JAZZ PHARMACEUTICALS INC
Form 10-Q
November 09, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended September 30, 2007

or

¨ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
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, or a non-accelerated filer. (Check one):

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

As of October 31, 2007, 24,550,554 shares of the registrant s Common Stock, $.0001 par value, were outstanding.

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FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2007

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 119,972	$ 78,948
Restricted cash	304	275
Marketable securities	10,939	
Accounts receivable, net	6,566	5,380
Inventories	3,231	3,026
Prepaid expenses	2,392	3,447
Other current assets	1,574	487
Total current assets	144,978	91,563
Property and equipment, net	3,286	2,107
Intangible assets	58,664	69,140
Goodwill	38,213	38,213
Long-term restricted cash and investments	12,085	12,000
Other long-term assets	1,541	1,548
Total assets	$ 258,767	$ 214,571
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Line of credit	$ 2,597	$ 2,191
Accounts payable	2,872	5,443
Accrued liabilities	23,892	12,943
Deferred revenue	1,999	1,422
Preferred stock warrant liability (including $5,965 as of December 31, 2006 held by related parties)		8,521
Total current liabilities	31,360	30,520
Deferred rent and other non-current liabilities		534
Deferred revenue, non-current	12,752	13,495
Liability under government settlement, non-current	14,881	
Senior secured notes	74,862	74,283
Commitments and contingencies (Note 7)		
Convertible preferred stock		263,852
Common stock subject to repurchase	13,222	8,183
Stockholders equity (deficit):		

Common stock	2	
Additional paid-in capital	368,136	1,335
Accumulated other comprehensive income	1	12
Accumulated deficit	(256,449)	(177,643)
Total stockholders equity (deficit)	111,690	(176,296)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 258,767	$ 214,571

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenues:				
Product sales, net	$ 13,436	$ 11,184	$ 38,676	$ 31,409
Royalties, net	253	150	824	336
Contract revenue	7,785	162	10,326	662
Total revenues	21,474	11,496	49,826	32,407
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technology)	1,938	2,044	5,620	5,367
Research and development	16,978	14,746	49,252	41,920
Selling, general and administrative	18,069	12,906	50,583	38,841
Amortization of intangible assets	2,287	2,400	6,936	7,200
Provision for government settlement			17,469	
Total operating expenses	39,272	32,096	129,860	93,328
Loss from operations	(17,798)	(20,600)	(80,034)	(60,921)
Interest income	1,969	516	4,360	1,688
Interest expense (including $2,321 and $2,288 for the three months ended September 30, 2007 and 2006, respectively, and $6,862 and $6,729 for the nine months ended September 30, 2007 and 2006, respectively, pertaining to related parties)	(3,511)	(3,272)	(10,093)	(10,818)
Other income (expense), net	(19)	(579)	1,816	(397)
Gain on extinguishment of development financing obligation		31,592		31,592
Gain on sale of product rights			5,145	
Net income (loss)	(19,359)	7,657	(78,806)	(38,856)
Beneficial conversion feature				(3,501)
Income (loss) attributable to common stockholders	$ (19,359)	$ 7,657	$ (78,806)	$ (42,357)
Income (loss) per share attributable to common stockholders, basic	$ (0.82)	$ 638.08	$ (7.50)	$ (3,850.64)
Weighted-average common shares used in computing income (loss) per share attributable to common stockholders, basic	23,671	12	10,505	11
Income (loss) per share attributable to common stockholders, diluted	$ (0.82)	$ 0.57	$ (7.50)	$ (3,850.64)
Shares used in computing income (loss) per share attributable to common stockholders, diluted	23,671	13,470	10,505	11

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30, 2007	2006
Operating activities		
Net loss	$ (78,806)	$ (38,856)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	921	488
Amortization of intangible assets	6,937	7,200
Loss on disposal of property and equipment	6	481
Fair value adjustment to acquired finished goods	54	689
Stock-based compensation expense	3,773	2,540
Excess of cash paid over accrued for interest	802	668
Revaluation of preferred stock warrant liability	(1,846)	397
Interest on development financing		1,147
Gain on extinguishment of development financing obligation		(31,592)
Gain on sale of product rights	(5,145)	
Changes in assets and liabilities:		
Accounts receivable	(1,177)	(2,471)
Inventories	(567)	(549)
Prepaid expenses and other current assets	(32)	1,408
Other assets	(318)	319
Accounts payable	(2,571)	1,043
Accrued liabilities	10,342	2,913
Deferred revenue	(166)	14,838
Deferred rent	(118)	(155)
Liability under government settlement	14,881	
Net cash used in operating activities	(53,030)	(39,492)
Investing activities		
Purchases of property and equipment	(2,106)	(1,237)
Purchases of marketable securities	(10,848)	
Decrease (increase) in restricted cash and investments	(114)	25
Proceeds from sale of product rights	9,000	
Net cash used in investing activities	(4,068)	(1,212)
Financing activities		
Proceeds from issuances of convertible preferred stock, net of issuance costs		34,994
Proceeds from issuances of common stock, net of issuance costs	76	10
Proceeds from sale of common stock in initial public offering, net of issuance costs	97,640	
Proceeds from line of credit	16,066	
Repayments under line of credit	(15,660)	
Proceeds from development financing		15,000
Net cash provided by financing activities	98,122	50,004
Net increase in cash and cash equivalents	41,024	9,300
Cash and cash equivalents, at beginning of period	78,948	20,614

Cash and cash equivalents, at end of period	$	119,972	$	29,914
Supplemental disclosure of cash flow information:				
Cash paid for interest (including $6,300 and $6,263 for the nine months ended September 30, 2007 and 2006, respectively, paid to related parties)	$	9,108	$	9,000
Supplemental disclosure of non-cash financing activities:				
Beneficial conversion feature - deemed dividend attributable to preferred stockholders	$		$	3,501
Conversion of preferred stock warrant liability to stockholders equity	$	6,675	$	

The accompanying notes are an integral part of these 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 Form S-1/A of Jazz Pharmaceuticals, Inc. (the Company or Jazz Pharmaceuticals) filed with the SEC on May 31, 2007. In the opinion of management, these financial statements have been prepared on the same basis as the annual financial statements and include all adjustments, consisting only of normal and recurring adjustments, considered necessary for the fair presentation of the Company s financial position and operating results. The results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 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 subsidiary, Orphan Medical, Inc. (Orphan Medical), after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

The Company has incurred significant losses from operations since its inception and expects losses to continue for the next several years. To achieve profitable operations, the Company must successfully identify, develop and commercialize its products and product candidates. Products developed by the Company will require approval by the United States Food and Drug Administration (FDA) and/or foreign regulatory authorities prior to commercial sale. 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 will need to raise additional funds to support its operations, and such funding may not be available on acceptable terms, or at all, which could materially and adversely affect the Company s business, financial condition, results of operations and growth prospects. The Company may seek additional sources of financing through development financings, collaborations or public or private debt or equity financings.

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 92% and 90% of gross accounts receivable as of September 30, 2007 and December 31, 2006, 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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Reverse Stock Split

On May 15, 2007, the Company filed a third amended and restated certificate of incorporation with the Delaware Secretary of State effecting a 1-for-11.06701 reverse split of the Company s preferred and common stock. All share and per share amounts have been retroactively restated in these condensed consolidated financial statements and notes for all periods presented.

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 $97.4 million, after deducting underwriting discounts and commissions and estimated offering expenses, not all of which had been paid as of September 30, 2007. In connection with the closing of the initial public offering, all of the Company s shares of preferred stock outstanding at the time of the offering were converted into 17,921,551 shares of common stock, and all of the Company s warrants to purchase Series BB preferred stock outstanding at the time of the offering were converted into warrants to purchase common stock.

Of the 17,921,551 shares of preferred stock that converted into common stock, 278,069 shares were held by the Company s executive officers and were subject to the terms of their employment agreements. Under the terms of these employment agreements, the Company may be required to purchase these shares of common stock at fair market value under certain circumstances. Effective upon the conversion of the preferred stock into common stock, the Company recorded an additional $4.2 million as common stock subject to repurchase, which represents the fair market value of the shares on the date of the employment agreements.

Changes to Authorized Shares

On June 6, 2007, the Company filed a fourth amended and restated certificate of incorporation with the Delaware Secretary of State under which the Company is authorized to issue 150,000,000 shares of common stock and 20,000,000 shares of preferred stock each having a par value of $0.0001.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainties in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48) effective January 1, 2007. FIN 48 requires that the Company recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. No cumulative adjustment to the Company s accumulated deficit was required upon the adoption of FIN 48.

As of September 30, 2007, the Company had approximately $1.5 million of unrecognized tax benefits, substantially all of which would, if recognized, affect the Company s tax expense. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Because of net operating loss carryforwards, substantially all of the Company s tax years remain open to federal tax examination. The Company files a United States federal income tax return and various state income tax returns, all of which typically have three tax years open at any point in time.

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Income (Loss) Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Numerator:				
Income (loss) attributable to common stockholders	$ (19,359)	$ 7,657	$ (78,806)	$ (42,357)
Denominator:				
Weighted-average common shares outstanding	24,551	618	11,231	618
Less: weighted-average common shares outstanding subject to repurchase	(880)	(606)	(726)	(607)
Weighted-average common shares used in computing income (loss) share attributable to common stockholders, basic	23,671	12	10,505	11
Shares subject to repurchase		32		
Assumed conversion of preferred stock to common stock		13,405		
Dilutive effect of stock options		21		
Shares used in computing income (loss) attributable to common stockholders, diluted	23,671	13,470	10,505	11
Income (loss) per share attributable to common stockholders, basic	$ (0.82)	$ 638.08	$ (7.50)	$ (3,850.64)
Income (loss) per share attributable to common stockholders, diluted	$ (0.82)	$ 0.57	$ (7.50)	$ (3,850.64)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Series A preferred stock (as if converted)				1,355
Series B preferred stock (as if converted)				5,884
Series B Prime preferred stock (as if converted)				6,375
Warrants to purchase Series BB preferred stock (as if exercised and converted)		786		786
Warrants to purchase common stock (as if exercised and converted)	786		786	
Options to purchase common stock	2,970	1,536	2,970	1,570
Common stock subject to repurchase	880	606	726	607
Restricted stock units	124		124	

Recent Accounting Pronouncements

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a

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materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of the Company s balance sheets and statement of operations and the related financial statement disclosures. SAB 108 was adopted by the Company in the first quarter of 2007. The Company has determined that the adoption of SAB 108 did not have a material effect on its results of operations and financial position.

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company effective January 1, 2008. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 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 Statement 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007 and is required to be adopted by the Company by January 1, 2008. The Company is currently evaluating the effect that the adoption of SFAS 159 will have on its results of operations and financial position.

In June 2007, the FASB ratified Emerging Issue Task Force (EITF) 07-3, Accounting for NonRefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007 and will be adopted by the Company effective January 1, 2008. The Company is currently evaluating the effect that the adoption of EITF 07-3 will have on its consolidated results of operations and financial position.

2. Inventories

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

	September 30, 2007	December 31, 2006
Raw materials	$ 106	$ 541
Finished goods	3,125	2,485
Total inventories	$ 3,231	$ 3,026

3. Goodwill and Intangible Assets

The gross carrying amount and net book value of intangible assets and goodwill were as follows (in thousands):

	September 30, 2007			December 31, 2006		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value

Developed technology - Xyrem ®	$ 39,700	$ 9,456	$ 30,244	$ 39,700	$ 6,327	$ 33,373
Developed technology - Antizol ®	31,100	7,407	23,693	31,100	4,956	26,144
Developed technology - Cystadane ®				4,300	687	3,613
Agreements not to compete	5,600	3,053	2,547	5,600	2,042	3,558
Trademarks	2,600	619	1,981	2,600	414	2,186
Other	400	201	199	400	134	266
Amortizable intangible assets	79,400	$ 20,736	$ 58,664	83,700	$ 14,560	$ 69,140
Goodwill	38,213			38,213		
Total	$ 117,613			$ 121,913		

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In March 2007, as more fully discussed in Note 10, the Company sold its rights to its Cystadane (betaine anhydrous) product, and as a result reduced the gross carrying amount and accumulated amortization of this intangible asset by $4.3 million and $761,000, respectively.

Future amortization costs per year for the Company s existing intangible assets other than goodwill as of September 30, 2007 were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2007 (remaining portion)	$ 2,287
2008	8,855
2009	8,581
2010	8,090
2011	7,713

4. Preferred Stock Warrant Liability

In June 2005, in connection with the issuance of the Company s $80.0 million aggregate principal amount senior secured notes, the Company issued warrants to purchase 785,728 shares of Series BB preferred stock at an exercise price of $20.36 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and were recorded as a preferred stock warrant liability. Prior to the Company s 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 the Company s initial public offering, the warrants became exercisable for common stock and the liability was reclassified to stockholders equity at its then fair value.

The Company recorded a charge of $579,000 in other income (expense), net, during the three months ended September 30, 2006, to reflect an increase in the fair value of the preferred stock warrant liability. The Company recorded a benefit of $1.8 million and a charge of $397,000 in other income (expense), net, during the nine months ended September 30, 2007 and 2006, respectively, to reflect changes the fair value of the preferred stock warrant liability.

The fair value of the warrants was estimated to be $6.7 million at June 6, 2007, the date the liability was reclassified to stockholders equity, and $8.5 million at December 31, 2006. The following assumptions were used to estimate the fair value of the warrants:

	June 6, 2007	December 31, 2006
Series BB preferred stock fair value	$ 17.59	$ 19.37
Volatility	54%	59%
Contractual term (years)	5.1	5.5
Risk-free rate	4.9%	4.7%
Expected dividend yield	0.0%	0.0%

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5. 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 nine months ended September 30, 2007 and 2006 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, common stock equivalents and awards under the Company s employee stock purchase plan (ESPP) was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Cost of product sales	$ 6	$ 3	$ 22	$ 5
Research and development	426	165	846	473
Selling, general and administrative	1,150	708	2,694	2,062
Total stock-based compensation expense	$ 1,582	$ 876	$ 3,562	$ 2,540

Employee stock-based compensation costs of $35,000 and $18,000 as of September 30, 2007 and December 31, 2006, respectively, were capitalized as a component of inventory and included in the condensed consolidated balance sheets.

Stock Options

The fair value of stock option grants was estimated at the grant date using the Black Scholes option valuation model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Weighted-average volatility	55%	61%	56%	61%
Weighted-average expected term	6.1	6.0	6.1	6.0
Range of risk-free rates	4.3-4.9%	4.7%	4.3-4.9%	4.6-5.1%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

The Company issued 5,017 shares of common stock as a result of stock option exercises during the nine months ended September 30, 2007.

As of September 30, 2007, total compensation cost related to unvested stock options not yet recognized was $12.5 million, which is expected to be recognized over a weighted-average period of 3.3 years.

Restricted Stock Units and Common Stock Equivalents

In August 2007, under the 2007 Equity Incentive Plan, the Company granted restricted stock units (RSUs), equivalent to approximately 124,000 shares of common stock, to employees. In August 2007, the Company paid directors fees in common stock equivalents (CSEs), in lieu of cash compensation. The fair value of RSUs and CSEs are determined on the date of grant based on the market price of the Company s common stock. The fair value of RSUs is recognized as expense ratably over the vesting period, generally four years. Director fees may be paid to directors, at their option, in CSEs which vest immediately and are convertible into common shares when the director leaves the Board of Directors. CSEs are recorded as expense on the date of grant. During the three and nine months ended September 30, 2007, the Company granted RSUs

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equivalent to approximately 124,000 shares with a fair value per share of $13.25, and CSEs equivalent to approximately 17,000 shares with a fair value per share of $12.75. As of September 30, 2007, total compensation cost related to RSUs not yet recognized was $1.3 million, which is expected to be allocated to expense and production costs over a weighted-average period of 3.9 years.

ESPP

Effective upon the Company s initial public offering, employees became eligible to participate in the ESPP. However, for logistical reasons, the Company did not communicate the details of the ESPP and employees were not able to notify the Company of their payroll withholdings until July 20, 2007, the grant date. The fair value of awards under the ESPP was estimated at the grant date using the Black Scholes option valuation model with assumptions similar to those used for stock option grants, except that the expected term used ranged 0.4 to 1.9 years, with a weighted-average expected term of 1.3 years. As of September 30, 2007, total compensation cost related to awards under the ESPP not yet recognized was $636,000, which is expected to be allocated to expense and production costs over a weighted-average period of 1.2 years.

6. 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 three and nine months ended September 30, 2007 and 2006, the difference between comprehensive loss and net loss represented unrealized gains on available-for-sale securities and was not material.

7. Commitments and Contingencies

Settlement of Investigation

In April 2006, the Company and Orphan Medical received subpoenas from the United States Department of Justice requiring both entities to provide the Department of Justice with certain information relating to Xyrem® (sodium oxybate), including information regarding the promotion and marketing of Xyrem.

On July 13, 2007, the Company entered into (i) a civil settlement agreement (the Civil Settlement Agreement) with the United States of America, acting through the United States Department of Justice, the United States Attorney s Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), the United States Office of Personnel Management and the United States Department of Defense TRICARE Management Activity to resolve the governmental investigation related to the promotion of Xyrem and (ii) a non-prosecution agreement with the United States Attorney s Office for the Eastern District of New York (the Non-prosecution Agreement) under which the United States Attorney s Office agreed that the Company would not be prosecuted for the matters that were the subject of the investigation. Orphan Medical, which was acquired by the Company in June 2005, entered into (i) a plea agreement with the United States Attorney s Office for the Eastern District of New York (the Plea Agreement), under which Orphan Medical pled guilty, on July 13, 2007, to one felony count of introducing a misbranded drug into interstate commerce and (ii) the Civil Settlement Agreement. The Company expects that it and Orphan Medical will also enter into agreements with Medicaid participating states, although to date the states have not provided the Company with any drafts of such agreements.

Pursuant to the Civil Settlement Agreement and the Plea Agreement, payments totaling approximately $20.0 million are required to be made over the period from July 20, 2007 through January 15, 2012. The total includes payments to Federal healthcare programs and Medicaid participating states, as well as restitution and fines. In addition, under the Non-prosecution Agreement, the Company agreed to guarantee payment by Orphan Medical of the amounts due under the Plea Agreement. The total payments due under the Civil Settlement Agreement and the Plea Agreement are payable as follows: $1.0 million in 2007 (which was paid in July 2007); $2.0 million in 2008; $2.5 million in 2009; $3.0 million in 2010; $3.0 million in 2011 and $8.5 million in 2012. All remaining amounts due under the Civil Settlement Agreement could be accelerated if the Company is acquired, or in the event of an uncured default resulting from the failure to make payments when due. In addition, all or a portion of the remaining amounts due under the Civil Settlement Agreement could be accelerated if the Company has net income in any year. Orphan Medical, which no longer directly markets products, may be excluded from participation in Federal healthcare programs as a result of the settlement.

The Company also entered into a five-year corporate integrity agreement with HHS-OIG (the Corporate Integrity Agreement) pursuant to which the Company agreed, among other things, to keep in place and continue its current compliance program which includes a compliance committee, a compliance officer, a code of conduct, comprehensive compliance policies, training and monitoring, a compliance hotline, an open door policy and a disciplinary process for compliance violations. The Company has agreed to provide periodic reports to HHS-OIG and an independent

review organization will review its compliance program.

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The settlement is neither an admission of liability by the Company nor a concession by the United States that its claims are not well founded. Participation in Federal healthcare programs by the Company, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach or deliberate violation, as the case may be, of the Civil Settlement Agreement, the Corporate Integrity Agreement or the Non-prosecution Agreement, the Company could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The Plea Agreement was approved by the United States District Court for the Eastern District of New York on July 13, 2007.

The Company recorded a charge of $17.5 million during the nine months ended September 30, 2007, which represents the present value of the settlement payments discounted at an interest rate of 4.6%. The non-current portion of this provision as of September 30, 2007 was $14.9 million and the current portion, which is included in accrued liabilities, was $1.8 million.

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 set forth under Legal Proceedings below.

The Company has agreed to indemnify its officers and directors, and the officers and directors of Orphan Medical, 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 December 31, 2006 and September 30, 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

See Settlement of Investigation above.

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. 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. Therefore, in accordance with SFAS 5, the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

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 the Company s results of operations or financial condition.

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8. 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 September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Xyrem	$ 9,646	$ 7,612	$ 27,898	$ 20,967
Antizol (1)	3,790	3,203	10,413	9,341
Cystadane (2)		369	365	1,101
Total	$ 13,436	$ 11,184	$ 38,676	$ 31,409

(1) Includes sales of Antizol-Vet, which were $48,000 and $69,000 in the three months ended September 30, 2007 and 2006, respectively, and $179,000 and $203,000 in the nine months ended September 30, 2007 and 2006, respectively.

(2) 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 September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
United States	$ 13,416	$ 10,590	$ 38,550	$ 30,435
Europe	7,675	449	10,752	1,259
All other	383	457	524	713
Total	$ 21,474	$ 11,496	$ 49,826	$ 32,407

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Express Scripts	46%	65%	56%	64%
Cardinal Health	*	*	*	12%
UCB	36%	*	21%	*

* Represented less than 10% of revenues.

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9. Product License Agreements

In January 2007, the Company entered into a product license agreement with Solvay Pharmaceuticals, Inc. (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, and agreed to make additional payments of up to $138.0 million upon achievement of development and commercial milestones. Up to $41.0 million of these milestone payments are payable at or prior to commercial launch of Luvox CR, and $2.0 million of these milestone payments are payable if the Company commercially launches Luvox. As the initial $2.0 million payment has no alternative future use, the Company expensed this amount as research and development expense in the three months ended March 31, 2007. In addition, the Company is required to pay Solvay royalties on commercial sales at specified rates.

10. Divestiture of Cystadane

In March 2007, the Company signed an agreement with a third party under which that third party purchased the Company s rights to Cystadane, along with its associated product registrations, commercial inventory and trademarks, for cash consideration of $9.0 million. The unrelated third party was also assigned certain contracts related to Cystadane, and assumed substantially all liabilities associated with Cystadane arising subsequent to March 1, 2007. The Company and the third party concurrently entered into a Transition Services Agreement under which the Company performed substantially all of the ongoing services necessary for the sale and promotion of Cystadane on behalf of the third party until June 2007. The Company recorded a gain of approximately $5.1 million in the nine months ended September 30, 2007 on the sale of the rights to Cystadane.

11. Gain on Extinguishment of Development Financing

In August 2005, the Company entered into an agreement with a third party under which the third party agreed to provide $30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development. The Company was obligated to repay the third party $37.5 million subject to, and conditioned upon, approval by the FDA to market the product in the United States. In addition, the Company agreed to pay royalties at specified rates based on sales of the product within the United States. Under that agreement, the Company received $15.0 million in 2005 and $15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, the Company notified the third party of the Company s intention to discontinue development of JZP-3 and not to seek product marketing approval from the FDA. As of the date the Company notified the third party of the Company s intention to discontinue development of JZP-3, the Company had recorded $31.6 million for future possible payments as a liability on its balance sheet, of which $30.0 million related to principal and $1.6 million related to interest accrued using the effective interest method. As a result of the Company s notification, and the subsequent formal termination of the contract in July 2006, the Company was not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3, and the Company recorded a gain of $31.6 million in the three and nine months ended September 30, 2006 resulting from the extinguishment of liabilities related to this development financing.

12. Facilities Leases

In March 2007, the Company entered into a lease agreement for approximately 13,000 square feet of office space in Palo Alto, California. The annual lease payments for this space are approximately $460,000. The fixed term expires in August 2008. In August 2007, the Company entered into a lease agreement for approximately 11,000 square feet of office space in Palo Alto, California, which expires in August 2009. The annual lease payments are approximately $419,000.

13. Line of Credit

In September 2007, the Company extended its existing line of credit under which the Company may borrow up to 80% of eligible accounts receivable up to a maximum of $5.0 million in borrowings, for an additional 60 days.

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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 the 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 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 available from third parties, 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, one product candidate for which an approvable letter has been issued by the United States Food and Drug Administration, or FDA, and four product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development. In March 2007, we sold our rights to a third marketed product, Cystadane®, for cash consideration of $9.0 million.

Our marketed products are:

Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our specialty sales force. Xyrem is distributed in the United States by Express Scripts Specialty Distribution Services, or Express Scripts, a specialty pharmaceutical distribution company, which is our only customer for Xyrem. 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 has commercially launched Xyrem in 13 countries, and Valeant launched Xyrem in Canada at the end of July 2007.

Antizol® (fomepizole). Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States. We also market Antizol-Vet®, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisoning in dogs.

Our late-stage product candidates are:

Luvox® CR (fluvoxamine maleate extended release capsules). Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay Pharmaceuticals, Inc., or Solvay, in January 2007. Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR in April 2006. In February 2007, the FDA issued an approvable letter for Luvox CR, and in June 2007, Solvay submitted its complete response to the approvable letter. In July 2007, the FDA accepted for review the submission of the complete response by Solvay, and the FDA s Prescription Drug User Fee Act, or PDUFA, date for taking action on the response is

December 22, 2007. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA for Luvox CR. Subject to the satisfaction of the requirements set forth in an approvable letter issued by the FDA to Solvay and FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through an expanded specialty sales force. During the remainder of 2007 and during

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2008, we expect to make significant expenditures relating to the planned launch and commercialization of Luvox CR, including milestone payments to Solvay, activities related to our preparation for marketing and promotion, expansion of our specialty sales force and production of commercial quantities of Luvox CR.

JZP-6 (sodium oxybate). We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. We are currently conducting two pivotal Phase III clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. We have granted to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline includes the following product candidates:

JZP-4 (Type IIa sodium channel antagonist). JZP-4, a controlled release formulation of an anticonvulsant that is in the same chemical class as Lamictal® (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline is being developed for the treatment of epilepsy and bipolar disorder.

JZP-8 (benzodiazepine). JZP-8, a novel formulation incorporating a benzodiazepine, is being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures on stable anti-epileptic regimens.

JZP-7 (dopamine agonist). JZP-7, a novel formulation incorporating a dopamine agonist, is being developed for the treatment of restless legs syndrome.

On June 6, 2007, we completed our initial public offering of 6,000,000 shares of our common stock at a public offering price of $18.00 per share. Net cash proceeds from the initial public offering were approximately $97.4 million, after deducting underwriting discounts and commissions and estimated offering expenses, not all of which had been paid as of September 30, 2007.

In July 2007, we and our wholly-owned subsidiary, Orphan Medical, Inc., settled a matter relating to an investigation by the United States, acting through the Department of Justice, the United States Attorney s Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General of the United States Department of Health and Human Services or HHS-OIG. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately $20.0 million in civil and criminal payments is required to be paid over the next several years in connection with this matter. We have agreed to guarantee payment of amounts payable by Orphan Medical.

We were not prosecuted; however, as part of the settlement we entered into a corporate integrity agreement with the HHS-OIG. That agreement requires us to maintain a comprehensive compliance program, which we have in place, and we will have additional ongoing compliance-related operating costs related to our compliance program and the corporate integrity agreement. See Part I, Item 1 Note 7, Commitments and Contingencies elsewhere in this report for additional details regarding this settlement.

In July 2007, we completed a pharmacokinetic study of JZP-2, a product candidate for the acute treatment of panic attacks associated with panic disorder. Based upon our analysis of the pharmacokinetic data generated by the study, we have discontinued this product candidate.

Since our inception, we have incurred significant net losses, and we expect to continue to incur net losses for the next several 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 are expanding 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. In addition, 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 programs and other operations.

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Revenues

Product Sales, Net

The following is a summary of our product sales, net for the three and nine months ended September 30, 2007 and 2006:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(In thousands)			
Xyrem	$ 9,646	$ 7,612	$ 27,898	$ 20,967
Antizol (1)	3,790	3,203	10,413	9,341
Cystadane (2)		369	365	1,101
Total	$ 13,436	$ 11,184	$ 38,676	$ 31,409

(1) Includes sales of Antizol-Vet, which were $48,000 and $69,000 in the three months ended September 30, 2007 and 2006, respectively, and $179,000 and $203,000 in the nine months ended September 30, 2007 and 2006, respectively.

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

Xyrem (sodium oxybate) oral solution. Revenues from sales of Xyrem represented primarily sales in the United States to Express Scripts. 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.

Antizol (fomepizole). Revenues from sales of Antizol in the United States represented primarily sales to pharmaceutical wholesalers. Our sales of Antizol to distributors outside of the United States have not been material. The orphan drug exclusivity for Antizol expired for ethylene glycol poisoning in 2004 and is scheduled to expire in December 2007 for methanol poisoning. If third parties introduce generic versions of Antizol, revenues and gross margins from sales of Antizol, could be negatively impacted by competition which may cause us to reassess the value of the Antizol intangible asset. The value of this asset as recorded on our condensed consolidated balance sheet at September 30, 2007 was $23.7 million. Antizol is stocked by hospitals for use in emergency rooms and sales are typically uneven from quarter to quarter. We do not believe that the increased sales during the three months ended September 30, 2007 are necessarily indicative of sales in future periods.

Cystadane (betaine anhydrous). We sold our rights to Cystadane in March 2007 for $9.0 million, and, accordingly, we will not receive future revenues from the sale of this product.

Royalties, Net

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products. Royalty income was $253,000 and $150,000 in the three months ended September 30, 2007, and 2006 respectively, and $824,000 and $336,000 in the nine months ended September 30, 2007 and 2006, 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 increase.

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Contract Revenues

Almost all of our contract revenues related to upfront or milestone payments received from UCB. UCB made nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, which we recognized upon achievement of the milestones. UCB also made a nonrefundable development milestone payment of $7.5 million in September 2007 in connection with the clinical trials of JZP-6, which we also recognized upon achievement. 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 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 $280,000 and $813,000 of contract revenues for the three and nine months ended September 30, 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 September 30, 2007, we incurred approximately $168.0 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 nine months ended September 30, 2007 and, for JZP projects currently under development, direct research and development expenses attributed to each project from its inception through September 30, 2007.

	Nine Months Ended September 30, 2007	From 2004 to September 30, 2007
Luvox CR	$ 5,775	$ 5,775
JZP-6	17,698	31,907
JZP-4	6,084	17,001
JZP-8	900	2,616
JZP-7	1,397	2,879
Other projects	1,322	
R&D support	16,076	
Total	$ 49,252	

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During the nine months ended September 30, 2007, our research and development expenses for Luvox CR primarily consisted of a $2.0 million payment upon execution of a product license agreement and $3.8 million of expenses in connection with the scale-up for commercial manufacturing of Luvox CR. For the year ending December 31, 2007, we expect to incur development expenses of approximately $8.0 to $10.0 million related to Luvox CR, some of which will relate to the manufacturing of commercial supplies of the product that might be sold to customers, which will not be capitalized into inventory prior to approval of the product candidate. In addition, expenses attributed to other projects during the nine months ended September 30, 2007 was reduced by $1.3 million as a result of an agreement with a former technology partner related to a project that was terminated in 2005.

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, beneficial conversion features, accrued expenses and in-process research and development. 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 Registration Statement on Form S-1/A filed with the Securities and Exchange Commission, or SEC, on May 31, 2007. There have been no material changes in our critical accounting policies and estimates and judgments since that date.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2007 and 2006

	Three Months Ended September 30,		Increase/	%Increase/	Nine Months Ended September 30,		Increase/	%Increase/
	2007	2006	(Decrease)	(Decrease)	2007	2006	(Decrease)	(Decrease)
	(In thousands)				(In thousands)			
Product sales, net	$ 13,436	$ 11,184	$ 2,252	20%	$ 38,676	$ 31,409	$ 7,267	23%
Royalties, net	253	150	103	69%	824	336	488	145%
Contract revenue	7,785	162	7,623	4706%	10,326	662	9,664	1460%
Cost of product sales	1,938	2,044	(106)	(5%)	5,620	5,367	253	5%
Research and development	16,978	14,746	2,232	15%	49,252	41,920	7,332	17%
Selling, general and administrative	18,069	12,906	5,163	40%	50,583	38,841	11,742	30%
Amortization of intangible assets	2,287	2,400	(113)	(5%)	6,936	7,200	(264)	(4%)
Provision for government settlement				N/A(1)	17,469		17,469	N/A(1)
Interest income	1,969	516	1,453	282%	4,360	1,688	2,672	158%
Interest expense	(3,511)	(3,272)	(239)	7%	(10,093)	(10,818)	725	(7%)
Other income (expense), net	(19)	(579)	560	(97%)	1,816	(397)	2,213	(557%)
Gain on extinguishment of development financing obligation		31,592	(31,592)	N/A(1)		31,592	(31,592)	N/A(1)
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 nine months ended September 30, 2007 as compared to the same periods in 2006 was primarily due to the growth of Xyrem sales, which increased by $2.0 million and $6.9 million, respectively. The product sales, net for the three and nine months ended September 30, 2007 were each reduced by $311,000 as a result of our decision to reserve for costs associated with an isolated manufacturing issue that occurred in one lot of Xyrem in Europe in 2006. We believe the increase in Xyrem sales was primarily attributable to our investments in Xyrem marketing programs and the continued integration of our expanded sales force as well as to increases in the price we charge Express Scripts instituted in August 2006 and May 2007. Sales of Antizol and Antizol-Vet increased by $587,000 and $1.1 million in the three and nine months ended September 30, 2007, respectively, compared to the same periods in 2006. Antizol is stocked by hospitals for use in emergency rooms and sales are typically uneven from quarter to quarter. We do not believe that the higher sales of Antizol in the three and nine months ended September 30, 2007 is necessarily indicative of sales in future periods. As a result of the sale of our rights to Cystadane in March 2007, we did not record any sales of this product in the three months ended September 30, 2007.

Royalties, Net

The increase in royalties, net in the three and nine months ended September 30, 2007 compared to same periods in 2006 was almost entirely due to an increase in royalties on sales of Xyrem by UCB.

Contract Revenue

Contract revenue in both the three and nine months ended September 30, 2007 included a $7.5 million payment due upon the achievement of a development milestone in the clinical trials of JZP-6 in August 2007. Contract revenue in the three and nine months ended September 30, 2007 also included $285,000 and $826,000, respectively, related primarily to the amortization of deferred revenues on $15.0 million of payments received from UCB in the second half of 2006. In addition, contract revenue in the nine months ended September 30, 2007 included a $2.0 million commercial milestone payment from UCB in March 2007, triggered by regulatory approval of Xyrem in Europe for the treatment of narcolepsy with cataplexy. Contract revenue in both the three and nine months ended September 30, 2006 included $162,000 related to the amortization of deferred revenues on $15.0 million of payments received from UCB in the second half of 2006. In addition, contract revenue in the nine months ended September 30, 2006 included $500,000 received from UCB upon achievement of a commercial milestone in June 2006.

Cost of Product Sales

The decrease in cost of product sales in the three months ended September 30, 2007 as compared to the three months ended September 30, 2006 was due to higher Xyrem unit costs in the three months ended September 30, 2006. The higher unit costs in the three months ended September 30, 2006 were due primarily to the sale of inventory with higher packaging costs.

The increase in cost of product sales in the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 was primarily due to an increase in product sales, partially offset by an expense in the nine months ended September 30, 2006 related to a fair value adjustment to inventory acquired as part of the acquisition of Orphan Medical and higher Xyrem unit costs resulting from higher packaging costs.

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Research and Development Expenses

Higher research and development expenses in the three and nine months ended September 30, 2007 as compared to the same periods in 2006 resulted from increased headcount and related expenses and to a lesser extent increased spending on development projects, partially offset by a benefit of $1.3 million, recorded in the three and nine months ended September 30, 2007, as a result of an agreement with a former technology partner related to a project that was terminated in 2005.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three months and nine months ended September 30, 2007 as compared to the same periods in 2006 primarily due to growth in headcount and related expenses, spending in preparation for the launch of Luvox CR, and higher expenses to support the sales force. Legal fees were lower in the three and nine months ended September 30, 2007 as compared to the same periods of 2006, primarily as a result of the costs in 2006 of our initial response to the government investigation described in Part II Item 1 Legal Proceedings . In order to prepare for the launch of Luvox CR, we plan to significantly expand our specialty sales force to approximately 200 positions by the end of 2007, many of which have recently been filled. As a result of these hires and other activities associated with the launch of Luvox CR we expect selling, general and administrative expenses to increase during the fourth quarter of 2007 and the first half of 2008.

Amortization of Intangible Assets

Our intangible assets consist primarily of developed technology, agreements not to compete and trademarks, all of which were recorded as a result of the acquisition of Orphan Medical in June 2005, and are amortized on a straight-line basis over their estimated useful lives. Amortization costs in the three and nine months ended September 30, 2007 were lower as compared to the same periods in 2006 as a result of the sale of our rights to Cystadane in March 2007. The orphan drug exclusivity for Antizol expired for ethylene glycol poisoning in 2004 and is scheduled to expire in December 2007 for methanol poisoning. If third parties introduce generic versions of Antizol, revenues and gross margins from sales of Antizol could be negatively impacted by competition which may cause us to reassess the carrying value of the Antizol intangible asset. The value of this asset as recorded on our condensed consolidated balance sheet at September 30, 2007 was $23.7 million.

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 United States 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 nine months ended September 30, 2007, which represents the present value of these payments discounted at an interest rate of 4.6%.

Interest Income

Interest income was higher in the three and nine months ended September 30, 2007 as compared to the same periods in 2006 primarily due to higher average cash balances as a result of our IPO in June 2007.

Interest Expense

Interest expense in the three and nine months ended September 30, 2007 and 2006 primarily related to interest on our $80.0 million principal amount of senior secured notes issued in June 2005. 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. In the nine months ended September 30, 2006, interest expense also included $1.1 million related to the financing of a product candidate in development. In June 2006, following the analysis of the results of a Phase III clinical trial, we decided to discontinue development of the product candidate and therefore did not accrue interest subsequent to May 31, 2006.

Other Income (Expense), Net

In connection with the issuance of senior secured notes in June 2005, we issued warrants to purchase 785,728 shares of Series BB preferred stock at an exercise price of $20.36 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and were recorded as 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.

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We recorded a charge of $579,000, in other income (expense), net, during the three months ended September 30, 2006, to reflect an increase in the fair value of the preferred stock warrant liability. We recorded a benefit of $1.8 million and a charge of $397,000, in other income (expense), net, during the nine months ended September 30, 2007 and 2006, respectively, to reflect changes in the fair value of the preferred stock warrant liability.

Gain on Extinguishment of Development Financing Obligation

In August 2005, we entered into an agreement with a third party under which the third party agreed to provide $30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development. We were obligated to repay the third party $37.5 million subject to, and conditioned upon, approval by the FDA to market the product in the United States. In addition, we agreed to pay royalties at specified rates based on sales of the product within the United States. Under that agreement, we received $15.0 million in 2005 and $15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of JZP-3 and not to seek product marketing approval from the FDA. As of the date we notified the third party of our intention to discontinue development of JZP-3, we had recorded $31.6 million for future possible payments as a liability on our balance sheet, of which $30.0 million related to principal and $1.6 million related to interest accrued using the effective interest method. As a result of our notification, and the subsequent formal termination of the contract in July 2006, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3, and we recorded a gain of $31.6 million in the three and nine months ended September 30, 2006 resulting from the extinguishment of liabilities related to this development financing.

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 $9.0 million in cash. In connection with this transaction, we recorded a $5.1 million gain in the nine months ended September 30, 2007.

Liquidity and Capital Resources

Since our inception, we have incurred significant net losses, and, as of September 30, 2007, we had an accumulated deficit of $256.4 million. We have not achieved profitability, and we anticipate that we will continue to incur net losses for the next several years .To date, our operations have been financed 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 one of our products and a product candidate and our initial public offering. In September 2007, we extended our existing line of credit for an additional 60 days under which we may borrow up to 80% of eligible accounts receivable up to a maximum of $5.0 million in borrowings.

As of September 30, 2007, we had $130.9 million in cash, cash equivalents and marketable securities, held primarily in obligations of United States government agencies, corporate debt securities and money market funds.

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

	Nine Months Ended September 30,	
	2007	2006
	(In thousands)	
Cash provided by (used in):		
Operating activities	$ (53,030)	$ (39,492)
Investing activities	(4,068)	(1,212)
Financing activities	98,122	50,004

Net cash used in operating activities during the nine months ended September 30, 2007 primarily reflected the net loss, offset in part by changes in working capital, depreciation and amortization, the liability under government settlement, the change in the preferred stock warrant liability and the gain on sale of product rights. Net cash used in operating activities during the nine months ended September 30, 2006 primarily reflected the net loss, offset in part by depreciation and amortization and

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the gain on the extinguishment of the development financing obligation. Net cash used in investing activities during the nine months ended September 30, 2007 and 2006 primarily related to purchases of property and equipment. In addition, investing activities during the nine months ended September 30, 2007 included proceeds of $9.0 million from the sale of our rights to Cystadane. Net cash provided by financing activities during the nine months ended September 30, 2007 was primarily attributable to the issuance of common stock in our 2007 initial public offering. Net cash provided by financing activities during the nine months ended September 30, 2006 was primarily attributable to issuances of preferred stock and funding under a development financing agreement.

We believe that our current cash, cash equivalents and marketable securities and interest earned thereon, together with planned financings and anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, 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. 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 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 will 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, or public or private debt or equity financings. If we raise funds through collaborations, 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.

Contractual Obligations

Other than payments due under the settlement of the government investigation and payments due under a new lease signed in August 2007, there have been no material changes in our contractual obligations, outside the ordinary course of business, as set forth in our Registration Statement on Form S-1/A, filed with the SEC on May 31, 2007. Payments due under the settlement of the government investigation are as follows:

	Principal	Interest	Total
		(In thousands)	
July 2007	$ 962	$ 38	$ 1,000
January 2008	1,626	374	2,000
January 2009	1,818	682	2,500
January 2010	2,405	595	3,000
January 2011	2,516	484	3,000
January 2012	8,142	358	8,500
Total	$ 17,469	$ 2,531	$ 20,000

If we are acquired, or, in the event of an uncured default resulting from the failure to make payments when due, $3.5 million plus interest payable under the civil settlement agreement described in Part II Item 1 Legal Proceedings , could become due immediately, to the extent then unpaid. In addition, if, in any calendar year, our audited financial statements show net income, we would have to pay 50% of the net income shown in those financial statements within 30 days of their issuance, up to the remainder of the then remaining unpaid amount under the civil settlement agreement. These additional payments would be applied to the payment schedule under the civil settlement agreement in reverse chronological order so that the amounts otherwise payable in 2012 would be paid first, then the amounts otherwise payable in 2011 and continuing in reverse order. Payments due under the civil settlement agreement that could be accelerated under these provisions are as follows: $537,000 otherwise payable in January 2009, $645,000 otherwise payable in January 2010, $645,000 otherwise payable in January 2011, and $1.8 million otherwise payable in January 2012.

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In August 2007, we signed a new 24 month lease for approximately 11,000 square feet of space in Palo Alto, California which will require us to make payments of approximately $419,000 per year.

Recent Accounting Pronouncements

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of our balance sheets and statement of operations and the related financial statement disclosures. SAB 108 was adopted by us in the first quarter of 2007. We have determined that the adoption of SAB 108 did not have a material effect on our results of operations or financial position.

In September 2006, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and will adopted by us effective January 1, 2008. We are currently evaluating the effect that the adoption of SFAS 157 will have on our results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 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 FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 159 will have on our results of operations and financial position.

In June 2007, the FASB ratified Emerging Issues Task Force, or EITF, 07-3, Accounting for NonRefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007 and will be adopted by us effective January 1, 2008. We are currently evaluating the effect that the adoption of EITF 07-3 will have on our consolidated results of operations and financial position.

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, 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.

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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.

Our exposure to market risk is confined to our cash, cash equivalents, marketable securities and restricted cash and investments, all of which have maturities of less than one year. The goals of our investment policy are liquidity and capital preservation. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including United States government agencies, corporate bonds, commercial paper and money market funds. Our cash and investments as of September 30, 2007 consisted primarily of obligations of United States government agencies, commercial paper and money market funds.

Our settlement with the government, which is disclosed more fully in Part II Item 1 Legal Proceedings , and our senior secured notes have fixed interest payments, and, therefore, we are not subject to market risk with respect to this obligation. Our line of credit bears interest at the prime rate of the financial institution from which we borrow, which is subject to change. However, interest expense in connection with this facility is not material.

We have no operations outside the United States, and almost all of our operating expenses and capital expenditures are denominated in United States dollars. We receive royalties on certain net product sales that are denominated in other currencies, primarily in Euro, but these royalties comprise a small portion of our revenues.

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 September 30, 2007.

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, improve 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 September 30, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

In April 2006, we and our wholly owned subsidiary, Orphan Medical, Inc., received subpoenas from the U.S. Department of Justice, acting through the United States Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem (sodium oxybate). 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 United States 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 United States Food and Drug Administration, or 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. This investigation has resulted in adverse publicity for Xyrem and for us.

On July 13, 2007, we entered into (i) a civil settlement agreement (the Civil Settlement Agreement) with the United States of America, acting through the United States Department of Justice, the United States Attorney s Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), the

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United States Office of Personnel Management and the United States Department of Defense TRICARE Management Activity to resolve the governmental investigation related to the promotion of Xyrem and (ii) a non-prosecution agreement with the United States Attorney s Office for the Eastern District of New York (the Non-prosecution Agreement) under which the United States Attorney s Office agreed we would not be prosecuted for the matters that were the subject of the investigation. Orphan Medical, which we acquired in June 2005, entered into (i) a plea agreement with the United States Attorney s Office for the Eastern District of New York (the Plea Agreement), under which Orphan Medical pled guilty, on July 13, 2007, to one felony count of introducing a misbranded drug into interstate commerce and (ii) the Civil Settlement Agreement. We expect that both Jazz Pharmaceuticals and Orphan Medical will also enter into agreements with Medicaid participating states, although to date the states have not provided the Company with any drafts of such agreements.

Pursuant to the Civil Settlement Agreement and the Plea Agreement, payments totaling approximately $20.0 million are required to be made over the period from July 20, 2007 through January 15, 2012. The total includes payments to Federal healthcare programs and Medicaid participating states, as well as restitution and fines. In addition, under the Non-prosecution Agreement, we agreed to guarantee payment by Orphan Medical of the amounts due under the Plea Agreement. The total payments due under the Civil Settlement Agreement and the Plea Agreement are payable as follows: $1.0 million in 2007 (which was paid in July 2007); $2.0 million in 2008; $2.5 million in 2009; $3.0 million in 2010; $3.0 million in 2011 and $8.5 million in 2012. All remaining amounts due under the Civil Settlement Agreement could be accelerated if we are acquired, or in the event of an uncured default resulting from the failure to make payments when due. In addition, all or a portion of the remaining amounts due under the Civil Settlement Agreement could be accelerated if we have net income in any year. Orphan Medical, which no longer directly markets products, may be excluded from participation in Federal healthcare programs as a result of the settlement.

We also entered into a five-year corporate integrity agreement with HHS-OIG (the Corporate Integrity Agreement) pursuant to which we agreed, among other things, to keep in place and continue our current compliance program which includes a compliance committee, a compliance officer, a code of conduct, comprehensive compliance policies, training and monitoring, a compliance hotline, an open door policy and a disciplinary process for compliance violations. We have agreed to provide periodic reports to HHS-OIG and our compliance program will be reviewed by an independent review organization.

The settlement is neither an admission of liability by us nor a concession by the United States that its claims are not well founded. Participation in Federal healthcare programs by Jazz Pharmaceuticals, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach or deliberate violation, as the case may be, of the Civil Settlement Agreement, the Corporate Integrity Agreement or the Non-prosecution Agreement, we could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The Plea Agreement was approved by the United States District Court for the Eastern District of New York on July 13, 2007.

While we have reached a settlement agreement with the United States Attorney s Office, and the other government agencies described above, 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 activities covered by the settlement. We cannot predict whether these actions are likely to occur, nor can we reasonably estimate the amount of any fines or penalties that might result from an adverse outcome.

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 Untied 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. 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.

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

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. We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described in our Registration Statement on Form S-1/A, filed with the SEC on May 31, 2007. In addition, the risks described under, and the captions entitled, We have broad discretion to use the net proceeds from this offering and our investment of these proceeds may not yield a favorable return. We may invest the proceeds of this offering in ways you disagree with and An active trading market for our common stock may not develop included in our Registration Statement on Form S-1/A, filed with the SEC on May 31, 2007 have been removed. 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

The FDA may not approve Luvox CR for marketing in the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. *

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR and Luvox in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox CR was developed by Solvay in collaboration with Elan Pharma International Limited. In December 2000, Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. In June 2001, as a result of challenges related to Elan s scale-up of the process to manufacture commercial quantities of Luvox CR, Solvay and Elan mutually agreed to withdraw the NDA for Luvox CR. In April 2006, Solvay resubmitted the Luvox CR NDA to the FDA, requesting approval to market the product for the treatment of obsessive compulsive disorder and social anxiety disorder. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA. In February 2007, the FDA issued an approvable letter to Solvay. The requirements set forth in the approvable letter include the completion of certain toxicology studies on the impurities that are generated by fluvoxamine maleate, the active pharmaceutical ingredient, or API, in Luvox CR, the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA and the re-analysis by Solvay of certain data set forth in the NDA. Solvay must satisfy the conditions set forth in the letter in order to obtain FDA approval. If Solvay is unable to meet these conditions, or for other reasons, the FDA may not approve Luvox CR for marketing in the United States or the approval could be delayed. Solvay submitted its complete response to the FDA in June 2007. In July 2007, the FDA accepted for review the submission of the complete response by Solvay, and the FDA s Prescription Drug User Fee Act, or PDUFA, date for taking action on the response is December 22, 2007.

Under the terms of our license agreement with Solvay, we made an initial payment of $2.0 million to Solvay. Although it is still uncertain when, or if, Luvox CR will be approved by the FDA, we intend to significantly expand our sales force, marketing and commercial operations departments and administrative staff in 2007 in anticipation of the commercial launch of Luvox CR. In addition, we have engaged numerous third party vendors, such as contract manufacturers, advertising agencies, market research firms and other service providers, to assist in the anticipated launch of Luvox CR, including Elan, who will manufacture quantities of Luvox CR sufficient for commercial launch. These expenses are significant and must be incurred prior to the approval of Luvox CR in order for us to be prepared to launch the product as soon as possible following approval. The costs cannot be recouped or applied to other products if the FDA does not approve Luvox CR. In addition, the failure to obtain FDA approval for Luvox CR would result in the loss of a major source of potential near-term revenue for us and postpone the time at which we could potentially become profitable.

For quantities of Luvox CR that may be used for commercial launch, and for product that was used in clinical studies, Solvay manufactured the API, fluvoxamine maleate. Solvay no longer manufactures the API, and manufacturing has been transferred to Lonza Group, Ltd., which we expect will, in the future, be our sole source of fluvoxamine maleate. We cannot assure you that Lonza can or will supply, in the time we need, sufficient quantities of API to enable Elan to manufacture the quantities of Luvox CR that we need. Lonza will need to be approved by the FDA as a supplier of the API, and we cannot assure you that this will happen, that it will happen in time for our planned launch of Luvox CR, or that there will not be an interruption in supply as a result of this change in API suppliers.

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Our only product candidate currently in Phase III clinical trials is JZP-6 for the treatment of fibromyalgia syndrome. The Phase III clinical trials may not show JZP-6 to be safe and effective for the treatment of fibromyalgia syndrome 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 syndrome, 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 syndrome. 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 second half 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 syndrome, or if the FDA or other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia syndrome. Favorable results from our prior Phase II clinical trials with JZP-6 for the treatment of fibromyalgia syndrome 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 syndrome. Unsuccessful Phase III pivotal clinical trials or a failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia syndrome could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Enrolling patients in fibromyalgia trials is difficult and time consuming. Lyrica® (pregabalin), a product marketed by Pfizer, Inc., was recently approved by the FDA for the management of fibromyalgia. We cannot predict what effect, if any, this approval will have on the rate of patient enrollment in our Phase III clinical trials.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia syndrome, 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 syndrome, 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 syndrome. This could make JZP-6 less attractive to physicians and patients than other products that may be approved for the treatment of fibromyalgia syndrome, which could limit potential sales of JZP-6.

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

Significant additional research and development, financial resources and additional personnel will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. As a condition to regulatory approval, each product candidate must undergo extensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The clinical trials for a product candidate can cost between $40.0 million and $100.0 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. For example, our Phase III clinical trial of JZP-3, a product candidate for the treatment of general anxiety disorder, was not successful after we incurred significant development costs, and we ceased further development of JZP-3.

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

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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. For example, other companies have stated publicly that they are testing product candidates for the treatment of fibromyalgia syndrome. Some 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.

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

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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 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 syndrome 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 syndrome in the same territories that UCB has the right to market and promote Xyrem for patients with narcolepsy. We have relied and will continue to rely in part on milestone payments from UCB to offset our development costs of JZP-6. UCB has the right to terminate our collaboration on 18 months notice (or less in certain circumstances). If UCB terminates our collaboration, 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 entered into an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, Inc., 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.

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 API of Xyrem and JZP-6, sodium oxybate, is a Schedule I

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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 continue to seek, to significantly increase 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; and if we are not successful in obtaining sufficiently increased quotas in 2007, this could adversely affect our commercial and/or clinical supplies of Xyrem and JZP-6 in 2008. In the future, we intend to seek further increased quotas to supply and manufacture JZP-6 as necessary to complete our clinical trials and, if approved, to commercialize the product. However, our manufacturing partners 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. 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. For example, we entered into an agreement with Patheon Pharmaceuticals, Inc., or Patheon, in March 2007 for the supply of Xyrem in connection with the planned termination, effective January 1, 2008, of our supply agreement with our current supplier. Patheon has not yet been qualified by the FDA to manufacture Xyrem, and we cannot assure you that Patheon will be qualified by the FDA to manufacture Xyrem on a timely basis, or at all, nor can we assure you that Patheon will obtain a quota from the DEA, or a quota that is sufficient to satisfy our commercial requirements of Xyrem. Furthermore, we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers on acceptable terms and at reasonable prices, or at all.

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.

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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, under our agreement with Solvay, Solvay provided fluvoxamine, the active pharmaceutical ingredient in Luvox CR, for quantities of Luvox CR that may be used for commercial launch, and for product that was used in clinical studies. Solvay no longer manufactures the API, and manufacturing has been transferred to Lonza Group, Ltd. who must be approved by the FDA as a supplier of the API. If Lonza is unable to timely provide fluvoxamine in the quantities we need, our launch of Luvox CR could be delayed or there could be an interruption in the supply of Luvox CR to the market. In addition, under our agreements with UCB and Valeant, we are responsible for the supply of Xyrem and JZP-6 to UCB and Xyrem, and potentially JZP-6, to Valeant. Our failure to meet our contractual obligations to supply UCB and Valeant 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 or Valeant.

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale.

Our 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. For example, if Luvox CR, for which we have obtained the exclusive rights to market and distribute in the United States from Solvay, is approved for commercial sale, Elan will manufacture Luvox CR for us in exchange for royalty and milestone payments and supply price payments. Luvox CR has never been produced 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 issued an approvable letter to Solvay, there is no assurance that Elan will be able to manufacture Luvox CR to specifications acceptable to the FDA, or if Luvox CR is approved, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of our products for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We could be materially adversely affected if we or our products are subject to negative publicity. For example, sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of gamma hydroxybutyrate, or GHB, which has been a drug of abuse and may not be sold legally in the 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 over the next several years in connection with this matter. 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 directly to consumers, 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 directly to consumers. Provigil (modafinil), 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 directly to consumers. 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 management of fibromyalgia syndrome. 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.

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

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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.

If Luvox CR is approved by the FDA, we intend to market it 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. Four branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including three selective serotonin reuptake inhibitors: Paxil (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft (sertraline HCl), which is marketed by Pfizer, and Prozac (fluoxetine hydrochloride), which is marketed by Eli Lilly. Anafranil (clomipramine hydrochloride), 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. Fluvoxamine, the generic equivalent of Luvox and a selective serotonin reuptake inhibitor, is the only other drug currently approved for the treatment of obsessive compulsive disorder. Four 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 (venlafaxine HCl). Paxil CR and Effexor XR, developed and sold by GlaxoSmithKline and Wyeth, respectively, do not have generic competitors, whereas Paxil and Zoloft have generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia syndrome. In June 2007, the FDA approved Lyrica (pregabalin), an anticonvulsant marketed by Pfizer for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy, for the management of fibromyalgia syndrome. There are currently no other products approved by the FDA for the treatment of fibromyalgia syndrome. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia syndrome, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. In addition to JZP-6 and Lyrica, we believe that there are currently two programs that have completed or are in Phase III clinical development for the treatment of fibromyalgia syndrome, including programs being conducted by 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 are conducting, or have completed, Phase III clinical trials of product candidates for the treatment of fibromyalgia syndrome. These product candidates may reach the market before JZP-6, or 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 syndrome and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

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

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

Our products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA has granted orphan drug exclusivity for Xyrem until July 2009 for cataplexy in patients with narcolepsy, and until November 2012 for excessive daytime sleepiness in patients with narcolepsy. Once our orphan drug exclusivity periods for Xyrem expire, other companies could introduce generic equivalents of Xyrem if the generic equivalents do not infringe our existing patents covering Xyrem. Once our orphan drug exclusivity period for Xyrem for the treatment of cataplexy expires in July 2009, prescriptions for Xyrem, 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 syndrome. Orphan exclusivity for Antizol for ethylene glycol poisoning expired in 2004 and the orphan exclusivity for Antizol for methanol poisoning will expire in December 2007. Once the orphan drug exclusivity expires, there are no legal barriers to one or more third parties introducing and selling generic forms of Antizol. We have filed a patent

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application covering Antizol, but no patent has yet issued and we cannot know when, or if, a patent will issue or if issued, if it would prevent or inhibit generic competition. 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 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. Further, there may be other patents that we are not aware of that cover some aspect of the Luvox CR formulation and that would prevent launch of the product or 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 small sales organization. If we are unable to appropriately expand our specialty sales force and sales organization in the United States to promote additional products, the commercial opportunity for our products may be diminished.

Our potential future commercial products, including Luvox CR and JZP-6, will require further expansion of our sales force and a significant 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 Luvox CR and 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 attract and 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 attract, 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 of our members of executive management team or other key personnel could delay or prevent the successful completion of some of our key activities.

Competition for qualified personnel in the life sciences industry is intense. We will need to hire additional personnel as we expand our development, clinical and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms. 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 will need to increase the size of our organization, and we may experience difficulties in managing growth. **

We are a small company, with 361 regular full-time employees as of October 31, 2007, approximately 55% of whom joined us in the last 12 months. To continue our commercialization and development activities, we will need to expand our employee base for managerial, operations, development, regulatory, sales, marketing, financial and other functions. 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 cannot recruit qualified employees when we need them, our key activities could be delayed. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, particularly with respect to the expansion of our sales and marketing organization and related functions for the potential commercialization of Luvox CR and JZP-6. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any growth 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

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patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

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

Furthermore, 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, generally of an NDA. The NDA must contain, among other things, data to demonstrate that the drug is safe and effective for its intended uses and that it

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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.

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. 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. 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

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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 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 will compete in a market with both

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branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products.

There have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries 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.

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 Antizol, which accounted for $12.5 million and $10.4 million in net product sales in 2006 and the first nine months of 2007, respectively, and the market participants to whom we expect to sell most of our future products, including Luvox CR, 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 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.

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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.

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, the FDA, other 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 we expect to continue for at least several years and, as a result, 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 expect to continue to incur net losses for the next several years. Our net losses for the nine month period ended September 30, 2007 and the year ended December 31, 2006 were $78.8 million and $59.4 million, respectively, and we had an accumulated deficit of $256.4 million at September 30, 2007. We expect our operating expenses to increase over the next several 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 will 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.

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 reduce operations. **

As of September 30, 2007, we had approximately $143.3 million in cash, cash equivalents, restricted cash and investments and marketable securities. Our cash flows used in operations for the nine month period ended September 30, 2007 and the

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year ended December 31, 2006 were approximately $53.0 million and $57.4 million, respectively. Substantially all of our $38.7 million and $43.3 million in net product sales during the nine month period ended September 30, 2007 and the year ended December 31, 2006, respectively, resulted from sales of Xyrem and Antizol. Sales of either or both products could decrease due to adverse market conditions, introduction of generic products, negative publicity or other events outside our control. We must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials of our product candidates and significant funds to our commercial operations. We believe that our current cash, cash equivalents and marketable securities and interest earned thereon, together with currently planned financings and anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, 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, including the cost and timing of expanding our marketing and sales capabilities;
- 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 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 and our initial public offering. In addition, the audit report in our 2006 consolidated financial statements contained an explanatory paragraph stating that our recurring losses from operations and cash used in operating activities raised substantial doubt about our ability to continue as a going concern.

Even though we recently completed our initial public offering, 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 programs and other 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, or public or private debt or equity financings. If we raise funds through collaborations, 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.

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

As of September 30, 2007, we had secured indebtedness of $82.6 million at face value, substantially all of which we incurred in connection with our acquisition of Orphan Medical. 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 of our debt, 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.

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 existing 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 assets acquired in the Orphan Medical acquisition only in accordance with the terms of our existing senior secured debt;
- not impair our lenders security interests in our assets; and
- maintain minimum cash balances.

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 our development efforts and clinical trials;

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 Xyrem;

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;

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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

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, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of September 30, 2007, we had 24,550,554 shares of common stock outstanding.

The 6,000,000 shares of common stock sold in our initial public offering are freely tradable without restrictions or further registration under the Securities Act of 1933, as amended. The remaining 18,550,554 shares of common stock outstanding as of September 30, 2007 are restricted as a result of securities laws or lock-up agreements. These shares will generally become available for sale in the public market as follows:

approximately 14,219,877 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), will be eligible for sale upon expiration of lock-up agreements on November 28, 2007; and

the remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective one-year holding periods, but could be sold earlier if the holders exercise any available registration rights.

Morgan Stanley & Co. Incorporated and Lehman Brothers Inc., may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements prior to expiration of the lock-up period.

As of September 30, 2007, the holders of 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 rights with respect to registration of such shares under the Securities Act of 1933, as amended. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights 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. In addition, we filed a registration statement on Form S-8 under the Securities Act of 1933, as amended, to register up to 4,957,794 shares of our common stock for issuance under our stock option and employee stock purchase plans.

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Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of September 30, 2007, our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 64.2% of our capital stock, of which 7.6% is beneficially owned by our executive officers. Accordingly, our executive officers, directors and principal stockholders 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 will 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, 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 and our independent registered public accounting firm 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. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

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

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

dividing our board of directors into three classes;

limiting the removal of directors by the stockholders;

eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;

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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 $18.00 per share. Our common stock commenced trading on June 1, 2007. The offering closed on June 6, 2007 after the sale of all securities registered, and as a result, we received net proceeds of approximately $97.4 million, after underwriters discounts of approximately $7.6 million and other expenses of $3.0 million.

As of September 30, 2007, we have used approximately $14.9 million of the net proceeds from the offering to fund the planned 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 the planned U.S. launch and commercialization of Luvox CR, including for development and commercial milestone payments to Solvay in connection with the acquisition of our U.S. rights to Luvox CR, to fund activities related to our preparation for marketing and promotion of Luvox CR and the expansion of our specialty sales force, to fund production of initial commercial quantities of Luvox CR, to fund our Phase III pivotal clinical trials of JZP-6 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 6. Exhibits.

Exhibit Number	Description of Document
3.1(1)	Fourth Amended and Restated Certificate of Incorporation of Jazz Pharmaceuticals, Inc.
3.2(2)	Amended and Restated Bylaws of Jazz Pharmaceuticals, Inc.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2(3)	Specimen Common Stock Certificate.
4.3(1)	Third Amended and Restated Investor Rights Agreement dated June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein.
4.4(4)	Senior Secured Note and Warrant Purchase Agreement, dated as of June 24, 2005, by and among Jazz Pharmaceuticals, Inc., Twist Merger Sub, Inc. and the Purchasers.
4.5(4)	Form of Senior Secured Note of Jazz Pharmaceuticals, Inc.
4.6(4)	Form of Series BB Preferred Stock Warrant of Jazz Pharmaceuticals, Inc.
10.57A(5)	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc., and Orphan Medical, Inc.
10.57B(5)	Non-prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc.
10.57C(5)	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.
10.57D(5)	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc.
10.62	Amendment to Employment Agreement, effective on September 1, 2007, by and between Jazz Pharmaceuticals, Inc. and Bruce Cozadd.
10.63#	Addendum No. 4 to Amended and Restated Master Services Agreement, dated as of July 16, 2007, by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.64	Form of Restricted Stock Unit Award of Jazz Pharmaceuticals, Inc.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

(1) Previously filed as the like numbered exhibit to Jazz Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q (No. 001-33500), as filed with the Securities and Exchange Commission on August 10, 2007 and incorporated by reference herein.

(2) Previously filed as Exhibit 3.4 to Jazz Pharmaceuticals, Inc. s Registration Statement on Form S-1/A (No. 333-141164), as filed with the Securities and Exchange Commission on May 17, 2007, as amended, and incorporated by reference herein.

(3) Previously filed as Exhibit 4.2 to Jazz Pharmaceuticals, Inc. s Registration Statement on Form S-1/A (No. 333-141164), as filed with the Securities and Exchange Commission on May 17, 2007, as amended, and incorporated by reference herein.

(4) Previously filed as the like numbered exhibit to Jazz Pharmaceuticals, Inc. s Registration Statement on Form S-1 (No. 333-141164), as filed with the Securities and Exchange Commission on March 9, 2007, as amended, and incorporated by reference herein.

(5) Previously filed as the like numbered exhibit to Jazz Pharmaceuticals, Inc. s Current Report on Form 8-K (No. 001-33500), as filed with the Securities and Exchange Commission on July 18, 2007 and incorporated by reference herein.

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

* The certifications attached as Exhibit 32.1 accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed by Jazz Pharmaceuticals, Inc. 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: November 7, 2007

Jazz Pharmaceuticals, Inc.

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

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(1) Previously filed as the like numbered exhibit to Jazz Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q (No. 001-33500), as filed with the Securities and Exchange Commission on August 10, 2007 and incorporated by reference herein.

(2) Previously filed as Exhibit 3.4 to Jazz Pharmaceuticals, Inc. s Registration Statement on Form S-1/A (No. 333-141164), as filed with the Securities and Exchange Commission on May 17, 2007, as amended, and incorporated by reference herein.

(3) Previously filed as Exhibit 4.2 to Jazz Pharmaceuticals, Inc. s Registration Statement on Form S-1/A (No. 333-141164), as filed with the Securities and Exchange Commission on May 17, 2007, as amended, and incorporated by reference herein.

(4) Previously filed as the like numbered exhibit to Jazz Pharmaceuticals, Inc. s Registration Statement on Form S-1 (No. 333-141164), as filed with the Securities and Exchange Commission on March 9, 2007, as amended, and incorporated by reference herein.

(5) Previously filed as the like numbered exhibit to Jazz Pharmaceuticals, Inc. s Current Report on Form 8-K (No. 001-33500), as filed with the Securities and Exchange Commission on July 18, 2007 and incorporated by reference herein.

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

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