JAZZ PHARMACEUTICALS INC
Form 10-Q
May 07, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2009

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

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

As of April 30, 2009, 28,925,352 shares of the registrant s Common Stock, $.0001 par value, were outstanding.

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QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2009

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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; Luvox® (fluvoxamine). This report also includes other trademarks, service marks, and trade names of other companies.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,015	$ 24,903
Restricted cash	775	1,913
Marketable securities		1,004
Accounts receivable, net of allowances of $296 and $176 at March 31, 2009 and December 31, 2008, respectively	7,012	6,643
Inventories	4,430	4,788
Prepaid expenses	2,206	2,366
Other current assets	2,106	2,382
Total current assets	33,544	43,999
Property and equipment, net	2,140	2,514
Intangible assets, net	35,794	32,526
Goodwill	38,213	38,213
Other long-term assets	246	246
Total assets	$ 109,937	$ 117,498
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 4,554	$ 5,736
Accrued liabilities	21,401	19,024
Line of credit		3,875
Senior secured notes (including $99,928 and $95,548 pertaining to related parties at March 31, 2009 and December 31, 2008, respectively)	123,970	118,534
Purchased product rights liability	6,000	14,000
Deferred revenue	12,605	12,322
Total current liabilities	168,530	173,491
Purchased product rights liability, noncurrent	12,000	
Deferred revenue, noncurrent	11,045	11,330
Liability under government settlement	10,658	13,063
Commitments and contingencies (Note 12)		
Common stock subject to repurchase		12,492
Stockholders deficit:		
Common stock	3	3
Additional paid-in capital	421,497	407,923
Accumulated other comprehensive income		4

Accumulated deficit	(513,796)	(500,808)
Total stockholders deficit	(92,296)	(92,878)
Total liabilities and stockholders deficit	$ 109,937	$ 117,498

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2009	**2008**
Revenues:		
Product sales, net	$ 21,319	$ 13,984
Royalties, net	472	365
Contract revenues	285	285
Total revenues	22,076	14,634
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technology)	1,943	2,298
Research and development	11,408	21,243
Selling, general and administrative	14,216	32,780
Amortization of intangible assets	1,732	2,121
Total operating expenses	29,299	58,442
Loss from operations	(7,223)	(43,808)
Interest income	21	897
Interest expense (including $4,525 and $2,825 for the three months ended March 31, 2009 and 2008, respectively, pertaining to related parties)	(5,794)	(3,787)
Other income (expense)	8	(12)
Net loss	$ (12,988)	$ (46,710)
Net loss per share, basic and diluted	$ (0.45)	$ (1.97)
Weighted-average common shares used in computing net loss per share, basic and diluted	28,925	23,743

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2009	**2008**
Operating activities		
Net loss	$ (12,988)	$ (46,710)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	370	524
Amortization of intangible assets	1,732	2,121
Loss on disposal of property and equipment	9	
Non-cash interest expense	535	330
Stock-based compensation expense	1,082	2,227
Changes in assets and liabilities:		
Accounts receivable	(369)	79
Inventories	358	10
Prepaid expenses and other current assets	259	(951)
Other assets	(4)	(232)
Accounts payable	(1,182)	6,059
Accrued liabilities	(90)	428
Accrued unpaid interest for senior secured notes	5,078	
Deferred revenue	(2)	(285)
Provision for government settlement	62	(1,770)
Net cash used in operating activities	(5,150)	(38,170)
Investing activities		
Purchases of property and equipment	(5)	(458)
Purchase of product rights	(1,000)	(10,000)
Decrease in restricted cash and investments	1,138	11,941
Transfer of restricted cash to marketable securities		(4,410)
Proceeds from maturities of marketable securities	1,004	
Net cash provided by (used in) investing activities	1,137	(2,927)
Financing activities		
Proceeds from exercise of stock options		2
Repayment under line of credit	(3,875)	(279)
Proceeds from sale of senior secured notes and warrants, net of issuance costs		39,200
Net cash (used in) provided by financing activities	(3,875)	38,923
Net decrease in cash and cash equivalents	(7,888)	(2,174)
Cash and cash equivalents, at beginning of period	24,903	102,945
Cash and cash equivalents, at end of period	$ 17,015	$ 100,771

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, 2008. In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. Certain amounts in the condensed consolidated statement of cash flows for the three months ended March 31, 2008 have been reclassified to conform to the presentation for the three months ended March 31, 2009. The reclassified amounts reflect the combining of the current and non current portions of the government settlement provision. The results for the three months ended March 31, 2009 are not necessarily indicative of the results to be expected for the year ending December 31, 2009 or for any other interim period or for any future year. The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. and our wholly-owned subsidiaries, Orphan Medical, LLC, or Orphan Medical, and JPI Commercial, LLC, or JPIC, after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

We have incurred significant losses from operations since our inception and as of March 31, 2009, we had cash and cash equivalents of $17.0 million.

In late 2007 and early 2008, we incurred significant expenses in preparation for the launch of Luvox CR. Sales of Luvox CR have not approached the levels that we had anticipated prior to our commercial launch. As a result, our net cash inflows have not been sufficient to support the operation of our business as we had planned.

In March 2008, JPIC sold $40.0 million aggregate principal amount of senior secured notes pursuant to a new debt arrangement. In addition, in March 2008, a total of $80.0 million aggregate principal amount of senior secured notes of Orphan Medical that bore interest at 15% per annum, due on June 24, 2011 were exchanged for the same principal amount of new senior secured notes issued by JPIC pursuant to the debt arrangement described above. We did not make the quarterly interest payments of $4.5 million and $5.1 million that were due on December 31, 2008 and March 31, 2009, respectively, to the holders of our $119.5 million principal amount of senior secured notes, or the Senior Notes, which constituted events of default under our agreement with the holders of the Senior Notes and permits the holders of more than 50% of the principal amount outstanding, to accelerate payment of the Senior Notes. As a result of these defaults, we could be required to prepay some or all of the Senior Notes, including a prepayment premium, and interest is due at an annual default rate of 17%. Accordingly, the Senior Notes and accrued but unpaid interest are now included in current liabilities. The agreement covering the Senior Notes provides that if annualized net product sales (which for this purpose includes royalties), determined on a quarterly basis, are less than $100.0 million, then we must maintain a restricted cash balance equal to 15% of the then outstanding principal amount of the Senior Notes for as long as our annualized net product sales are less than $100.0 million. We did not meet the net sales test for the three months ended March 31, 2009 and we do not have sufficient cash to maintain the required restricted cash balance and continue to operate our business. We are currently unable to borrow under our line of credit due to the events of default on the Senior Notes.

In an effort to reduce the net cash used in operations, we implemented three reductions in force during 2008, focused our development efforts on JZP-6 and slowed development work on most of our other projects. We are continuing to review our operations in order to identify additional measures to further reduce spending. In February 2009, we amended our agreement with Solvay Pharmaceuticals, Inc., or Solvay, from which we licensed Luvox CR, to eliminate our obligation to make royalty payments on net sales of Luvox CR and to extend the time frame in which other obligations are due. We also entered into arrangements with various government entities to postpone until October 2009 criminal and civil payments (totaling $2.5 million) that otherwise would have been due in January 2009.

In light of the circumstances described above, we are seeking a number of financing and strategic alternatives with respect to all aspects of our business and we are in discussions with the holders of the Senior Notes with respect to our defaults and the status of the Senior Notes.

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If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses, by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs including JZP-6 and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code. We may also be required to license to third parties products and product candidates that we would prefer to develop and commercialize ourselves or to sell the rights to one or more commercial products to third parties in either case on terms that may not be advantageous to us.

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements for the three months ended March 31, 2009 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Concentration of Credit Risks

We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, and to international distributors in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, we have not experienced significant credit losses on our accounts receivable. Our five largest customers accounted for an aggregate of approximately 98% and 97% of gross accounts receivable as of March 31, 2009 and December 31, 2008, respectively.

Use of Estimates

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

Revenue Recognition

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. Revenues from sales of Xyrem within the United States are recognized upon transfer of title, which occurs when our specialty pharmaceutical distributor, Express Scripts Specialty Distribution Services, Inc., or Express Scripts, removes product from our consigned inventory location at our facility for shipment to a patient. Prior to the sale of our rights to Antizol® (fomepizole) and Antizol-Vet® in August 2008, Antizol and Antizol-Vet were shipped to our wholesaler customers in the U.S. with free on board destination shipping terms, and we recognized revenues when delivery occurred. All of our international sales have customer acceptance clauses and therefore we recognize revenues when we are notified of acceptance or when the time to inspect and reject a shipment has lapsed.

Luvox CR was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of obsessive compulsive disorder and social anxiety disorder and we shipped initial stocking orders to our wholesaler customers in the first quarter of 2008. Luvox CR is subject to rights of return six months prior to and up to twelve months after product expiration. We are not able to reliably estimate expected returns of Luvox CR at the time of shipment and therefore we have recognized revenue when units were dispensed through prescriptions at which point, we believe, the product is not subject to return. In order to estimate units dispensed, we purchase dispensing data which we believe to be accurate and reliable and not subject to material adjustments from an independent prescription tracking service. We recorded revenue of $3.6 million for the three months ended March 31, 2009, related to Luvox CR, net of estimated wholesaler fees, discounts, chargebacks and rebates. As of March 31, 2009 we recorded a deferred revenue liability related to shipments of Luvox CR of $1.2 million which represents amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates.

During the three months ended March 31, 2009, as a result of a final rule issued by the Department of Defense, we recorded as a reduction of revenues a reserve of $670,000 for potential rebates due for drugs sold by retail pharmacies to TRICARE beneficiaries on or after January 28, 2008. Of the total amount recorded, $477,000 and $193,000 relate to net product sales during 2008 and the three months ended March 31, 2009, respectively.

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Net Loss Per Common Share

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

	Three Months Ended March 31,	
	2009	2008
Numerator:		
Net loss	$ (12,988)	$ (46,710)
Denominator:		
Weighted-average common shares outstanding	28,925	24,622
Less: weighted-average common shares outstanding subject to repurchase		(879)
Weighted-average common shares used in computing net loss per share, basic and diluted	28,925	23,743
Net loss per share, basic and diluted	$ (0.45)	$ (1.97)

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

	For the Three Months Ended March 31,	
	2009	2008
Warrants to purchase common stock (as if exercised)	3,300	1,348
Options to purchase common stock	5,186	3,400
Common stock subject to repurchase		879
Common stock issuable under directors deferred compensation plan	43	19
Restricted stock units	48	

Recently Adopted Accounting Standards

In December 2007, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standard, or FAS, No. 141(R), Business Combinations, or FAS 141(R), and FAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51, or FAS 160. FAS 141(R) requires an acquirer to measure the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. FAS 160 clarifies that a noncontrolling interest in a subsidiary should be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. FAS 141(R) and FAS 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is prohibited. Our adoption of FAS 141(R) and FAS 160 was effective on January 1, 2009 and had no impact on our consolidated results of operations and financial position since we have not undertaken a business combination.

In December 2007, the FASB ratified Emerging Issues Task Force, or EITF, 07-1, Accounting for Collaborative Agreements, or EITF 07-1. EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, which includes arrangements entered into regarding development and commercialization of products. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaborative relationship. Our adoption of EITF 07-1 was effective on January 1, 2009 and had no impact on our consolidated results of operations and financial position since we were not participants in a collaborative agreement within the scope of EITF 07-01.

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In February 2008, the FASB issued FASB Staff Position, or FSP, No. FAS 157-2, Effective Date of FASB Statement No. 157, or FSP FAS 157-2, which delays the effective date of FAS No. 157, Fair Value Measurements, or FAS 157, for one year for all nonfinancial assets and nonfinancial liabilities, except those recognized or disclosed at fair value in the financial statements on a recurring basis. Our adoption of FSP FAS 157-2 was effective on January 1, 2009 and had no impact on our consolidated results of operations and financial position.

In June 2008, the FASB ratified EITF consensus No. 07-5, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock, or EITF 07-5. EITF 07-5 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity s own stock, which would qualify as a scope exception under FAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Our adoption of EITF 07-5 was effective on January 1, 2009 and had no impact on our consolidated results of operations and financial position.

In April 2009, the FASB issued FSP No. 141(R)-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, or FSP FAS 141(R)-1, which amends and clarifies FAS 141(R) to address application issues raised by preparers of financial statements, auditors, and members of the legal profession on initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. FSP FAS 141(R)-1 is effective for assets or liabilities arising from contingencies in business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Our adoption of FSP FAS 141(R)-1 had no impact on our consolidated results of operations and financial position since we have not undertaken a business combination.

In April 2009, the FASB issued FSP No. FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments, or FSP FAS No. 107-1 and APB 28-1, which requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP FAS 107-1 and APB 28-1 also amends APB Opinion No. 28 Interim Financial Reporting, to require disclosures in summarized financial information at interim reporting periods. FSP FAS 107-1 and APB 28-1 is effective for interim reporting periods ending after June 15, 2009. We are currently evaluating the effect that our adoption of FSP FAS 107-1 and APB 28-1 will have on our results of operations and financial position.

In April 2009, the FASB issued FSP No. FAS 115-2 and FAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, or FSP FAS 115-2 and FAS 124-2, which amends the other-than-temporary impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. FSP FAS 115-2 and FAS 124-2 is effective for interim reporting periods ending after June 15, 2009. We are currently evaluating the effect that our adoption of FSP FAS 115-2 and FAS 124-2 will have on our results of operations and financial position.

In April 2009, the FASB issued FSP No. FAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly, FSP FAS 157-4, which provides additional guidance for estimating fair value in accordance with FAS 157 when the volume and level of activity for the asset or liability have significantly decreased and for identifying circumstances that indicate a transaction is not orderly (i.e. distressed or forced). FSP FAS 157-4 is effective for interim reporting periods ending after June 15, 2009. We are currently evaluating the effect that our adoption of FSP FAS 157-4 will have on our results of operations and financial position.

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2. Inventories

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

	March 31, 2009	December 31, 2008
Raw materials	$ 2,526	$ 2,175
Work in process	59	156
Finished goods (1)	1,845	2,457
Total inventories	$ 4,430	$ 4,788

(1) Includes, at March 31, 2009 and at December 31, 2008, deferred cost of sales of $702,000 and $495,000, respectively, for which the related revenue has been deferred.

3. Goodwill and Intangible Assets

The gross carrying amount of goodwill was $38.2 million at March 31, 2009 and December 31, 2008. The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	March 31, 2009			December 31, 2008		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology - Xyrem	$ 39,700	$ 15,713	$ 23,987	$ 39,700	$ 14,670	$ 25,030
Developed technology - Luvox CR	9,700	426	9,274	4,700		4,700
Agreements not to compete	3,900	2,938	962	3,900	2,743	1,157
Trademarks	2,600	1,029	1,571	2,600	961	1,639
Total	$ 55,900	$ 20,106	$ 35,794	$ 50,900	$ 18,374	$ 32,526

During the three months ended March 31, 2009, we recorded an increase of $5.0 million in the value of the intangible asset related to Luvox CR developed technology which will be amortized over 4.7 years, the remaining estimated useful life of the Luvox CR developed technology. See Note 9 for additional information regarding the increase in the intangible asset.

Future amortization costs per year for our existing intangible assets other than goodwill as of March 31, 2009 were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2009 (remaining portion)	$ 5,464
2010	6,883
2011	6,506
2012	6,506
2013	5,991

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4. Fair Value Measurement

The following tables summarize, by major security type, our financial assets that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	March 31, 2009			
	Cash	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Cash	$ 6,188	$	$	$ 6,188
Money market funds		11,602		11,602
Total	$ 6,188	$ 11,602	$	$ 17,790
Amounts classified as cash and cash equivalents				$ 17,015
Amounts classified as restricted cash				775
Total				$ 17,790

	December 31, 2008			
	Cash	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Cash	$ 1,161	$	$	$ 1,161
Obligations of U.S. government agencies			1,004	1,004
Money market funds		25,655		25,655
Total	$ 1,161	$ 25,655	$ 1,004	$ 27,820
Amounts classified as cash and cash equivalents				$ 24,903
Amounts classified as restricted cash				1,913
Amounts classified as marketable securities				1,004
Total				$ 27,820

5. Debt Obligations

Senior Secured Notes and Warrants

We did not make the quarterly interest payments of $5.1 million and $4.5 million that were due on March 31, 2009 and December 31, 2008, respectively, to the holders of the $119.5 million principal amount of Senior Notes, which constituted events of default under our agreement with the holders of the Senior Notes and permits LB I Group Inc., a related party, as the holder of more than 50% of the principal amount outstanding, to accelerate payment of the Senior Notes. In both January and April 2009, we received notices of default from LB I Group Inc. but to date we have not received a notice of acceleration. As a result of the events of default, interest on the Senior Notes accrues on the outstanding principal amount at an annual default rate of 17% (instead of 15%) effective January 1, 2009. Interest will continue to accrue at this higher rate until all defaults are cured. If we were to receive a notice of acceleration, we would immediately owe the holders of Senior Notes the principal amount on the notes, a prepayment premium and accrued but unpaid interest. We do not have sufficient cash to repay these amounts.

As of March 31, 2009, the carrying amount of the Senior Notes, which includes accrued but unpaid interest of $9.6 million, is classified as a current liability and the related debt issuance costs of $2.0 million are reported in other current assets.

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As a result of the defaults under the terms of the agreement with the holders of the Senior Notes, we could be required to prepay some or all of the Senior Notes, including a prepayment premium. The agreement covering the Senior Notes provides that if annualized net product sales (which for this purpose includes royalties), determined on a quarterly basis, are less than $100.0 million, then we must maintain a restricted cash balance equal to 15% of the then outstanding principal amount of the Senior Notes for as long as our annualized net product sales are less than $100.0 million. We did not meet the net sales test for the three months ended March 31, 2009 and we do not have sufficient cash to maintain the required restricted cash balance and continue to operate our business.

6. Common Stock

Common Stock Subject to Repurchase

In February 2004, each of our then executive officers entered into an employment agreement with us which permitted the executive officer or the officer s estate to require us to repurchase vested shares at fair market value upon termination of the executive officer s employment due to death or disability. The fair value of vested shares held by our executive officers as of the date of such agreements or Agreement Date Fair Value, was recorded as common stock subject to repurchase and following the date of such agreements, the Agreement Date Fair Value of shares held by our executive officers was recorded as common stock subject to repurchase as such shares vested. In February 2009, the remaining employment agreements expired and as a result, we reclassified the balance of $12.5 million from common stock subject to repurchase to additional paid-in capital.

7. Comprehensive Loss

Comprehensive loss includes net loss and all changes in stockholders deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. The difference between comprehensive loss and net loss during both the three months ended March 31, 2009 and 2008 represented the change in unrealized gains/losses on available-for-sale securities and was not material.

8. Segment Information

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

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

	Three Months Ended March 31,	
	2009	**2008**
Xyrem	$ 17,719	$ 11,341
Luvox CR	3,600	
Antizol and Antizol-Vet (1)		2,643
Total	$ 21,319	$ 13,984

(1) We sold our rights to Antizol and Antizol-Vet in August 2008.

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

	Three Months Ended March 31,

	2009	2008
United States	$ 21,321	$ 13,593
Europe	750	645
All other	5	396
Total	$ 22,076	$ 14,634

We received 80% and 78% of our total revenues from Express Scripts, a significant customer, in the three months ended March 31, 2009 and 2008, respectively.

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9. In-Licensing Agreements

In February 2009, we amended our product license agreement with Solvay relating to the rights to market Luvox CR and Luvox in the U.S. such that the existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR, which was subsequently met in April 2009, and future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million, of which $1.0 million was paid in March 2009, and $5.0 million is payable during the remainder of 2009 ($1.0 million is due in June 2009 and $2.0 million is due in each of September and December 2009), $4.0 million is payable in 2010, $4.5 million is payable in 2011 and $5.0 million is payable in 2012. If we pay these amounts when due, the payment due in 2012 will decrease to $4.5 million. In addition, we agreed to pay Solvay $5.0 million in 2015 if net sales of Luvox CR reach a cumulative amount of $100.0 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the U.S. as of December 31, 2014. As a result of the amendment, we recorded a $5.0 million liability and a corresponding increase in intangible assets for our continuing right to market Luvox CR and Luvox in the U.S. Under the amendment, future cash payments are equal to the carrying value of our obligation and as a result, we did not recognize a gain and we did not record any expense related to the amended agreement. As of March 31, 2009, $6.0 million of the remaining amount due under the amended agreement, which includes $1.0 million due in March 2010, was reported as a current liability and $12.0 million was reported as a noncurrent liability.

10. Stock-Based Compensation

We account for employee stock-based compensation in accordance with FAS No. 123(R), Share-Based Payment, or FAS 123R, which requires compensation expense related to share-based transactions, including employee stock options, to be measured and recognized in the financial statements based on fair value. Employee stock-based compensation expense recognized in each of the three months ended March 31, 2009 and 2008 was calculated based on awards ultimately expected to vest, and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based compensation expense recognized under FAS 123R related to stock options, restricted stock units, phantom shares and awards under our employee stock purchase plan was as follows (in thousands):

	Three Months Ended March 31,	
	2009	2008
Selling, general and administrative	$ 732	$ 1,637
Research and development	314	547
Cost of product sales	36	43
Total stock-based compensation expense	$ 1,082	$ 2,227

Employee stock-based compensation expenses of $31,000 as of March 31, 2009 and December 31, 2008, respectively, were capitalized as a component of inventories and included in the condensed consolidated balance sheets.

Stock Options

During the three months ended March 31, 2009, we granted options to purchase 2,453,350 shares of common stock. The weighted-average grant date fair values per share of the options granted during the three months ended March 31, 2009 and 2008 were $0.95 and $7.58, respectively. The fair values of these stock option grants were estimated at the grant dates using the Black Scholes option pricing model with the following assumptions:

	Three months ended March 31,	
	2009	2008
Weighted-average volatility	92%	59%
Weighted-average expected term (years)	6.1	6.1
Range of risk-free rates	1.8-2.3%	2.7-3.3%

Expected dividend yield	0.0%	0.0%

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11. Restructuring Expense

As part of a strategic decision to focus on our commercial products, JZP-6, our late-stage product candidate, and lower operating expenses, we recorded separate restructuring charges in 2008 totaling $3.5 million of which $708,000 was recorded as part of research and development expense and the remainder included in selling, general and administrative expense. We expect to settle the remaining accrual of $115,000 by June 30, 2009.

The following table represents adjustments made in the three months ended March 31, 2009 to our restructuring charges incurred (in thousands):

	Employee Expenses (1)	Auto Lease Expenses (2)	Facility Expenses (3)	Total
Cumulative amount incurred as of December 31, 2008	$ 2,139	$ 374	$ 950	$ 3,463
Adjustment to charges incurred in prior periods	(75)	(57)		(132)
Cumulative amount incurred as of March 31, 2009	$ 2,064	$ 317	$ 950	$ 3,331

The following table represents activity in our restructuring accrual during the three months ended March 31, 2009 (in thousands):

	Employee Expenses (1)	Auto Lease Expenses (2)	Facility Expenses (3)	Total
Balance as of December 31, 2008	$ 979	$ 374	$ 120	$ 1,473
Cash payments made during the three months ended March 31, 2009	(885)	(271)	(70)	(1,226)
Adjustment to charges incurred in prior periods	(75)	(57)		(132)
Balance as of March 31, 2009	$ 19	$ 46	$ 50	$ 115

(1) Includes employee severance, health insurance premium and outplacement assistance expenses.

(2) Includes auto lease termination expenses.

(3) Includes excess facilities, property and equipment expenses.

12. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into contracts and 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 against us that have not yet been made. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations except as disclosed in our prior public filings.

We have agreed to indemnify our directors, executive officers, vice presidents, Chief Medical Officer and Principal Accounting Officer 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 this indemnification 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 that the fair value of these indemnification obligations is not material. Accordingly, we have not recognized any liabilities relating to these obligations as of March 31, 2009 and December 31, 2008. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Legal Proceedings

From time to time we are involved in legal proceedings arising in the ordinary course of business. We currently have no ongoing litigation and are not aware of any claims that could lead to litigation 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. As discussed in Note 1 to the condensed consolidated financial statements, our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. 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 and we encourage you to review the examples of our forward-looking statements under the heading 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 developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development, acquisition and in-licensing activities, and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and to compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products, one product candidate in late Phase III clinical trials and several product candidates in various stages of clinical development.

Our marketed products and late-stage product candidate are:

Xyrem (sodium oxybate) oral solution. Xyrem is the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles. According to the National Institutes of Health, 150,000 or more individuals in the U.S. are affected by narcolepsy. We promote Xyrem in the U.S. for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring the rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the U.S. to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 13 countries.

Luvox CR (fluvoxamine maleate) Extended-Release Capsules. Once-Daily Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder on February 28, 2008. We shipped initial stocking orders of Luvox CR to our wholesaler customers in March 2008 and began promoting the product through our specialty sales force in April 2008. Luvox CR is a once-daily extended-release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI. SSRIs are used in the treatment of depression, anxiety disorders and some personality disorders. According to the National Institute of Mental Health, obsessive compulsive disorder and social anxiety disorder affect approximately 2.2 million and 15 million adults in the U.S., respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the U.S. from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the U.S.

JZP-6 (sodium oxybate). We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. According to the American College of Rheumatology, between two and four percent of the U.S. population suffers from fibromyalgia. The product is currently in Phase III clinical trials; the program includes two Phase III pivotal clinical trials and a long term safety trial. In November 2008, we announced positive preliminary top-line results from the first of the two Phase III pivotal clinical trials. The randomized, double-blind, placebo-controlled study achieved its primary endpoints, demonstrating that

JZP-6 significantly decreased pain and fatigue, and improved daily function, in patients with fibromyalgia. We expect preliminary data from the second Phase III pivotal clinical trial, for which patient dosing has been completed, in mid-2009. Subject to successful completion of the remaining Phase III pivotal clinical trial, we plan to submit a new drug application, or NDA, for JZP-6 in the fourth quarter of 2009. If our NDA is approved by the FDA, we expect to market JZP-6 in the U.S. to specialists who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnerships with third parties. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the U.S.

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Our other product candidates in clinical development are JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens, JZP-4 (sodium and calcium channel antagonist), being developed for the treatment of epilepsy and bipolar disorder, and JZP-7 (ropinirole gel), being developed for the treatment of restless legs syndrome. We do not anticipate significant additional development progress on JZP-8, JZP-4 or JZP-7 unless or until we partner a program or otherwise obtain financing that we believe is sufficient to continue development.

In late 2007 and early 2008, we incurred significant expenses in preparation for the launch of Luvox CR. Sales of Luvox CR have not approached the levels that we had anticipated prior to our commercial launch. As a result, our net cash inflows have not been sufficient to support the operation of our business as we had planned and we have undertaken efforts to significantly reduce our operating expenses. We did not make quarterly interest payments of $4.5 million and $5.1 million that were due on December 31, 2008 and March 31, 2009, respectively, to the holders of our $119.5 million principal amount of senior secured notes, or the Senior Notes, which constituted events of default under our agreement with the holders of the Senior Notes and permits the holders of more than 50% of the principal amount outstanding to accelerate payment of the Senior Notes. As a result of the default, under the terms of the Senior Notes, we could be required to prepay some or all of the Senior Notes, including a prepayment premium, and interest is due at an annual default rate of 17%.

We are currently operating the company in a manner that we believe maximizes the value of our business for our creditors and stockholders by focusing on selling and marketing Xyrem and Luvox CR, continuing our JZP-6 clinical program, with respect to which we expect to obtain the preliminary results of a second Phase III pivotal clinical trial in mid-2009, and looking for additional ways to reduce our operating expenses. We are also seeking to raise additional funds. If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses by, among other things, curtailing significantly, delaying or eliminating part or all of our development programs, including JZP-6, and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

As of March 31, 2009, we had cash and cash equivalents of $17.0 million. While we believe that our current cash resources, together with anticipated revenues from product sales, would be sufficient to fund our operations, they are not sufficient to fund both our operations and payment of interest or repayment of principal on the Senior Notes. In addition, we have based this estimate on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from product sales, and we could exhaust our available financial resources sooner than we currently expect. The sufficiency of our current cash resources, and our need for additional capital and the timing thereof, will depend on many factors, including primarily the amount of revenues that we receive from sales of Xyrem and Luvox CR, as well as other factors set forth in Part II Item 1A of this Quarterly Report on Form 10-Q under the headings *Our operations have resulted in negative cash flows, we are seeking to raise additional funds to fund our operating expenses and debt obligations as soon as possible, which could cause us to have to accept terms that are harmful to our business, dilutive to our stockholders or otherwise disadvantageous to our existing stockholders, and if we are unable to secure additional funding, we may be required to significantly scale back our operations, significantly reduce our headcount, seek protection under the provisions of the U.S. Bankruptcy Code, and/or discontinue many of our activities which could negatively affect our business and prospects* and *We have a history of net losses, which may continue for the next few years and, if we are to grow our business in the future, we will need to commit substantial resources which could increase the extent of any future losses.*

Our sales of Luvox CR were $3.1 million for the three months ended December 31, 2008 and $3.6 million for the three months ended March 31, 2009, and we expect to see continued growth in sales of Luvox CR in 2009. In early 2009, we renegotiated the payments that we owe to Solvay under the license agreement, as a result of which $1.0 million was paid in March 2009, $5.0 million is payable to Solvay during the remainder of 2009 and $13.0 million is payable between 2010 and 2012. We also have a commitment, in connection with the FDA s approval of Luvox CR, to conduct two Phase IV clinical trials of the product. We continue to monitor our sales of Luvox CR and our expenses to manufacture, market, sell and support the product, but the product may not become profitable within a commercially reasonable period, or at all. If necessary, we will decrease our efforts in support of the product.

We are currently seeking a number of financing and strategic alternatives and are in discussions with the holders of the Senior Notes, including in particular LB I Group Inc., an affiliate of Lehman Brothers Holdings, Inc., which holds approximately 75% of the principal amount of the Senior Notes, with respect to our March 31, 2009 and December 31, 2008 payment defaults and the status of the Senior Notes. There can be no assurance that we can reach such resolution, obtain sufficient financing or enter into other transactions to satisfy our Senior Note obligations in a timely manner, or at all. At any time, LB I Group, Inc., as the holder of 75% of the principal amount of the Senior Notes, can accelerate our obligations under the Senior Notes and require payment of the full principal amount of the Senior Notes, plus interest and a prepayment premium. We do not have sufficient cash resources to pay the amount that would become payable in the event of an acceleration of the Senior Notes, and even if we could obtain additional financing, it is unlikely that we could obtain an amount sufficient to repay the Senior Notes in full. The holders of the Senior Notes have a first priority security interest in all of our assets other than our inventory and accounts receivable and, in the event of an acceleration of our obligations and our failure to pay the amount that would then become due, the holders of the Senior Notes could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code.

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In the event that we were to seek protection under the provisions of the U.S. Bankruptcy Code, we could seek to reorganize our business, or we or a trustee appointed by the court could be required to liquidate our assets. In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we were required to liquidate our assets, we might realize significantly less from them than the value that could be obtained in a transaction outside of a bankruptcy proceeding. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to our secured and unsecured creditors, including the holders of the Senior Notes, before any funds would be available to pay our stockholders, and it is uncertain if there would be any amounts available for our stockholders. If we are required to liquidate under the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares.

In light of the circumstances described above, we are seeking to raise funds or consummate a strategic transaction as soon as possible. We may seek to do so through public or private debt or equity financings, collaborations, partnering arrangements, development financings or a corporate transaction with a third party. It is likely that the consent of the holders of the Senior Notes would be required for some of these transactions. We cannot assure you that the holders of the Senior Notes would consent to any transactions that we might propose. Because the holders of the Senior Notes currently have a first priority security interest in our assets, they may be unwilling to consent to any transaction that limits their rights or impacts the protection of their security interest. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing would likely be substantially dilutive to our stockholders, particularly in light of the prices at which our common stock has been recently trading. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. If we raise funds through collaborations, partnering arrangements, development financings or a strategic transaction, we may be required to relinquish, on terms that are not favorable to us, rights to some or all of our products or product candidates that we would otherwise seek to develop or commercialize ourselves. The terms of any future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization of our products or product candidates. Our need to raise capital soon may require us to accept terms that may harm our business or be disadvantageous to our current stockholders, particularly in light of the current illiquidity and instability in the global financial markets.

The financial statements included in this Quarterly Report on Form 10-Q have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern. Our independent registered public accounting firm issued an opinion on our consolidated financial statements for the year ended December 31, 2008, that stated that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern.

Revenues

Product Sales, Net

The following is a summary of our product sales, net:

	Three Months Ended March 31,	
	2009	2008
	(In thousands)	
Xyrem	$ 17,719	$ 11,341
Luvox CR	3,600	
Antizol and Antizol-Vet (1)		2,643
Total	$ 21,319	$ 13,984

(1) We sold our rights to Antizol® (fomepizole) and Antizol-Vet® in August 2008.

Xyrem (sodium oxybate) oral solution. Revenues from sales of Xyrem primarily represent sales in the U.S. to Express Scripts. Revenues from international sales of Xyrem under our agreements with UCB and Valeant have not been material. The FDA has granted Xyrem orphan drug exclusivity in the U.S. for both excessive daytime sleepiness and cataplexy in patients with narcolepsy. This provides marketing exclusivity in the U.S. until July 2009 for the cataplexy indication and November 2012 for the excessive daytime sleepiness indication. In addition to orphan

drug exclusivity, Xyrem is covered by two formulation patents that are listed in the FDA s approved drug products with therapeutic equivalence evaluation document, or Orange Book. The patents will expire in 2020. An additional process patent that covers the product is not listed in the Orange Book and expires in 2019.

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Luvox CR (fluvoxamine maleate) extended release capsules. Revenues from sales of Luvox CR primarily represent product dispensed through prescriptions in the United States. Luvox CR has three years of marketing exclusivity beginning on February 28, 2008, the date the product was approved by the FDA. In addition, a patent covering the orally administered formulation of extended-release fluvoxamine, requiring the release of fluvoxamine over a period of not less than 12 hours, was issued to Elan. In the U.S., the patent expires in 2020.

Antizol (fomepizole). Revenues from sales of Antizol in the U.S. primarily represent sales to pharmaceutical wholesalers. In August 2008, we sold our rights to and interests in Antizol and Antizol-Vet, along with the associated product registrations, commercial inventory and trademarks, for $5.8 million and recorded a gain of $3.9 million.

Royalties, Net

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products. Royalty income was $472,000 and $365,000 in the three months ended March 31, 2009 and 2008, respectively. Although we do not expect royalty revenues to comprise a substantial portion of our revenues, we expect royalty revenues to increase as sales of Xyrem by UCB increase.

Contract Revenues

Almost all of our contract revenues consist of upfront or milestone payments received from UCB. In connection with the expansion of our agreement with UCB in 2006, UCB made an upfront payment of $5.0 million in June 2006 and subsequently an additional payment of $10.0 million in September 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. These payments are being recognized as revenue through 2019, the estimated performance period of the contract, which resulted in contract revenues of $280,000 during each of the three months ended March 31, 2009 and 2008.

In July 2008, we received a nonrefundable payment of $10.0 million from UCB. We expect to recognize the $10.0 million payment as revenue during the three months ended June 30, 2009, as the last patient has completed our second Phase III pivotal clinical trial of sodium oxybate for the treatment of fibromyalgia in April 2009.

Research and Development Expenses

Conducting a significant amount of research and development has been central to our business model. Since our formation in 2003 through March 31, 2009, we incurred approximately $270.0 million in research and development expenses. In the latter part of 2008, in order to preserve our cash resources, we significantly curtailed our investment in research and development programs other than JZP-6. We continue to spend significant amounts on Phase III clinical trials of our JZP-6 product candidate. Our ability to invest in research and development is dependent upon our obtaining additional cash resources.

Our research and development expenses consisted of expenses incurred in identifying, developing and testing our product candidates. These expenses consisted primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators fees, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that we have licensed, allocated expenses such as facilities and information technology that support our research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under our license agreements for product candidates in development.

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We designate development projects to which we have allocated significant research and development resources with the term JZP and a unique number. Earlier-stage development and product lifecycle extension projects are included in Terminated and other projects in the following table. Early product concept feasibility studies and other research activities are included in R&D support in the following table. The expenditures summarized in the following table reflect costs directly attributable to each development candidate and to our Terminated and other projects. We do not allocate salaries, benefits or other indirect costs to our development candidates or Terminated and other projects, but include these costs in R&D support in the following table. The following table summarizes our research and development expenses for the three months ended March 31, 2009 and for JZP projects currently under development and Luvox CR from project inception through March 31, 2009 (in thousands):

	Project Inception to March 31, 2009	Three Months Ended March 31, 2009
JZP-6	$ 80,124	$ 7,700
JZP-4	22,093	(28)
Luvox CR (1)	9,676	
JZP-7	8,441	638
JZP-8	6,501	206
Terminated and other projects		185
R&D support		2,707
Total		$ 11,408

(1) Our research and development expenses for Luvox CR consisted primarily of expenses in connection with the scale-up for commercial manufacturing of Luvox CR, including the cost of inventory manufactured prior to FDA approval on February 28, 2008. Expenses subsequent to FDA approval were either expensed as part of cost of product sales as a period expense or capitalized in inventory.

The process of developing and obtaining FDA approval of products is costly and time consuming. Development activities and clinical trials can take years to complete, and failure can occur any time during the clinical trial process. Although we design our development programs to mitigate risk, the successful development of our product candidates is highly uncertain. Development timelines, probability of success and development costs vary widely among product candidates. As a result, we are unable to determine the time and completion costs related to the development of our product candidates or estimate when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

Critical Accounting Policies and Significant Estimates

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

In addition, the financial statements included in this Quarterly Report on Form 10-Q have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

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Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2008. Other than the estimates described below, our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

Intangible Assets

In February 2009, we amended our product license agreement with Solvay for the rights to market Luvox CR and Luvox in the U.S. such that the existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR that was subsequently achieved in April 2009 and future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million. As a result we recorded an increase of $5.0 million in the value of the intangible asset for Luvox CR developed technology during the first quarter of 2009 which will be amortized over 4.7 years, the remaining estimated useful life of the asset.

Results of Operations

Comparison of Three Months Ended March 31, 2009 and 2008

	Three Months Ended March 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2009	2008		
	(In thousands)			
Product sales, net	$ 21,319	$ 13,984	$ 7,335	52%
Royalties, net	472	365	107	29%
Contract revenues	285	285		0%
Cost of product sales (excluding amortization of acquired developed technology)	1,943	2,298	(355)	(15%)
Research and development	11,408	21,243	(9,835)	(46%)
Selling, general and administrative	14,216	32,780	(18,564)	(57%)
Amortization of intangible assets	1,732	2,121	(389)	(18%)
Interest income	21	897	(876)	(98%)
Interest expense	5,794	3,787	2,007	53%
Other income (expense)	8	(12)	20	(167%)

Product Sales, Net

The increase in product sales, net in the three months ended March 31, 2009, as compared to the same period in 2008, was primarily due to increases of $6.4 million in Xyrem sales and the launch of Luvox CR, offset by a decrease of $2.6 million in Antizol sales as a result of the sale of our product rights in August 2008. The increase in Xyrem sales was primarily due to significant price increases in 2008, and to a lesser extent increase in sales volumes, partially offset by estimated rebates due under the TRICARE rebate program of $635,000 ($462,000 related to 2008 net product sales and $173,000 related to net product sales in the three months ended March 31, 2009).

Royalties, Net

The increase in royalties, net in the three months ended March 31, 2009, as compared to same period in 2008, was entirely due to the increase in royalties we received under our agreement with UCB related to UCB s sales of Xyrem.

Contract Revenues

We recognized contract revenues of $280,000 in each of the three months ended March 31, 2009 and 2008, primarily related to previously deferred upfront payments which are being recognized as contract revenues ratably through 2019, the expected performance period under our agreement with UCB.

Cost of Product Sales

The decrease in cost of product sales in the three months ended March 31, 2009, as compared to the same period in 2008, was primarily due to lower Antizol cost of product sales as a result of the sale of our Antizol product rights in August 2008 and to lower manufacturing overhead expenses, partially offset by higher Luvox CR cost of product sales.

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Research and Development Expenses

Lower research and development expenses in the three months ended March 31, 2009, as compared to the same period in 2008, resulted from lower spending on all of our JZP and other projects and Luvox CR for which we incurred research and development expenditures in the two months prior to approval of the product by the FDA in February 2008. Expenditures on JZP-6 are expected to comprise substantially all of our research and development expenses in 2009, unless or until we are able to partner programs or obtain other financing to fund our other programs. As a result, research and development expenses will likely be significantly lower in 2009 than in 2008.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were lower in the three months ended March 31, 2009, as compared to the same period in 2008, primarily due to a reduction in the number of employees as a result of our three reductions in force in 2008 and to lower marketing expenses. We expect that selling, general and administrative expenses will be significantly lower in 2009 than in 2008.

Amortization of Intangible Assets

Our intangible assets consist primarily of developed technology related to Xyrem and Luvox CR which are amortized on a straight-line basis over their estimated useful lives. Amortization costs in the three months ended March 31, 2009 were lower as compared to the same period in 2008, primarily due to the sale of our rights to and interests in Antizol and Antizol-Vet in August 2008. We expect amortization costs will be lower in 2009 than in 2008 due to a $29.8 million write down of the Luvox CR intangible asset in 2008.

Interest Income

Interest income was lower in the three months ended March 31, 2009, as compared to the same periods in 2008, due to lower average cash balances and to lower average interest rates.

Interest Expense

Interest expense relates primarily to interest on the Senior Notes, and, to a lesser extent, interest on our liability under a government settlement. The increase in interest expense in the three months ended March 31, 2009, as compared to the same period in 2008, was primarily due to interest expense recorded on the additional $40.0 million principal amount of the Senior Notes we issued in March 2008 and to a two percent increase in the annual interest rate on the principal amount of the Senior Notes as a result of the defaults under our agreement with the holders of the Senior Notes. Interest on the Senior Notes is comprised of the accretion of the notes which were recorded at a discount related to warrants that were issued in conjunction with the Senior Notes, amortization of debt issuance costs and quarterly cash payments for interest.

Liquidity and Capital Resources

Since our inception, we have incurred significant net losses and, as of March 31, 2009, we had cash and cash equivalents of $17.0 million.

We have reduced the net cash used in our operations by implementing three reductions in force in 2008 and focusing our efforts on our commercial products and JZP-6, and we are continuing to review our operations in order to identify additional measures to further reduce spending. In addition, we have negotiated changes in the terms of some of our liabilities. In February 2009, we amended our product license agreement with Solvay as a result of which the then existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR, which was subsequently met in April 2009, and future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million, of which $1.0 million was paid in March 2009, $5.0 million is payable in the remainder of 2009, $4.0 million is payable in 2010, $4.5 million is payable in 2011 and $5.0 million is payable in 2012. If we pay these amounts when due, the payment due in 2012 will decrease to $4.5 million. In addition, we agreed to pay Solvay $5.0 million in 2015 if net sales of Luvox CR have reached a cumulative amount of $100.0 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the U.S. as of December 31, 2014. In the first quarter of 2009, we entered into arrangements with various government entities to postpone until October 2009 criminal and civil payments (totaling $2.5 million) that otherwise would have been due in January 2009.

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We did not make quarterly interest payments of $4.5 million and $5.1 million that were due on December 31, 2008 and March 31, 2009, respectively, to the holders of our $119.5 million principal amount of senior secured notes, or the Senior Notes, which constituted events of default under our agreement with the holders of the Senior Notes. As a result of the defaults, under the terms of the Senior Notes, we could be required to prepay some or all of the Senior Notes, including a prepayment premium, and interest is due at an annual default rate of 17%. We are currently seeking a number of financing and strategic alternatives and are in discussions with the holders of the Senior Notes, including in particular LB I Group Inc., an affiliate of Lehman Brothers Holdings, Inc., which holds approximately 75% of the principal amount of the Senior Notes, with respect to our December 31, 2008 and March 31, 2009 payment defaults and the status of the Senior Notes. There can be no assurance that we can reach such resolution, obtain sufficient financing or enter into other transactions to satisfy our Senior Note obligations in a timely manner, or at all. At any time, the holders of 50% or more of the principal amount of the Senior Notes can accelerate our obligations under the Senior Notes and require payment of the full principal amount of the Senior Notes, plus interest and a prepayment premium. We do not have sufficient cash resources to pay the amount that would become payable in the event of an acceleration of the Senior Notes, and even if we could obtain additional financing, it is unlikely that we could obtain an amount sufficient to repay the Senior Notes in full. In addition, the agreement covering the Senior Notes provides that if annualized net product sales (which for this purpose includes royalties), determined on a quarterly basis, are less than $100.0 million, then we must maintain a restricted cash balance equal to 15% of the then outstanding principal amount of the notes for as long as our annualized net product sales are less than $100.0 million. We did not meet the net sales test for the three months ended March 31, 2009 and we do not have sufficient cash to maintain the required restricted cash balance and continue to operate our business. We are currently unable to borrow under our line of credit due to the events of default on the Senior Notes. In addition, we have not drawn down funds and have not issued shares of our common stock under our committed equity financing facility, or CEFF, and, for so long as the average price of our common stock remains lower than $4.50 per share, which our common stock has recently been trading well below, we will not be able to sell shares under the CEFF.

The holders of the Senior Notes have a first priority security interest in all of our assets other than our inventory and accounts receivable and, in the event of an acceleration of our obligations and our failure to pay the amount that would then become due, the holders of the Senior Notes could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code.

In that event, we could seek to reorganize our business, or we or a trustee appointed by the court could be required to liquidate our assets. In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we needed to liquidate our assets, we might realize significantly less from them than the value that could be obtained in a transaction outside of a bankruptcy proceeding. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to secured and unsecured creditors, including the holders of the Senior Notes, before any funds would be available to pay our stockholders. If we are required to liquidate under the federal bankruptcy laws, it is unlikely that stockholders would receive any value for their shares.

While we believe that our current cash resources, together with anticipated revenues from product sales, would be sufficient to fund our operations, they are not sufficient to fund both our operations and any payment of interest or repayment of principal on the Senior Notes. In addition, we have based this estimate on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from sales of Xyrem and Luvox CR, and we could exhaust our available financial resources sooner than we currently expect. The sufficiency of our current cash resources, and our need for additional capital and the timing thereof, will depend on many factors, including primarily the amount of revenues that we receive from sales of Xyrem and Luvox CR, as well as other factors set forth in Item 1A of this Quarterly Report on Form 10-Q under the headings *Our operations have resulted in negative cash flows, we are seeking to raise additional funds to fund our operating expenses and debt obligations as soon as possible, which could cause us to have to accept terms that are harmful to our business, dilutive to our stockholders or otherwise disadvantageous to our existing stockholders, and if we are unable to secure additional funding, we may be required to significantly scale back our operations, significantly reduce our headcount, seek protection under the provisions of the U.S. Bankruptcy Code, and/or discontinue many of our activities which could negatively affect our business and prospects* and *We have a history of net losses, which may continue for the next few years and, if we are to grow our business in the future, we will need to commit substantial resources which could increase the extent of any future losses.*

In light of the circumstances described above, including our default under our Senior Notes and discussions with the noteholders, we are seeking to raise funds or consummate a strategic transaction as soon as possible. We may seek to do so through collaborations, partnering arrangements, development financings, public or private debt or equity financings or a corporate transaction with a third party. It is likely that the consent of the holders of the Senior Notes would be required for some of these transactions. We cannot assure you that the Senior Note holders would consent to any transactions that we might propose. Because the holders of the Senior Notes currently have a first priority security interest in our assets, they may be unwilling to consent to any transaction that limits their rights or impacts the protection of their security interest. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing would likely be substantially dilutive to our stockholders, particularly given the prices at which our common stock has been recently trading. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. If we raise funds through collaborations, partnering arrangements, development financings or a strategic partnership, we may be required to relinquish, on terms that are not favorable to

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us, rights to some, or all, of our products or product candidates that we would otherwise seek to develop or commercialize ourselves. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization of our products or product candidates. Our need to raise capital soon may require us to accept terms that may harm our business or be disadvantageous to our current stockholders, particularly in light of the current illiquidity and instability in the global financial markets.

If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs, including JZP-6, and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

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

	Three Months Ended March 31,	
	2009	2008
	(In thousands)	
Net cash used in operating activities	$ (5,150)	$ (38,170)
Net cash provided by (used in) investing activities	1,137	(2,927)
Net cash (used in) provided by financing activities	(3,875)	38,923
Net decrease in cash and cash equivalents	$ (7,888)	$ (2,174)

Net cash used in operating activities during the three months ended March 31, 2009 and 2008, primarily reflected the net loss, adjusted for non-cash items including depreciation and amortization and stock-based compensation expense in addition to the change in working capital. Net cash provided by investing activities during the three months ended March 31, 2009 primarily related to the release of restricted cash and the maturity of an investment in a marketable security partially offset by a payment for the purchase of rights to Luvox CR. Net cash used in investing activities during the three months ended March 31, 2008 primarily related to a milestone payment for the purchase of rights to Luvox CR, offset in part by the release of cash restricted under our previous senior secured note agreement. Net cash used in financing activities during the three months ended March 31, 2009 was attributable to the repayment of our line of credit. Net cash provided by financing activities during the three months ended March 31, 2008 was primarily attributable to net proceeds from the issuance of senior secured notes in March 2008.

Contractual Obligations

In addition to our contractual obligations set forth in our Annual Report on Form 10-K for the year ended December 31, 2008, the following table reflects a summary of material contractual obligations that have been modified or have been incurred during the first three months of 2009 and remain outstanding as of March 31, 2009:

		Payments due by period			
Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
		(In thousands)			
Amounts due to Solvay (1)	$ 18,000	$ 6,000	$ 8,750	$ 3,250	$
Total	$ 18,000	$ 6,000	$ 8,750	$ 3,250	$

(1) In February 2009, we amended our product license agreement with Solvay as a result of which the then existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR, which was subsequently met in April 2009 as well as the future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million, of which $1.0 million was paid in March 2009, $5.0 million is payable in the remainder of 2009 ($1.0 million is due in June 2009 and $2.0 million is due in each of September and December 2009), $4.0 million is payable in 2010, $4.5 million is payable in 2011 and $5.0 million is payable in 2012. If we pay these amounts when due, the payment due in 2012 will decrease to $4.5 million. In addition, we agreed to pay

Solvay $5.0 million in 2015 if net sales of Luvox CR have reached a cumulative amount of $100.0 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the U.S. as of December 31, 2014. Since we cannot determine when or if this milestone will be achieved it is not included in the table above.

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Related Parties

As of March 31, 2009, LB I Group Inc., an entity affiliated with Lehman Brothers Holdings Inc., holds $89.5 million of the principal amount of the Senior Notes and warrants to purchase 479,853 shares of common stock at an exercise price of $20.36 per share and warrants to purchase 470,836 shares of common stock at an exercise price of $14.23 per share. As of March 31, 2009, an affiliate of Kohlberg Kravis Roberts & Co. L.P., holds approximately $6.8 million of the principal amount of the Senior Notes and warrants to purchase 70,156 shares of common stock at an exercise price of $20.36 per share. No payments of interest under our Senior Notes were made during the three months ended March 31, 2009. As of March 31, 2009, we had accrued but unpaid interest of $9.6 million of which $7.2 million is owed to LB I Group Inc. and $545,000 is owed to the affiliate of Kohlberg Kravis Roberts & Co. L.P.

Off-Balance Sheet Arrangements

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

Cautionary Note Regarding Forward-Looking Statements

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the three months ended March 31, 2009, there were no material changes to our market risk disclosures as set forth in Item 7A. Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2008.

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 Exchange Act Rule 13a 15(e)) 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, subject to the limitations described below, our disclosure controls and procedures were effective as of March 31, 2009.

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 sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met. We continue to implement and refine our disclosure controls and procedures and our internal control over financial reporting.

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Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1A. Risk Factors.

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. 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, 2008, filed with the SEC. 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.

Risks Relating to Our Financial Condition

We have defaulted on our senior debt and our lenders have the right to accelerate our obligations at any time, which raises substantial doubt about our ability to continue as a going concern.*

We did not make the quarterly interest payments of $4.5 million and $5.1 million that were due on December 31, 2008 and March 31, 2009, respectively, to the holders of our $119.5 million principal amount of senior secured notes, or the Senior Notes. In early January and early April 2009, we received notices of default on behalf of the holders of the Senior Notes regarding the two payments that we did not make. In addition, the agreement covering the Senior Notes provides that if annualized net product sales (which for this purpose includes royalties), determined on a quarterly basis, are less than $100.0 million, then we must maintain a restricted cash balance equal to 15% of the then outstanding principal amount of the Senior Notes for as long as our annualized net product sales are less than $100.0 million. We did not meet the net sales test for the three months ended March 31, 2009 and we do not have sufficient cash to maintain the required restricted cash balance and continue to operate our business. We are seeking a number of financing and strategic alternatives and are in discussions with our holders of the Senior Notes, including in particular LB I Group Inc., an affiliate of Lehman Brothers Holdings, Inc., which holds approximately 75% of the principal amount of the Senior Notes, with respect to our December 31, 2008 and March 31, 2009 payment defaults and the status of the Senior Notes. There can be no assurance that we can reach such resolution, obtain sufficient financing or enter into other transactions to satisfy our Senior Note obligations in a timely manner, or at all.

At any time, the holders of 50% or more of the principal amount of the Senior Notes can accelerate our obligations under the Senior Notes and require payment of the full principal amount of the Senior Notes, plus interest and a prepayment premium. We do not have sufficient cash resources to pay the amount that would become payable in the event of an acceleration of the Senior Notes, and even if we could obtain additional financing, it is unlikely that we could obtain an amount sufficient to repay the Senior Notes in full. Our independent registered public accounting firm issued an opinion on our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2008 that states that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern.

The holders of the Senior Notes could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code, and in that event, it is unlikely that stockholders would receive any value for their shares.

The holders of the Senior Notes have a first priority security interest in all of our assets other than our inventory and accounts receivable and, in the event of an acceleration of our obligations and our failure to pay the amount that would then become due, the noteholders could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code.

In that event, we could seek to reorganize our business, or we or a trustee appointed by the court could be required to liquidate our assets. In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we needed to liquidate our assets, we might realize significantly less from them than the value that could be obtained in a transaction outside of a bankruptcy proceeding. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to secured and unsecured creditors, including the holders of the Senior Notes, before any funds would be available to pay our stockholders. If we were required to liquidate under the federal bankruptcy laws, it is unlikely that stockholders would receive any value for their shares.

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Our operations have resulted in negative cash flows, we are seeking to raise additional funds to fund our operating expenses and debt obligations as soon as possible, which could cause us to have to accept terms that are harmful to our business, dilutive to our stockholders or otherwise disadvantageous to our existing stockholders, and if we are unable to secure additional funding, we may be required to significantly scale back our operations, significantly reduce our headcount, seek protection under the provisions of the U.S. Bankruptcy Code, and/or discontinue many of our activities which could negatively affect our business and prospects.*

As of March 31, 2009, we had cash and cash equivalents of $17.0 million. While we believe that our current cash resources, together with anticipated revenues from product sales, would be sufficient to fund our operations, they are not sufficient to fund both our operations and any payment of interest or repayment of principal on the Senior Notes. In addition, we have based the estimate related to funding our operations on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from sales of Xyrem and Luvox CR, and we could exhaust our available financial resources sooner than we currently expect.

In light of the circumstances described above, including our default under our Senior Notes and discussions with the noteholders, we are seeking to raise funds or consummate a strategic transaction as soon as possible. We may seek to do so through collaborations, partnering arrangements, development financings, public or private debt or equity financings or a corporate transaction with a third party. It is likely that the consent of the holders of the Senior Notes would be required for some of these transactions. We cannot assure you that the Senior Note holders would consent to any transactions that we might propose. Because the holders of the Senior Notes currently have a first priority security interest in our assets, they may be unwilling to consent to any transaction that limits their rights or impacts the protection of their security interest. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing would likely be substantially dilutive to our stockholders, particularly given the prices at which our common stock has been recently trading. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. If we raise funds through collaborations, partnering arrangements, development financings or a strategic transaction we may be required to relinquish, on terms that are not favorable to us, rights to some, or all, of our products or product candidates that we would otherwise seek to develop or commercialize ourselves. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization of our products or product candidates. Our need to raise capital soon may require us to accept terms that may harm our business or be disadvantageous to our current stockholders, particularly in light of the current illiquidity and instability in the global financial markets.

If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs, including JZP-6, and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

We have reduced the net cash used in our operations by implementing three reductions in force in 2008 and focusing our efforts on our commercial products and JZP-6, and we are continuing to review our operations in order to identify additional measures to further reduce spending. We cannot predict with certainty the level of our product sales. If product sales do not meet our expectations and/or we do not raise additional funds, we will need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we have taken and may take in the future may not be sufficient to enable us to meet our cash requirements or for us to reach profitability, and they may negatively affect our business and prospects.

We have a substantial amount of debt, on which we are in default, which may adversely affect our ability to operate our business.

There is currently outstanding $119.5 million principal amount of the Senior Notes on which we are in default.

Even if the holders of the Senior Notes do not accelerate our obligations under the Senior Notes, that debt, combined with our other financial obligations and contractual commitments, could have other important negative consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;

- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, and important corporate activities;

limit our flexibility in planning for, or reacting to, changes in our business and our industry;

place us at a competitive disadvantage compared to our competitors who have less debt; and

limit our ability to borrow additional amounts for working capital and execution of our business strategy.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects.

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

Even if we are able to resolve the defaults under our Senior Notes, our business may be subject to a number of limitations. The terms of our Senior Notes currently contain, and any future indebtedness would likely contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. Our existing debt includes covenants, including requirements that we:

- generally not borrow additional amounts without the approval of our lenders;
- dispose of certain assets only in accordance with the terms of our existing senior secured debt;
- not impair our lenders security interests in our assets; and
- repay a portion of the debt early under certain circumstances.

In addition, the agreement covering the Senior Notes provides that if annualized net product sales (which for this purpose includes royalties), determined on a quarterly basis, are less than $100.0 million for the three months ended March 31, 2009, then we must maintain a restricted cash balance equal to 15% of the then outstanding principal amount of the Senior Notes for as long as our annualized net product sales are less than $100.0 million. We did not meet the net sales test for the three months ended March 31, 2009 and we do not have sufficient cash to maintain the required restricted cash and continue to operate our business. If we are not able to maintain any required restricted cash balance under the terms of the Senior Notes or to change the terms of the Senior Notes, the holders of the Senior Notes may exercise their rights and remedies under the Senior Notes, which may include the acceleration of the indebtedness.

We have a history of net losses, which may continue for the next few years and, if we are to grow our business in the future, we will need to commit substantial resources, which could increase the extent of any future losses.*

We have a limited operating history and have incurred significant net losses since our inception in 2003, and we may continue to incur net losses for the next few years. Our net loss for the three months ended March 31, 2009 was $13.0 million and we had an accumulated deficit of $513.8 million at March 31, 2009.

To grow our business in the future, we will need to commit substantial resources to costly and time-consuming product development and clinical trials of our product candidates and significant funds to our commercial operations. Our future capital requirements will depend on many factors, including:

- the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;
- market acceptance of and the number of prescriptions written for our products;
- selling and marketing costs associated with Xyrem and Luvox CR in the U.S.;
- revenues from current and potential future development and/or commercial collaboration partners;

the results from our second Phase III pivotal clinical trial for JZP-6;

the scope, rate of progress, results and costs of our preclinical studies, clinical trials, including our Phase IV clinical trial commitment to the FDA for Luvox CR, and other research and development activities;

the number and characteristics of product candidates that we pursue;

the cost and timing of establishing clinical and commercial supplies of our product candidates;

the cost and timing of obtaining regulatory approval;

payments of milestones to third parties;

increased expenses associated with our current employees and new employees hired to support our continued growth;

the cost of investigations, litigation and/or settlements related to regulatory activities;

the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and

the extent to which we acquire, in-license or invest in new businesses, products or product candidates.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

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Risks Related to Our Business

We may not be able to successfully increase sales of Xyrem or Luvox CR in the U.S., which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

An increase in revenue from sales of our commercial products in 2009 is a critical part of our budget for 2009 and affects our negotiations with the holders of our Senior Notes and potential future sources of financing. We cannot assure you that Xyrem or Luvox CR prescriptions will increase at the level estimated in our budget, or at all. Sales and prescriptions of Xyrem increased in 2008 and during the first quarter of 2009; however, cataplexy and excessive daytime sleepiness associated with narcolepsy are orphan conditions, which means that a relatively limited number of people suffer from those conditions. In December, we significantly increased the price of Xyrem. While the increase does not appear to have negatively affected sales of the product, we cannot assure you that this or future price increases will not negatively affect sales of Xyrem. Sales of and prescriptions for Luvox CR have been lower than anticipated since its launch. On February 5, 2009, we amended our Luvox CR license agreement with Solvay. Under the terms of the amendment, we paid Solvay $1.0 million in March 2009, and are required to pay them $5.0 million in 2009, $4.0 million in 2010, $4.5 million in 2011 and other payments thereafter. If sales of Luvox CR do not increase, they may not cover these payments plus the cost to manufacture, market and sell the product and our Phase IV clinical trial commitment to the FDA. If sales of Xyrem and Luvox CR do not increase as expected, we may be required to further reduce our operating expenses, and our ability to raise additional funds would likely be adversely affected, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our only product candidate currently in Phase III clinical trials is JZP-6 for the treatment of fibromyalgia. The Phase III clinical trials may not show JZP-6 to be safe and effective for the treatment of fibromyalgia or the FDA or foreign regulatory authorities may not approve JZP-6 for marketing, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

We are currently developing JZP-6 for the treatment of fibromyalgia. Our Phase III clinical program for JZP-6 includes two Phase III pivotal clinical trials, both of which must have statistically significant positive results before we can submit an NDA to the FDA seeking approval of JZP-6 for the treatment of fibromyalgia. Although we received favorable results from the first Phase III pivotal clinical trial in November 2008, these results may not be indicative of the clinical results from the second Phase III pivotal clinical trial. Our Phase III clinical program for JZP-6 is costly, and we do not expect to have preliminary results from our second Phase III pivotal clinical trial until mid-2009. We do not know if the second Phase III pivotal clinical trial will show JZP-6 to be safe and effective for the treatment of fibromyalgia, or if the FDA or other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia. Further, although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this active pharmaceutical ingredient for the treatment of fibromyalgia. An unsuccessful second Phase III pivotal clinical trial or a failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Lyrica (pregabalin), marketed by Pfizer, Cymbalta (duloxetine), marketed by Eli Lilly, and Savella (milnacipran), marketed by Forest Laboratories, were approved by the FDA in June 2007, June 2008, and January 2009, respectively, for the treatment of fibromyalgia. With treatments for fibromyalgia already approved, the FDA may be less willing to approve JZP-6 for the treatment of fibromyalgia.

There are currently no approved fibromyalgia treatments in the European Union. We cannot be sure that the European Agency for the Evaluation of Medicinal Products, or EMEA, will approve any treatment, or JZP-6 in particular, for fibromyalgia. For example, in October 2008 and April 2009 panels of European regulators recommended against approving Cymbalta and Lyrica, respectively, as treatments for fibromyalgia.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA may require us to have a Risk Evaluation and Mitigation Strategy program, or REMS, similar to the one we use for Xyrem. Under the Xyrem REMS, Xyrem must be distributed through a single central pharmacy. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy must verify the prescription and obtain additional information by contacting the patient s insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one month supply, and physicians may only prescribe up to six months of supply of Xyrem.

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

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

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

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

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

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the U.S. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames we expect, or at all, our revenues would be adversely affected. If UCB terminates its relationship with us, we would need to find another party or parties to commercialize Xyrem in UCB s licensed territories. We may be unable to find another party or parties on acceptable terms, or at all, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, under the terms of our collaboration with UCB, we granted UCB the exclusive right to commercialize JZP-6 for the treatment of fibromyalgia in the same territories that UCB has the right to market and promote Xyrem for patients with narcolepsy. We have relied in part on milestone payments from UCB to offset our development costs of JZP-6. 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 JZP-6 in UCB s territories and may need to execute alternative financing plans to help fund our development of JZP-6. We may be unable to do either of these on acceptable terms, or at all. There are currently no approved fibromyalgia treatments in the European Union. We cannot be sure that the EMEA will approve any treatment, or JZP-6 in particular, for fibromyalgia. For example, in October 2008 and April 2009 panels of European regulators recommended against approving Cymbalta and Lyrica, respectively, as treatments for fibromyalgia.

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

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the U.S. must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our Xyrem REMS is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem, and our sales, would be adversely affected. Changing central pharmacy distributors could take a significant amount of time. In addition, sodium oxybate, the active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. The new central pharmacy would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem, including the REMS approved by the FDA. If we change central pharmacies, new contracts might also be required with

government and other insurers who pay for Xyrem. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the U.S.

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Our supplier of the active pharmaceutical ingredient and our product manufacturer for Xyrem must obtain DEA quotas in order to supply us with Xyrem, JZP-6 and sodium oxybate, and these quotas may not be sufficient to satisfy our clinical and commercial needs.

The DEA limits the quantity of certain Schedule I and II controlled substances that may be produced in the U.S. in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturers must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier s and contract manufacturer s DEA quotas, our supplier and contract 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. In cooperation with our manufacturing partners, we sought and received significant increases in their 2007 quotas from the DEA for sodium oxybate, Xyrem and JZP-6 to satisfy the forecasted demand for Xyrem and to conduct our clinical studies of JZP-6. We did not succeed in obtaining the entire quota we requested for 2007. The quota our suppliers received from the DEA for 2008 was greater than what was issued for 2007, but was less than what we requested for 2008. We believe, although we cannot assure you, that our quota for 2009 will be sufficient to meet our commercial, clinical and development needs. In the future and in cooperation with our procurement and manufacturing partners, we will continue to seek increased quotas to satisfy our clinical and commercial needs. However, we may not be successful in obtaining increased quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem or sodium oxybate for the marketplace or for use in our clinical studies, or both.

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

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

The availability of our products for commercial sale is dependent upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a prior approval supplement and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer.

For Xyrem, JZP-6 or sodium oxybate, the new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem for the marketplace.

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

Lonza, Inc., or Lonza, is our sole supplier of sodium oxybate, the active pharmaceutical ingredient in Xyrem and, through Solvay, for fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. We expect Lonza will continue to be our sole supplier of sodium oxybate and fluvoxamine maleate for the foreseeable future. We cannot assure you that Lonza can or will continue to supply, in the time we need, sufficient quantities of active pharmaceutical ingredient to enable Elan and Patheon to manufacture the quantities of Luvox CR and Xyrem, respectively, that we need.

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

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with 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 or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. For example, if Lonza is unable to timely provide fluvoxamine maleate in the quantities we need there could be an interruption in the supply of Luvox CR to the market. In addition, under our agreement with UCB, we are responsible for the supply of Xyrem and, if approved, JZP-6 to UCB. Our failure to meet our contractual obligations to supply UCB with adequate quantities of Xyrem and JZP-6 would result in lost revenues to us and, if material, could result in termination of our agreements by UCB.

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

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

- the clinical indications for which a product is approved;
- prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;

relative convenience and ease of administration;

the cost of treatment in relation to alternative treatments, including generic products;

the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and

the availability of adequate reimbursement by third parties.

As an example, sales of Luvox CR have been significantly less than we had anticipated at the time of the acquisition of the rights to this product and prior to its launch in the first quarter of 2008.

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

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

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

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

insufficient funds to complete the trials.

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

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

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

From time to time, there is negative publicity about illicit GHB and its effects, including with respect to illegal use, overdoses, serious injury and death and 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. Because sodium oxybate is a derivative of GHB, patients, physicians and regulators may 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 the connection to GHB. Xyrem s label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

In April 2006, we and our subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. We and Orphan Medical have settled this matter with the U.S., acting through the Department of Justice, the U.S. Attorney s Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately $20.0 million in civil and criminal payments is required to be paid in connection with this matter, of which $1.0 million was paid in July 2007, $2.0 million was paid in January 2008, and $2.5 million is due in October 2009; the remaining will be due over the next three years.

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

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

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

The FDA has required that Xyrem s label include a box warning regarding the risk of abuse. A box 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 box warning also means, among other things, that the product cannot be advertised through reminder ads, ads which mention the pharmaceutical brand name but not the indication or medical condition it treats. Provigil, the only other product approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, does not have a box warning and can be advertised with reminder ads. In addition, Xyrem s type of FDA approval under the FDA s Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Unlike Xyrem, Provigil was not approved under the FDA s Subpart H regulations and is not subject to the pre-review requirements. Accordingly, promotional materials for Provigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

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

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

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

We are marketing Luvox CR in the U.S. for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Six other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including five selective serotonin

reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is

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marketed by Pfizer, Prozac, which is marketed by Eli Lilly, Pexeva, which is a branded generic marketed by Noven Therapeutics and Luvox, which is not currently marketed. Anafranil, the sixth other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the U.S. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than non-generic branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Four other products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended-release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR. Each of these products have generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia. In June 2007, the FDA approved Lyrica, an anticonvulsant marketed by Pfizer for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy, for the treatment of fibromyalgia. In June 2008, the FDA approved Cymbalta, a selective serotonin and norepinephrine reuptake inhibitor marketed by Eli Lilly for the treatment of major depressive disorder and generalized anxiety disorder, and diabetic peripheral neuropathic pain, for the treatment of fibromyalgia. In January 2009, the FDA approved Savella, a selective serotonin and norepinephrine reuptake inhibitor marketed by Forest Laboratories for the treatment of fibromyalgia. There are currently no other products approved by the FDA for the treatment of fibromyalgia. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with other large, established companies. Our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize generic or branded products that are safer or more effective, have fewer side effects or are less expensive than our products. In addition, we have undertaken several cost-cutting measures that may affect our ability to compete with other companies and due to our financial condition we may be required to take additional cost-cutting measures in the future.

Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may. For example, other major pharmaceutical companies have completed or we believe are close to completing Phase III clinical trials of product candidates for the treatment of fibromyalgia, and these are large pharmaceutical companies with far greater resources than we have. Three of these product candidates have received FDA approval and have already reached the market. These treatments, as well as other product candidates that may reach the market before JZP-6, may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III pivotal clinical trials for JZP-6 for the treatment of fibromyalgia and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

Our competitors may market their products more effectively than we do. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from the sales of our products.

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

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

Patent protection is not available for the active pharmaceutical ingredient in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Although Xyrem is covered by patents expiring in 2019 and 2020 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem and Luvox CR is covered by a patent covering the orally administered formulation of extended-release fluvoxamine, it is possible that other companies could manufacture generic equivalents of Xyrem and Luvox CR in ways that are not covered by the claims of these patents.

Part of our business strategy includes the ongoing development of proprietary product improvements to Xyrem, including new and enhanced dosage forms. However, we may not be successful in developing or obtaining FDA and other regulatory approvals of these improvements. Although the active pharmaceutical ingredient in Xyrem and JZP-6 is a DEA scheduled compound for which a quota is required and the FDA has required a REMS for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a similar REMS for distribution, our competitors will not be prevented from introducing a generic equivalent. We have filed a patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system, but we cannot

assure you that this patent will issue or, if issued, whether it will provide any significant protection of Xyrem from generic competition.

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Luvox CR is covered by a patent owned by Elan with claims covering the orally administered extended-release formulation of fluvoxamine. It is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. There may be other patents that we are not aware of that cover some aspect of the Luvox CR formulation and that would prevent us from continuing to commercialize Luvox CR or that would require us to pay royalties or other forms of consideration.

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

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

In order to grow our business, we will need to acquire or in-license additional products and product candidates that we believe have significant commercial potential. We do not believe we will be able to acquire or in-license additional products and product candidates until our financial condition improves. Any growth through acquisitions or in-licensing will be dependent upon the continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition or in-licensing, or we may not have the financial resources necessary to pursue such opportunities. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.

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

In November 2008, we reduced the size of our sales force as a result of the lower than expected demand for Luvox CR. Each of our remaining sales representatives is now responsible for a larger territory than he or she was responsible for prior to the reduction in force. We cannot predict if the smaller sales force will be effective at promoting our commercial products or if having a smaller sales force will negatively affect sales.

Our potential future commercial products, including JZP-6, may require expansion of our sales force and sales support organization, and we will need to commit significant additional management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel. Turnover in our sales force could negatively affect sales of our products. If we elect to rely on third parties to sell our products in the U.S., we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately size our sales force or collaborate with third parties to sell our products, our ability to generate revenues would be adversely affected.

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

Our success depends in part on our continued ability to retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. Any member of our executive management team and any other key employees may terminate his or her employment at any time without notice and without cause or good reason. In December 2008, Matthew K. Fust, our then Executive Vice President and Chief Financial Officer, left the company , and in April 2009, Dr. Samuel R. Saks, our then Chief Executive Officer and member of our Board of Directors, left the company.

In June 2008, we reduced the number of non-sales employees in our company in connection with efforts to focus, in the near term, on our commercial products and later-stage product candidates. In November 2008, we significantly reduced the number of sales representatives. In December 2008, we further reduced the number of non-sales employees in our company. These reductions in force may negatively affect our ability to retain or attract talented employees. Competition for qualified personnel in the life sciences industry remains intense. If we need to hire additional personnel to expand our development, clinical and commercial activities, or to support those activities, we may not be able to attract

and retain quality personnel on acceptable terms. Our current financial uncertainty adds to the risk of our loss of or our inability to recruit needed employees.

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If we need to accelerate our activities or expand our business, and cannot recruit qualified employees when we need them, our key activities could be delayed. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage our personnel resources effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

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

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

Risks Related to Our Intellectual Property

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon 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 U.S. 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. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;

our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

we may not develop additional proprietary products that are patentable; or

the patents of others may have an adverse effect on our business.

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

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

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

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

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party s activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity.

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

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

The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable and we may not be able to do this.

Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the U.S.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. 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,

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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 U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

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

Risks Related to Our Industry

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

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

Earlier in 2008, the FDA announced that, in light of staffing issues, it has given its managers discretion to miss Prescription Drug User Fee Act, or PDUFA, deadlines for completing reviews of NDAs. If the FDA were to miss a PDUFA deadline for one of our products, delaying the approval and launch, the delay could have a material adverse effect on our business.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

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 marketability of the product or otherwise reduce the size of the potential market for that product. Following any regulatory approval of our products, we will be subject to continuing 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, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products in the U.S. or overseas or at our contract manufacturers facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products and our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits, including class action suits. The FDA and other governmental authorities also actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

sodium oxybate Xyrem and JZP-6. These statutes and regulations include anti-kickback statutes and false claims statutes.

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

Federal false claims laws prohibit 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.

Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other health care companies have also been prosecuted on other legal theories of Medicare fraud. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company s products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and the reporting of gifts to individual physicians in the states. Other states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for or payments to individual prescribers. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. The minimum amount of the rebate for each unit of product is set by law at 15.1% of the average manufacturing price of that product, or if it is greater, the difference between the average manufacturing price and the best price we make available to any customer. The rebate amount also includes an inflation adjustment, if necessary.

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

Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Services pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Services pricing program extends discounts comparable to the Medicaid rebates to a variety of community

health clinics and other entities that receive health services grants from the Public Health Services, as well as hospitals that serve a disproportionate share of poor patients and children.

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

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the U.S., 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 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 policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR is competing in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts 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.

There have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries, 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, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides a new Medicare prescription drug benefit that became effective in January 2006, and mandates other reforms. Although we cannot predict the full effect on our business of the implementation of this new legislation, it is possible that the new benefit, which is managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. In addition, a final rule published by the Department of Defense in March 2009 under the National Defense Authorization Act of 2008, requires a retroactive rebate to January 2008 on all prescriptions filled under the TRICARE retail pharmaceutical program. These changes could harm our ability to market our products and generate revenues. Currently, there are legislative proposals that would permit the U.S. Secretary of Health and Human Services to negotiate directly with pharmaceutical companies to obtain lower prices for drugs covered under Medicare Part D.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. During the recent presidential election campaign, the candidates discussed healthcare reform proposals which, if enacted, could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Sales of our products in the U.S. may be adversely affected by consolidation among wholesale drug distributors and the growth of large retail drug store chains.

The market participants to whom we sell Luvox CR, and the market participants to whom we expect to sell most of our future products, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. In addition, excess inventory levels held by large distributors can lead to periodic and unanticipated reductions in our revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

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

Under current U.S. law, there is a general prohibition on imports of unapproved products. The FDA has published internal guidance that sets forth the agency s enforcement priorities for imported drugs. Under this policy, the FDA allows its personnel to use their discretion in permitting entry into the U.S. of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the U.S. from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will permit pharmacists and wholesalers to import prescription drugs into the U.S. from Canada

under specified circumstances. These additional import

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provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the U.S. to be imported or reimported to the U.S. from Canada, Europe and other countries. In addition, there have been indications that the new presidential administration is considering changing certain rules to make it easier to import drugs from other countries, and we cannot predict what, if any changes will happen. If these provisions or changes in the rules take effect, the volume of prescription drug imports from Canada and elsewhere could increase significantly and our products could face competition from lower priced imports.

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

We licensed Xyrem to Valeant to distribute in Canada. Due to government price regulation in Canada, products are generally sold in Canada for lower prices than in the U.S. Due to the REMS for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the U.S. Luvox CR is not approved in Canada.

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

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

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

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

Risks Relating to Ownership of Our Common Stock

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

Our stock has a very low average trading volume and our stockholders may not be able to sell any or all of their holdings quickly or at all. If we were to file for bankruptcy protection, it is likely that our common stock would have little or no value.

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The stock market in general and the market for life sciences companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

- our financial situation, including our defaults under our Senior Notes;
- our ability or inability to raise the additional capital we currently need and the terms on which we raise it;
- our ability or inability to consummate a strategic transaction and the terms of any such transaction;
- conditions or trends in the pharmaceutical industry, the credit and financial markets or the U.S. and worldwide economy in general;
- the success of Luvox CR in the U.S.;
- the success of our development efforts and clinical trials, including in particular with respect to JZP-6;
- negative publicity concerning one of our products or product candidates;
- announcement of FDA approval or non-approval of our product candidates, or specific label indications for their use, or delays in the FDA review process;
- the failure or delay by the DEA in providing sufficient quotas for sodium oxybate, Xyrem or JZP-6;
- actual or expected fluctuations in our operating results, including as a result of fluctuating demand for our commercial products as a result of purchases by wholesalers in connection with product launches, stockpiling or inventory drawdowns by our customers, or otherwise;
- changes in the market prices for our products;
- the success of our efforts to acquire or in-license additional products or product candidates;

introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

announcements of product innovations by us, our partners or our competitors;

changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements;

actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;

developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

actual or expected changes in our growth rates or our competitors growth rates;

changes in the market valuation of similar companies;

trading volume of our common stock; and

sales of our common stock by us or our stockholders.

Our common stock is currently at risk for delisting from The NASDAQ Global Market. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain adequate financing for the continuation of our operations would be substantially impaired.*

Our common stock is currently listed on The NASDAQ Global Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Global Market. These requirements

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include maintaining a minimum closing bid price of $1.00 per share, and the closing bid price of our common stock on April 24, 2009 was $0.60 per share. These requirements also include maintaining a minimum market value of publicly held shares, and, as of April 24, 2009, we did not meet this minimum requirement. Although NASDAQ has temporarily suspended the minimum closing bid price and minimum market value of publicly held shares requirements until July 20, 2009, there can be no assurance that we will meet these requirements after such date, and it is possible that NASDAQ may notify us prior to July 20, 2009 that we have failed to meet the minimum listing requirements that have not been suspended and initiate the delisting process. If our common stock is delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease, and our ability to obtain adequate financing for the continuation of our operations would be substantially impaired.

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 March 31, 2009, we had 28,925,352 shares of common stock outstanding, all of which shares, less shares subject to a repurchase option in our favor tied to the holders continued service to us (which will be eligible for sale upon lapse of the repurchase option), were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144.

As of April 24, 2009, the holders of up to approximately 19,306,128 shares of common stock, based on shares outstanding as of that date, including 785,728 shares underlying outstanding warrants, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, under an amended and restated investor rights agreement that we entered into with these holders. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights under the amended and restated investor rights agreement with respect to registration of the shares of common stock acquired on exercise. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital. On March 17, 2008, we entered into a registration rights agreement pursuant to which we agreed to file a registration statement covering the resale of the 562,192 shares underlying the warrants that we issued in connection with the expansion of our senior secured debt in March 2008. In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under our stock option and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

We entered into a committed equity financing facility, or CEFF, on May 7, 2008 with Kingsbridge Capital Limited, or Kingsbridge. The perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. The registration rights agreement entered into in connection with the CEFF requires that we use commercially reasonable efforts to ensure that the registration statement in connection with the CEFF remains effective for the term of such agreement. Kingsbridge will not be obligated to purchase shares of our common stock under the CEFF unless certain conditions are met. These conditions include a minimum trading price of $4.50 for our common stock, and our common stock has recently been trading well below that minimum. Accordingly, we do not expect to utilize this financing facility in the near term.

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

As of April 24, 2009, our executive officers and directors, together with their respective affiliates, beneficially owned approximately 61.8% of our capital stock, of which approximately 4.3% was beneficially owned by our executive officers. Accordingly, our executive officers and directors together with their respective affiliates are able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules of the Securities and Exchange Commission and The NASDAQ Stock Market LLC have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel must continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and

regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may incur substantial costs to maintain the same or similar coverage.

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The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. For example, we were required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our Annual Report on Form 10-K for the year ended December 31, 2008, and to allow our independent registered public accounting firm to issue a report on the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2009. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we have hired and will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

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

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

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless 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.

Our business requires significant funding, and we currently invest more in product development than we earn from sales of our products. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. Therefore, 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. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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Item 3. Defaults upon Senior Securities

We did not make the quarterly interest payments of $4.5 million and $5.1 million that were due on December 31, 2008 and March 31, 2009, respectively, to the holders of our $119.5 million principal amount of our senior secured notes, or Senior Notes. In early January and early April, 2009, we received notices of default on behalf of the holders of the Senior Notes regarding the two payments that we did not make. As a result of the defaults, under the terms of the Senior Notes, we could be required to prepay some or all of the Senior Notes, including a prepayment premium, and interest is due, effective January 1, 2009, at an annual default rate of 17% (instead of 15%). Interest will continue to accrue at this higher rate until all defaults are cured. In addition, the agreement covering the Senior Notes provides that if annualized net product sales (which for this purpose includes royalties), determined on a quarterly basis, are less than $100.0 million, then we must maintain a restricted cash balance equal to 15% of the then outstanding principal amount of the Senior Notes for as long as our annualized net product sales are less than $100.0 million. We did not meet the net sales test for the three months ended March 31, 2009 and we do not have sufficient cash to maintain the required restricted cash balance and continue to operate our business.

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Item 6. Exhibits.

Exhibit Number	Description of Document
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
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.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(6)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(7)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(5)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(6)
4.5A	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(6)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(6)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(6)
4.5D	Form of Common Stock Warrant of the Registrant.(6)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(6)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(7)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(7)
4.7	Form of Registered Direct Common Warrant.(8)
10.79	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(9)
10.81+	Amended and Restated Executive Change in Control and Severance Benefit Plan.(9)
10.82	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc.(9)
10.83	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(9)
10.84	2009 Executive Officer Compensation Arrangements
10.85	Consulting Agreement dated April 3, 2009 by and between the Registrant and Samuel R. Saks, MD
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 Acting Principal 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 Acting Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

+ Indicates management contract or compensatory plan.

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

(1) Incorporated herein by reference to the same numbered exhibit to 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.

(2) Incorporated herein by reference to Exhibit 3.4 to the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(3) Incorporated herein by reference to the same numbered exhibit to 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) Incorporated herein by reference to Exhibit 4.3 to 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.

(5) Incorporated by reference to Exhibit 4.6 to the Registrant s registration statement on Form S-1 (File No. 333-141164), as filed with the SEC on March 9, 2007.

(6) Incorporated herein by reference to the same numbered exhibit to 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.

(7) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.

(8) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.

(9) Incorporated herein by reference to the same numbered exhibit to the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.

* 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.

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SIGNATURES

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

Dated: May 7, 2009

Jazz Pharmaceuticals, Inc.

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

/s/ Joan E. Colligan
Joan E. Colligan
Acting Principal Financial Officer
(Principal Financial Officer)

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