JAZZ PHARMACEUTICALS INC
Form 10-Q
November 05, 2010
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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, 2010

or

¨ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from to

Commission File Number: 001-33500

JAZZ PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**05-0563787**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3180 Porter Drive

Palo Alto, CA 94304

(650) 496-3777

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company 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 November 1, 2010, 38,918,545 shares of the registrant s Common Stock, $.0001 par value, were outstanding.

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JAZZ PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2010

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

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

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,853	$ 15,595
Restricted cash	400	2,988
Accounts receivable, net of allowances of $322 and $288 at September 30, 2010 and December 31, 2009, respectively	14,114	12,313
Inventories	4,476	3,426
Prepaid expenses	1,992	1,653
Other current assets	962	979
Total current assets	44,797	36,954
Property and equipment, net	716	1,124
Intangible assets, net	23,895	29,858
Goodwill	38,213	38,213
Other long-term assets	371	1,247
Total assets	$ 107,992	$ 107,396
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Revolving credit facility	$ 7,350	$ 9,399
Accounts payable	3,891	2,158
Accrued liabilities	19,075	14,296
Current portion of long-term debt (including $1,355 pertaining to a related party at December 31, 2009)	15,995	23,759
Purchased product rights liability	4,375	4,000
Liability under government settlement	4,002	2,954
Deferred revenue	3,412	2,675
Total current liabilities	58,100	59,241
Deferred rent	86	29
Deferred revenue, non-current	9,338	10,191
Purchased product rights liability, non-current	5,625	9,000
Liability under government settlement, non-current	6,978	10,658
Long-term debt, less current portion (including $5,196 pertaining to a related party at December 31, 2009)	28,670	91,107

Commitments and contingencies (Note 12)		
Stockholders deficit:		
Common stock	4	3
Additional paid-in capital	498,516	434,811
Accumulated deficit	(499,325)	(507,644)
Total stockholders deficit	(805)	(72,830)
Total liabilities and stockholders deficit	$ 107,992	$ 107,396

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Product sales, net	$ 43,838	$ 29,992	$ 117,649	$ 77,789
Royalties	630	532	1,909	1,522
Contract revenues	285	285	854	10,854
Total revenues	44,753	30,809	120,412	90,165
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technology)	3,091	2,338	8,775	6,856
Research and development	7,317	7,644	21,494	30,244
Selling, general and administrative	18,040	15,061	51,926	42,934
Intangible asset amortization	1,862	2,057	5,963	5,611
Total operating expenses	30,310	27,100	88,158	85,645
Income from operations	14,443	3,709	32,254	4,520
Interest income	1	2	5	29
Interest expense (including $0 and $296 for the three months ended September 30, 2010 and 2009, respectively, and $570 and $937 for the nine months ended September 30, 2010 and 2009, respectively, pertaining to a related party)	(1,197)	(5,384)	(11,651)	(17,034)
Other (expense) income	(4)	1	(2)	(4)
Loss on extinguishment of debt			(12,287)	
Net income (loss)	$ 13,243	$ (1,672)	$ 8,319	$ (12,489)
Net income (loss) per share:				
Basic	$ 0.34	$ (0.05)	$ 0.24	$ (0.42)
Diluted	$ 0.32	$ (0.05)	$ 0.22	$ (0.42)
Weighted-average common shares used in computing net income (loss) per share:				
Basic	38,965	30,895	35,294	29,635
Diluted	41,737	30,895	38,233	29,635

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

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JAZZ PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2010	2009
Operating activities		
Net income (loss)	$ 8,319	$ (12,489)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	713	1,103
Amortization of intangible assets	5,963	5,611
Loss on disposal of property and equipment	313	14
Stock-based compensation expense	5,969	3,509
Long-term debt, non-cash interest expense	2,175	1,849
Loss on extinguishment of debt, non-cash portion	3,803	
Changes in assets and liabilities:		
Accounts receivable	(1,801)	(2,559)
Inventories	(1,031)	133
Prepaid expenses and other current assets	(391)	1,158
Other assets	(260)	(274)
Accounts payable	1,733	(496)
Accrued liabilities	4,779	(4,902)
Deferred revenue	(116)	(10,676)
Deferred rent	57	7
Liability under government settlement	(2,632)	362
Net cash provided by (used in) operating activities	27,593	(17,650)
Investing activities		
Purchases of property and equipment	(618)	(47)
Purchase of product rights	(3,000)	(3,000)
Decrease in restricted cash and investments	2,588	963
Proceeds from maturities of marketable securities		1,004
Net cash used in investing activities	(1,030)	(1,080)
Financing activities		
Repayment of senior secured notes (including $6,816 paid to a related party)	(119,496)	
Proceeds from offering of common stock, net of issuance costs	56,817	
Proceeds from term loan, net	48,688	
Repayment of term loan	(4,166)	
Proceeds from private offerings, net of issuance costs		6,780
Proceeds from employee stock purchases and exercise of stock options	901	152
Net repayment of revolving credit facilities	(2,049)	(875)
Net cash (used in) provided by financing activities	(19,305)	6,057
Net increase (decrease) in cash and cash equivalents	7,258	(12,673)

Cash and cash equivalents, at beginning of period	15,595	24,903
Cash and cash equivalents, at end of period	$ 22,853	$ 12,230
Supplemental disclosure of non-cash investing and financing activities:		
Liability for purchase of product rights	$	$ 5,000
Warrants to purchase common stock issued in conjunction with unregistered sales of equity securities	$	$ 2,700

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

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Summary of Significant Accounting Policies

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10 Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2009. In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. Certain amounts related to deferred cost of goods sold in the condensed consolidated statements of cash flows for the nine months ended September 30, 2009 have been reclassified to conform to the presentation for the nine months ended September 30, 2010. The results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010 or for any other interim period or for any future period. The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. and our wholly-owned subsidiaries, Orphan Medical, LLC and JPI Commercial, LLC after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

Although we reported net income for the three and nine months ended September 30, 2010, we have incurred significant cumulative losses since our inception in 2003 and we may incur net losses in the future. As of September 30, 2010, our accumulated deficit was $499.3 million, the principal amount outstanding on our long-term debt was $45.8 million and we had cash and cash equivalents of $22.9 million. We believe our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and meet all of our existing obligations through at least 2011. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses. Our assumptions concerning our product sales and expenses may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, any of which could have a material adverse effect on our business.

We are subject to risks common to companies in the pharmaceutical industry with development and commercial operations including, but not limited to, risks and uncertainties related to commercial success and acceptance of our products by patients, physicians and payors, competition from branded and generic products, regulatory approvals, regulatory requirements, including those of the U.S. Food and Drug Administration, or FDA, and the U.S. Drug Enforcement Administration, or DEA, dependence on key customers and sole source suppliers and protection of intellectual property rights. In addition, most of our revenues are derived from sales of one product, Xyrem, as to which an Abbreviated New Drug Application, or ANDA, has been filed with the FDA by a party seeking to market a generic form of Xyrem. We have only one product candidate in late stage development, JZP-6, and we recently received a complete response letter, or CRL, from the FDA with respect to that product candidate stating that the FDA cannot approve our new drug application, or NDA, in its present form. We plan to meet with the FDA to discuss and clarify the letter, in order to determine the appropriate course of action for us with respect to JZP-6. We cannot assure you when, or whether, we will receive sufficient clarification from the FDA, or of the timing or cost of the continued development of JZP-6, or if its development will be continued, or whether our NDA for JZP-6 will be approved by the FDA.

Concentration of Credit Risks

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents, restricted cash, marketable securities and accounts receivable. Our investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents and issuers of investments to the extent recorded on the balance sheet.

We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, and to international distributors in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, we have not experienced significant credit losses on our accounts receivable. Five customers accounted for 99% of gross accounts receivable as of both September 30, 2010 and December 31, 2009.

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Concentration of Supply Risk

We rely on certain sole suppliers for drug substance and certain sole manufacturing partners for each of our marketed products and certain of our product candidates. In addition, certain of our sole suppliers themselves rely on sole suppliers. Lonza, Inc., or Lonza, our sole supplier of sodium oxybate, formally notified us in March 2010 that our agreement for the supply of sodium oxybate will terminate on December 31, 2011, at the end of its current term. Under the agreement, Lonza has an obligation to meet our sodium oxybate supply needs through 2011. Recently, the DEA increased the aggregate quota, and Lonza manufactured additional sodium oxybate for us.

In April 2010, we entered into an agreement with a new supplier, Siegfried (USA) Inc., or Siegfried, in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve Siegfried as a new supplier of sodium oxybate. Siegfried is conducting the necessary activities and plans to seek FDA approval as a supplier of sodium oxybate as soon as possible. We expect Siegfried to be approved by the FDA as a supplier by the second half of 2011 but we cannot be certain that this will occur.

Use of Estimates

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

Net Income (Loss) Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Numerator:				
Net income (loss)	$ 13,243	$ (1,672)	$ 8,319	$ (12,489)
Denominator:				
Weighted-average common shares outstanding basic	38,965	30,895	35,294	29,635
Dilutive effect of employee equity incentive and purchase plans	1,864		1,948	
Dilutive effect of warrants	908		991	
Weighted-average common shares outstanding diluted	41,737	30,895	38,233	29,635
Net income (loss) per share:				
Basic	$ 0.34	$ (0.05)	$ 0.24	$ (0.42)
Diluted	$ 0.32	$ (0.05)	$ 0.22	$ (0.42)

Potentially dilutive common shares from employee stock plans and warrants are determined by applying the treasury stock method to the assumed exercise of warrants and stock options, the assumed vesting of outstanding restricted stock units, and the assumed issuance of common stock under our employee stock purchase plan. The following table represents the weighted-average

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Warrants to purchase common stock	1,348	3,300		3,595
Options to purchase common stock	3,675	2,559	3,268	2,904
Restricted stock units		35		42
Total	5,023	5,894	3,268	6,541

As of September 30, 2010, we had options to purchase 6,075,402 shares of common stock outstanding with a weighted average exercise price of $9.91 and a weighted average remaining contractual term of 7.7 years and 13,220 restricted stock units outstanding with a weighted average remaining contractual term of 0.9 years which had been granted to employees and members of our board of directors. As of September 30, 2010, we also had warrants to purchase common stock outstanding as follows:

Warrants issued in conjuction with:	Shares	Expiration Date	Exercise Price
$80.0 million senior secured notes	785,728	June 2012	$ 9.34
$40.0 million senior secured notes	562,192	March 2013	$ 9.34
Equity financing facility	220,000	November 2013	$ 9.20
Public offering	1,731,724	July 2014	$ 7.37
Private offering	947,867	July 2016	$ 4.00

Recent Accounting Pronouncements

In March 2010, the Financial Accounting Standards Board, or FASB, ratified authoritative guidance which amends the revenue recognition guidance related to milestone payments. The FASB concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Under the guidance, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. This guidance will not have an impact on our results of operations and financial position as we have applied the milestone method to previously received milestone payments as this method is an acceptable alternative applied in practice.

In October 2009, the FASB issued authoritative guidance which amends the revenue recognition guidance to require companies to allocate revenue in multiple-element arrangements based on an element s estimated selling price if vendor-specific or other third-party evidence is not available. The guidance is effective beginning January 1, 2011. Earlier adoption is permitted. We are currently evaluating the effect that the adoption of this guidance will have on our results of operations and financial position, if any.

2. Inventories

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

	September 30, 2010	December 31, 2009
Raw materials	$ 1,561	$ 1,245
Work in process	1,199	676
Finished goods	1,716	1,505

Total inventories	$ 4,476	$ 3,426

3. Goodwill and Intangible Assets

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

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	September 30, 2010	December 31, 2009
Goodwill	$ 38,213	$ 38,213

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

	September 30, 2010			December 31, 2009		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology Xyrem	$ 39,700	$ (21,971)	$ 17,729	$ 39,700	$ (18,842)	$ 20,858
Developed technology Luvox CR	9,700	(4,695)	5,005	9,700	(2,443)	7,257
Agreements not to compete				3,900	(3,523)	377
Trademarks	2,600	(1,439)	1,161	2,600	(1,234)	1,366
Total	$ 52,000	$ (28,105)	$ 23,895	$ 55,900	$ (26,042)	$ 29,858

Based on intangible assets recorded as of September 30, 2010, and assuming the underlying assets will not be impaired in the future and that we will not change the expected lives of the assets, future amortization costs were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2010 (remaining portion)	$ 1,862
2011	7,448
2012	5,696
2013	4,445
2014	4,444

4. Fair Value Measurement

Available-for-sale investments consisted of the following as of September 30, 2010 and December 31, 2009 (in thousands):

	September 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 46	$	$	$ 46

	September 30, 2010
Available-for-sale investments	$ 46
Cash	22,807
Restricted cash	400
Total	$ 23,253

Reported as	September 30, 2010
Amounts classified as cash and cash equivalents	$ 22,853
Amounts classified as restricted cash	400
Total	$ 23,253

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	December 31, 2009		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 5,072	$	$	$ 5,072

	December 31, 2009
Available-for-sale investments	$ 5,072
Cash	10,523
Restricted cash	2,988
Total	$ 18,583

Reported as	December 31, 2009
Amounts classified as cash and cash equivalents	$ 15,595
Amounts classified as restricted cash	2,988
Total	$ 18,583

Since our inception, there have been no significant realized gains or losses on cash equivalents or marketable securities.

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

	September 30, 2010		December 31, 2009	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Estimated Fair Value
Money market funds	$ 46	$ 46	$ 5,072	$ 5,072

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

	September 30, 2010		December 31, 2009	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt	$ 44,665	$ 45,156	$ 114,866	$ 123,628

We used a discounted cash flow analysis based on our estimated incremental borrowing rates for similar types of borrowing arrangements to calculate the fair value of our long-term debt.

5. Debt and Financing Obligations

Retired Senior Secured Notes

In March, May and June 2010 we repaid $3.0 million, $53.0 million and $63.5 million principal amount of our previously-outstanding senior secured notes, respectively. In addition to the principal repayments in May and June 2010, we paid prepayment penalties and fees totaling $8.5 million in accordance with our agreement with the holders of the senior secured notes, and recorded non-cash charges related to unamortized debt discount and debt issuance costs of $3.8 million during the nine months ended September 30, 2010. As of June 30, 2010, the senior secured notes were repaid in full.

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Term Loan and Revolving Credit Facility

In June 2010, we entered into a credit agreement with a lender which provides for a term loan in an aggregate principal amount of $50.0 million and a $15.0 million revolving credit facility, both of which mature in June 2013. On June 30, 2010, we borrowed $57.4 million under the credit agreement, consisting of the term loan of $50.0 million and $7.4 million under the revolving credit facility, and we used all of the borrowed funds, together with cash on hand, to repay all of the remaining outstanding senior secured notes, which otherwise had a final maturity of June 2011. We also terminated our previous revolving line of credit. Borrowings under the term loan and revolving credit facility bear interest at a variable rate based on the higher of the prime rate or the federal funds rate plus 0.5% plus, in each case, a margin ranging from 1% to 2.5% or, at our option, the Eurodollar rate plus a margin ranging from 3% to 5%. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.5% to 0.75% per annum. The interest rate margins and the commitment fee will vary based on our consolidated leverage ratio, as defined in the credit agreement.

The borrowing availability under the revolving credit facility will vary according to the levels of our eligible accounts receivable and other terms and conditions described in the credit agreement and is limited to $8.0 million until January 1, 2011 and $15.0 million thereafter. Borrowings under the revolving credit facility and the term loan are secured by substantially all of our assets. The term loan is repayable in twelve equal quarterly installments of $4.2 million beginning with the first payment of $4.2 million we made on September 30, 2010. If we prepay the term loan (in whole or in part), or if we terminate or reduce the lender s commitments to make loans under the revolving credit facility, we must pay a prepayment fee equal to (a) 2% of the aggregate amount of the term loan prepaid or commitments terminated or reduced during the first year of the credit agreement, and (b) 1% of the aggregate amount of the term loan prepaid or commitments terminated or reduced during the second year of the credit agreement.

The credit agreement contains customary operating covenants, including covenants that restrict our ability to: incur indebtedness and liens; effect mergers, consolidations and other fundamental changes; dispose of significant assets or enter into sale-leaseback transactions; pay dividends or make other restricted payments; make loans, advances or certain investments including acquisitions of companies and products; or enter into transactions with affiliates. The credit agreement also requires us to comply with financial covenants requiring us to maintain a minimum consolidated fixed charge coverage ratio, a maximum consolidated leverage ratio and minimum monthly liquidity, each as defined in the credit agreement. The minimum monthly liquidity covenant requires us to maintain cash and availability under the revolving line of credit of not less than $10.0 million combined beginning October 1, 2010 through March 31, 2011 and not less than $20.0 million combined thereafter. As of September 30, 2010, we were in compliance with all material covenants under the credit agreement.

The $45.8 million principal amount of the term loan was recorded net of a debt discount of $1.2 million related to fees paid to the lender under the credit agreement as of September 30, 2010. As of September 30, 2010, the interest rate on the term loan was 5.75%. Interest expense associated with the term loan is recorded using the interest method and includes non-cash interest related to the debt discount and debt issuance costs. The effective interest rate on the term loan is 8.1%. The current portion of the carrying amount of the term loan was $16.0 million as of September 30, 2010.

As of September 30, 2010, $7.4 million was outstanding under the revolving credit facility which bore interest at 5.75%. As of December 31, 2009, $9.4 million was outstanding under our previous revolving bank line of credit which bore interest at 6.5%. Our previous revolving bank line of credit was terminated effective June 30, 2010.

6. Common Stock

Common Stock Offering

In May 2010, we issued 7,000,000 shares of our common stock in an underwritten public offering for net proceeds of $56.8 million, after deducting underwriting discounts, commissions and offering expenses.

Stock Option Exercises, Vested Restricted Stock Units and Employee Stock Purchase Plan (ESPP)

During the nine months ended September 30, 2010, we issued 402,839 shares of common stock as a result of the vesting of restricted stock units and stock option exercises for proceeds of $646,000.

In May 2010, we issued 259,906 shares of our common stock under our ESPP for proceeds of $255,000.

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7. Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (loss) and all changes in stockholders deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. During the three and nine months ended September 30, 2010, comprehensive income was equal to net income. During the three and nine months ended September 30, 2009, the difference between comprehensive loss and net loss represented the change in unrealized gains/losses on available-for-sale securities and was not significant.

8. Segment Information

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Xyrem	$ 37,231	$ 25,038	$ 99,699	$ 65,119
Luvox CR	6,607	4,954	17,950	12,670
Total	$ 43,838	$ 29,992	$ 117,649	$ 77,789

The following table presents a summary of total revenues including net product sales, royalties and contract revenues attributed to domestic and foreign sources (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
United States	$ 43,564	$ 29,761	$ 117,172	$ 76,746
Europe	907	1,044	2,950	13,066
All other	282	4	290	353
Total	$ 44,753	$ 30,809	$ 120,412	$ 90,165

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Express Scripts	83%	81%	82%	71%
UCB Pharma Limited (1)	*	*	*	14%

(1) In April 2009, we recognized as revenue a $10.0 million nonrefundable milestone payment received from UCB Pharma Limited, or UCB, in July 2008. See Note 9 for additional information.

* Represented less than 10% of our total revenues.

9. Collaboration and License Agreements

Under the terms of our agreement with UCB, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. In April 2009, upon the completion of the last patient in our second Phase III pivotal clinical trial of sodium oxybate for the treatment of fibromyalgia, we recognized as revenue a $10.0 million nonrefundable milestone payment we received from UCB in July 2008 that was previously recorded as deferred revenue. In addition, we recognized contract revenues of $280,000 in each of the three months ended September 30, 2010 and 2009, and $840,000 in each of the nine months ended September 30, 2010 and 2009 related to previously deferred upfront payments which are being recognized as contract revenue ratably through 2019, the expected performance period under the agreement.

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10. Stock-Based Compensation

Stock-based compensation expense related to stock options, restricted stock units, shares of common stock credited to each director s phantom stock account under our directors deferred compensation plan, and stock awards under our employee stock purchase plan was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Selling, general and administrative	$ 1,632	$ 1,039	$ 4,297	$ 2,545
Research and development	478	262	1,488	875
Cost of product sales	67	12	184	89
Total	$ 2,177	$ 1,313	$ 5,969	$ 3,509

Employee stock-based compensation costs of $65,000 and $46,000 as of September 30, 2010 and December 31, 2009, respectively, were capitalized as a component of inventories and included in the condensed consolidated balance sheets.

Stock Options

We granted options to employees and to members of our board of directors to purchase shares of our common stock as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Options granted	274,875	109,900	1,623,800	2,679,000
Weighted-average grant date fair value	$ 6.14	$ 4.02	$ 7.83	$ 1.06

The fair value of options granted was estimated at the grant date using the Black Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Weighted-average volatility	88%	85%	85%	92%
Weighted-average expected term (years)	5.8	5.7	6.0	6.1
Range of risk-free rates	1.7-2.1%	2.6-3.1%	1.7-3.1%	1.8-3.1%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

Phantom Shares

In August 2010, certain directors elected to defer receipt of their retainer fees to be paid in our common stock under our Directors Deferred Compensation Plan, and we recorded phantom shares equivalent to 24,166 shares of our common stock with a market value per share of $8.21 under that plan. In August 2009, we recorded phantom shares equivalent to 38,432 shares of our common stock with a market value per share of $6.33. Total compensation cost related to phantom shares of our common stock credited to the directors phantom stock accounts was approximately $198,000 for the three and nine months ended September 30, 2010 and $243,000 for the three and nine months ended September 30, 2009.

11. Income Tax Expense

During the three and nine months ended September 30, 2010, our effective income tax rate was 0%. This rate was lower than the federal statutory rate of 35% due to our application of federal net operating loss carryforwards to offset both regular taxable income and alternative minimum taxable income and reflects our utilization of deferred state tax benefits.

12. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights.

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Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations.

We have agreed to indemnify our officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we have not recognized any liabilities relating to these obligations as of September 30, 2010 and December 31, 2009. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Legal Proceedings

In August and September 2009, we received Paragraph IV certification notices from Actavis Elizabeth, LLC, or Actavis, and from Anchen Pharmaceuticals, Inc., or Anchen, advising that each has filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. We have not been informed as to the timing or status of the FDA s review of either party s filing, or whether either filer has complied with FDA requirements for proving bioequivalence, or which party was first to file its ANDA with the FDA. Actavis Paragraph IV certification alleged that the United States patent covering Luvox CR, which is owned by Elan Pharma International Limited, or Elan, and licensed to us, is invalid on the basis that the inventions claimed therein were obvious. Anchen s Paragraph IV certification alleged that the Elan patent would not be infringed by Anchen s manufacture, use or sale of the generic product for which the ANDA was submitted and that the Elan patent is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, we and Elan, as plaintiffs, filed a lawsuit against Actavis, Anchen, and Anchen Incorporated, the parent of Anchen, in the United States District Court for the District of Delaware claiming infringement of the patent by the defendants. On October 14, 2009, we and Elan, as plaintiffs, also filed a lawsuit in the United States District Court for the Central District of California against Anchen and Anchen Incorporated claiming infringement of the Elan patent.

On August 25, 2010, we and Elan entered into settlement agreements with Anchen. Under the agreements, we, Elan and Anchen have agreed to dismiss all of the claims brought in the litigation without prejudice, Anchen has agreed not to contest the validity or enforceability of the Elan patent in the United States, and we, Elan and Anchen have agreed to release each other from all claims arising in the litigation or relating to the product Anchen intends to market under its ANDA. Settlement agreements of ANDA litigation can be reviewed by the Federal Trade Commission and the U.S. Department of Justice at their discretion. In addition, we have granted a sublicense to Anchen of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicense is non-transferable, non-sublicensable and royalty-free and is exclusive even as to us and Elan (except with respect to Luvox CR) for a period of time. The sublicense will commence on February 15, 2013 or earlier upon the occurrence of certain events. On October 5, 2010, the United States District Court for the Central District of California dismissed the case against Anchen without prejudice. On the same date, the United States District Court for the District of Delaware also dismissed the case against Anchen without prejudice.

The lawsuit against Actavis is still pending in Delaware. We cannot predict the outcome of this litigation.

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

Phase IV Clinical Study Commitment

The FDA approval of Luvox CR included a commitment for two Phase IV clinical studies, one in adolescent patients with social anxiety disorder, or SAD, and one a long-term duration of effect study in patients with SAD. If they were to be performed, the cost of these Phase IV studies would likely be significant. We have been in discussions with the FDA concerning our Phase IV clinical study commitment, and as a result of these discussions, in April 2010, we submitted a labeling supplement to the NDA for Luvox CR to remove the SAD indication from the label. This supplement is under active review by the FDA. Based upon our discussions with the FDA, we believe that if the labeling supplement is approved by the FDA, we would then be released from the Phase IV clinical study commitment.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described in Part II Item 1A Risk Factors included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations see Cautionary Note Regarding Forward-Looking Statements that appears at the end of this discussion. These statements, like all statements in this report, speak only as of their date (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Overview

We are a specialty pharmaceutical company that, since our inception, has focused on the development and commercialization of pharmaceutical products to meet important unmet medical needs, currently in neurology and psychiatry. We currently market two products: Xyrem (sodium oxybate) oral solution and Luvox CR (fluvoxamine maleate) Extended-Release Capsules. We are building a portfolio of products through a combination of internal development, acquisition and in-licensing activities, and we utilize our specialty sales force to promote our products in our target markets. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes our two marketed products, Xyrem and Luvox CR. Our development pipeline includes: our JZP-6 product candidate, sodium oxybate for the treatment of fibromyalgia, for which we recently received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, as discussed below; our solid oral dosage forms of sodium oxybate; our JZP-8 product candidate in development for the treatment of recurrent acute repetitive seizures in epilepsy patients; and our JZP-4 product candidate for the treatment of epilepsy and bipolar disorder, which we are seeking to partner or out-license.

Xyrem

Xyrem is the only product approved by the FDA for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. We promote Xyrem in the United States for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. 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. UCB currently markets Xyrem in 15 countries in Europe. We have three issued patents covering our formulation for Xyrem, one of which expires in 2019, and two of which expire in 2020, in the United States. We have four issued U.S. patents covering our distribution system for Xyrem which expire in 2024. Two of the formulation patents and three of the distribution system patents are listed in the FDA s approved drug products with therapeutic equivalence evaluation documents, or Orange Book. In addition, we have orphan drug exclusivity for the excessive daytime sleepiness in narcolepsy indication for Xyrem until November 2012; all narcolepsy patients suffer from excessive daytime sleepiness.

On October 5, 2010, the FDA s website indicated that an abbreviated new drug application, or ANDA, was submitted to the FDA on July 8, 2010 by a party seeking to market a generic form of Xyrem. On October 18, 2010, we received notice from Roxane Laboratories, Inc, or Roxane, that it filed an ANDA with the FDA seeking to market a generic form of Xyrem. We believe that the ANDA noticed to us by Roxane is the ANDA filed with the FDA on July 8, 2010. We are currently reviewing the details of Roxane s notice. Under the Hatch-Waxman Act, we have 45 days from receipt of the notice to determine if we will file a patent infringement suit. If we bring such a suit, a stay of approval of up to 30 months from our receipt of Roxane s notice will be imposed by the FDA on Roxane s ANDA. We intend to vigorously enforce our intellectual property rights. If generic products were to be introduced, our revenue from Xyrem product sales would decline.

Luvox CR

Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder, or OCD, and social anxiety disorder, or SAD, in February 2008. We began promoting Luvox CR through our specialty sales force in April 2008. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay (which was recently acquired by Abbott Laboratories) retained the rights to market and distribute Luvox CR outside of the United States. Luvox CR is covered by a product-specific patent issued to Elan, which manufactures the product for us. In 2009, two companies filed ANDAs, seeking to market generic forms of Luvox CR and sent us certifications as required by the FDA that their products did not infringe the Elan patent, or that the patent is invalid. We filed suit against both

companies; one of the suits was settled during the third quarter of 2010 and the other is pending in Delaware. If generic products were to be introduced, our revenue from Luvox CR product sales would decline.

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In July 2010 we received a warning letter from the FDA concerning our promotional materials for Luvox CR. We have proposed a plan to the FDA and have taken actions to address the FDA s concerns. We have agreed with the FDA on a corrective action plan and we intend to complete our actions promptly.

JZP-6

We are developing and seeking FDA approval for sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. Our development program includes two completed Phase III pivotal clinical trials and a long-term safety trial. In November 2008 and June 2009, we announced positive top-line results from our first and second Phase III pivotal clinical trials, respectively. The two randomized, double-blind, placebo-controlled studies demonstrated that sodium oxybate significantly decreased pain and fatigue, and improved daily function and patient global impression of change, in patients with fibromyalgia. We submitted a new drug application, or NDA, for JZP-6 in December 2009 and the NDA was filed by the FDA in February 2010 with a Prescription Drug User Fee Act action date of October 11, 2010.

The FDA s Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee reviewed JZP-6 at a joint meeting on August 20, 2010 and voted 20-2 against approval of the NDA as submitted. On October 8, 2010, the FDA sent us a CRL regarding our NDA for JZP-6. The CRL states that the FDA cannot approve the NDA in its present form. In the letter, the FDA discusses a number of topics, including the need for additional clinical studies, the appropriate patient population, methods for ensuring safe use, and the proposed Risk Evaluation and Mitigation Strategy, or REMS, program, concentration of the formulation and the trade name for the product. We plan to meet with the FDA to discuss and clarify the letter, in order to determine the appropriate course of action for us with respect to JZP-6. We cannot assure you when, or whether, we will receive sufficient clarification from the FDA, or of the timing or cost of the continued development of JZP-6, or if its development will be continued, or whether the NDA for JZP-6 will be approved by the FDA.

We have licensed to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States in exchange for development funding, commercial milestones and royalties that expire in 2024. In August 2010, UCB announced that it had filed an application with the European Medicines Agency, or EMA, for the approval of JZP-6, which UCB intends to market under the Xyrem trade name if it is approved in Europe. Currently, there are no approved treatments for fibromyalgia in the European Union. Under the terms of our agreement with UCB, we are entitled to a milestone payment of up to $25 million upon EMA approval of JZP-6, royalties on UCB s sales and additional commercial milestone payments of up to $100 million on sales of sodium oxybate. UCB has announced that it expects feedback from the European authorities during the first half of 2011.

Our JZP-6 product candidate is covered by one or more of our formulation patents covering Xyrem, and we expect that its distribution system, if the product is approved by the FDA, will be covered by one or more of our distribution system patents. JZP-6 is also covered by a patent covering the use of sodium oxybate to treat fibromyalgia that expires in 2017.

Other Product Candidates

Our other product candidates in clinical development are solid oral dosage forms of sodium oxybate and JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens. We are seeking a partner to continue development of JZP-4 (elpetrigine), our product candidate for the treatment of epilepsy and bipolar disorder.

Financial Outlook

Until 2010, we incurred significant net losses in our business. Our net loss was $6.8 million for the year ended December 31, 2009, and $184.3 million for 2008. For the first nine months of 2010, we had net income of $13.2 million, and, although we expect to have significant net income for the full years 2010 and 2011, we may incur net losses in the future. The improvements for 2010 have been due to a significant increase in our product sales and a decrease in our expenses, as discussed below. However, our estimates of product sales and expenses for the full years 2010 and 2011 may prove to be wrong or other factors may adversely affect our business, and our net income could be lower than we expect .

We depend primarily on sales of Xyrem, and to a lesser extent Luvox CR, to fund our operations and generate our net income. The increase in our Xyrem revenues for 2010 resulted primarily from price increases, and to a lesser extent from increasing sales volume. On November 1, 2010, we implemented a price increase of approximately 20% for Xyrem. We cannot be certain that this or any future price increases will not cause a disruption in Xyrem sales and any decrease in sales would have a negative effect on our revenues.

We believe our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and meet all of our existing obligations through at least 2011. We have an active business development effort, and we may seek to in-license or acquire products and/or companies. If the FDA approves

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our NDA for JZP-6, we would incur significant expenses to launch the product, and we cannot predict its commercial success, if launched. If significant additional studies are required by the FDA with respect to JZP-6, we could expend significant resources if we were to choose to conduct the studies. To in-license products or acquire products or other companies, launch JZP-6 or conduct significant additional clinical trials, we may need to raise additional funds, and we do not know if such funds would be available to us on terms we would find acceptable, or at all.

Quota from the U.S. Drug Enforcement Agency, or DEA, is required in order to manufacture Xyrem and its active ingredient, sodium oxybate. Obtaining quota from the DEA is a difficult and time-consuming process, and the DEA has historically not given our suppliers the amounts of quota requested to meet our needs although we have never had a supply disruption. Insufficient quota could result in shortages of our commercial product or delays in our development and clinical activities.

We depend on single source suppliers for sodium oxybate, the active ingredient in both Xyrem and JZP-6. Lonza, Inc., or Lonza, our sole supplier of sodium oxybate, formally notified us in March 2010 that our agreement for the supply of sodium oxybate will terminate on December 31, 2011, at the end of its current term. Under the agreement, Lonza has an obligation to meet our sodium oxybate supply needs through 2011. Recently, the DEA increased the aggregate quota, and Lonza manufactured additional sodium oxybate for us.

In April 2010, we entered into an agreement with a new supplier, Siegfried (USA) Inc., or Siegfried, in order to help ensure that we have an uninterrupted supply of sodium oxybate. However, the FDA must approve Siegfried as a new supplier of sodium oxybate. As part of the transition to Siegfried, we are also expecting to transition to a new supplier for the precursor of sodium oxybate. Siegfried is conducting the necessary activities and plans to seek FDA approval as a supplier of sodium oxybate as soon as possible. We expect Siegfried to be approved by the FDA as a supplier by the second half of 2011 but we cannot be certain that this will occur.

Lonza has advised us that it is selling its plant to a third party that intends to operate the plant as a manufacturing facility. We have had initial discussions with the third party concerning the possibility of the plant being a source of supply of sodium oxybate for us, but no agreement has been reached.

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

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2009. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

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Results of Operations

Comparison of Three and Nine Months Ended September 30, 2010 and 2009

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease)
	2010	2009			2010	2009		
	(In thousands)				(In thousands)			
Product sales, net	$ 43,838	$ 29,992	$ 13,846	46%	$ 117,649	$ 77,789	$ 39,860	51%
Xyrem	37,231	25,038	12,193	49%	99,699	65,119	34,580	53%
Luvox CR	6,607	4,954	1,653	33%	17,950	12,670	5,280	42%
Royalties, net	630	532	98	18%	1,909	1,522	387	25%
Contract revenues	285	285		0%	854	10,854	(10,000)	N/A (1)
Cost of product sales (excluding amortization of acquired developed technology)	3,091	2,338	753	32%	8,775	6,856	1,919	28%
Research and development	7,317	7,644	(327)	(4%)	21,494	30,244	(8,750)	(29%)
Selling, general and administrative	18,040	15,061	2,979	20%	51,926	42,934	8,992	21%
Amortization of intangible assets	1,862	2,057	(195)	(9%)	5,963	5,611	352	6%
Interest income	1	2	(1)	(50%)	5	29	(24)	(83%)
Interest expense	1,197	5,384						