to present components of other comprehensive income as part of the statement of changes in stockholders equity and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In September 2011, the FASB issued amended guidance related to the goodwill impairment test which allows companies to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We do not believe the adoption of this amendment will have a material impact on our results of operations or financial position.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents and marketable securities. 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, cash equivalents and marketable securities and issuers of investments to the extent recorded on the balance sheet.

We are also subject to credit risk from our accounts receivable related to our product sales. 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 82% and 79% of gross accounts receivable as of September 30, 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.

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):

	$32,4820000	$32,4820000	$32,4820000	$32,4820000
	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2011	**2010**	**2011**	**2010**
Numerator:				
Net income	$ 32,482	$ 13,243	$ 87,511	$ 8,319
Denominator:				
Weighted-average common shares outstanding - basic	42,028	38,965	41,206	35,294
Dilutive effect of employee equity incentive and purchase plans	2,632	1,864	2,773	1,948
Dilutive effect of warrants	2,581	908	2,598	991

Weighted-average common shares outstanding - diluted	47,241	41,737	46,577	38,233
Net income per share:				
Basic	$ 0.77	$ 0.34	$ 2.12	$ 0.24
Diluted	$ 0.69	$ 0.32	$ 1.88	$ 0.22

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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):

	00,000000000	00,000000000	00,000000000	00,000000000
	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2011	**2010**	**2011**	**2010**
Options to purchase common stock	1,335	3,675	1,122	3,268
Warrants to purchase common stock	-	1,348	-	-

2. Inventories

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

	September 30, 2011	**December 31, 2010**
Raw materials	$ 2,065	$ 2,986
Work in process	688	705
Finished goods	1,544	1,355
Totals	$ 4,297	$ 5,046

3. Fair Value

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

	00$113,3480	00$113,3480	00$113,3480	00$113,3480	00$113,3480	00$113,3480	00$113,3480	00$113,3480
	September 30, 2011				**December 31, 2010**			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Money market funds	$ 72,802	$ -	$ -	$ 72,802	$ 25,046	$ -	$ -	$ 25,046
Obligations of U.S. government agencies	12,135	-	(2)	12,133	-	-	-	-
Total available-for-sale investments	$ 84,937	$ -	$ (2)	$ 84,935	$ 25,046	$ -	$ -	$ 25,046

	September 30, 2011	**December 31, 2010**
Available-for-sale investments	$ 84,935	$ 25,046
Cash	28,413	19,748
Restricted cash	-	400

Totals	$ 113,348	$ 45,194

Reported as	September 30, 2011	December 31, 2010
Amounts classified as cash and cash equivalents	$ 101,215	$ 44,794
Amounts classified as restricted cash	-	400
Amounts classified as marketable securities	12,133	-
Totals	$ 113,348	$ 45,194

Marketable securities consist of obligations of U.S. government agencies and were measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of the measurement date. Level 2 inputs, obtained from various third party data providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data. All marketable securities held as of September 30, 2011 had contractual maturities of less than one year, and no securities were sold in the three and nine months ended September 30, 2011. Unrealized losses as of September 30, 2011, related to the marketable securities were immaterial and we believe the impairment was temporary. In determining that the decline in fair value of these securities was temporary, we considered the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; and our ability and intent to not sell these securities before the recovery of their amortized cost basis. No marketable securities held as of September 30, 2011 had been in a continuous loss position for more than 12 months.

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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):

	Markets for0 September 30, 2011			Markets for0 December 31, 2010	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Estimated Fair Value
Money market funds	$ 72,802	$ -	$ 72,802	$ 25,046	$ 25,046
Obligations of U.S. government agencies	-	12,133	12,133	-	-
Totals	$ 72,802	$ 12,133	$ 84,935	$ 25,046	$ 25,046

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three and nine months ended September 30, 2011.

On July 1, 2011, we repaid in full our long-term debt (see Note 5). Prior to the extinguishment of our long-term debt, we estimated the fair value of our long-term debt using a discounted cash flow analysis based on our incremental borrowing rates for similar types of borrowing arrangements. The carrying amount and the estimated fair value of our long-term debt were as follows (in thousands):

	Markets for0 September 30, 2011		Markets for0 December 31, 2010	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt	$ -	$ -	$ 40,693	$ 40,864

4. Goodwill and Intangible Assets

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

	Markets for0 September 30, 2011	Markets for0 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):

	Net Book Value September 30, 2011			Net Book Value December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
	$ 39,700	$ 26,143	$ 13,557	$ 39,700	$ 23,014	$ 16,686

Developed technology - Xyrem						
Developed technology - Luvox CR	9,700	7,698	2,002	9,700	5,446	4,254
Trademarks	2,600	1,712	888	2,600	1,507	1,093
Totals	$ 52,000	$ 35,553	$ 16,447	$ 52,000	$ 29,967	$ 22,033

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Based on intangible assets recorded as of September 30, 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,	Shares issued Estimated Amortization Expense
2011 (remaining portion)	$ 1,862
2012	5,696
2013	4,445
2014	4,444
Total	$ 16,447

5. Debt and Financing Obligations

Term Loan and Revolving Credit Facility

On July 1, 2011, we repaid in full the $33.3 million principal amount of our term loan and a prepayment penalty of $0.3 million. As a result of the repayment, we recorded a loss on extinguishment of debt of $1.1 million, which consisted of a $0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and the $0.3 million prepayment penalty.

Borrowing availability under our revolving credit facility was $14.7 million and no amounts were outstanding as of September 30, 2011.

6. Stockholders Equity

Common Stock

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

	Nine Months Ended September 30, 2011	
	Shares issued	Proceeds
Option exercises & vesting of restricted stock units	1,200	$ 10,513
Employee stock purchase plan	260	296
Warrant exercises	343	2,659
Cashless warrant exercises	381	-
Directors deferred compensation plan	14	-
Totals	2,198	$ 13,468

Comprehensive Income

Comprehensive income was as follows (in thousands):

	Shares issued	Shares issued	Shares issued	Shares issued

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net income	$ 32,482	$ 13,243	$ 87,511	$ 8,319
Unrealized loss on available-for-sale investments	(2)	-	(2)	-
Total comprehensive income	$ 32,480	$ 13,243	$ 87,509	$ 8,319

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7. 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 classified as follows (in thousands):

	0000000000 Three Months Ended September 30,		0000000000 Nine Months Ended September 30,	
	2011	2010	2011	2010
Selling, general and administrative	$ 2,156	$ 1,632	$ 6,986	$ 4,297
Research and development	838	478	2,342	1,488
Cost of product sales	201	67	430	184
Totals	$ 3,195	$ 2,177	$ 9,758	$ 5,969

Stock Options

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

	0000000000 Three Months Ended September 30,		0000000000 Nine Months Ended September 30,	
	2011	2010	2011	2010
Shares	61	275	1,312	1,624
Grant date fair value	$ 24.56	$ 6.14	$ 17.99	$ 7.83
Black-Scholes option pricing model assumption information:				
Volatility	71%	88%	74%	85%
Expected term (years)	5.6	5.8	5.6	6.0
Range of risk-free rates	1.1-2.0%	1.7-2.1%	1.1-2.7%	1.7-3.1%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

8. Segment Reporting

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):

	$188,741 00 Three Months Ended September 30,		$188,741 00 Nine Months Ended September 30,	
	2011	2010	2011	2010
Xyrem	$ 62,547	$ 37,231	$ 161,503	$ 99,699
Luvox CR	9,669	6,607	24,080	17,950
Product sales, net	72,216	43,838	185,583	117,649
Royalties	792	630	2,304	1,909
Contract revenues	285	285	854	854

Total revenues	$ 73,293	$ 44,753	$ 188,741	$ 120,412

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

	00000000	00000000	00000000	00000000
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
United States	$ 72,218	$ 43,564	$ 185,048	$ 117,172
Europe	1,071	907	3,362	2,950
All other	4	282	331	290
Total revenues	$ 73,293	$ 44,753	$ 188,741	$ 120,412

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

	00,0000000000	00,0000000000	00,0000000000	00,0000000000
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Express Scripts	85%	83%	85%	82%

9. Income Tax Expense

During the three and nine months ended September 30, 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 September 30, 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.

Commitments

If the proposed merger between us and Azur Pharma is consummated, we will be required to pay our investment banker a fee of $1.5 million upon close which is in addition to $1.5 million we recorded as expense for services rendered in the three months ended September 30, 2011.

In the event that the Merger Agreement is terminated (other than in certain limited circumstances), we will be required to reimburse Azur Pharma for its costs and expense in connection with the preparation of the SEC filings and for certain potential claims or action against Azur

Pharma in connection with the proposed merger. As of September 30, 2011, amounts potentially owed to Azur Pharma under the Merger Agreement would be insignificant.

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

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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.

On September 10, 2011, we received a Paragraph IV Certification from Torrent Pharma Limited, or Torrent, advising us that it had filed an ANDA with the FDA requesting approval to market a generic version of Luvox CR. Torrent s Paragraph IV Certification alleges that U.S. Patent No. 7,465,462, or the 462 patent, owned by Elan Pharma International Limited, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, will not be infringed by the manufacture, use, sale or offer for sale of the generic product for which the ANDA was submitted and that the 462 patent is invalid. On October 21, 2011, we and Alkermes, as plaintiffs, filed a lawsuit against Torrent in the United States District Court for the District of Delaware asserting infringement of the 462 patent by Torrent in response to Torrent s Paragraph IV Certification. We are seeking a permanent injunction that prevents Torrent from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. We cannot predict the outcome of this litigation.

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

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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 and statements related to the anticipated completion of the proposed merger with Azur Pharma 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 $72.2 million and $185.6 million in the three and nine months ended September 30, 2011, respectively: 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 approved 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 and nine months ended September 30, 2011, net income was $32.5 million and $87.5 million, respectively, and operating cash flows were $46.1 million and $107.9 million, respectively. 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. We continue to be dependent on sales of Xyrem, which accounted for 87% of our year-to-date net product sales in 2011, and our primary focus is to build upon the success of the product by growing sales of Xyrem in its approved indications, continuing to invest in our franchise and enforcing our intellectual property rights. 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 the litigation. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected.

On July 1, 2011, we repaid in full the $33.3 million principal amount of a term loan and a prepayment penalty of $0.3 million. As a result of the repayment, we recorded a loss on extinguishment of debt of $1.1 million, which consisted of a $0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and the $0.3 million prepayment penalty. As of September 30, 2011, we had $113.3 million of cash and marketable securities.

Currently we do not have any product candidates in clinical development. We are actively looking for appropriate opportunities to in-license or acquire additional products and product candidates to leverage and expand our commercial and development capabilities. On September 19, 2011, we and Azur Pharma Public Limited Company (formerly Azur Pharma Limited), a public limited company formed under the laws of Ireland, or Azur Pharma, announced the signing of an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, pursuant to which we and Azur Pharma will combine our businesses in a stock transaction in which (a) Azur Pharma will effectuate a reorganization described in the Merger Agreement and (b) a wholly owned subsidiary of Azur Pharma will merge with and into our company, and as a result of this merger, our company will survive as a wholly owned subsidiary of Azur Pharma. At or prior to the completion of the merger, Azur Pharma will change its name to Jazz Pharmaceuticals plc, or New Jazz. Following the completion of the merger, our former stockholders will own slightly less than 80% of New Jazz, and Azur Pharma s shareholders will own the remainder, slightly over 20%. The New Jazz ordinary shares will be registered with the Securities and Exchange Commission, or SEC, and are expected to be listed on the NASDAQ Global Stock Market under the symbol JAZZ, the same trading symbol currently used by us. We anticipate the closing of the merger will be in the first quarter of 2012, at which time New Jazz s capitalization is estimated to be approximately 60 million shares fully diluted. Pursuant to the Merger Agreement, effective as of the closing of the merger, directors of our company and the chief executive officer of Azur Pharma are expected to be the directors of New Jazz. This transaction, which has been approved by our board of directors and the board of directors of Azur Pharma, is subject to customary closing conditions including approval of our stockholders and Azur Pharma s shareholders and regulatory approvals. Certain affiliates of ours who hold approximately 43% of our common stock have agreed to vote in favor of the merger.

On October 26, 2011, Azur Pharma filed with the SEC a registration statement on Form S-4 (File No. 333-177528) that included our preliminary proxy statement that we filed separately on the same day and that also constituted a preliminary prospectus of Azur Pharma regarding the New Jazz ordinary shares that would be issued to our stockholders in the proposed merger. After the registration statement has been declared effective by the SEC, we will mail a definitive proxy statement/prospectus to all of our stockholders in connection with the proposed merger and will

convene a special meeting of stockholders to vote on the proposed merger and related matters.

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Results of Operations

Comparison of Three and Nine Months Ended September 30, 2011 and 2010

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2011	2010			2011	2010		
	(In thousands)				(In thousands)			
Product sales, net	$ 72,216	$ 43,838	$ 28,378	65%	$ 185,583	$ 117,649	$ 67,934	58%
Xyrem	62,547	37,231	25,316	68%	161,503	99,699	61,804	62%
Luvox CR	9,669	6,607	3,062	46%	24,080	17,950	6,130	34%
Royalties	792	630	162	26%	2,304	1,909	395	21%
Contract revenues	285	285	-	0%	854	854	-	0%
Cost of product sales (excluding amortization of acquired developed technology)	3,901	3,091	810	26%	10,080	8,775	1,305	15%
Selling, general and administrative	30,547	18,040	12,507	69%	72,552	51,926	20,626	40%
Research and development	3,279	7,317	(4,038)	(55%)	10,356	21,494	(11,138)	(52%)
Intangible asset amortization	1,862	1,862	-	0%	5,586	5,963	(377)	(6%)
Interest income and other, net	4	(3)	7	N/A(1)	6	3	3	100%
Interest expense	129	1,197	(1,068)	(89%)	1,565	11,651	(10,086)	(87%)
Loss on extinguishment of debt	1,097	-	1,097	N/A(1)	1,097	12,287	(11,190)	(91%)

(1) Comparison to prior period is not meaningful.

Product Sales, Net

Xyrem product sales increased in the three and nine months ended September 30, 2011 compared to the same periods in 2010, primarily due to price increases and to a lesser extent increases in sales volume of 11.4% and 11.5% in the three and nine months ended September 30, 2011, respectively. Luvox CR product sales increased in the three and nine months ended September 30, 2011 compared to the same periods in 2010 due to a combination of sales volume increases and price increases. We expect total product sales to increase significantly in 2011 over 2010.

Royalties

Royalties increased modestly in the three and nine months ended September 30, 2011 compared to the same periods 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 and nine months ended September 30, 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 and nine months ended September 30, 2011 compared to the same periods in 2010 was higher primarily due to higher product sales. As a percentage of product sales, costs were 5.4% in both the three and nine months ended September 30, 2011, compared to 7.1% and 7.5%, respectively, for the same periods in 2010. 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 throughout 2011.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three and nine months ended September 30, 2011 compared to the same periods in 2010, primarily due to higher legal and professional services expenses and, to a lesser extent, headcount related expenses, including higher stock-based compensation expense. Selling, general and administrative expenses in the three and nine months ended September 30, 2011 included legal and professional services expenses of $6.0 million incurred in connection with the proposed merger with Azur Pharma. We expect that selling, general and administrative expenses will be higher in 2011 than in 2010 due to expenses related to the proposed merger with Azur Pharma, legal expenses associated with protecting our sodium oxybate business, and increases in headcount related expenses, including stock-based compensation expense.

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Research and Development Expenses

Research and development costs were lower in the three and nine months ended September 30, 2011 compared to the same periods in 2010 primarily due to lower spending on development projects. 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 which were initially established at the date of acquisition. We expect that intangible asset amortization expense will be slightly less in 2011 than in 2010.

Interest Income and Other, Net

Interest income was insignificant in the three and nine months ended September 30, 2011 and 2010 due to low interest rates.

Interest Expense

Interest expense in 2011 relates primarily to interest on a term loan that we repaid in full on July 1, 2011 and, to a small extent, interest on our liability under a 2007 government litigation settlement. Interest expense was lower in the three and nine months ended September 30, 2011 compared to the same periods in 2010 due to lower average long-term debt balances and lower average interest rates on our long-term debt.

Loss on Extinguishment of Debt

The loss on extinguishment of debt in the three and nine months ended September 30, 2011 related to the repayment of a term loan on July 1, 2011 and consisted of a $0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and a $0.3 million prepayment penalty. The loss on extinguishment of debt in the nine months ended September 30, 2010 related to our repayment of long-term debt and consisted of $8.5 million of prepayment premiums and fees, and a $3.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount.

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, non-cash interest expense associated with a debt discount and debt issuance costs, loss on extinguishment of debt and transaction costs related to the proposed merger with Azur Pharma. 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 employees 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 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 (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
GAAP net income	$ 32,482	$ 13,243	$ 87,511	$ 8,319
Add:				
Intangible asset amortization	1,862	1,862	5,586	5,963
Stock-based compensation expense	3,195	2,177	9,758	5,969
Non-cash interest expense	-	252	394	2,175
Loss on extinguishment of debt	1,097	-	1,097	12,287
Azur Pharma transaction related costs	5,974	-	5,974	-
Deduct:				
Contract revenues	(285)	(285)	(854)	(854)
Adjusted net income	$ 44,325	$ 17,249	$ 109,466	$ 33,859
GAAP net income per diluted share	$ 0.69	$ 0.32	$ 1.88	$ 0.22
Adjusted net income per diluted share	$ 0.94	$ 0.41	$ 2.35	$ 0.89
Shares used in computing GAAP and adjusted net income per diluted share amounts	47,241	41,737	46,577	38,233

Liquidity and Capital Resources

As of September 30, 2011, we had cash and marketable securities of $113.3 million and we had generated year-to-date cash flows from operations of $107.9 million. On July 1, 2011, we repaid in full the $33.3 million principal amount of a term loan and paid a prepayment penalty of $0.3 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.

We currently have borrowing availability of $14.7 million under a revolving credit facility provided by our credit agreement, which contains customary operating covenants and requires us to comply with certain financial covenants. The facility has a commitment fee payable on the undrawn amount which is currently 0.5% per annum. In September 2011, we terminated a committed equity financing facility, or CEFF, that we had entered into with Kingsbridge Capital Limited in May 2008. We had not drawn down any funds under the CEFF.

To grow our business over the longer-term, we will need to commit substantial resources to product acquisition and in-licensing costs, to product development and clinical trials of product candidates, and to 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. Any equity financing would be dilutive to our stockholders, and the consent of the lender under our credit agreement could be required.

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The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2011	2010
Net cash provided by operating activities	$ 107,937	$ 36,077
Net cash used in investing activities	(15,633)	(1,030)
Net cash used in financing activities	(35,883)	(27,789)
Net increase in cash and cash equivalents	$ 56,421	$ 7,258

Net cash provided by operating activities during the nine months ended September 30, 2011 and 2010 primarily reflected net income adjusted for items including depreciation, amortization, non-cash interest expense, stock-based compensation expense, changes in working capital, the loss on extinguishment of long-term debt and scheduled payments related to the settlement of government litigation.

Net cash used in investing activities during the nine months ended September 30, 2011 primarily related to purchases of marketable securities, scheduled payments under our agreement for the rights to market Luvox CR and to a lesser extent purchases of property and equipment, partially offset by releases of restricted cash. Net cash used in investing activities during the nine months ended September 30, 2010 primarily related to scheduled payments under our agreement for the rights to market Luvox CR and to a lesser extent purchases of property and equipment partially offset by releases of restricted cash.

Net cash used in financing activities during the nine months ended September 30, 2011 included a repayment of $41.7 million for the full principal amount outstanding under a term loan and $7.4 million for net repayments of our revolving credit facility, partially offset by proceeds from employee stock option exercises and warrant exercises. Net cash used in financing activities during the nine months ended September 30, 2010 was due to the repayment of $119.5 million principal amount of senior secured debt and $8.5 million of related prepayment penalties and fees, a repayment of $4.2 million of a term loan and a net repayment of $2.0 million of our revolving credit facilities, partially offset by proceeds of $56.8 million from a common stock offering and borrowings of $48.7 million under a term loan.

Contractual Obligations

If the proposed merger between us and Azur Pharma is consummated, we will be required to pay our investment banker a fee of $1.5 million upon close which is in addition to $1.5 million we recorded as expense for services rendered in the three months ended September 30, 2011.

In the event that the Merger Agreement is terminated (other than in certain limited circumstances), we will be required to reimburse Azur Pharma for its costs and expense in connection with the preparation of the SEC filings and for certain potential claims or action against Azur Pharma in connection with the proposed merger. As of September 30, 2011, amounts potentially owed to Azur Pharma under the Merger Agreement would be insignificant.

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, 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 as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010 have not changed substantially.

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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 words such as should, expect, anticipate, estimate, may, predict, intend, plan, believe and other words and terms of similar meaning and expression in connection wi 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, matters related to the anticipated completion of the proposed merger with Azur Pharma, our goals, plans, expectations and projections regarding our financial position, results of operations, cash flows, market position, acquisition and in-licensing opportunities and efforts, 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 nine months ended September 30, 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 September 30, 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 September 30, 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 the outcome of this matter.

On September 10, 2011, we received a Paragraph IV Certification from Torrent Pharma Limited, or Torrent, advising us that it had filed an ANDA with the FDA requesting approval to market a generic version of Luvox CR. Torrent s Paragraph IV Certification alleges that U.S. Patent No. 7,465,462, or the 462 patent, owned by Elan Pharma International Limited, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, will not be infringed by the manufacture, use, sale or offer for sale of the generic product for which the ANDA was submitted and that the 462 patent is invalid. On October 21, 2011, we and Alkermes, as plaintiffs, filed a lawsuit against Torrent in the United States District Court for the District of Delaware asserting infringement of the 462 patent by Torrent in response to Torrent s Paragraph IV Certification. We are seeking a permanent injunction that prevents Torrent from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. We cannot predict the outcome of this litigation.

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

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 volume growth for 2011 compared to 2010, we cannot assure you that Xyrem sales volume will continue to grow. We have periodically significantly increased the price of Xyrem, most recently in September 2011, and we cannot assure you that price adjustments 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;

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- our manufacturing partners ability to obtain sufficient quota from the U.S. Drug Enforcement Administration, 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 boxed warning, that further restrict how we market and sell Xyrem; and
- 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 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 sued 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 any potential new suppliers of sodium oxybate, as well as our product manufacturer, must each obtain separate 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

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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 effect on Xyrem s commercial success.

Under the risk management plan, all of the Xyrem sold 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. and its affiliate CuraScript, Inc., or ESSDS, 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, 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.

In late April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA as required. Promptly after learning of them, we reported to the FDA all of the previously unreported cases that we and ESSDS had identified. We also began immediately taking specific steps to strengthen our own procedures, and those between us and ESSDS, to ensure that all adverse events are reported to us, and to the FDA, in an appropriate and timely manner.

In early May 2011, we received a Form 483 as a result of an FDA inspection, which included the inspector s observations concerning our adverse event reporting system. That document discussed the failure to report serious adverse events, including certain cases of deaths as described above, and also noted deficiencies in certain of our drug safety procedures. After receipt of the Form 483, we continued our efforts to improve our systems, and those used by us and ESSDS, to ensure that we correct the deficiencies noted in the Form 483, and those efforts are continuing. In October 2011, we received a warning letter from the FDA relating to the matters covered by the Form 483. We have responded to the warning letter, advising the FDA of the efforts we have taken to date and are continuing to take, and we are continuing to strengthen our procedures and take appropriate corrective actions to address all of the matters covered in the warning letter. While we have responded to the warning letter in a timely manner and we intend to demonstrate our compliance to the FDA s satisfaction, we cannot assure you that we will be able to adequately address the FDA s requirements pursuant to the warning letter, and the failure to do so could have a material and adverse effect on our business, financial condition and results of operations.

The information we have received concerning the cases discussed above 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. We are continuing to attempt to gather additional information about the deaths of patients who have been prescribed Xyrem, which we have discussed with the FDA, and we plan to provide the FDA with additional information we gather. As a result of our review to date, we believe that the adjusted annual all-cause mortality rate has been consistent since the product s launch and that it does not constitute a new safety signal for Xyrem. We cannot assure you that additional information we may learn will not modify our current assessment, that the FDA will agree with this assessment or that the FDA will not 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.

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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.

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

Although Luvox CR is covered by a product-specific patent issued to Elan Pharma International Limited, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, 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. In September 2011, we received a Paragraph IV Certification from Torrent Pharma Limited, or Torrent, advising us that Torrent has filed an ANDA with the FDA requesting approval to market a generic version of Luvox CR. We filed lawsuits against these companies after receipt of their certifications. We and Alkermes 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 lawsuits against Actavis and Torrent are pending in the United States District Court for the District of Delaware, but, we cannot assure you that these lawsuits will prevent the introduction of additional generic forms of Luvox CR for any particular length of time, or at all. In general, generic competition results in decreases in the prices at which branded products can be sold, particularly when there are multiple generic products available in the marketplace. Generic competition for Luvox CR would have an adverse effect on our results of operations.

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

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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 by the end 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 or otherwise meet the FDA requirements for approval, 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, including the proposed merger with Azur Pharma Public Limited Company (formerly Azur Pharma Limited), or Azur Pharma, 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 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;

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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 receipt of a Form 483 observation in May 2011 or the related warning letter 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 (sodium oxybate for the treatment of fibromyalgia), 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.

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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.

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.

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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, we have received three Paragraph IV certifications which allege that the Alkermes patent listed in the Orange Book for Luvox CR is invalid. The expiration date for the Alkermes 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.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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;

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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 Alkermes are prosecuting separate lawsuits against Actavis and Torrent related to their respective Paragraph IV certifications 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

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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, labeling, advertising and promotion, distributing and exporting 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. 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 healthcare 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.

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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 with a term extending 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.

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to other administrative or judicially imposed sanctions, including warning letters, untitled letters, other civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, withdrawal of products from the market and refusal to approve pending NDAs or supplements to approved NDAs. 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud.

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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 the other parties with whom we work 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 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid 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 that administers the Medicaid rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 and subsequent legislation, or PPACA, made significant changes to the Medicaid rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the PPACA increased the minimum Medicaid rebate for innovator drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and caps the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the PPACA and subsequent legislation changed the definition of average manufacturer price. Finally, the PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a new branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of $2.5 billion in 2011 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

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The CMS has yet to issue regulations to implement any of the PPACA s changes to the Medicaid rebate program. We cannot assure that there will not be additional increases in rebates or other costs and charges associated with participating in the Medicaid rebate program. Regulations continue to be issued and coverage expanded by various governmental agencies relating to these rebate programs, increasing the cost and complexity of compliance.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service s 340B drug pricing discount 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. The 340B ceiling price is calculated using a statutory formula which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. To the extent the PPACA, as discussed above, changes the statutory and regulatory definitions of average manufacturer price and the Medicaid rebate amount, these changes also will affect our 340B ceiling price calculations.

These 340B 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 low-income patients. The PPACA expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the PPACA. Except for children s hospitals, the PPACA exempts orphan drugs those designated under section 526 of the Federal Food Drug and Cosmetic Act from the ceiling price requirements for these newly-eligible entities.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the CMS of our current average manufacturer prices 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 data for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations serve to increase our costs for complying with the laws and regulations governing the Medicaid rebate program. 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. Price recalculations also may affect the price that we are required to charge certain safety-net providers under the Public Health Service 340B drug discount program.

In addition to retroactive rebates and the potential for 340B Program 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. Our failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the submission is late beyond the due date. In the event that the CMS terminates our rebate agreement, no Federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, the CMS and the Office of the Inspector General indicated that they intend more aggressively to 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. The 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 the CMS to be incomplete or incorrect.

The PPACA 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

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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 U.S. Department of Defense, or DoD, in March 2009 (and reissued in October 2010), implementing the terms of Section 703 of the National Defense Authorization Act for Fiscal Year 2008, established a program under which the DoD expects rebates from pharmaceutical manufacturers on all prescriptions of covered drugs (including innovator drugs and biologics) filled under the TRICARE retail pharmacy program from January 28, 2008 forward, unless the 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 the DoD on TRICARE retail pharmacy utilization on a prospective basis. These rebates are meant to enable the DoD to access pricing that is either close to or equal to Federal Ceiling Prices, as defined under the Veterans Health Care Act of 1992. Pursuant to the final rule, we entered into a pricing agreement with the DoD in July 2009. These legislative and regulatory changes, including our execution of a DoD pricing agreement, 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 rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, 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. The risk of product liability claims may also increase when a company receives a warning letter. 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.

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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;
- the extent of generic competition for our products;
- the cost of acquiring and/or licensing 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 third-party claims; and
- changes in laws and regulations, including, for example, healthcare 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.

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. While we repaid the term loan under our credit agreement in full in early July 2011, the credit agreement remains in effect and covers revolving credit borrowings we may draw down from time to time. Our failure to comply with any of the covenants in the credit agreement could result in a default under the terms of the credit agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings, which could restrict our operations, particularly our ability to respond to changes in our

business or to take specified actions.

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. Section 382 of the Internal Revenue Code is an extremely complex provision with respect to which there are many uncertainties. 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.

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Risks Relating to Our Common Stock

The market price of our common stock has been volatile and may continue to be volatile in the future, 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 October 24, 2011, we had 42,157,349 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. In addition, concurrently with our entry into the merger agreement with Azur Pharma on September 19, 2011, certain of our stockholders with which our directors are affiliated, who owned in the aggregate approximately 43% of the outstanding shares of our common stock as of that date, entered into a voting agreement with Azur Pharma and our company pursuant to which they agreed to vote all of our shares they owned now and in the future in favor of the merger agreement and the merger at our special meeting of the stockholders to vote on the proposed merger. The voting agreements also prohibit each of these stockholders from selling or otherwise transferring any of our shares during the term of the voting agreements. The voting agreements are expected to terminate immediately following the stockholder vote.

As of October 24, 2011, the holders of up to approximately 13,509,306 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, the sale could adversely affect the market price of 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. 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.

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 October 24, 2011, our executive officers and directors, together with the stockholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 48.1% of our capital stock. Accordingly, our executive officers and directors, together with their respective affiliates or associates, are likely 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, such as the proposed merger with Azur Pharma, 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.

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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.

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.

Risks Relating to the Proposed Merger with Azur Pharma

Failure to consummate the merger could negatively impact our stock price and our future business and financial results.*

If the proposed merger between us and Azur Pharma is not consummated, our ongoing businesses may be adversely affected and, without realizing any of the benefits of having consummated the merger, we will be subject to a number of risks, including the following:

- we may be required to reimburse Azur Pharma for certain expenses incurred by Azur Pharma in connection with certain governmental filings or certain lawsuits;

- we will be required to pay significant costs relating to the proposed reorganization and merger, including legal, accounting, filing and possible other fees and mailing, financial printing and other expenses in connection with the transaction whether or not the merger is consummated;

- the current prices of our common stock may reflect a market assumption that the merger will occur, meaning that a failure to complete the merger could result in a decline in the price of our common stock; and

- matters relating to the reorganization and merger (including integration planning) have required and will continue to require substantial commitments of time and resources by our management, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

We also could be subject to litigation related to any failure to consummate the merger or to perform our obligations under the merger agreement, or related to any enforcement proceeding commenced against us. If the merger is not consummated, these risks may materialize and may adversely affect our business, financial results and stock price.

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Obtaining required approvals necessary to satisfy the conditions to the completion of the merger may delay or prevent completion of the merger, result in additional expenditures of money and resources and/or reduce the anticipated benefits of the merger.*

The merger is subject to customary closing conditions. These closing conditions include, among others, the receipt of required approvals of our stockholders, the effectiveness of the registration statement on Form S-4 filed by Azur Pharma regarding the proposed merger, the consummation of the reorganization of Azur Pharma and the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR Act.

We cannot assure you that the required stockholder approval will be obtained or that the required closing conditions will be satisfied, and, if all required consents and approvals are obtained and the closing conditions are satisfied, no assurance can be given as to the terms, conditions and timing of the approvals. If in connection with our filings under the HSR Act, we and Azur Pharma agree to any material requirements, limitations, costs or restrictions in order to obtain any approvals required to consummate the reorganization and the merger, these requirements, limitations, costs or restrictions could adversely affect the anticipated benefits of the merger. This could result in a failure to consummate these transactions or have a material adverse effect on the combined company s business and results of operations.

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

On July 7, 2011, we issued 3,028 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 4,125 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 1,097 shares to effect the net exercise of the warrants in accordance with their terms.

On July 29, 2011, we issued 53,964 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 70,156 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 16,192 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.

Item 5. Other Information

On September 19, 2011, we and Azur Pharma Public Limited Company (formerly Azur Pharma Limited), a public limited company formed under the laws of Ireland, or Azur Pharma, announced the signing of an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, pursuant to which we and Azur Pharma will combine our businesses in a stock transaction in which (a) Azur Pharma will effectuate a reorganization described in the Merger Agreement and (b) a wholly owned subsidiary of Azur Pharma will merge with and into our company, and as a result of this merger, our company will survive as a wholly owned subsidiary of Azur Pharma. At or prior to the completion of the merger, Azur Pharma will change its name to Jazz Pharmaceuticals plc, or New Jazz. Pursuant to the Merger Agreement, effective as of the closing of the merger, directors of our company and the chief executive officer of Azur Pharma are expected to be the directors of New Jazz. Our entry into the Merger Agreement was reported on a current report on Form 8-K, filed with the SEC on September 19, 2011.

On November 7, 2011, our directors Samuel D. Colella and Michael W. Michelson notified the Chairman of our board of directors of their respective intent not to seek an appointment to serve as a director of New Jazz if and when the merger becomes effective, and to therefore resign from our board of directors effective and contingent upon the closing of the merger. Each of Messrs. Colella and Michelson indicated that his decision is for personal reasons, in part due to the increased commitments required in connection with New Jazz being domiciled in Ireland. Each of them also indicated that his decision not to seek appointment to the New Jazz board of directors was not a result of any disagreement with our management or our board. As a result of their respective decisions, contingent upon the closing of the merger, each of their respective terms of office as a member of our board of directors will end as of the effective date of the merger.

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Item 6. Exhibits.

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 21, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., the Registrant and Seamus Mulligan as Indemnitors Representative (incorporated herein by reference to exhibit 2.1 in the Registrant s quarterly report on Form 8-K (File No. 001-33500), as filed with the SEC on September 19, 2011).
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).
4.4	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).
4.7	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).

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Number	Description of Document
4.8A	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).
4.8B	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	Offer Letter from the Registrant to Jeffrey Tobias, M.D.
10.2+	Form of Notice to Option Holder Re: Outstanding Nonstatutory Stock Options to Purchase Shares of Registrant s Common Stock (incorporated herein by reference to exhibit 10.1 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 28, 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.
101.INS++	XBRL Instance Document
101.SCH++	XBRL Taxonomy Extension Schema Document
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document

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

\+ Indicates management contract or compensatory plan.

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

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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SIGNATURES

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

Dated: November 8, 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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++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.