JAZZ PHARMACEUTICALS INC
Form 10-Q
August 11, 2008
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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 June 30, 2008

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 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 Smaller reporting company ¨

(Do not check if a 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 July 31, 2008, 28,747,953 shares of the registrant s Common Stock, $.0001 par value, were outstanding.

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JAZZ PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2008

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,202	$ 102,945
Restricted cash	1,998	1,939
Marketable securities	1,500	
Accounts receivable, net of allowances of $167 and $218 at June 30, 2008 and December 31, 2007, respectively	5,221	5,389
Inventories	6,219	2,213
Prepaid expenses	3,680	3,224
Other current assets	376	381
Total current assets	70,196	116,091
Property and equipment, net	4,260	3,941
Intangible assets, net	71,074	36,040
Goodwill	38,213	38,213
Long-term restricted cash and investments		12,000
Other long-term assets	2,848	1,269
Total assets	$ 186,591	$ 207,554
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Line of credit	$ 6,099	$ 3,459
Accounts payable	8,522	2,856
Accrued liabilities	31,252	29,047
Purchased product rights liability	21,000	
Deferred revenue	3,430	1,494
Total current liabilities	70,303	36,856
Non-current portion of deferred revenue	11,899	12,468
Liability under government settlement	13,063	14,881
Senior secured notes (including $91,582 and $52,581 as of June 30, 2008 and December 31, 2007, respectively, held by related parties)	113,704	75,116
Common stock subject to repurchase	13,241	13,241
Commitments and contingencies (Note 15)		
Stockholders equity (deficit):		
Common stock	2	2
Additional paid-in capital	379,437	371,440
Accumulated other comprehensive income		19

Accumulated deficit	(415,058)	(316,469)
Total stockholders equity (deficit)	(35,619)	54,992
Total liabilities and stockholders equity (deficit)	$ 186,591	$ 207,554

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 June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues:				
Product sales, net	$ 14,751	$ 13,615	$ 28,735	$ 25,240
Royalties, net	503	360	868	571
Contract revenues	285	289	569	2,541
Total revenues	15,539	14,264	30,172	28,352
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technology)	2,796	1,679	5,094	3,682
Research and development	21,882	17,407	43,125	32,274
Selling, general and administrative	34,109	18,175	66,889	32,514
Amortization of intangible assets	3,846	2,287	5,966	4,649
Provision for government settlement		17,469		17,469
Total operating expenses	62,633	57,017	121,074	90,588
Loss from operations	(47,094)	(42,753)	(90,902)	(62,236)
Interest income	450	1,300	1,347	2,391
Interest expense (including $4,038 and $2,287 for the three months ended June 30, 2008 and 2007, respectively, and $6,863 and $4,541 for the six months ended June 30, 2008 and 2007, respectively, pertaining to related parties)	(5,235)	(3,314)	(9,021)	(6,582)
Other (expense) income, net	(1)	4,904	(13)	1,835
Gain on sale of product rights				5,145
Net loss	$ (51,880)	$ (39,863)	$ (98,589)	$ (59,447)
Net loss per share, basic and diluted	$ (2.17)	$ (5.27)	$ (4.14)	$ (15.59)
Weighted-average common shares used in computing net loss per share, basic and diluted	23,858	7,561	23,800	3,813

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)

	Six Months Ended June 30,	
	2008	**2007**
Operating activities		
Net loss	$ (98,589)	$ (59,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,151	589
Amortization of intangible assets	5,966	4,649
Loss on disposal of property and equipment	138	6
Fair value adjustment to acquired finished goods		54
Stock-based compensation expense	4,102	1,980
Non-cash interest expense	843	487
Revaluation of preferred stock warrant liability		(1,846)
Gain on sale of product rights		(5,145)
Changes in assets and liabilities:		
Accounts receivable	168	(1,073)
Inventories	(4,028)	(565)
Prepaid expenses and other current assets	(451)	732
Other assets	(501)	(52)
Accounts payable	5,666	(1,535)
Accrued liabilities	3,229	8,522
Deferred revenue	1,367	147
Deferred rent		(43)
Liability under government settlement	(1,818)	14,881
Net cash used in operating activities	(82,757)	(37,659)
Investing activities		
Purchases of property and equipment	(1,609)	(1,513)
Transfer of long-term restricted investments to marketable securities	(4,410)	
Proceeds from maturities of marketable securities	2,910	
Decrease (increase) in restricted cash and investments	11,941	(85)
Proceeds from sale of product rights		9,000
Purchase of developed technology	(20,000)	
Net cash provided by (used in) investing activities	(11,168)	7,402
Financing activities		
Proceeds from employee stock purchases and exercise of stock options	976	76
Proceeds from sale of common stock in initial public offering, net of issuance costs		98,290
Proceeds from line of credit	9,279	12,758
Repayments under line of credit	(6,639)	(11,815)
Proceeds from sale of senior secured notes and warrants, net of issuance costs	38,566	
Net cash provided by financing activities	42,182	99,309
Net increase (decrease) in cash and cash equivalents	(51,743)	69,052
Cash and cash equivalents, at beginning of period	102,945	78,948

Cash and cash equivalents, at end of period	$ 51,202	$ 148,000
Supplemental disclosure of cash flow information:		
Cash paid for interest (including $6,187 and $4,200 for the six months ended June 30, 2008 and 2007, respectively, paid to related parties)	$ 8,170	$ 6,081
Supplemental disclosure of non-cash financing activities:		
Conversion of preferred stock warrant liability to stockholders equity	$	$ 6,675
Warrants to purchase common stock issued in conjunction with senior secured notes	$ 2,000	$
Warrants to purchase common stock issued in conjunction with equity financing facility	$ 850	$
Common stock issued as employee bonuses	$ 999	$

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 (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 (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 the Annual Report on Form 10-K for the year ended December 31, 2007 of Jazz Pharmaceuticals, Inc. (the Company or Jazz Pharmaceuticals). 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 the Company s financial position and operating results. The results for the three and six months ended June 30, 2008 are not necessarily indicative of the results to be expected for the year ending December 31, 2008 or for any other interim period or for any future year. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Orphan Medical, LLC (Orphan Medical) and JPI Commercial, LLC (JPIC), after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

The Company has incurred significant losses from operations since its inception and may continue to incur losses for the next few years. To achieve profitable operations, the Company must successfully identify, develop and commercialize its products. Products developed by the Company will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sales. The regulatory approval process is expensive, time consuming and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company s products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products. The Company may need to raise additional funds to support its operations, and such funding may not be available to it on acceptable terms, or at all. The Company may seek additional sources of financing through development financings, collaborations, partnering arrangements, or public or private debt or equity financings, and may also seek to reduce expenses related to its operations. If the Company is unable to raise additional funds when needed, it may not be able to continue development of its product candidates or the Company could be required to delay, scale back or eliminate some or all of its development programs and other operations.

Luvox CR® was approved by the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder and the Company shipped initial stocking orders to its wholesaler customers in the first quarter of 2008. The Company cannot predict with certainty the timing or level of Luvox CR sales, and if sales of Luvox CR do not reach the levels the Company expects, the Company may be unable to meet its cash requirements under its current operating plan. The Company may be required to reduce its planned expenditures, perhaps significantly, to preserve cash, particularly if the Company is unable to raise additional funds when needed.

Concentration of Credit Risks

The Company monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit to pharmaceutical companies, pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, the Company has not experienced significant credit losses on its accounts receivable. The Company s five largest customers accounted for an aggregate of approximately 97% and 93% of gross accounts receivable as of June 30, 2008 and December 31, 2007, 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 consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

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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 U.S. are recognized upon transfer of title, which occurs when the Company s specialty pharmaceutical distributor removes product from the Company s consigned inventory location at its facility for shipment to a patient. Prior to the Company s sale of the Company s rights to Antizol, Antizol-Vet®, and Cystadane®, Antizol, Antizol-Vet and Cystadane were shipped to the Company s wholesaler customers in the U.S. with free on board destination shipping terms, and the Company recognized revenues when delivery occurred. The Company s international sales often have customer acceptance clauses and therefore the Company recognizes revenues when it is notified of acceptance or when the time to inspect and reject a shipment has lapsed. When sales to international customers do not have acceptance clauses, the Company recognizes revenues when title transfers, which is generally when the product leaves the Company s logistics provider s facilities.

Luvox CR® was approved by the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder and the Company shipped initial stocking orders to its wholesaler customers in the first quarter of 2008. Luvox CR is subject to rights of return within six months prior to and up to twelve months after product expiration. Given the Company s limited history of selling Luvox CR, the Company currently cannot reliably estimate expected returns of Luvox CR at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Luvox CR and instead recognizes revenue on a sell-through basis using dispensing data generated by an independent prescription tracking service. Units dispensed through prescriptions are generally not subject to return. When trade channel inventories are reduced to targeted stocking levels and the Company has sufficient data to determine product acceptance in the marketplace the Company will recognize revenue on sales of Luvox CR at the time title passes to its customers, or on a sell-in basis, and provide for an estimate of future product returns. Through June 30, 2008, the Company has billed its wholesaler customers, who have certain industry standard rights of return, an aggregate of $3.2 million. The Company concluded, based on prescription data and the level of trade channel inventories, that it is unable to determine the extent of Luvox CR acceptance by the market and consequently is unable to estimate the extent of product returns. Therefore, the Company recorded revenue of $587,000 for the three and six months ended June 30, 2008, on a sell-through basis net of estimated wholesaler fees, discounts, chargebacks and rebates. As of June 30, 2008, the Company had recorded a liability of $2.3 million, which represented amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates, and is included under the caption Deferred Revenue on the condensed consolidated balance sheet. Luvox CR cost of product sales of approximately $189,000 related to shipments for which revenue has not been recognized is included under the caption Inventories on the condensed consolidated balance sheet.

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 June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Numerator:				
Net loss	$ (51,880)	$ (39,863)	$ (98,589)	$ (59,447)
Denominator:				
Weighted-average common shares outstanding	24,736	8,252	24,679	4,461
Less: weighted-average common shares outstanding subject to repurchase	(878)	(691)	(879)	(648)
Weighted-average common shares used in computing net loss per share, basic and diluted	23,858	7,561	23,800	3,813
Net loss per share, basic and diluted	$ (2.17)	$ (5.27)	$ (4.14)	$ (15.59)

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The following securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have an antidilutive effect (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Warrants to purchase common stock	1,478	786	1,175	786
Options to purchase common stock	3,728	1,945	3,564	1,945
Common stock subject to repurchase	878	602	879	602
Restricted stock units	110		113	

Recently Adopted Accounting Standards

Effective January 1, 2008, the Company adopted Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). Under EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. The Company s adoption of EITF 07-3 did not have a material effect on the Company s consolidated results of operations and financial position.

Effective January 1, 2008, the Company adopted Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities* (SFAS 159), which provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in SFAS 159 are elective; however, the amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115), applies to all entities with available-for-sale and trading securities. Under SFAS 159, entities that elect the fair value option (by instrument) will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value option election is irrevocable, unless a new election date occurs. SFAS 159 establishes presentation and disclosure requirements to help financial statement users understand the effect of the entity s election on its earnings, but does not eliminate disclosure requirements of other accounting standards. Assets and liabilities that are measured at fair value must be displayed on the face of the balance sheet. The Company chose not to elect the fair value option for its financial assets and liabilities existing at January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the three and six months ended June 30, 2008. Therefore, the adoption of SFAS 159 had no impact on the Company s consolidated results of operations and financial position.

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157), for financial assets and liabilities and any other assets and liabilities carried at fair value. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. On November 14, 2007, the FASB agreed to a one-year deferral for the implementation of SFAS 157 for nonfinancial assets and nonfinancial liabilities. The Company s adoption of SFAS 157 for financial assets and liabilities and any other assets and liabilities carried at fair value did not have a material effect on the Company s consolidated results of operations and financial position. The Company is currently evaluating the effect that the adoption of SFAS 157 for nonfinancial assets and liabilities will have on its consolidated results of operations and financial condition.

2. Inventories

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

	June 30, 2008	December 31, 2007
Raw materials	$ 3,712	$ 500
Finished goods (1)	2,507	1,713
Total inventories	$ 6,219	$ 2,213

(1) Includes, at June 30, 2008, deferred costs of sales of $422,000 for which the related revenue has been deferred.

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3. Goodwill and Intangible Assets

The gross carrying amount of goodwill was $38.2 million at June 30, 2008 and December 31, 2007. The gross carrying amounts and net book values of the intangible assets were as follows (in thousands):

	June 30, 2008			December 31, 2007		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology - Xyrem	$ 39,700	$ 12,584	$ 27,116	$ 39,700	$ 10,499	$ 29,201
Developed technology - Antizol	2,715	679	2,036	2,715		2,715
Developed technology - Luvox CR	41,000	2,401	38,599			
Agreements not to compete	5,600	4,053	1,547	5,600	3,389	2,211
Trademarks	2,600	824	1,776	2,600	687	1,913
Total	$ 91,615	$ 20,541	$ 71,074	$ 50,615	$ 14,575	$ 36,040

During the six months ended June 30, 2008, the Company recorded an intangible asset of $41.0 million related to Luvox CR developed technology with an estimated useful life of approximately five years. See Note 10 for additional information.

In August 2008, the Company sold its rights to Antizol to an unrelated third party. See Note 16 for additional information. Future amortization costs per year for the Company s existing intangible assets other than goodwill as of June 30, 2008, and excluding the Antizol intangible asset, were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2008 (remaining portion)	$ 6,861
2009	13,496
2010	13,093
2011	12,716
2012	12,716

4. Fair Value Measurement

As stated in Note 1, on January 1, 2008, the Company adopted SFAS 157 as it applies to its financial assets and financial liabilities. SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Fair value is defined as the estimated exit price received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date rather than on an entry price which represents the purchase price of an asset or liability. SFAS 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs (i.e. inputs that reflect the reporting entity s own assumptions about the assumptions that market participants would use in estimating the fair value of an asset or liability) are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of June 30, 2008, the Company measured its available-for-sale securities using significant observable prices that are based on inputs not quoted on active markets, but corroborated by market data, Level 2 in the fair value hierarchy, resulting in a fair value estimate of $54.7 million. No other financial assets and liabilities were carried at fair value as of June 30, 2008.

The Company chose not to elect the fair value option as prescribed by SFAS 159 for its financial assets and liabilities that had not been previously carried at fair value. Therefore, material financial assets and liabilities not carried at fair value, such as the Company s short- and long-term debt obligations and trade accounts receivable and payable, are still reported at their carrying values.

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5. Debt Obligations

Line of Credit

In May 2008, the Company amended its existing line of credit so that the Company may borrow up to 75% of eligible accounts receivable up to a maximum of $15.0 million in borrowings.

Senior Secured Notes and Warrants

On March 17, 2008, JPIC, a wholly-owned subsidiary of the Company, sold $40.0 million aggregate principal amount of senior secured notes pursuant to a new debt arrangement. As part of the transaction, the Company issued to the purchasers of these notes warrants to purchase a total of 562,192 shares of its common stock exercisable at an exercise price of $14.23 per share at any time until March 17, 2013. The Company paid an arrangement fee of $800,000 and incurred issuance costs of $634,000 in connection with the transaction. The warrants were recorded as a debt discount at an estimated fair value of $2.0 million and were recorded, net of issuance costs, in stockholders equity. The fair value of the warrants was estimated using the Black-Scholes option pricing model with the following assumptions: a volatility of 51%, a term of 5.0 years, a risk-free rate of 2.2% and an expected dividend yield of 0%. The recorded debt is accreted by the amount of the debt discount over the terms of the notes, and the issuance costs, which are recorded in other long-term assets, are amortized over the term of the notes using the effective interest method. The notes bear interest at 15% per annum, payable quarterly in arrears, and are due on June 24, 2011. In addition, on March 17, 2008, a total of $80.0 million aggregate principal amount of senior secured notes of Orphan Medical were exchanged for the same principal amount of new senior secured notes issued by JPIC pursuant to the new debt arrangement described above at the same interest rate. In the transactions, the Company guaranteed the repayment obligations of JPIC and granted the note holders a security interest in all of the Company s assets and those of the Company s wholly-owned subsidiaries. The Company has also agreed to restrictions on working capital borrowings, dividends and certain other payments. Under the debt agreement, the Company may borrow from other sources up to $15.0 million secured by its accounts receivable and inventory. JPIC may be required, upon the occurrence of certain events and if the Company s annualized net product sales fall below a certain specified level, to redeem up to $30.0 million of the outstanding principal amount of senior secured notes. JPIC may, at its option, prepay some or all of the notes subject to a repayment premium. The repayment premium on the first $40.0 million principal amount is 10% of the principal repayment. The repayment premium on any additional principal repayment was 20% of the principal repayment at June 30, 2008, and reduces ratably to zero on June 24, 2011. If there is an event of default under the terms of the notes, JPIC may be required to prepay some or all of the notes, including a repayment premium. The repayment premium for an event of default was 20.0% of the principal amount of the notes as of June 30, 2008 and will be reduced to zero ratably over the term of the notes.

Subject to satisfying conditions related to the Company s net product sales and certain closing conditions, the Company has the option pursuant to the new debt arrangement described above, prior to January 31, 2009, to sell to the purchasers of the new $40.0 million of senior secured notes issued on March 17, 2008 up to $30.0 million aggregate principal amount of senior secured notes and warrants to purchase shares of the Company s common stock at an exercise price based upon the closing stock price for a specified period prior to the sale of the notes and warrants.

The Company is not required to maintain a restricted cash balance under this arrangement. However, if at any time after the quarter ending March 31, 2009, the Company s product sales do not reach certain specified levels, JPIC would be required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of notes. Under a terminated agreement pursuant to which $80.0 million of senior secured notes were issued in 2005 (and later exchanged for new notes as described above), the Company was required to maintain a restricted cash balance of $12.0 million as of December 31, 2007.

Prior to the issuance of the new $40.0 million senior secured notes on March 17, 2008, LB I Group Inc., a related party and an entity affiliated with Lehman Brothers Holdings Inc., purchased certain senior notes and warrants then outstanding, including certain senior notes and warrants held by an affiliate of Kohlberg Kravis Roberts & Co. L.P., a significant stockholder and a related party. Subsequent to this purchase and the issuance of the new $40.0 million senior secured notes, entities affiliated with Kohlberg Kravis Roberts & Co. L.P. held notes with an aggregate principal amount of $7.1 million and warrants to purchase 70,156 shares of common stock exercisable at $20.36 per share. Subsequent to the issuance of the new $40.0 million senior secured notes on March 17, 2008, LB I Group Inc. held notes with an aggregate principal amount of $89.5 million, warrants to purchase 479,853 shares of common stock exercisable at $20.36 per share and warrants to purchase 470,836 shares of common stock exercisable at $14.23 per share. Subject to certain conditions and if the Company exercises its option, LB I Group Inc. is also obligated to purchase notes with an aggregate principal amount of up to $27.0 million from JPIC, of the $30.0 million described above. The Company paid LB I Group Inc. the arrangement fee of $800,000 described above in connection with the issuance of the new $40.0 million senior secured notes.

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6. Convertible Preferred Stock and Preferred Stock Warrant Liability

In connection with the Company s initial public offering, on June 6, 2007, all shares of convertible preferred stock were converted to common stock and all outstanding warrants exercisable for convertible preferred stock became exercisable for common stock. The related preferred stock warrant liability was reclassified to stockholders equity at its then fair value of $6.7 million. The Company recorded benefits of $4.9 million and $1.8 million, in other income, during the three and six months ended June 30, 2007, respectively, to reflect decreases in the fair value of the preferred stock warrant liability.

7. Common Stock

Committed Equity Financing Facility

In May 2008, the Company entered into a committed equity financing facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), that entitles the Company to sell and obligates Kingsbridge to purchase up to the lesser of $75.0 million of the Company s common stock or 4,922,064 shares over a three-year period, subject to early termination in certain circumstances. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 220,000 shares of the Company s common stock with an exercise price of $11.20 per share. The warrant is exercisable for a period of five years beginning six months after the date of issuance. The fair value of the warrant was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 3.18%, volatility of 52%, an expected term of 5.5 years and an expected dividend yield of 0%. The estimated fair value of the warrant of $850,000 was recorded in stockholders equity.

Subject to certain conditions and limitations, from time to time under the CEFF, the Company may require Kingsbridge to purchase shares of its common stock at a price that is between 90% and 94% of the volume weighted average price on each trading day during an eight day pricing period. The maximum number of shares the Company may require Kingsbridge to purchase in any pricing period is, the greater of (i) 1.5% of the Company s market capitalization at the time of the commencement of the pricing period or (ii) the lesser of (A) 3.0% of the Company s market capitalization at the time of the commencement of the pricing period or (B) a number of shares determined by a formula based in part on the average trading volume and trading price of the Company s common stock prior to the date of the draw down notice issued by the Company with respect to that pricing period; provided, however, that the shares the Company can require Kingsbridge to purchase in any pricing period cannot exceed an aggregate purchase price of $25 million. If the average price of the Company s common stock is lower than $4.50 or declines more than 10% from the closing price on the trading day immediately prior to the start of a pricing period, the Company cannot draw under the CEFF during that pricing period for so long as the price remains below either of these thresholds.

As of June 30, 2008, the Company had not issued shares or drawn down funds under the CEFF and, in connection with the registered direct public offering described in Note 16, the Company has agreed not to issue shares or draw down funds under the CEFF until after September 13, 2008.

Stock Bonus

In May 2008, the Company issued 125,532 shares of common stock with a fair value of $999,000 to employees as settlement of a liability under the Company s employee bonus plan.

ESPP and Stock Option Exercises

In May 2008, the Company issued 149,856 shares of its common stock for proceeds of $974,000 under its employee stock purchase plan. The Company issued 1,807 shares of common stock as a result of stock option exercises during the six months ended June 30, 2008 for proceeds of $2,000.

Initial Public Offering

On June 6, 2007, the Company completed its initial public offering of 6,000,000 shares of its common stock at a public offering price of $18.00 per share. Net cash proceeds from the initial public offering were $97.5 million, after deducting underwriting discounts and commissions and offering expenses.

8. Comprehensive Loss

Comprehensive loss includes net loss and all changes in stockholders equity (deficit) during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. For the six months ended June 30, 2008 and 2007, the difference between comprehensive loss and net loss represented the change in unrealized gains/losses on available-for-sale securities and was not material.

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9. Segment Information

Management has determined that the Company operates 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 June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Xyrem	$ 12,405	$ 9,628	$ 23,746	$ 18,252
Antizol (1)	1,632	3,987	4,275	6,623
Luvox CR (2)	714		714	
Cystadane (3)				365
Total	$ 14,751	$ 13,615	$ 28,735	$ 25,240

(1) Includes sales of Antizol-Vet, which were $73,000 and $66,000 in the three months ended June 30, 2008 and 2007, respectively, and $148,000 and $131,000 in the six months ended June 30, 2008 and 2007, respectively. The Company sold its rights to Antizol and Antizol-Vet to an unrelated third party in August 2008.

(2) Includes sales of the active pharmaceutical ingredient in Luvox CR of $127,000.

(3) The Company sold its rights to Cystadane to a third party in March 2007.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
United States	$ 14,291	$ 13,621	$ 27,884	$ 25,134
Europe	784	553	1,428	3,077
All other	464	90	860	141
Total	$ 15,539	$ 14,264	$ 30,172	$ 28,352

The following table presents a summary of total revenues from significant customers as a percentage of the Company s total revenues:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Express Scripts	78%	67%	78%	64%
UCB Pharma Limited	*	*	*	10%

* Represented less than 10% of the Company s total revenues.

10. Product License

In January 2007, the Company entered into a product license agreement with Solvay for the rights to market Luvox CR and Luvox in the United States. The Company made a $2.0 million payment upon execution of the agreement which was recorded as research and development expense in the six months ended June 30, 2007. As a result of approval by the FDA and the first commercial sale of Luvox CR, both of which occurred during the three months ended March 31, 2008, the Company is obligated to make payments under this agreement, as amended, of $41.0 million in 2008, of which $10.0 million was paid on March 28, 2008, $10.0 million was paid on April 7, 2008, $10.5 million is payable on September 30, 2008 and $10.5 million is payable on December 31, 2008. The Company is obligated to pay Solvay up to an additional $95.0 million in commercial milestone payments associated with Luvox CR, as well as royalties on net product sales at specified rates. Luvox CR s FDA approval included a commitment for two Phase IV clinical trials, one in adolescent patients with social anxiety disorder (SAD) and the other a duration of effect study in patients with SAD. Solvay is required to reimburse the Company for fifty percent of the costs to be incurred in connection with these clinical trials up to $1.0 million.

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11. Collaboration and License Agreements

Under the terms of an agreement with UCB Pharma Limited (UCB), UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. UCB made a nonrefundable milestone payment to the Company of $2.0 million in March 2007, which was recorded as contract revenue in the six months ended June 30, 2007. The Company recognized contract revenues of $280,000 during each of the three months ended June 30, 2008 and 2007, and $560,000 and $532,000 during the six months ended June 30, 2008 and 2007, respectively, related to previously deferred upfront payments which are being recognized as contract revenue ratably through 2019, the expected performance period under the agreement. In July 2008, the Company amended its agreement with UCB. See Note 16 for additional information.

12. Stock-Based Compensation

The Company accounts for employee stock-based compensation under SFAS No. 123(R), *Share-Based Payment* (SFAS 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 the three and six months ended June 30, 2008 and 2007 was calculated based on awards ultimately expected to vest, and has been reduced for estimated forfeitures. SFAS 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 SFAS 123R related to stock options, restricted stock units, phantom shares and awards under the Company s employee stock purchase plan was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Cost of product sales	$ 60	$ 11	$ 103	$ 22
Research and development	500	220	1,047	414
Selling, general and administrative	1,315	809	2,952	1,544
Total stock-based compensation expense	$ 1,875	$ 1,040	$ 4,102	$ 1,980

Employee stock-based compensation expense of $21,000 and $43,000 as of June 30, 2008 and December 31, 2007, respectively, were capitalized as a component of inventory and included in the condensed consolidated balance sheets.

Stock Options

During the three months and six months ended June 30, 2008, the Company granted stock options to purchase 699,350 and 792,925 shares of common stock, respectively. The weighted-average grant-date fair value per share of the stock options granted during the three months and six months ended June 30, 2008 was $4.68 and $5.02, respectively. The fair value of these stock option grants was estimated at the grant date using the Black Scholes option pricing model with the following weighted-average assumptions:

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Weighted-average volatility	59%	56%	59%	60%
Weighted-average expected term	6.1	6.0	6.1	6.4
Range of risk-free rates	2.9-3.4%	4.9%	2.7-3.4%	4.5-4.9%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

The Company issued 1,807 shares of common stock as a result of stock option exercises during the six months ended June 30, 2008.

13. Sale of Product Rights

In March 2007, the Company sold its rights to Cystadane, associated product registrations, commercial inventory and trademarks for cash consideration of $9.0 million and recorded a gain of $5.1 million. In August 2008, the Company sold its rights to Antizol and Antizol-Vet to an unrelated third party. See Note 16 for additional information.

14. Workforce Reduction

In June 2008, as part of a strategic decision to reduce its emphasis on early-stage research and development activities, reduce research and development commitments and streamline administrative operations, the Company completed a workforce reduction of 33 employees and recorded a charge of $463,000 in the three and six months ended June 30, 2008, of

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which $246,000 is recorded in research and development expense and the remainder in selling, general and administrative expense. Approximately $450,000 of the charge relates to severance, health insurance premium and outplacement assistance payments, of which $101,000 was unpaid as of June 30, 2008 and is scheduled to be paid by September 30, 2008. The remaining $13,000 relates to the accelerated vesting of restricted stock units for terminated employees.

15. Commitments and Contingencies

Indemnification

In the normal course of business, the Company enters 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. The Company s exposure under these agreements is unknown because it involves future claims that may be made against the Company that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to these indemnification obligations except as disclosed in the Company s prior public filings.

The Company has agreed to indemnify its officers and directors, and the officers and directors of Orphan Medical and JPIC, 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 the Company could be required to make under this indemnification is unlimited; however, the Company maintains insurance policies that may limit its exposure and may enable it 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, the Company believes that the fair value of these indemnification obligations is not material. Accordingly, the Company has not recognized any liabilities relating to these obligations as of June 30, 2008 and December 31, 2007. 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 the Company may incur substantial liabilities as a result of these indemnification obligations.

Legal Proceedings

In April 2006, the Company and Orphan Medical received subpoenas from the United States Department of Justice in connection with the sale and marketing of Xyrem. In July 2007, the Company reached a comprehensive settlement with the government in connection with this matter and agreed to make payments totaling approximately $20.0 million over the next several years of which the Company has paid $3.0 million as of June 30, 2008. The Company recorded a charge of $17.5 million in the three and six months ended June 30, 2007, which represents the present value of these payments discounted at an interest rate of 4.6%. As of June 30, 2008, the non-current portion of this provision was $13.1 million and the current portion, which is included in accrued liabilities, was $2.2 million.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical and former officers of Orphan Medical in the United States District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005. The purpose of the special meeting was to consider and vote upon a proposal to adopt the definitive merger agreement pursuant to which the Company acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the United States District Court for the District of Minnesota. On February 16, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint, with leave to amend. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. Oral argument on the motion was heard on June 8, 2007. On September 13, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint with prejudice. On September 28, 2007, the plaintiff filed a Notice of Appeal to the United States Court of Appeals for the Eighth Circuit. On November 21, 2007, the plaintiff filed its brief with the United States Court of Appeals for the Eighth Circuit. On December 21, 2007, the defendants filed their brief with the United States Court of Appeals for the Eighth Circuit. On January 8, 2008, the plaintiff filed a reply brief. Oral arguments were heard on May 15, 2008. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome.

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

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16. Subsequent Events

Registered Direct Public Offering

On July 21, 2008, the Company completed a registered direct public offering of units consisting of an aggregate of 3,848,289 shares of common stock and warrants to purchase an aggregate of 1,731,724 shares of common stock at a public offering price of $6.75625 per unit for net proceeds of approximately $24.5 million after deducting the placement agents fees and other estimated offering expenses payable by the Company. The warrants are exercisable for $7.37 per share of common stock at any time on or after January 21, 2009 and prior to July 21, 2014. In connection with the offering, the Company has agreed not to issue shares or draw down funds under the CEFF until after September 13, 2008.

The investors in the registered direct public offering include certain third party institutional investors as well as certain of the Company s existing stockholders, including KKR JP, LLC, Thoma Cressey Fund VII, L.P., Thoma Cressey Friends Fund VII, L.P., Jazz Investors, LLC, Prospect Venture Partners II, L.P., Prospect Associates II, L.P., Versant Venture Capital II, L.P., Versant Side Fund II, L.P., and Versant Affiliates Fund II-A, L.P. Certain members of the Company s Board of Directors are affiliated and/or associated with such existing stockholders.

Amendment of License Agreement

On July 23, 2008, the Company entered into an Amendment No. 2 (the UCB Amendment) to its Amended and Restated License and Distribution Agreement dated as of June 30, 2006 (the License and Distribution Agreement) with UCB. Under the UCB Amendment, the timing and size of a certain milestone payment has been adjusted and UCB s ability to terminate the License and Distribution Agreement in whole or in part was revised. Pursuant to the terms of the original License and Distribution Agreement, UCB was required to pay $7.5 million to the Company within 30 days after the last patient completed or had withdrawn from the Company s second Phase III trial of sodium oxybate for the treatment of fibromyalgia. Pursuant to the UCB Amendment, $10.0 million was paid to the Company in July 2008 in lieu of the $7.5 million payment. UCB would be entitled to a credit of $2.5 million against future royalties otherwise due under the License and Distribution Agreement if sodium oxybate does not receive marketing authorization for fibromyalgia in the European Union for certain specified reasons. In addition, under the terms of the UCB Amendment, the notice period for UCB s right to terminate the entire License and Distribution Agreement without cause has been reduced from 18 months to 12 months, and a provision has been added permitting UCB to terminate its rights to sodium oxybate for the fibromyalgia indication on six months notice at any time prior to the receipt of marketing approval of sodium oxybate for fibromyalgia in the European Union.

Sale of Product Rights

Effective August 1, 2008, the Company sold its rights and interests to Antizol and Antizol-Vet for cash consideration of $5.5 million (the Product Sale) and existing inventory, raw materials and work in process for cash consideration of $0.3 million. In addition, for the next three years, the Company may receive annual product payments equal to a specified percentage of net sales of Antizol and Antizol-Vet if sales reach certain thresholds (the Future Product Payments). Pursuant to the terms of the Company s senior secured notes, the holders of the senior secured notes have the right to receive the $5.5 million proceeds from the Product Sale and, so long as the senior secured notes are outstanding, the Future Product Payments as partial prepayment of the outstanding principal of the senior secured notes. The holders of a majority of the senior secured notes have waived this right. The Company will pay the remaining holders $0.5 million as their pro rata share of the proceeds of the Product Sale and, so long as the senior secured notes are outstanding, the Company will pay them their pro rata share of any Future Product Payments.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described in Part II Item 1A Risk Factors included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business 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 identifying, 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 and 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. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies, we also explore potential new indications for known drug compounds. 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 and four product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our marketed products 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 cataplexy and excessive daytime sleepiness 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 United States are affected by narcolepsy. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our approximately 200 person specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB 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. Selective serotonin reuptake inhibitors 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 United States, 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 United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. During the remainder of 2008, we expect to continue to make significant expenditures relating to the commercialization of Luvox CR.

Our clinical development pipeline consists of the following product candidates:

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. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia. We are currently conducting two Phase III pivotal

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clinical trials, and we expect preliminary data in the fourth quarter of 2008 from the first Phase III pivotal clinical trial, for which we have completed patient enrollment at 550 subjects. In Phase II clinical trials, JZP-6 achieved a statistically significant improvement compared to placebo in pain based on the pain visual analog scale, which the FDA and the European Agency for the Evaluation of Medicinal Products have indicated is the appropriate primary endpoint for our Phase III pivotal clinical trials. Subject to successful completion of the Phase III clinical trials, 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 United States to specialists who treat fibromyalgia patients, through an expanded specialty sales force or in partnerships with third parties. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

JZP-8 (intranasal clonazepam). JZP-8, an intranasal formulation of clonazepam, is being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens. Recurrent acute repetitive seizures are bouts of multiple seizures occurring over a short period of time. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are unresponsive, or refractory, to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures. We have received orphan drug designation from the FDA for this product candidate for the treatment of recurrent acute repetitive seizures. We are currently conducting a Phase II clinical trial of JZP-8 to evaluate the effectiveness and safety of several dosage strengths for the treatment of recurrent acute repetitive seizures in patients with epilepsy who have seizures while on stable anti-epileptic regimens.

JZP-4 (sodium channel antagonist). JZP-4, a controlled release formulation of an anticonvulsant that is believed to work through a similar mechanism of action as Lamictal® (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy, and according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder. We are currently conducting product formulation activities in preparation for the potential initiation of a Phase II clinical program for JZP-4 in 2009.

JZP-7 (ropinirole gel). JZP-7, a transdermal gel formulation of ropinirole, is being developed for the treatment of restless legs syndrome. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome. We are currently conducting certain pre-clinical activities in preparation for the potential initiation of a Phase III clinical program for JZP-7 in 2009.

A number of other product candidates are in early stages of development, including the use of sodium oxybate for the treatment of movement disorders.

In March 2008, JPI Commercial, LLC, or JPIC, a wholly-owned subsidiary, sold $40.0 million aggregate principal amount of senior secured notes. As part of the transaction, we issued to the purchasers of these notes warrants to purchase a total of 562,192 shares of our common stock exercisable at an exercise price of $14.23 per share at any time until March 17, 2013. We paid an arrangement fee of $800,000 and incurred other issuance costs of $634,000 in connection with the transaction. We plan to use the net proceeds to fund a portion of milestone payments due under our license agreement with Solvay, to fund Luvox CR launch expenses and for general corporate purposes. The notes bear interest at 15% per annum, payable quarterly in arrears, and are due on June 24, 2011. In addition, on March 17, 2008, a total of $80.0 million aggregate principal amount of senior secured notes of Orphan Medical, LLC, or Orphan Medical, a wholly-owned subsidiary, were exchanged for the same principal amount of new senior secured notes issued by JPIC at the same interest rate. For additional information see Liquidity and Capital Resources below.

In May 2008, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, that entitles us to sell and obligates Kingsbridge to purchase up to the lesser of $75.0 million of our common stock or 4,922,064 shares over a three-year period, subject to certain conditions and restrictions. For additional information see Liquidity and Capital Resources below.

In June 2008, as part of a strategic decision to reduce our emphasis on early-stage research and development activities, reduce research and development commitments and streamline administrative operations we implemented a workforce reduction of 33 employees and recorded a charge of $463,000. At the same time, we determined that we would only initiate the Phase II clinical program for JZP-4 and the Phase III clinical program for JZP-7 if we are able to partner or otherwise secure additional sources of funding for these programs.

In July 2008, we completed a registered direct public offering of units consisting of an aggregate of 3,848,289 shares of common stock and warrants to purchase an aggregate of 1,731,724 shares of common stock at a public offering price of $6.75625 per unit for net proceeds of approximately $24.5 million after deducting the placement agents fees and other estimated offering expenses payable by us. We plan to use the net proceeds primarily to fund our commercial activities in

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support of the launch of Luvox CR, including payment of a portion of the milestone payments due to Solvay in 2008, to complete the Phase III clinical studies of JZP-6, and for general corporate purposes. The warrants are exercisable for $7.37 per share of common stock at any time on or after January 21, 2009 and prior to July 21, 2014. In connection with the offering, we agreed not to issue shares or draw down funds under the CEFF until after September 13, 2008.

In July 2008, we amended the terms of our license agreement with UCB to adjust the timing and size of a certain milestone payment. Pursuant to the amendment, we received a milestone payment of $10.0 million in July 2008, $7.5 million of which would otherwise have been due when the last patient completed or had withdrawn from the second Phase III study in fibromyalgia. For additional information see Liquidity and Capital Resources below.

Since our inception, we have incurred significant net losses, and we may continue to incur net losses for the next few years as we develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We expanded our commercial organization significantly for the launch of Luvox CR. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, we may need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations.

Revenues

Product Sales, Net

The following is a summary of our product sales, net for the three and six months ended June 30, 2008 and 2007:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(In thousands)		(In thousands)	
Xyrem	$ 12,405	$ 9,628	$ 23,746	$ 18,252
Antizol (1)	1,632	3,987	4,275	6,623
Luvox CR (2)	714		714	
Cystadane (3)				365
Total	$ 14,751	$ 13,615	$ 28,735	$ 25,240

(1) Includes sales of Antizol-Vet, which were $73,000 and $66,000 in the three months ended June 30, 2008 and 2007, respectively, and $148,000 and $131,000 in the six months ended June 30, 2008 and 2007, respectively. We sold our rights to Antizol and Antizol-Vet to an unrelated third party in August 2008.

(2) Includes sales of the active pharmaceutical ingredient in Luvox CR of $127,000.

(3) We sold our rights to Cystadane to a third party in March 2007.

Xyrem (sodium oxybate) oral solution. Revenues from sales of Xyrem primarily represented sales in the United States to Express Scripts Specialty Distribution Services, Inc. Revenues from sales of Xyrem under our agreements with UCB and Valeant have not been material. Orphan drug exclusivity for Xyrem in the United States expires in 2009 for the treatment of cataplexy in patients with narcolepsy, and in 2012 for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Luvox CR (fluvoxamine maleate extended release capsules). Revenues from sales of Luvox CR represented sales in the United States to patients based on units dispensed through prescriptions as of June 30, 2008. Marketing exclusivity for Luvox CR under the provisions of the Hatch-Waxman Act in the United States will expire in February 2011.

Antizol (fomepizole). Revenues from sales of Antizol in the United States primarily represented sales to pharmaceutical wholesalers. Antizol was stocked by hospitals for use in emergency rooms. In August 2008, we sold our rights and interests to Antizol and Antizol-Vet to an unrelated third party for cash consideration of $5.5 million and existing inventory, raw materials and work in process for cash consideration of $0.3 million.

Cystadane (betaine anhydrous). We sold our rights to Cystadane in March 2007 for $9.0 million.

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Royalties, Net

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products. Royalty income was $503,000 and $360,000 in the three months ended June 30, 2008 and 2007, respectively, and $868,000 and $571,000 in the six months ended June 30, 2008 and 2007, respectively. Although we do not expect royalty revenues to comprise a substantial portion of our revenues in the near future, we expect royalty revenues to increase as sales of Xyrem by UCB and Valeant increase.

Contract Revenues

Almost all of our contract revenues consist of upfront or milestone payments received from UCB. UCB made a nonrefundable commercial milestone payment of $2.0 million in March 2007, which we recognized upon achievement of the milestone. In connection with the expansion of our agreement with UCB in 2006, UCB made an upfront payment of $5.0 million 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. This amortization resulted in contract revenues of $280,000 in each of the three months ended June 30, 2008 and 2007 and $560,000 and $532,000 in the six months ended June 30, 2008 and 2007, respectively.

Research and Development Expenses

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 salaries, 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.

Conducting a significant amount of research and development is central to our business model. Since our formation in 2003 through June 30, 2008, we incurred approximately $231.6 million in research and development expenses, and we plan to continue to make significant investments in research and development for the foreseeable future in order to realize the potential of our portfolio of product candidates and earlier-stage research and development projects. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and length of the clinical trials.

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 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 Other projects. We do not allocate salaries, benefits or other indirect costs to our development candidates or 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 six months ended June 30, 2008 and, for JZP projects currently under development and Luvox CR, direct research and development expenses attributed to each project from its inception through June 30, 2008:

	Six Months Ended June 30, 2008	Project Inception to June 30, 2008
		(In thousands)
JZP-6	$ 21,251	$ 59,918
JZP-4	1,907	21,863
Luvox CR (1)	1,242	9,676
JZP-7	2,576	6,013
JZP-8	2,238	5,354
Terminated projects (2)	(125)	
Other projects	1,992	

R&D support	12,044
Total	$ 43,125

(1) During the six months ended June 30, 2008, our research and development expenses for Luvox CR primarily consisted of expenses in connection with the scale-up for commercial manufacturing of Luvox CR 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.

(2) Relates to a decrease in estimated expenses accrued for two terminated projects.

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Critical Accounting Policies and Significant Estimates

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

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2007. Other than the policies and estimates listed 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, 2007.

Intangible Assets

We believe we will receive substantially all of the cash flows from our $41.0 million investment in the Luvox CR developed technology intangible asset over a period of five years from the date Luvox CR was approved by the FDA. Accordingly, we have selected that period of time as the estimated useful life of the asset. The assumptions and forecasts used to estimate these cash flows are extremely subjective and require a high degree of judgment. The most significant assumption in these estimates is the extent to which competitive products could impact our net sales.

The method of amortization should reflect the pattern in which the economic benefits of the intangible asset are consumed. If that pattern cannot be reliably determined, a straight-line amortization method should be used. We do not believe we should pattern the amortization of the intangible asset using expected cash flows because they are inherently subjective and potentially unreliable and, in addition, cash flows are negative during the product launch period, which would result in periods where no amortization expense is recorded. We believe the rights we have purchased represent a consistent periodic economic benefit to us since we cannot use our right to sell Luvox CR more in one period than in any other and, accordingly, we will amortize the asset on a straight-line basis.

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We evaluate our intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. The estimates and assumptions used in our analysis are very subjective. Changes in our estimates and assumptions could have a material adverse effect on our results of operations.

Revenue Recognition

Luvox CR® was approved by the 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 within six months prior to and up to twelve months after product expiration. Given our limited history of selling Luvox CR, we currently cannot reliably estimate expected returns of Luvox CR at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of Luvox CR and instead recognize revenue on a sell-through basis using dispensing data generated by an independent prescription tracking service. Units dispensed through prescriptions are generally not subject to return. When trade channel inventories are reduced to targeted stocking levels and we have sufficient data to determine product acceptance in the marketplace we will recognize revenue on sales of Luvox CR at the time title passes to our customers, or on a sell-in basis, and provide for an estimate of future product returns. Through June 30, 2008, we billed our wholesaler customers, who have certain industry standard rights of return, $3.2 million. We concluded, based on prescription data and the level of trade channel inventories, that we are unable to determine the extent of Luvox CR acceptance by the market and consequently we are unable to estimate the extent of product returns. On a sell-through basis, we recorded revenue of $587,000 for the three and six months ended June 30, 2008, net of estimated wholesaler fees, discounts, chargebacks and rebates. As of June 30, 2008, we had recorded a deferred revenue liability of $2.3 million which represents amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates. As of June 30, 2008, we had included in our inventories Luvox CR cost of product sales of approximately $189,000 related to shipments for which revenue has been deferred. We believe the independent prescription data we used to record revenue related to Luvox CR is accurate and reliable and not subject to subsequent adjustments. While we record Luvox CR revenue on a sell-through basis, we believe our estimated wholesaler fees, discounts, chargebacks and rebates are subject to minimal future adjustments. When we are able to record Luvox CR revenues on a sell-in basis our estimates related to product returns, indirect rebates payable to contracted managed care organizations and Medicaid supplemental rebates will be subject to variability and adjustment. As a result, when we do recognize revenue from sales of Luvox CR on a sell-in basis, it may be subject to greater period to period fluctuations than products with long established histories.

There have been no significant changes in the estimates and assumptions we used to record revenue from sales of Xyrem during the six months ended June 30, 2008.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2008 and 2007

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	Increase/ (Decrease)
	(In thousands)				(In thousands)			
Product sales, net	$ 14,751	$ 13,615	$ 1,136	8%	$ 28,735	$ 25,240	$ 3,495	14%
Royalties, net	503	360	143	40%	868	571	297	52%
Contract revenues	285	289	(4)	(1%)	569	2,541	(1,972)	(78%)
Cost of product sales (excluding amortization of acquired developed technology)	2,796	1,679	1,117	67%	5,094	3,682	1,412	38%
Research and development	21,882	17,407	4,475	26%	43,125	32,274	10,851	34%
Selling, general and administrative	34,109	18,175	15,934	88%	66,889	32,514	34,375	106%
Amortization of intangible assets	3,846	2,287	1,559	68%	5,966	4,649	1,317	28%
Provision for government settlement		17,469	(17,469)	N/A(1)		17,469	(17,469)	N/A(1)
Interest income	450	1,300	(850)	(65%)	1,347	2,391	(1,044)	(44%)
Interest expense	(5,235)	(3,314)	(1,921)	58%	(9,021)	(6,582)	(2,439)	37%
Other (expense) income, net	(1)	4,904	(4,905)	(100%)	(13)	1,835	(1,848)	(101%)
Gain on sale of product rights				N/A(1)		5,145	(5,145)	N/A(1)

(1) No comparable data for prior period or comparison to prior period is not meaningful.

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Product Sales, Net

The increase in product sales, net in the three and six months ended June 30, 2008, as compared to the same periods in 2007 was primarily due to the growth of Xyrem sales, which increased by $2.8 million and $5.5 million, respectively. We believe the increase in Xyrem sales was primarily attributable to the expansion of our sales force and, to a lesser extent, increases in the price we charged our central pharmacy customer for Xyrem of 7.0% in January 2008 and 9.0% in May 2007. In the three and six months ended June 30, 2008, we recorded revenue on sales of Luvox CR of $587,000 and on sales of the active pharmaceutical ingredient in Luvox CR of $127,000. Antizol sales declined by $2.4 million and $2.3 million, respectively, in the three and six months ended June 30, 2008, as compared to the same periods in 2007, due to generic competition. Prior to the sale of our rights to Antizol and Antizol-Vet in August 2008, we recorded sales of Antizol of $1.6 million and $4.3 million in the three and six months ended June 30, 2008, respectively. Prior to the sale of our rights to Cystadane in March 2007, we recorded Cystadane sales of $365,000 in the six months ended June 30, 2007.

Royalties, Net

The increase in royalties, net in the three and six months ended June 30, 2008, as compared to same periods in 2007, was entirely due to an increase in sales of Xyrem by UCB.

Contract Revenues

UCB made a nonrefundable milestone payment to us of $2.0 million in March 2007 which was recorded as contract revenue in the six months ended June 30, 2007. In addition, we recognized contract revenues of $285,000 and $289,000 in the three months ended June 30, 2008 and 2007, respectively, and $569,000 and $541,000 in the six months ended June 30, 2008 and 2007, respectively, primarily related to previously deferred upfront payments which are being recognized as contract revenue ratably through 2019, the expected performance period under our agreement with UCB.

Cost of Product Sales

Cost of product sales as a percentage of product sales increased to 19.0% and 17.7% in the three and six months ended June 30, 2008, respectively, compared to 12.3% and 14.6% in the three and six months ended June 30, 2007, respectively. The increase was primarily due to $1.0 million and $1.4 million of manufacturing period costs related to Luvox CR in the three and six months ended June 30, 2008, respectively. We expect Luvox CR cost of product sales to normalize by the end of 2008, at which time royalties, which are included as a component of cost of product sales, will account for a higher proportion of cost of product sales. Xyrem cost of product sales as a percentage of Xyrem product sales ranged from 11.2% to 12.9% in the three and six months ended June 30, 2007 and 2008.

Research and Development Expenses

Higher research and development expenses in the three and six months ended June 30, 2008, as compared to the same periods in 2007, resulted from increased spending on development projects, primarily for JZP-6 and, to a lesser extent, JZP-7 and JZP-8, offset in part by decreased spending on JZP-4 and Luvox CR. We expect the level of research and development expenses for the second half of 2008 to be lower than the level of research and development expenses during the first half of 2008.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three and six months ended June 30, 2008, as compared to the same periods in 2007, primarily due to growth in headcount and related expenses, in particular related to the expansion of our sales force, marketing expenditures related to the launch of Luvox CR, and higher expenses to support our sales force. Legal fees were lower in the three and six months ended June 30, 2008, as compared to the same periods in 2007, primarily as a result of the costs in 2007 related to a government investigation. We expect selling, general and administrative expenses for the year ending December 31, 2008 to be higher than in the year ended December 31, 2007.

Amortization of Intangible Assets

Our intangible assets consist primarily of developed technology, agreements not to compete and trademarks, all of which are amortized on a straight-line basis over their estimated useful lives. Amortization costs in the three and six months ended June 30, 2008 were higher as compared to the same periods in 2007, as a result of amortization costs associated with the Luvox CR intangibles, offset by lower amortization costs on the Antizol intangibles. We expect amortization costs for the year ending December 31, 2008 to be higher than in the year ended December 31,

2007.

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Provision for Government Settlement

In April 2006, we and Orphan Medical received subpoenas from the United States Department of Justice in connection with the sale and marketing of Xyrem. In July 2007, we reached a comprehensive settlement with the government in connection with this matter and agreed to make payments totaling approximately $20.0 million, including interest, over the next several years. We recorded a charge of $17.5 million in the three and six months ended June 30, 2007, which represented the present value of these payments discounted at an interest rate of 4.6%.

Interest Income

Interest income was lower in the three and six months ended June 30, 2008, as compared to the same periods in 2007, due to lower average cash balances and to lower average interest rates.

Interest Expense

Interest expense in the three and six months ended June 30, 2008, as compared to the same periods in 2007, increased primarily due to interest expense related to the settlement of a government investigation and interest expense recorded on the additional $40.0 million principal amount of senior secured notes we issued in March 2008. Interest on the notes is comprised of the accretion of a discount related to warrants that were issued in conjunction with the notes, amortization of debt issuance costs and quarterly cash payments for interest, and was calculated using the effective interest method.

Other (Expense) Income, Net

We recorded benefits of $4.9 million and $1.8 million for the three and six months ended June 30, 2007, respectively, to reflect decreases in the fair value of the preferred stock warrant liability. Prior to our initial public offering the preferred stock warrant liability was revalued at the end of each reporting period to fair value using the Black-Scholes option pricing model. On June 6, 2007, upon completion of our initial public offering, the warrants became exercisable for common stock and the liability was reclassified to stockholders equity at its then fair value.

Gain on Sale of Product Rights

In March 2007, we entered into an agreement under which an unrelated third party purchased our rights to Cystadane along with the associated product registrations, commercial inventory and trademarks, for cash consideration of $9.0 million. In connection with this transaction, we recorded a gain of $5.1 million in the six months ended June 30, 2007.

Liquidity and Capital Resources

Since our inception, we have incurred significant net losses, and, as of June 30, 2008, we had an accumulated deficit of $415.1 million. We have not achieved profitability, and we may continue to incur net losses for the next few years.

To date, our operations have been financed primarily through the sale of convertible preferred stock prior to our initial public offering, the sale of common stock in our initial public offering, the sale of senior secured notes and warrants, project development financing, short-term borrowings under a line of credit, milestone payments received from our collaboration with UCB and the sale of units consisting of common stock and warrants in our registered direct public offering completed in July 2008.

As of June 30, 2008, we had $52.7 million in unrestricted cash, cash equivalents and marketable securities, held primarily in obligations of United States government agencies, corporate debt securities and money market funds.

In May 2008, we amended our existing line of credit so that we may borrow up to 75% of eligible accounts receivable, up to a maximum of $15.0 million in borrowings.

On March 17, 2008, JPIC, a wholly-owned subsidiary, sold $40.0 million aggregate principal amount of senior secured notes pursuant to a new debt arrangement. As part of the transaction, we issued to the purchasers of these notes warrants to purchase a total of 562,192 shares of our common stock exercisable at an exercise price of $14.23 per share at any time until March 17, 2013. We paid an arrangement fee of $800,000 and incurred other expenses in connection with the transaction. The notes bear interest at 15% per annum, payable quarterly in arrears, and are due on June 24, 2011. In addition, on March 17, 2008, a total of $80.0 million aggregate principal amount of senior secured notes of Orphan Medical were exchanged for the same principal amount of new senior secured notes issued by JPIC pursuant to the new debt arrangement

described above at the same interest rate. In these transactions, we guaranteed the repayment obligations of JPIC and granted the note holders a

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security interest in all of our assets and those of our wholly-owned subsidiaries. We have also agreed to restrictions on working capital borrowings, dividends and certain other payments. Under the debt agreement, we may borrow from other sources up to $15.0 million secured by our accounts receivable and inventory. JPIC may be required, upon the occurrence of certain events and if our annualized net product sales fall below a certain specified level, to redeem up to $30.0 million of the outstanding principal amount of senior secured notes. JPIC may, at its option, prepay some or all of the notes subject to a repayment premium. The repayment premium on the first $40.0 million principal amount is 10% of the principal repayment. The repayment premium on any additional principal repayment was 20% of the principal repayment at June 30, 2008, and reduces ratably to zero on June 24, 2011. If there is an event of default under the terms of the notes, JPIC may be required to prepay some or all of the notes, including a repayment premium. The repayment premium for an event of default was 20.0% of the principal amount of the notes as of June 30, 2008 and will be reduced to zero ratably over the term of the notes. We are not required to maintain a restricted cash balance under this arrangement. However, if at any time after the quarter ending on March 31, 2009, our product sales do not reach certain specified levels, JPIC would be required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of notes. Under a terminated agreement pursuant to which $80.0 million of senior secured notes were issued in 2005 (and later exchanged for new notes as described above), we were required to maintain a restricted cash balance of $12.0 million as of December 31, 2007. Subject to satisfying conditions related to our net product sales and certain closing conditions, we have the option pursuant to the new debt arrangement described above, prior to January 31, 2009, to sell to the purchasers of the new $40.0 million of senior secured notes issued on March 17, 2008 up to $30.0 million aggregate principal amount of senior secured notes and warrants to purchase shares of our common stock at an exercise price based upon the closing stock price for a specified period prior to the sale of the notes and warrants.

On May 7, 2008, we entered into the CEFF with Kingsbridge pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to $75.0 million of our common stock over a three year period starting June 19, 2008, subject to early termination in certain circumstances. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 220,000 shares of our common stock with an exercise price of $11.20 per share. The warrant is exercisable for a period of five years beginning six months after the date of issuance. Under the CEFF, the maximum number of shares that we may sell to Kingsbridge is 4,922,064 shares (exclusive of the shares underlying the warrant issued to Kingsbridge). Subject to certain conditions and limitations, from time to time under the CEFF, we may require Kingsbridge to purchase shares of our common stock at a price that is between 90% and 94% of the volume weighted average price on each trading day during an eight day pricing period. The maximum number of shares we may require Kingsbridge to purchase in any pricing period is, the greater of (i) 1.5% of our market capitalization at the time of the commencement of the pricing period or (ii) the lesser of (A) 3.0% of our market capitalization at the time of the commencement of the pricing period or (B) a number of shares determined by a formula based in part on the average trading volume and trading price of our common stock prior to the date of the draw down notice issued by us with respect to that pricing period; provided, however, that the shares we can require Kingsbridge to purchase in any pricing period cannot exceed an aggregate purchase price of $25 million. If the average price of our common stock is lower than $4.50 or declines more than 10% from the closing price on the trading day immediately prior to the start of a pricing period, we cannot draw under the CEFF during that pricing period for so long as the price remains below either of these thresholds. We filed a registration statement which became effective as of June 19, 2008 with respect to the resale of shares issuable pursuant to the CEFF and underlying the warrant, and the registration rights agreement requires us to maintain the effectiveness of the registration statement for up to two years following the termination of the common stock purchase agreement. If we fail to maintain the effectiveness of the registration statement or if we suspend the use of the registration statement, under certain circumstances we may be required to pay certain amounts to Kingsbridge (or issue to Kingsbridge additional shares of common stock in lieu of cash payment) as liquidated damages. We are not obligated to sell any of the $75.0 million of common stock available under the CEFF and there are no minimum commitments or minimum use penalties. The CEFF does not contain any restrictions on our operating activities, automatic pricing resets or minimum market volume restrictions. We have not drawn down funds and have not issued shares of our common stock under the CEFF as of June 30, 2008 and, in connection with the registered direct public offering (described below), we have agreed not to issue shares or draw down funds under the CEFF until after September 13, 2008.

On July 21, 2008, we completed a registered direct public offering of units consisting of an aggregate of 3,848,289 shares of common stock and warrants to purchase an aggregate of 1,731,724 shares of common stock at a public offering price of $6.75625 per unit for net proceeds of approximately $24.5 million after deducting the placement agents fees and other estimated offering expenses payable by us. The warrants are exercisable for $7.37 per share of common stock at any time on or after January 21, 2009 and prior to July 21, 2014.

On July 23, 2008, we entered into an amendment to our license and distribution agreement with UCB. Under the terms of the amendment, the timing and size of a certain milestone payment has been adjusted and UCB s ability to terminate the license and distribution agreement with UCB in whole or in part was revised. Under the terms of the original license and distribution agreement with UCB, UCB was required to pay $7.5 million to us within 30 days after the last patient completed or had withdrawn from our second Phase III trial of sodium oxybate for the treatment of fibromyalgia. Under the terms of the

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amendment, $10.0 million was paid to us in July 2008 in lieu of the $7.5 million payment. UCB would be entitled to a credit of $2.5 million against future royalties otherwise due under our license and distribution agreement with UCB if the sodium oxybate does not receive marketing authorization for fibromyalgia in the European Union for certain specified reasons. In addition, under the terms of the amendment, the notice period for UCB s right to terminate the entire license and distribution agreement without cause has been reduced from 18 months to 12 months, and a provision has been added permitting UCB to terminate its rights to sodium oxybate for the fibromyalgia indication on six-months notice at any time prior to the receipt of marketing approval of sodium oxybate for fibromyalgia in the European Union.

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

	Six Months Ended June 30,	
	2008	2007
	(In thousands)	
Net cash used in operating activities	$ (82,757)	$ (37,659)
Net cash (used in) provided by investing activities	(11,168)	7,402
Net cash provided by financing activities	42,182	99,309
Net (decrease) increase in cash and cash equivalents	$ (51,743)	$ 69,052

Net cash used in operating activities during the six months ended June 30, 2008 primarily reflected the net loss, offset in part by changes in working capital and depreciation and amortization. Net cash used in operating activities during the six months ended June 30, 2007 primarily reflected the net loss, changes in working capital and the gain on our sale of our rights to Cystadane, offset in part by depreciation and amortization and the revaluation of our preferred stock warrant liability. Net cash used in investing activities during the six months ended June 30, 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 provided by investing activities during the six months ended June 30, 2007 included proceeds of $9.0 million from the sale of our rights to Cystadane. Net cash provided by financing activities during the six months ended June 30, 2008 was primarily attributable to the issuance of new senior secured notes on March 17, 2008. Net cash provided by financing activities during the six months ended June 30, 2007 was primarily attributable to net proceeds from our initial public offering.

We believe that our current cash, including proceeds from our recent registered direct public stock offering, the recent payment from UCB, the proceeds from the sale of our rights to Antizol, and cash equivalents, and interest earned thereon, together with the proceeds from the possible future sale of additional notes by our wholly-owned subsidiary JPIC under the senior secured note and warrant purchase agreement among JPIC, us and the purchasers named therein and anticipated revenues from product sales and royalties, would be sufficient to satisfy our current operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect. See Part II Item 1A Risk Factors Our operations have generated negative cash flows, and if we are unable to secure additional funding when we need it, we may be required to further reduce operations and other risk factors included in Part II Item 1A for a discussion of the factors that will influence our future capital requirements.

We may need to raise additional funds to finance our business and support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through development financings, collaborations, partnering arrangements, or public or private debt or equity financings, in addition to any financing available under the CEFF and the proceeds from the future sale of additional notes. If we raise funds through collaborations or partnering arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our product candidates that we would otherwise seek to develop or commercialize ourselves or to sell the rights to one or more commercial products to third parties. 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 may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development of our product candidates or commercialization of our products. Our failure to raise capital when needed may harm our business and operating results.

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Contractual Obligations

In addition to our contractual obligations set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, the following table reflects a summary of material contractual obligations we have incurred during the first six months of 2008 and remain outstanding as of June 30, 2008:

		Payments due by period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
		(In thousands)			
Contractual Obligations					
Senior secured notes (1)	$ 57,900	$ 6,000	$ 51,900	$	$
Milestone payments (2)	21,000	21,000			
Operating lease obligation(3)	816	680	136		
Total	$ 79,716	$ 27,680	$ 52,036	$	$

(1) Represents our payment obligations on $40.0 million aggregate principal amount of new notes issued on March 17, 2008 which are due in full on June 24, 2011. During the first six months of 2008, we paid $1.7 million of this obligation which is not included in the table above. Our payment obligations on the $80.0 million of new senior secured notes issued by JPIC in exchange for the same principal amount of senior secured notes issued by Orphan Medical, are not included in the table above since these payment obligations were included in our contractual obligations table in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

(2) Represents milestone payments due under our license agreement with Solvay as a result of the approval by the FDA and the first commercial sale of Luvox CR. During the first six months of 2008, we paid $20.0 million of this obligation which is not included in the table above. Milestone payments and royalty payments under our license and collaboration agreements that we cannot, as of June 30, 2008, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur are not included in the table above. As a result, we have not included in the table above an additional $95.0 million in commercial milestone payments due under our agreement with Solvay associated with Luvox CR, as well as royalties on net product sales at specified rates. FDA approval for Luvox CR includes a post marketing commitment to conduct a safety and efficacy study in adolescent patients with social anxiety disorder and a long-term safety and efficacy study in patients with social anxiety disorder. Costs associated with these studies are also not included in the table above. Solvay is required to reimburse us a portion of these costs.

(3) In February 2008, we exercised our option to extend the lease on our corporate office building for one year beginning August 2008. In addition to these lease payments, we are obligated to pay for operating expenses for the leased property. Our payment obligations for the minimum rental payments for our corporate office building and two other office spaces in Palo Alto, California and automobile lease payments for the sales force are not included in the table above since these payment obligations were included in our contractual obligations table in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

Related Parties

Prior to the issuance of the new $40.0 million senior secured notes on March 17, 2008, as described in Liquidity and Capital Resources above, LB I Group Inc., an entity affiliated with Lehman Brothers Holdings Inc., purchased certain senior notes and warrants then outstanding, including certain senior notes and warrants held by an affiliate of Kohlberg Kravis Roberts & Co. L.P., a significant stockholder. Subsequent to the issuance of the new $40.0 million senior secured notes, LB I Group Inc. held notes with an aggregate principal amount of $89.5 million, warrants to purchase 479,853 shares of common stock exercisable at $20.36 per share and warrants to purchase 470,836 shares of common stock exercisable at $14.23 per share. Subject to certain conditions, LB I Group Inc. is obligated to purchase from JPIC additional notes with an aggregate principal amount of up to $27.0 million. We paid LB I Group Inc. an arrangement fee of $800,000 in connection with the issuance of the new $40.0 million senior secured notes. Subsequent to the issuance of the new $40.0 million senior secured notes, entities affiliated with Kohlberg Kravis Roberts & Co. L.P. held notes with an aggregate principal amount of $7.1 million and warrants to purchase 70,156 shares of common stock exercisable at $20.36 per share.

In the registered direct public offering we completed in July 2008, the investors included certain third party institutional investors as well as certain of the Company s existing stockholders, including KKR JP, LLC, Thoma Cressey Fund VII, L.P., Thoma Cressey Friends Fund VII, L.P., Jazz Investors, LLC, Prospect Venture Partners II, L.P., Prospect Associates II, L.P., Versant Venture Capital II, L.P., Versant Side Fund II, L.P., and Versant Affiliates Fund II-A, L.P. Certain members of the Company s Board of Directors are affiliated and/or associated with such existing stockholders.

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Off-Balance Sheet Arrangements

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

Cautionary Note Regarding Forward-Looking Statements

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the six months ended June 30, 2008, 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, 2007, filed with the SEC.

Item 4T. 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 June 30, 2008.

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.

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 June 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical and former officers of Orphan Medical in the United States District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005. The purpose of the special meeting was to consider and vote upon a proposal to adopt the definitive merger agreement pursuant to which we acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the United States District Court for the District of Minnesota. On February 16, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint, with leave to amend. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. Oral argument on the motion was heard on June 8, 2007. On September 13, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint with prejudice. On September 28, 2007, the plaintiff filed a Notice of Appeal to the United States Court of Appeals for the Eighth Circuit. On November 21, 2007, the plaintiff filed its brief with the United States Court of Appeals for the Eighth Circuit. On December 21, 2007, the defendants filed their brief with the United States Court of Appeals for the Eighth Circuit. On January 8, 2008, the plaintiff filed a reply brief. Oral arguments were heard on May 15, 2008. We cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome.

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

Item 1A. Risk Factors.

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of their investment. We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described in our Annual Report on Form 10-K for the year ended December 31, 2007, 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 Related to Our Business

We may not be able to successfully market or supply Luvox CR in the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

On February 28, 2008, the FDA approved Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. Under the terms of our license agreement with Solvay, we made an initial payment of $2.0 million, paid $10.0 million on March 28, 2008 and $10.0 million on April 7, 2008, and will pay Solvay $10.5 million on September 30, 2008 and $10.5 million on December 31, 2008. Elan is manufacturing commercial launch quantities of Luvox CR for us. In anticipation of the commercial launch of Luvox CR, we significantly expanded our sales force, marketing and commercial operations departments and administrative staff in the fourth quarter of 2007. In addition, we have engaged numerous third party vendors, such as advertising agencies, market research firms and other service providers, to assist in the launch of Luvox CR. These expenses are significant and have been incurred prior to the commercial launch of Luvox CR in order for us to be prepared to launch the product as soon as possible following approval. Most of the costs cannot be recouped or applied to other products. If our efforts to market Luvox CR are not as successful as we currently anticipate, the time at which we could potentially become profitable would be postponed, or we might never become profitable, and our ability to raise additional funds could be impaired.

For quantities of Luvox CR that are being used for commercial launch, and for product that was used in clinical studies, Solvay manufactured the active pharmaceutical ingredient, fluvoxamine maleate. Solvay no longer manufactures the active pharmaceutical ingredient, and manufacturing has been transferred to Lonza, Inc., or Lonza, which we expect will continue to be our sole source of 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 to manufacture the quantities of Luvox CR that we need.

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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.

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 may not otherwise 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 conducting two Phase III pivotal clinical trials for the use of JZP-6 to treat fibromyalgia, 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. Our Phase III clinical program for JZP-6 is costly, and we do not expect to have preliminary results from our first Phase III study until the fourth quarter of 2008. We do not know if our ongoing Phase III pivotal clinical trials 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. Favorable results from our prior Phase II clinical trials with JZP-6 for the treatment of fibromyalgia may not be indicative of the clinical results from our Phase III pivotal clinical trials. Further, although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of cataplexy and excessive daytime sleepiness 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. Unsuccessful Phase III pivotal clinical trials 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, and our ability to raise funds could be impaired.

Lyrica (pregabalin), a product marketed by Pfizer, and Cymbalta (duloxetine), a product marketed by Eli Lilly, were approved by the FDA in June 2007 and June 2008, respectively, for the treatment of fibromyalgia. Additionally, Forest Laboratories (with Cypress Bioscience) filed an NDA for milnacipran in December 2007 seeking FDA approval for the treatment of fibromyalgia. With treatments for fibromyalgia already approved, and others that may be approved before JZP-6, and which the FDA may believe have a lower risk profile to the general public if marketed, the FDA may be less willing to approve JZP-6 for the treatment of fibromyalgia.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA is likely to require us to have a risk management program similar to the one we use for Xyrem. Under the Xyrem risk management program, 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 physician s office and 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 patients may not receive more than a three month supply at any time.

The Xyrem risk management program is labor intensive, complex and expensive to operate. Since Xyrem is currently prescribed for a relatively small number of patients, the risk management program does not prevent us from effectively supplying Xyrem to narcolepsy patients. However, significantly more patients are diagnosed with fibromyalgia, and if the same or a similar risk management program is required for JZP-6, scale-up of the risk management program 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.

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

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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; and
- varying interpretation of data by the FDA or foreign regulatory agencies.

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 more significant financial and human resources than we do.

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

condition, results of operations and growth prospects.

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

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

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

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If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates.

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.

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

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the United States. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames we expect, or at all, our revenues would be adversely affected. 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.

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

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the United States must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our risk management program 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 distributor 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 risk management program approved by the FDA. If we change distributors, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new distributor could result in product shortages, which would adversely affect sales of Xyrem in the United States.

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Our supplier of the active pharmaceutical ingredient and our product manufacturer 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 United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our 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 quotas issued by the DEA for 2008 were greater than initially issued for 2007; however, we believe that the quota for 2008 may not be sufficient to satisfy all of our commercial and clinical 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 for the marketplace or JZP-6 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. 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, DEA quotas relating to Xyrem and JZP-6, and the limited market size for our approved products, 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.

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 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 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.

Our current product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale. Luvox CR has only recently been manufactured on a commercial scale and the NDA for Luvox CR was previously withdrawn as a result of difficulties encountered during the scale-up of manufacturing.

Our current product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. If our manufacturers are unable to produce sufficient quantities of our products for commercialization or at a cost that we expect, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Luvox CR, for which we have obtained the exclusive rights to market and distribute in the United States from Solvay and which was approved for commercial sale in February 2008, is being manufactured for us by Elan in exchange for royalty and milestone payments and supply price payments. Luvox CR has only recently been manufactured on a commercial scale, and the NDA for Luvox CR was withdrawn in June 2001 by Solvay and Elan as a result of difficulties encountered during the scale-up of manufacturing of Luvox CR. Although the FDA has approved Luvox CR, there is no assurance that Elan will be able to continue to manufacture Luvox CR in sufficient quantities to meet potential future demand.

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

From time to time, there is negative publicity about 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 GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally. 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. In April 2006, a physician who was a speaker for Orphan Medical, and for a short time for us, was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for us, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce.

We and Orphan Medical have settled this matter with the United States, acting through the Department of Justice, the U.S. Attorney s Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately $20.0 million in civil and criminal payments will be paid in connection with this matter, of which $1.0 million was paid in July 2007 and $2.0 million was paid in January 2008; the remaining will be paid over the next four years. We agreed to guarantee payment of amounts payable by Orphan Medical.

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.

Even though we have executed definitive settlement agreements, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states attorneys general with respect to the activities covered by the settlement. We cannot predict whether this additional action will occur, nor can we reasonably estimate the amount of any fines or penalties that might result from an adverse outcome.

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 recently approved a product for the treatment of fibromyalgia. This product 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.

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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 cataplexy and excessive daytime sleepiness 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 United States 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. Five other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including four selective serotonin reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly, and Luvox, which is not currently marketed. Anafranil, the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than 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. Effexor XR, developed and sold by Wyeth, does not have direct generic competitors, whereas Paxil, Paxil CR and Zoloft 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. 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. Forest Laboratories (with Cypress Bioscience) filed an NDA for milnacipran in December 2007 seeking FDA approval for the treatment of fibromyalgia. These are large pharmaceutical companies with far greater resources than we have.

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.

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 Phase III clinical trials of product candidates for the treatment of fibromyalgia. Two 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 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

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covering Xyrem. Once our orphan drug exclusivity period for Xyrem for the treatment of cataplexy expires in July 2009, prescriptions for Xyrem, 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, it is possible that other companies could manufacture generic equivalents of Xyrem 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 risk management program for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a risk management program 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.

Luvox CR is covered by a patent application filed by Elan with claims covering the orally administered extended release formulation of fluvoxamine. This patent may not issue, and even if this patent issues, 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 commercializing 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 United States 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 enter into acceptable agreements to commercialize our products in international markets.

If appropriate regulatory approvals are obtained, we generally intend to commercialize our products in most markets outside of the United States through arrangements with third parties. If we decide to sell our products in markets outside of the United States, we may not be able to enter into any arrangements on acceptable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we promoted our products directly in international markets. If we choose to market our products directly in markets outside of the United States, we may not be able to develop an effective international sales force. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenues outside of the United States would be limited. In either case, our marketing efforts (and those of our partners) outside of the United States may be subject to regulatory requirements and politico-economic climates that are dissimilar to those in the United States and which could impose unforeseen costs or restrictions on us or our partners.

We may not be able to successfully acquire or in-license additional products or product candidates as part of growing our business.

In order to grow our business, we intend to acquire or in-license additional products and product candidates that we believe have significant commercial potential. 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. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.

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We currently have a relatively small sales organization compared with most other pharmaceutical companies with marketed products. If we are unable to appropriately expand our specialty sales force and sales organization in the United States to adequately promote our current and potential future products, the commercial opportunity for our products may be diminished.

We expanded our sales force significantly in anticipation of the launch of Luvox CR. We cannot be sure that we will retain these new sales representatives, or that they will be effective at promoting our commercial products. Our potential future commercial products, including JZP-6, may require further 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 will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel. If we elect to rely on third parties to sell our products in the United States, we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately expand 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. Although the members of our executive management team have employment contracts with us through February 2009, each member of our executive management team and each of our other key employees may terminate his or her employment at any time without notice and without cause or good reason.

We recently 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. Competition for qualified personnel in the life sciences industry is intense, and it is particularly difficult to recruit new employees to the San Francisco Bay Area, where our offices are located, in large part due to high housing costs. 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.

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 United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any

patent may be challenged, invalidated, held

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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 United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

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

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

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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 United States.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

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

Risks Related to Our Industry

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

The research, testing, manufacturing, selling and marketing of pharmaceutical products are subject to extensive regulation by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our products. We are not permitted to market our product candidates in the United States until we receive approval from the FDA,

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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 this year, 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 United States or overseas or at our contract manufacturers facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products 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. These statutes and regulations include anti-kickback statutes and false claims statutes.

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

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.

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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. 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.

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

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement levels. Third party payors are increasingly challenging the prices charged for medical products and services

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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. We do not yet know what the reimbursement levels and other requirements will be for Luvox CR which was approved by the FDA in February 2008.

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 and measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control. 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. This 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 presidential election campaign, the candidates have been discussing 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 United States 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 United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will permit pharmacists and wholesalers to import prescription drugs into the United States from Canada under specified circumstances. These additional import provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been

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introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the United States to be imported or reimported to the United States from Canada, Europe and other countries. If these provisions 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 United States. Due to the risk management program for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the United States. 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 Our Financial Condition

We have a history of net losses, which may continue for at least few years and, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.*

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 six months ended June 30, 2008 was $98.6 million and we had an accumulated deficit of $415.1 million at June 30, 2008. We expect our operating expenses to continue at similar rates, and they could increase, over the next few years as we continue to market Luvox CR, develop, acquire or in-license additional products or product candidates, conduct clinical trials for our product candidates, undertake research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We may need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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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.

Our operations have generated negative cash flows, and if we are unable to secure additional funding when we need it, we may be required to further reduce operations.*

As of June 30, 2008, we had approximately $52.7 million in unrestricted cash, cash equivalents and marketable securities. Our net cash used in operations for the six months ended June 30, 2008, and the year ended December 31, 2007 was approximately $82.8 million and $81.1 million, respectively. Prior to the commercial launch of Luvox CR in March 2008, substantially all of our net product sales resulted from sales of Xyrem and Antizol. We recently sold our rights to Antizol, and sales of Xyrem and Luvox CR could decrease due to adverse market conditions, negative publicity or other events outside our control. We recently reduced our activities to focus on our commercial products and later stage product candidates, including a reduction in the size of our work force. Even with this change, we must continue 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. We believe that after taking into account proceeds from our recent registered direct stock offering, the recent payment from UCB and the proceeds from the sale of our rights to Antizol, our current cash and cash equivalents and interest earned thereon, together with the proceeds from the possible future sale of additional notes by our wholly-owned subsidiary JPI Commercial, LLC, or JPIC, under the senior secured note and warrant purchase agreement among JPIC, us and the purchasers named therein, and anticipated revenues from product sales and royalties, will be sufficient to satisfy our current operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect. 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 Luvox CR and Xyrem in the United States;
- revenues from current and potential future development and/or commercial collaboration partners;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials 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.

Although we generate product revenues, since our inception in 2003, we have financed our operations primarily through the sale of preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates, our collaboration with UCB related to Xyrem and JZP-6, the sale of common stock in our initial public offering and the sale of units consisting of common stock and warrants in our registered direct public offering completed in July 2008.

We will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development and clinical programs and commercial operations. 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. We may seek to raise additional funds through development financings, collaborations,

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partnering arrangements, or public or private debt or equity financings. If we exercise our right to draw down amounts under the committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, that we entered into on May 7, 2008, Kingsbridge will not be obligated to purchase shares of our common stock under the CEFF unless certain conditions are met, which include: a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; and the effectiveness of the registration statement that we have filed with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant that we issued to Kingsbridge. In any case, pursuant to an agreement we made in connection with the registered direct public offering we completed in July 2008, we are not able to issue shares or draw down funds under the CEFF until after September 13, 2008. If we wish to have JPIC sell more senior secured notes, the senior secured note purchasers are only obligated to purchase those notes if various conditions are met, including that our net products sales have reached certain levels by the end of 2008. If we raise funds through collaborations or partnering arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our products or product candidates that we would otherwise seek to develop or commercialize ourselves. 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 may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization or our products. Our failure to raise capital when needed may harm our business and operating results.

We are launching Luvox CR and, as is the case with new product launches, we cannot predict with certainty the timing or level of Luvox CR sales. If sales of Luvox CR do not reach the levels we expect and if we do not obtain additional cash resources from financings, collaborations or partnering arrangements, we may be unable to meet our cash requirements under our current operating plan. If product sales do not meet our expectations and we do not raise additional funds, we will need to reduce our planned expenditures, perhaps significantly, to preserve our cash. We recently implemented plans to reduce our expenditures by focusing on our commercial products and later stage product candidates and eliminating some jobs. If necessary, we would implement, beginning as early as the third quarter of 2008, appropriate plans and additional measures to further reduce discretionary spending and capital expenditures, terminate or slow additional product development programs, further reduce headcount, license or sell some of our product candidates or products, or implement a combination of these and other cost cutting measures.

We have a substantial amount of debt, which may adversely affect our cash flows and our ability to operate our business.

On March 17, 2008, we incurred $40.0 million of additional secured indebtedness in connection with the sale of senior secured notes and warrants and the exchange of existing senior debt which increased our aggregate senior debt to $120.0 million at face value. Our substantial debt combined with our other financial obligations and contractual commitments could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general 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, capital expenditures, acquisitions and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a competitive disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, under specified circumstances, our lenders could demand repayment of all or a portion of our debt, including if annualized net sales of our products fall below certain specified levels, which would have a material adverse effect on our business, financial condition and results of operations. If we do not have sufficient earnings to service our debt, we may be required to refinance all or part of our existing debt, sell assets,

borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all.

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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.

Our senior secured debt contains, 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;
- repay a portion of the debt early under certain circumstances; and
- maintain restricted cash balances under certain circumstances.

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.

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. Security prices for companies similar to us experience significant price and volume fluctuations. The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

- the success of Luvox CR in the United States;
- the success of our development efforts and clinical trials;
- 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;

our ability or inability to raise additional capital and the terms on which we raise it;

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;

conditions or trends in the pharmaceutical industry, the financial markets or the economy in general;

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

changes in the market valuation of similar companies;

trading volume of our common stock; and

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sales of our common stock by us or our stockholders.

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

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, including shares issued under the CEFF, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. In addition, 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. As of July 31, 2008, we had 28,747,953 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, other than shares subject to the lock-up agreements that our executive officers, directors and certain of our security holders entered into with the placement agents of our registered direct public offering that we completed in July 2008. The lock-up period under these agreements generally expire on October 14, 2008; however, these lock-up agreements may be waived or terminated at any time without notice.

As of July 31, 2008, 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, as well as the shares underlying the warrants we may issue in a further expansion of that debt, and to use our reasonable best efforts to cause such registration statement to become and remain effective. The registration rights agreement entered into in connection with the CEFF requires that we use commercially reasonable efforts to have the registration statement in connection with the CEFF declared effective and ensure that it remains effective for the term of such agreement. 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.

The CEFF may result in dilution to our stockholders.*

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of $75.0 million of our common stock or 4,922,064 shares of our common stock over a three-year period. We are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement that we have filed with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant we issued to Kingsbridge. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge, or issue Kingsbridge additional shares of our common stock in lieu of this payment. If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to ten percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price. In connection with the registered direct public offering we completed in July 2008, we agreed not to issue shares or draw down funds under the CEFF until after September 13, 2008.

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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 July 31, 2008, our executive officers and directors, together with their respective affiliates, beneficially owned 65.3% of our capital stock, of which 7.0% 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.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must 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 fiscal year ending 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;

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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.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On May 31, 2007, our registration statement on Form S-1/A (Registration No. 333-141164) was declared effective by the SEC for our initial public offering, pursuant to which we registered 6,000,000 shares of common stock to be sold by us. The stock was offered at a price to the public of $18.00 per share. Our common stock commenced trading on June 1, 2007. The offering closed on June 6, 2007 after the sale of 6,000,000 shares, and as a result, we received net proceeds of approximately $97.5 million, after underwriters discounts of approximately $7.6 million and other expenses of $2.9 million. None of the net proceeds were used to make direct or indirect payments to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers and to non-employee directors as compensation for their services.

As of June 30, 2008, we have used approximately $89.6 million of the net proceeds from the offering to fund the U.S. launch and commercialization of Luvox CR, to fund our Phase III pivotal clinical trials of JZP-6 and to fund continued development of and feasibility activities for our portfolio of clinical and early-stage product candidates. We intend to use the remaining net proceeds to fund marketing and promotion of Luvox CR, to fund a portion of commercial milestone payments to Solvay in connection with the acquisition of our U.S. rights to Luvox CR, to fund our Phase III pivotal clinical trials of JZP-6 and to fund continued development of and feasibility activities for our portfolio of clinical and early-stage product candidates. We continually assess the specific uses and allocations for these funds. Pending use of the remaining net proceeds of this offering, we have invested the funds in short-term, interest bearing, investment grade securities.

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Item 4. Submission of Matters to a Vote of Security Holders.

On June 3, 2008, our 2008 Annual Meeting of Stockholders was held at our corporate offices in Palo Alto, California. During this meeting, our stockholders voted on the following two proposals:

(a) Proposal to elect four Class I directors to serve until the 2011 Annual Meeting of Stockholders or until their successors have been duly elected and qualified or until their earlier death, resignation or removal:

	Votes	
Nominee	**For**	**Authority Withheld**
Bryan C. Cressey	21,586,395	385,545
Jaimin R. Patel(1)	21,584,897	387,043
James B. Tananbaum, M.D.	21,578,897	393,043
Nathaniel M. Zilkha	21,585,547	386,393

(1) On July 16, 2008, Jaimin R. Patel notified us of his intent to resign as a member of our Board of Directors, which resignation was effective immediately. On July 16, 2008, the Board of Directors, upon the recommendation of the Nominating and Corporate Governance Committee of the Board, elected Alex Albert to the Board to fill the vacancy created by the resignation of Mr. Patel. Mr. Albert will serve in the class of directors whose term of office expires at the Company s 2011 Annual Meeting of Stockholders and until his successor is duly elected and qualified, or until his earlier death, resignation or removal.

Our Class II directors, Samuel R. Saks, M.D., Samuel D. Colella, and James C. Momtazee, will each continue to serve on our Board of Directors until our 2009 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal. Our Class III directors, Bruce C. Cozadd, Michael W. Michelson, Kenneth W. O Keefe, and Alan M. Sebulsky will each continue to serve on our Board of Directors until our 2010 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal.

(b) Proposal to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008.

For	**Against**	**Abstain**	**Broker Non-Vote**
21,964,927	4,276	2,737	0

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)

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Number	Description of Document
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)
10.70	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited. (7)
10.72	2008 Executive Officer Compensation Arrangements. (9)
10.73	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant s 2007 Equity Incentive Plan. (9)
10.74#	Master Services Agreement dated May 6, 2008, by and between the Registrant and CuraScript, Inc. (9)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

Confidential treatment has been granted with respect to certain 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 herein by reference to Exhibit 4.6 to the Registrant s registration statement on Form S-1, as amended (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.

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* The certification attached as Exhibit 32.1 accompanies 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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SIGNATURE

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: August 8, 2008

Jazz Pharmaceuticals, Inc.

/s/ Matthew K. Fust
Matthew K. Fust
Executive Vice President and Chief Financial Officer
(Duly Authorized and Principal Accounting and

Financial Officer)

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