

# ACORDA THERAPEUTICS INC

## FORM 10-Q (Quarterly Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2009

OR

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-50513

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**ACORDA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of Incorporation)

**13-3831168**  
(I.R.S. Employer  
Identification Number)

**15 Skyline Drive  
Hawthorne, New York 10532  
(914) 347-4300**

(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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

(Do not check if a  
smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

<u>Class</u>	<u>Outstanding at October 31, 2009</u>
Common Stock, \$0.001 par value	38,120,149 shares
per share	

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**ACORDA THERAPEUTICS, INC.**

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*This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this report and in the "Risk Factors" section in our Annual Report on Form 10-K for the year ended December 31, 2008, and our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2009 and June 30, 2009, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not assume any obligation to update any forward-looking statements.*

## PART I

## Item 1. Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

	September 30, 2009 (unaudited)	December 31, 2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 25,707,978	\$ 29,612,916
Restricted cash	300,515	297,655
Short-term investments	266,705,723	216,435,416
Trade accounts receivable, net	4,245,849	4,622,486
Prepaid expenses	4,054,092	3,330,069
Finished goods inventory held by the Company	3,414,607	3,670,949
Finished goods inventory held by others	2,360,821	2,472,692
Other current assets	4,530,303	1,605,572
Total current assets	311,319,888	262,047,755
Property and equipment, net of accumulated depreciation	3,343,837	2,348,147
Intangible assets, net of accumulated amortization	15,603,434	16,565,456
Non-current portion of deferred cost of license revenue	6,875,001	—
Other assets	454,807	539,328
Total assets	\$ 337,596,967	\$ 281,500,686
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,642,848	\$ 10,124,840
Accrued expenses and other current liabilities	12,288,791	13,993,753
Deferred product revenue—Zanaflex tablets	8,202,933	7,867,046
Deferred product revenue—Zanaflex Capsules	18,922,955	16,436,474
Current portion of deferred license revenue	9,428,571	—
Current portion of revenue interest liability	6,402,048	6,181,100
Total current liabilities	64,888,146	54,603,213
Non-current portion of deferred license revenue	98,214,285	—
Put/call liability	412,500	337,500
Non-current portion of revenue interest liability	10,745,172	12,497,745
Long-term convertible notes payable	7,060,241	6,904,883
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at September 30, 2009 and December 31, 2008; issued and outstanding 37,783,586 and 37,613,356 shares as of September 30, 2009 and December 31, 2008, respectively	37,784	37,614
Additional paid-in capital	561,846,272	550,683,383
Accumulated deficit	(405,843,291)	(344,376,410)
Accumulated other comprehensive income	235,858	812,758
Total stockholders' equity	156,276,623	207,157,345
Total liabilities and stockholders' equity	\$ 337,596,967	\$ 281,500,686

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(unaudited)

	Three-month period ended September 30, 2009	Three-month period ended September 30, 2008	Nine-month period ended September 30, 2009	Nine-month period ended September 30, 2008
Gross sales—Zanaflex	\$ 14,463,303	\$ 13,666,496	\$ 43,834,948	\$ 39,441,848
Less: discounts and allowances	(1,606,126)	(1,224,065)	(5,959,234)	(4,153,070)
Net sales	12,857,177	12,442,431	37,875,714	35,288,778
License revenue	2,357,144	—	2,357,144	—
Grant revenue	—	23,097	—	76,022
Total net revenue	15,214,321	12,465,528	40,232,858	35,364,800
Less: cost of sales	(2,602,064)	(2,700,772)	(8,112,490)	(8,516,743)
Less: cost of license revenue	(164,999)	—	(164,999)	—
Gross profit	12,447,258	9,764,756	31,955,369	26,848,057
Operating expenses:				
Research and development	8,197,789	8,650,305	23,982,123	25,758,150
Sales and marketing	15,551,217	14,419,938	44,107,063	36,349,099
General and administrative	7,698,916	5,948,193	23,090,359	17,391,817
Total operating expenses	31,447,922	29,018,436	91,179,545	79,499,066
Operating loss	(19,000,664)	(19,253,680)	(59,224,176)	(52,651,009)
Other expense (net):				
Interest and amortization of debt discount expense	(704,229)	(873,838)	(3,703,552)	(5,002,014)
Interest income	314,000	1,239,144	1,478,996	3,505,296
Other income (expense)	—	32,612	5,365	38,630
Gain on fixed asset disposal	(38,914)	—	(23,514)	—
Total other expense (net)	(429,143)	397,918	(2,242,705)	(1,458,088)
Net loss	\$ (19,429,807)	(18,855,762)	\$ (61,466,881)	(54,109,097)
Net loss per share—basic and diluted	\$ (0.51)	\$ (0.53)	\$ (1.63)	\$ (1.65)
Weighted average common shares outstanding used in computing net loss per share—basic and diluted	37,749,920	35,265,445	37,700,747	32,723,694

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(unaudited)

	Nine-month period ended September 30, 2009	Nine-month period ended September 30, 2008
Cash flows from operating activities:		
Net loss	\$ (61,466,881)	\$ (54,109,097)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	2,686,000
Share-based compensation expense	8,885,986	7,096,851
Amortization of net premiums and discounts on short-term investments	3,399,860	(2,431,768)
Amortization of revenue interest issuance cost	78,242	82,464
Depreciation and amortization expense	2,074,183	2,509,431
(Gain) loss on put/call liability	75,000	(50,000)
Loss on disposal of property and equipment	23,514	—
Changes in assets and liabilities:		
Decrease in accounts receivable	376,637	249,030
(Increase) decrease in prepaid expenses and other current assets	(3,648,754)	236,157
Decrease in inventory held by the Company	823,951	2,786,920
Decrease (increase) in inventory held by others	111,871	(416,224)
Increase in non-current portion of deferred cost of license revenue	(6,875,001)	—
Decrease in other assets	6,279	49,570
(Decrease) increase in accounts payable, accrued expenses, other current liabilities	(2,778,130)	7,620,667
Increase in deferred license revenue	107,642,856	—
Increase (decrease) in deferred product revenue—Zanaflex tablets	335,887	(142,104)
Increase in deferred product revenue—Zanaflex Capsules	2,486,481	1,679,610
Restricted cash	(2,860)	(7,434)
Net cash provided by (used in) operating activities	51,549,121	(32,159,927)
Cash flows from investing activities:		
Purchases of property and equipment	(1,903,764)	(737,092)
Purchases of intangible assets	—	(5,000,000)
Purchases of short-term investments	(278,897,068)	(229,461,739)
Proceeds from maturities of short-term investments	224,650,000	127,300,000
Net cash used in investing activities	(56,150,832)	(107,898,831)
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	2,277,073	204,682,184
Repayments of revenue interest liability	(1,580,300)	(1,460,948)
Repayments of notes payable	—	(187,645)
Net cash provided by financing activities	696,773	203,033,591
Net (decrease) increase in cash and cash equivalents	(3,904,938)	62,974,833
Cash and cash equivalents at beginning of period	29,612,916	16,810,415
Cash and cash equivalents at end of period	<u>\$ 25,707,978</u>	<u>\$ 79,785,248</u>
Supplemental disclosure:		
Cash paid for interest	3,158,931	3,379,794
Non-cash activities:		
Accrued inventory	567,609	2,100,213
Accrued property and equipment	209,349	—

See accompanying Unaudited Notes to Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements**

**(unaudited)**

**(1) Organization and Business Activities**

Acorda Therapeutics, Inc. ("Acorda" or the "Company") is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis (MS), spinal cord injury and other disorders of the central nervous system (CNS).

The management of the Company is responsible for the accompanying unaudited interim consolidated financial statements and the related information included in the notes to the consolidated financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, including normal recurring adjustments necessary for the fair presentation of the Company's financial position and results of operations and cash flows for the periods presented. Results of operations for interim periods are not necessarily indicative of the results to be expected for the entire year.

These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company as of and for the year ended December 31, 2008 included in the Company's Annual Report on Form 10-K for such year, as filed with the Securities and Exchange Commission (the SEC).

The Company finances its operations through a combination of issuance of equity securities, revenues from Zanaflex Capsules, collaboration and licensing agreements, loans and, to a lesser extent, grants. There are no assurances that the Company will be successful in obtaining an adequate level of financing needed to fund its development and commercialization efforts. To the extent the Company's capital resources are insufficient to meet future operating requirements, the Company will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund its operations. The Company may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, the Company may be required to curtail its sales and marketing efforts, delay, reduce the scope of or eliminate some of its research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that it might otherwise seek to develop or commercialize independently.

**(2) Summary of Significant Accounting Policies**

*Principles of Consolidation*

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America and include the results of operations of the Company and its majority owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include research and development and share-based

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

**(unaudited)**

**(2) Summary of Significant Accounting Policies (Continued)**

compensation accounting, which are largely dependent on the fair value of the Company's equity securities. In addition, the Company recognizes revenue based on estimated prescriptions filled. The Company adjusts its inventory value based on an estimate of inventory that may be returned. Actual results could differ from those estimates.

***Revenue Recognition***

The Company applies the revenue recognition guidance in Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When the Right of Return Exists*, [Accounting Standards Codification (ASC) 605-15-25], which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules. Zanaflex Capsules has limited historical return data. Due to the uncertainty of returns for both products, the Company is accounting for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the cost basis of the product held by the wholesaler as a component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized is based on (1) the estimated prescription demand, based on pharmacy sales for its products; and (2) the Company's analysis of third-party information, including third-party market research data. The Company's estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition reflects the Company's estimates of actual product prescribed to the end-user. The Company expects to be able to apply a more traditional revenue recognition policy such that revenue is recognized upon shipment to the customer when it has sufficient data to develop reasonable estimates of expected returns based upon historical returns.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. Product shipping and handling costs are included in cost of sales. These reserves are recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*, [ASC 605-50-55], which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement. At the time product is shipped to wholesalers, an adjustment is recorded for estimated chargebacks, rebates, and discounts. These reserves are established by management as its best estimate based on available information and are adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebates, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. In addition, the Company records a charge to cost of goods sold for the cost basis of the estimated product returns the Company believes may ultimately be realized at the time of product shipment to wholesalers. The Company has recognized this charge at the date of shipment since it is probable that it will receive a level of

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

**(unaudited)**

**(2) Summary of Significant Accounting Policies (Continued)**

returned products; upon the return of such product it will be unable to resell the product considering its expiration dating; and it can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns.

The Company recognizes collaboration revenues and expenses by analyzing each element of the agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

***Concentration of Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of investments in cash and cash equivalents, restricted cash and accounts receivable. The Company maintains cash and cash equivalents and restricted cash with approved financial institutions. The Company is exposed to credit risks and liquidity risks in the event of default by the financial institutions or issuers of investments in excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution.

***Earnings per Share***

Net loss per share is computed in accordance with SFAS No. 128, *Earnings Per Share*, [ASC 260-10-55], by dividing the net loss by the weighted average number of shares of common stock outstanding. The Company has certain options, restricted stock and a convertible promissory note which have not been used in the calculation of diluted net loss per share because to do so would be anti-dilutive. As such, the numerator and the denominator used in computing both basic and diluted net loss per share for each year are equal.

***Segment Information***

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product candidates or by location and does not have separately reportable segments as defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, [ASC 280-10-50].

***Recent Accounting Pronouncements***

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. This standard replaces SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, and establishes only two levels of U.S. generally

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

**(unaudited)**

**(2) Summary of Significant Accounting Policies (Continued)**

accepted accounting principles (GAAP), authoritative and nonauthoritative. The FASB Accounting Standards Codification (the Codification) will become the single source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become nonauthoritative. This standard is effective for financial statements for interim or annual reporting periods ending after September 15, 2009. The Company has begun to use the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it is not expected to have any impact on the Company's consolidated financial statements.

***Subsequent Events***

Effective June 30, 2009, the Company implemented SFAS No. 165, *Subsequent Events* [ASC 855-10-50]. The Company evaluated all events or transactions that occurred after September 30, 2009 up through November 6, 2009, the date the Company issued these financial statements. During this period the Company did not have any material recognizable or nonrecognizable subsequent events.

**(3) Share-based Compensation**

The Company accounts for share-based compensation, including options and nonvested shares, according to the provisions of SFAS No. 123R, *Share-Based Payment*, [ASC 718-50-30]. During the three-month periods ended September 30, 2009 and 2008, the Company recognized share-based compensation expense of \$3.2 million and \$2.7 million, respectively. During the nine-month periods ended September 30, 2009 and 2008, the Company recognized share-based compensation expense of \$8.9 million and \$7.1 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2009 and related balances outstanding as of that date are reflected below. The weighted average fair value per share of options granted to employees for the three-month periods ended September 30, 2009 and 2008 were approximately \$16.75 and \$18.30, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2009 and 2008 were approximately \$17.59 and \$20.91, respectively.

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

(unaudited)

**(3) Share-based Compensation (Continued)**

A summary of share-based compensation activity for the nine-month period ended September 30, 2009 is presented below:

*Stock Option Activity*

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Intrinsic Value</u>
Balance at January 1, 2009	3,284,323	\$ 13.55		
Granted	793,888	21.90		
Cancelled	(197,543)	16.82		
Exercised	(170,230)	13.38		
Balance at September 30, 2009	3,710,438	\$ 15.17	7.3	\$ 31,347,756
Vested and expected to vest at September 30, 2009	3,622,900	\$ 15.01	7.2	\$ 31,126,223
Vested and exercisable at September 30, 2009	2,145,161	\$ 11.24	6.2	\$ 26,092,714

*Restricted Stock Activity*

<u>Restricted Stock</u>	<u>Number of Shares</u>
Nonvested at January 1, 2009	150,163
Granted	208,291
Vested	—
Forfeited	(25,477)
Nonvested at September 30, 2009	332,977

As of September 30, 2009, there was \$23.0 million of total unrecognized compensation costs related to unvested options and restricted stock awards that the Company expects to recognize over a weighted average period of approximately 2.4 years.

**(4) Income Taxes**

The Company had available net operating loss carry-forwards (NOL) of approximately \$216.5 million and \$262.2 million as of September 30, 2009 and December 31, 2008, respectively, for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2010 and 2028. The Company also has research and development tax credit carryforwards of approximately \$1.6 million as of both September 30, 2009 and December 31, 2008, for federal income tax reporting purposes that are available to reduce federal income taxes, if any, and expire in future years beginning in 2018.

At September 30, 2009 and December 31, 2008, the Company had a deferred tax asset of \$139.4 million and \$119.5 million, respectively, offset by a full valuation allowance. Since inception, the

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

(unaudited)

**(4) Income Taxes (Continued)**

Company has incurred substantial losses and expects to incur substantial losses in future periods. The Tax Reform Act of 1986 (the Act) provides for a limitation of the annual use of NOL and research and development tax credit carryforwards (following certain ownership changes, as defined by the Act) that could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes. Because of the above mentioned factors, the Company has not recognized its gross deferred tax assets as of and for all periods presented. As of September 30, 2009, management believes that it is more likely than not that the gross deferred tax assets will not be realized based on future operations and reversal of deferred tax liabilities. Accordingly, the Company has provided a full valuation allowance against its gross deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

**(5) Fair Value Measurements**

The following table presents information about our assets and liabilities measured at fair value on a recurring basis as of September 30, 2009 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability. The Company's Level 1 assets consist of time deposits and investments in a Treasury money market fund and high-quality government bonds. The Company's Level 3 liability represents our put/call liability related to the Paul Royalty Fund (PRF) transaction.

	Level 1	Level 2	Level 3
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 18,948,149	\$ —	\$ —
Short-term investments	266,705,723	—	—
<b>Liabilities Carried at Fair Value:</b>			
Put/call liability	—	—	412,500

The following table presents additional information about assets and/or liabilities measured at fair value on a recurring basis and for which the Company utilizes Level 3 inputs to determine fair value.

	Balance as of December 31, 2008	Realized gains (losses) included in net loss	Unrealized losses included in other comprehensive loss	Balance as of September 30, 2009
<b>Liabilities Carried at Fair Value:</b>				
Put/call liability	\$ 337,500	\$ (75,000)	\$ —	\$ 412,500

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

(unaudited)

**(5) Fair Value Measurements (Continued)**

The Company evaluates fair value of positions classified within the Level 3 category based on revenue projections, business, general economic and market conditions that could be reasonably evaluated as of the valuation date.

**(6) Short-Term Investments**

The Company has accounted for its investments in accordance with SFAS No. 115, [ASC 320-10-25], and determined that all of its short-term investments are classified as available-for-sale. Available-for-sale securities are carried at fair value with interest on these securities included in interest income. Available-for-sale securities consisted of the following:

	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
September 30, 2009				
US Treasury bonds	\$ 266,469,865	\$ 236,351	\$ (493)	\$ 266,705,723
December 31, 2008				
Commercial paper	\$ 119,302,891	\$ 585,564	\$ —	\$ 119,888,455
US Treasury bonds	96,319,767	228,848	(1,654)	96,546,961

The contractual maturities of available-for-sale debt securities at September 30, 2009 and December 31, 2008 are within one year. The Company has determined that there were no other-than-temporary declines in the fair values of its short term investments as of September 30, 2009. Short-term investments with maturity of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$18,948,149 and \$27,283,767 as of September 30, 2009 and December 31, 2008, respectively.

**(7) Collaboration Agreement**

On June 30, 2009, the Company entered into an exclusive collaboration and license agreement with Biogen Idec International GmbH (Biogen Idec) to develop and commercialize Fampridine-SR in markets outside the United States (the Collaboration Agreement). Under the Collaboration Agreement, Biogen Idec was granted the exclusive right to commercialize Fampridine-SR and other products containing aminopyridines developed under that agreement in all countries outside of the United States, which grant includes a sublicense of the Company's rights under an existing license agreement between the Company and Elan Pharma International Limited, a subsidiary of Elan Corporation plc (Elan). Biogen Idec will have responsibility for regulatory activities and future clinical development of Fampridine-SR in ex-U.S. markets worldwide. The Company also entered into a related supply agreement with Biogen Idec (the Supply Agreement), pursuant to which the Company will supply Biogen Idec with its requirements for the licensed products through the Company's existing supply agreement with Elan.

Under the Collaboration Agreement, the Company was entitled to an upfront payment of \$110.0 million as of June 30, 2009, which was received on July 1, 2009, and will be entitled to receive additional payments of up to approximately \$400 million based on the successful achievement of future regulatory and sales milestones. Due to the uncertainty surrounding the achievement of the future

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

**(unaudited)**

**(7) Collaboration Agreement (Continued)**

regulatory and sales milestones, these payments will not be recognized as revenue unless and until they are earned. The Company is not able to reasonably predict if and when the milestones will be achieved. Under the Collaboration Agreement, Biogen Idec will be required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. In addition, the consideration that Biogen Idec will pay for licensed products under the Supply Agreement will reflect the price owed to the Company's suppliers under its supply arrangements with Elan or other suppliers for ex-U.S. sales, including manufacturing costs and royalties owed. The Company and Biogen Idec may also carry out future joint development activities regarding licensed product under a cost-sharing arrangement. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen Idec, will participate in overseeing the development and commercialization of Fampridine-SR and other licensed products in markets outside the United States pursuant to that agreement. Acorda will continue to develop and commercialize Fampridine-SR independently in the United States.

As of June 30, 2009, the Company recorded a license receivable and deferred revenue of \$110.0 million for the upfront payment due to the Company from Biogen Idec under the Collaboration Agreement. Also, as a result of such payment to Acorda, a payment of \$7.7 million became payable by Acorda to Elan and was recorded as a cost of license payable and deferred expense. The payment of \$110.0 million was received from Biogen Idec on July 1, 2009 and the payment of \$7.7 million was made to Elan on July 7, 2009. The granting of the sublicense to Biogen Idec and the Company's continued activities under the Collaboration Agreement are treated as a single unit of accounting for revenue recognition purposes. As a result, the Company will recognize the non-refundable upfront payment from Biogen Idec as revenue and the associated payment to Elan as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement. The Company recognized \$2.4 million in license revenue, a portion of the \$110.0 million received from Biogen Idec and \$165,000 in cost of license revenue, a portion of the \$7.7 million paid to Elan during the three-month period ended September 30, 2009. The Company currently estimates the recognition period to be approximately 12 years.

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

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q.

### **Background**

Since we commenced operations in 1995, we have devoted substantially all of our resources to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis (MS), spinal cord injury (SCI) and other disorders of the central nervous system (CNS). Our marketed drug, Zanaflex Capsules, is U.S. Food and Drug Administration (FDA)-approved for the management of spasticity.

We announced positive results from a Phase 3 clinical trial of our lead product candidate, Fampridine-SR, for the improvement of walking ability in people with MS in September 2006. A second Phase 3 trial of Fampridine-SR in MS, MS-F204, was initiated in June 2007 and favorable results from that study were released in June 2008. The objective of this study was to show that individuals treated with Fampridine-SR are significantly more likely to have consistent improvements in their walking than those treated with placebo. A Thorough QT cardiac study was initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential of Fampridine-SR to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and supratherapeutic doses, was found to be no different than placebo.

On January 30, 2009, we announced the submission of a New Drug Application (NDA) to the FDA for Fampridine-SR. The Fampridine-SR NDA submission is based on data from a comprehensive development program assessing the safety and efficacy of Fampridine-SR, including two Phase 3 trials that involved 540 people with MS and were conducted under Special Protocol Assessments (SPAs) from the FDA. The safety and efficacy profile of Fampridine-SR was consistent across Phase 2 and Phase 3 trials. Overall, the NDA filing included more than 50 clinical studies of Fampridine-SR. As of June 30, 2009, 177 subjects from MS-F202 had been enrolled in an extension trial and 84, or approximately 47%, remained active in the trial, with duration of treatment of active patients ranging from 3.4 to 5.3 years. As of the same date, 269 patients from MS-F203 had been enrolled in a separate extension study and 180 of these, or approximately 66.9%, remained active, with duration of treatment of active patients ranging from 1.1 to 3.6 years. Also, as of this same date, 214 patients from MS-F204 had been enrolled in a third extension study and 176, or approximately 82%, remained active, with duration of treatment of active patients ranging from 14.3 months to 22.4 months. The total exposure to Fampridine-SR in our MS studies as of June 30, 2009, including both double-blind and open label studies, is approximately 1,750 patient-years.

We announced the receipt of a refuse to file letter (RTF) from the FDA on March 31, 2009 regarding our NDA for Fampridine-SR. The FDA raised what it termed "format issues" regarding the eCTD (electronic) submission, requesting that some of the data in the NDA be reformatted, as well as requesting that some additional supporting information and pharmacokinetic data from a fed/fasted study be included in the filing. The FDA did not request or recommend additional clinical or other studies.

We announced the resubmission of our NDA for Fampridine-SR to the FDA on April 23, 2009. On May 6, 2009, we announced that the FDA had accepted our NDA for filing, and had assigned it Priority Review and a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009. The PDUFA date is the target date for the FDA to complete its review of the Fampridine-SR NDA.

We announced notification by the European Medicines Agency (EMA) that Fampridine-SR is eligible to be submitted for a Marketing Authorization Application (MAA) via the Agency's

Centralized Procedure on June 8, 2009. The Centralized Procedure provides for a single, coordinated review that is conducted by the EMEA on behalf of all European Union (EU) member states. The EMEA also designated Fampridine-SR as a New Active Substance (NAS); if approved, compounds designated as an NAS receive a 10-year market exclusivity period in EU member states.

On October 14, 2009 the FDA Peripheral and Central Nervous System Drugs (PCNSD) Advisory Committee voted 12 to 1 that clinical data on Fampridine-SR 10 mg twice daily demonstrated substantial evidence of effectiveness as a treatment to improve walking in people with MS and voted 10 to 2 (1 abstention) that it is clinically meaningful and can be safe for use. The PCNSD Advisory Committee also recommended by a vote of 12 to 1 that we be required to evaluate the effects of doses lower than 10 mg twice daily, but by a 10 to 2 vote (1 abstention) that these studies not be required prior to approval. At the request of the FDA, the PCNSD Advisory Committee also discussed possible conditions for use, including for patients with renal impairment or history of seizure. Acorda has proposed a Risk Evaluation and Mitigation Strategy (REMS) program, which could include healthcare professional and patient education around appropriate use of Fampridine-SR. The FDA can seek the advice of an advisory committee such as the PCNSD Advisory Committee when evaluating a potential new treatment, but it is not required to follow its recommendation.

Following the PCNSD Advisory Committee meeting on Fampridine-SR, we submitted additional information on our proposed Risk Evaluation and Mitigation Strategy (REMS) program, which could include healthcare professional and patient education around appropriate use of Fampridine-SR. The FDA accepted this submission as a solicited major amendment to the Fampridine-SR NDA. The FDA has the option to extend the PDUFA date when a sponsor submits a major amendment that provides a substantial amount of new data not previously reviewed by the FDA. On October 21, 2009 the FDA extended the PDUFA date for its review of the NDA for Fampridine-SR to January 22, 2010.

On June 30, 2009, we entered into a Collaboration and License Agreement (Collaboration Agreement) with Biogen Idec International GmbH (Biogen Idec), a Swiss subsidiary of Biogen Idec Inc. Under the Collaboration Agreement, Acorda and Biogen Idec have agreed to collaborate on the development and commercialization of products containing aminopyridines, including Fampridine-SR, initially directed to the treatment of multiple sclerosis. The Collaboration Agreement includes a sublicense of our rights under an existing license agreement with Elan. We have also entered into a related supply agreement (Supply Agreement) pursuant to which we will supply Biogen Idec with its requirements for the licensed products through our existing supply agreement with Elan. Biogen Idec Inc. has guaranteed the performance of Biogen Idec's obligations under the Collaboration Agreement and the Supply Agreement.

Under the Collaboration Agreement, Biogen Idec, itself or through its affiliates, has the exclusive right to commercialize licensed products in all countries outside of the United States, while we retain the right to commercialize licensed products in the United States. Each party will have the exclusive right to develop licensed products for its commercialization territory, although the parties may also decide to jointly carry out mutually agreed future development activities under a cost-sharing arrangement. If Biogen Idec does not participate in the development of licensed products for certain indications or forms of administration, it may lose the right to develop and commercialize the licensed products for such indication or form of administration. Biogen Idec may sublicense its rights to certain unaffiliated distributors. During the term of the Collaboration Agreement and for two years after the Collaboration Agreement terminates, neither party nor its affiliates may, other than pursuant to the Collaboration Agreement, research, develop, manufacture or commercialize any competing product, defined as one that contains aminopyridine or any other compound that acts at least in part through direct interaction with potassium channels to improve neurological function in multiple sclerosis, spinal cord injury or other demyelinating conditions, except that we may exploit the licensed products anywhere in the world following termination of the Collaboration Agreement.

In consideration for the rights granted to Biogen Idec under the Collaboration Agreement, we were entitled to a non-refundable upfront payment of \$110.0 million as of June 30, 2009, which was received on July 1, 2009. Also, as a result of such payment to us, a payment of \$7.7 million became payable by us to Elan. We currently estimate the revenue recognition period to be approximately 12 years. The Company recognized \$2.4 million in license revenue related to the \$110.0 million received from Biogen Idec and \$165,000 in cost of license revenue related to the \$7.7 million paid to Elan during the three-month period ended September 30, 2009. We are also eligible to receive up to \$400 million from Biogen Idec should specified regulatory and sales milestones be met. There can be no guarantee that any such milestones will in fact be met.

Under the Collaboration Agreement, we will also be entitled to receive double-digit tiered royalties on sales of licensed products by Biogen Idec, its affiliates or certain distributors outside of the United States. Such royalties for products combining a licensed compound with at least one other clinically active therapeutic, prophylactic or diagnostic ingredient are determined based on the contribution of the licensed compound to the overall sales or value of the combination product. Biogen Idec may offset against the royalties payable to us a portion of certain royalties which it may need to pay to third parties. In addition, Biogen Idec will pay us, in consideration for its purchase and sale of the licensed products, any amounts due to Elan for ex-U.S. sales, including royalties owed under the terms of our previous agreements with Elan.

Biogen Idec will exclusively purchase all of Biogen Idec's, its affiliates' and its sublicensees' requirements of the licensed products from us. The purchase price paid by Biogen Idec for licensed products under the Collaboration Agreement and Supply Agreement reflects the prices owed to our suppliers under our supply arrangements with Elan or other suppliers.

The Collaboration Agreement will terminate upon the expiration of Biogen Idec's royalty payment obligations, which occurs, on a licensed product-by-licensed product and country-by-country basis, upon the latest of expiration of the last-to-expire patent covering a licensed product, fifteen years following first commercial sale of such licensed product, the expiration of regulatory exclusivity and the existence of certain levels of sales by competing products. The Collaboration Agreement and the Supply Agreement will automatically terminate upon the termination of our license agreement with Elan in its entirety or with respect to all countries outside of the United States. We cannot terminate our license agreement with Elan without Biogen Idec's prior written consent under certain circumstances. Biogen Idec may terminate the Collaboration Agreement in its entirety or on a country-by-country basis at any time upon 180 days' prior written notice, subject to our right to accelerate such termination. The Collaboration Agreement may also be terminated by either party if the other party fails to cure a material breach under the agreement, which termination will be limited to a particular country or region under certain circumstances. However, if Biogen Idec has the right to terminate the Collaboration Agreement due to our material uncured breach, Biogen Idec may instead elect to keep the agreement in effect, but decrease the royalty rates they pay us by a specified percentage. We may also terminate the Collaboration Agreement if Biogen Idec does not commercially launch a licensed product within a specified time period after receiving regulatory approval for such licensed product or otherwise fails to meet certain commercialization obligations. In addition, we may terminate the Collaboration Agreement under certain circumstances if (i) Biogen Idec, its affiliates or its sublicensees challenge certain of our patents or (ii) there is a change in control of Biogen Idec or its parent company or certain dispositions of assets by Biogen Idec, its parent or its affiliated companies, followed by a change in the sales and marketing personnel responsible for the licensed products in Biogen Idec's territory of more than a specified percentage within a certain period of time after such change in control or disposition. The Supply Agreement may be terminated by either party if the other party fails to cure a material breach under the Supply Agreement. In addition, the Supply Agreement will terminate automatically upon termination of the Collaboration Agreement, and the Collaboration Agreement will terminate automatically if the Supply Agreement is terminated for any reason other than for a material breach that we are responsible for. To the extent permitted by law, each party may

terminate the Collaboration Agreement and the Supply Agreement if the other party is subject to bankruptcy proceedings.

If the Supply Agreement is terminated by Biogen Idec for an uncured material breach, we will waive our right for Elan to exclusively supply the licensed products to us solely to permit Biogen Idec to negotiate terms with Elan for the supply of licensed products to Biogen Idec. If the Supply Agreement is otherwise terminated, Biogen Idec will not have any future obligations to purchase licensed products from us and we will not have any future obligations to supply Biogen Idec with licensed products. If the Collaboration Agreement is terminated, Biogen Idec will assign to us all regulatory documentation and other information necessary or useful to exploit the licensed products in the terminated countries and will grant us a license under Biogen Idec's and its affiliates' relevant patent rights, know-how and trademarks to exploit the licensed products in the terminated countries. Such assignment and license will be at no cost to us unless the Collaboration Agreement is terminated by Biogen Idec for a material uncured breach that we are responsible for, in which case the parties will negotiate a payment to Biogen Idec to reflect the net value of such assigned and licensed rights.

Neither party may assign the agreements without the prior written consent of the other, except to an affiliate or, in certain cases, to a third party acquirer of the party.

In connection with the entry into the Collaboration Agreement, Acorda, Biogen Idec and Elan entered into a consent agreement (the Consent). Under the Consent, Elan consented to our sublicense of rights to Biogen Idec, and Acorda, Biogen Idec and Elan agreed to set up a committee to coordinate activities under the agreements between Acorda and Elan with respect to the development, supply and commercialization of the licensed products for Biogen Idec's territory. The Consent also amends our agreements with Elan by, among other things, permitting us to allow Biogen Idec to grant sublicenses to certain unaffiliated distributors, permitting us to allow Biogen Idec to package the licensed products and requiring Elan to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

Biogen, which is responsible under the Collaboration Agreement for the filing of the MAA, has announced that it plans to file with the EMEA in early 2010.

We believe Fampridine-SR is the first potential therapy in late-stage clinical development for MS that seeks to improve the function of damaged nerve fibers and, if approved, could be complementary to existing drugs used to treat MS. To our knowledge, there are no current therapies indicated to improve walking ability in people with MS.

We have three preclinical programs focused on novel approaches to repair damaged components of the CNS. We believe all of our preclinical programs—neuregulins, remyelinating antibodies and chondroitinase—have broad applicability and have the potential to be first-in-class therapies. While these programs have initially been focused on MS and SCI, we believe they may be applicable across a number of CNS disorders, including stroke and traumatic brain injury, because many of the mechanisms of tissue damage and repair are similar. In addition, we believe that these programs may have applicability beyond the nervous system, including in such fields as cardiology, oncology, orthopedics and ophthalmology. In 2008, we began to work with a contract manufacturer to develop larger scale manufacturing and purification processes for one of the neuregulins, GGF2, under good manufacturing practices (cGMP) in preparation for a potential future Investigational New Drug (IND) application to support human clinical trials for the treatment of congestive heart failure (CHF). Acorda and the FDA held a pre-IND meeting to discuss an IND filing for CHF. Based on feedback from the FDA, we now expect to file an IND in early 2010 pending final results of animal toxicology and other preclinical activities. If we are able to establish a proof of concept for treatment of CHF through human clinical studies, we believe that this may enable us to enter into a partnership with a cardiovascular-focused company, and that such a partnership, if achieved, could more efficiently move GGF2 forward in a cardiac indication, while potentially providing us the capital to support our work on GGF2 in neurological indications. We have also begun work with contract manufacturers to scale up

manufacturing and purification processes for one of the remyelinating antibodies (rHIgM22) under cGMPs for preparation for a future IND application.

Our marketing efforts are focused on Zanaflex Capsules, which we launched in April 2005. Zanaflex tablets lost compound patent protection in 2002 and both Zanaflex Capsules and Zanaflex tablets compete with 12 generic tizanidine products. Although we currently distribute Zanaflex tablets, we do not, and do not intend to, actively promote Zanaflex tablets. As a result, prescriptions for Zanaflex tablets have declined and we expect that they will continue to decline. Our goal is to convert as many sales of Zanaflex tablets and generic tizanidine tablets to sales of Zanaflex Capsules as possible. We believe that sales of Zanaflex Capsules will constitute a significant portion of our total revenue until we begin to generate sales of Fampridine-SR, if approved. Zanaflex Capsules and tablets commercial operations were cash flow positive in 2008. A slight downward trend in prescriptions was observed over the first three quarters of 2009.

We are conducting prelaunch activities to prepare for the commercialization of Fampridine-SR, if approved.

We also are conducting activities to provide disease state education and awareness programs to health-care providers and consumers about mobility and walking impairment issues for people with MS. For health-care providers, these activities include a disease state awareness booth at major medical meetings, a physician direct mail campaign and advertisements in medical publications. For consumers, these activities include a booth at consumer events, an online website ([moveoverms.org](http://moveoverms.org)), and advertisements in publications.

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it filed an Abbreviated New Drug Application (ANDA) with the FDA for generic versions of each of the three Zanaflex Capsules dosage strengths marketed by us. In response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) in the United States District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules. The patent expires in 2021. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We have denied those counterclaims. If the ANDA were approved by the FDA and Apotex were successful in challenging the validity of the patent, Apotex could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules.

In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing our request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex's motion in December 2008. Fact discovery in the case has been completed. The court has also determined that a Markman hearing on the construction of certain terms contained in the patent will be held, and the parties have completed related depositions and submission of the briefs to the Court. The hearing was set for November 18, 2009 but the Court has postponed it without yet setting a new date. Apotex has filed a motion to exclude certain evidence from consideration at the hearing, which we have opposed.

We have established our own specialty sales force in the United States, which consisted of 73 sales professionals and account management as of September 30, 2009, including approximately 52 sales representatives. This sales force has targeted neurologists and other prescribers who specialize in treating people with conditions that involve spasticity. We also employ an internal and field-based team who call on managed care organizations, pharmacists and distribution customers. In addition, we retain TMS Professional Markets Group, LLC to provide a small, dedicated sales force of pharmaceutical telesales professionals who contact primary care, specialist physicians and pharmacists. We expect to double our sales representatives to approximately 100 people, in anticipation of and in time for the launch of Fampridine-SR, if approved.

## Results of Operations

### *Three-Month Period Ended September 30, 2009 Compared to September 30, 2008*

#### *Gross Sales*

We recognize product sales using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$14.5 million for the three-month period ended September 30, 2009, as compared to \$13.7 million for the three-month period ended September 30, 2008. The increase was due to a 10% price increase effective January 1, 2009. A slight downward trend in prescriptions was observed over the first three quarters of 2009.

#### *Discounts and Allowances*

We recorded discounts and allowances of \$1.6 million for the three-month period ended September 30, 2009 as compared to \$1.2 million for the three-month period ended September 30, 2008. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the three-month period ended September 30, 2009 consisted of \$785,000 in fees for services payable to wholesalers, \$597,000 in allowances for chargebacks and rebates and \$225,000 in cash discounts and patient program rebates. Discounts and allowances for the three-month period ended September 30, 2008 consisted of \$651,000 in fees for services payable to wholesalers, \$449,000 in allowances for chargebacks and rebates, and \$124,000 in cash discounts and patient program rebates.

#### *Grant Revenue*

We earned no grant revenue for the three-month period ended September 30, 2009 compared to \$23,000 for the three-month period ended September 30, 2008. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

#### *Cost of Sales*

We recorded cost of sales of \$2.6 million for the three-month period ended September 30, 2009 as compared to \$2.7 million for the three-month period ended September 30, 2008. Cost of sales for the three-month period ended September 30, 2009 consisted of \$1.4 million in inventory costs primarily related to recognized revenues, \$878,000 in royalty fees based on net product shipments, \$321,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$50,000 in period costs related to freight and stability testing. Cost of sales for the three-month period ended September 30, 2008 consisted of \$1.3 million in inventory costs primarily related to recognized revenues, \$741,000 in royalty fees based on net product shipments, \$596,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$44,000 in period costs related to packaging, freight, and stability testing. Payments to and interest expense related to our Paul Royalty Fund (PRF) transaction discussed below in the section titled "Liquidity and Capital Resources" do not impact our cost of sales.

#### *Research and Development*

Research and development expenses for the three-month period ended September 30, 2009 were \$8.2 million as compared to \$8.7 million for the three-month period ended September 30, 2008, a decrease of approximately \$500,000, or 5%. The decrease was primarily attributable to a decrease in

regulatory expenses relating to Fampridine-SR of \$762,000 or 33% to \$1.5 million as well as a decrease in MS clinical development program expense of \$823,000 or 42% to \$1.1 million.

These decreases were offset by an increase in research and development expense of \$573,000 or 29% to \$2.6 million primarily related to work on one of our preclinical pipeline products, GGF2, including an increase in staff and compensation to support this initiative. This overall increase in expense was primarily associated with animal toxicology expenses and the development of larger scale manufacturing and purification processes for GGF2, under cGMP, in preparation for a potential future IND application to support human clinical trials. The overall decrease in research and development expense was also offset by an increase in clinical and regulatory staff and compensation of \$451,000 to support the overall growth of the organization and manufacturing and stability fees for Fampridine-SR of \$108,000.

#### *Sales and Marketing*

Sales and marketing expenses for the three-month period ended September 30, 2009 were \$15.6 million compared to \$14.4 million for the three-month period ended September 30, 2008, an increase of approximately \$1.1 million or 8%. This increase was primarily attributable to an increase of \$1.3 million in disease state education and awareness programs and pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved.

#### *General and Administrative*

General and administrative expenses for the three-month period ended September 30, 2009 were \$7.7 million compared to \$5.9 million for the three-month period ended September 30, 2008, an increase of approximately \$1.8 million, or 29%. This increase was the result of an increase in costs associated with medical affairs educational programs of \$983,000 and an increase in staff and compensation and other expenses of \$545,000 related to supporting the growth of the overall organization.

#### *Other Income (Expense)*

Other income (expense) was \$429,000 in expense for the three-month period ended September 30, 2009 compared to \$398,000 in income for the three-month period ended September 30, 2008, a decrease of approximately \$827,000 or 208%. The decrease was primarily due to a decrease in interest income of \$925,000 resulting from a lower average interest rate than for the same period in 2008. The decrease in interest income was partially offset by a \$170,000 decrease in interest expense principally related to the PRF revenue interest agreement.

#### ***Nine-Month Period Ended September 30, 2009 Compared to September 30, 2008***

#### *Gross Sales*

We recognize product sales using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$43.8 million for the nine-month period ended September 30, 2009, as compared to \$39.4 million for the nine-month period ended September 30, 2008. The increase was due to a 10% price increase effective January 1, 2009. A slight downward trend in prescriptions was observed over the first three quarters of 2009.

*Discounts and Allowances*

We recorded discounts and allowances of \$6.0 million for the nine-month period ended September 30, 2009 as compared to \$4.2 million for the nine-month period ended September 30, 2008. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the nine-month period ended September 30, 2009 consisted of \$2.8 million in allowances for chargebacks and rebates which includes a Tricare rebate reserve of \$990,000, of which \$351,000 is related to the first three quarters of 2009 and an adjustment of \$639,000 is related to 2008. These rebates and adjustments resulted from a Department of Defense (DOD) regulation finalized during the three-month period ended March 31, 2009 which purports to require manufacturers to pay rebates to DOD on utilization distributed to Tricare beneficiaries through retail pharmacies retroactive to January 28, 2008. The application of the regulation is currently being challenged in court by a coalition representing a number of manufacturers. Discounts and allowances for the nine-month period ended September 30, 2009 also consisted of \$2.0 million in fees for services payable to wholesalers and \$1.1 million in cash discounts and patient program rebates. Discounts and allowances for the nine-month period ended September 30, 2008 consisted of \$1.6 million in fees for services payable to wholesalers, \$1.5 million in allowances for chargebacks and rebates, and \$1.1 million in cash discounts and patient program rebates.

*Grant Revenue*

We earned no grant revenue for the nine-month period ended September 30, 2009 compared to \$76,000 for the nine-month period ended September 30, 2008. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

*Cost of Sales*

We recorded cost of sales of \$8.1 million for the nine-month period ended September 30, 2009 as compared to \$8.5 million for the nine-month period ended September 30, 2008. The decrease was principally due to the decrease in amortization of intangible assets resulting from having completed the amortization of the Zanaflex trademark portion of our intangible asset as of December 31, 2008. Cost of sales for the nine-month period ended September 30, 2009 consisted of \$4.2 million in inventory costs primarily related to recognized revenues, \$2.8 million in royalty fees based on net product shipments, \$962,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$152,000 in period costs related to freight and stability testing. Cost of sales for the nine-month period ended September 30, 2008 consisted of \$4.0 million in inventory costs primarily related to recognized revenues, \$2.5 million in royalty fees based on net product shipments, \$1.8 million in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$210,000 in period costs related to freight and stability testing. Payments to and interest expense related to our PRF transaction discussed below in the section titled "Liquidity and Capital Resources" do not impact our cost of sales.

*Research and Development*

Research and development expenses for the nine-month period ended September 30, 2009 were \$24.0 million as compared to \$25.8 million for the nine-month period ended September 30, 2008, a decrease of approximately \$1.8 million, or 7%. The decrease was primarily attributable to our acquisition of certain in-process research and development assets of Neurorecovery, Inc. (NRI) during the three-month period ended March 31, 2008, resulting in a one time non-cash expense of approximately \$2.7 million. In addition, MS clinical development program expense decreased \$3.3 million or 49% to \$3.5 million for the nine-month period ended September 30, 2009, primarily due

to the conclusion of our Phase 3 clinical trial of Fampridine-SR in 2008 as well as a decrease in regulatory expenses relating to Fampridine-SR of \$942,000 or 19% to \$3.9 million.

These decreases were offset by an increase in research and development expense of \$3.2 million or 65% primarily related to work on one of our preclinical pipeline products, GGF2, including an increase in staff and compensation to support this initiative. This overall increase in expense was primarily associated with animal toxicology expenses and the development of larger scale manufacturing and purification processes for GGF2, under cGMP, in preparation for a potential future IND application to support human clinical trials. The overall decrease in research and development expense was also offset by an increase in clinical and regulatory staff and compensation of \$1.6 million to support the overall growth of the organization and manufacturing and stability fees for Fampridine-SR of \$363,000. Research and development expense for the fourth quarter 2009 is not expected to differ materially from the third quarter 2009. If our GGF2 development program proceeds to clinical trials in 2010, there will be the potential for increased R&D costs next year.

#### *Sales and Marketing*

Sales and marketing expenses for the nine-month period ended September 30, 2009 were \$44.1 million compared to \$36.3 million for the nine-month period ended September 30, 2008, an increase of approximately \$7.8 million or 21%. This increase was primarily attributable to an increase of \$7.6 million in disease state education and awareness programs and pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved, and an increase in sales and marketing staff and compensation of \$799,000 to support the promotion of Zanaflex Capsules and Fampridine-SR pre-launch activities, offset by a decrease of \$203,000 in Zanaflex Capsules sales and marketing initiatives and a decrease in other selling related expenses of \$874,000. If Fampridine-SR is approved, we expect to see an increase in sales and marketing expenses in the launch year.

#### *General and Administrative*

General and administrative expenses for the nine-month period ended September 30, 2009 were \$23.1 million compared to \$17.4 million for the nine-month period ended September 30, 2008, an increase of approximately \$5.7 million, or 33%. This increase was the result of an increase in staff and compensation and other expenses of \$2.1 million related to supporting the growth of the overall organization, an increase in costs associated with medical affairs educational programs of \$2.1 million, an increase in legal fees of \$622,000 and an increase in business development expenses of \$465,000 related to our collaboration and licensing agreement efforts.

#### *Other Income (Expense)*

Other income (expense) was \$2.2 million of expense for the nine-month period ended September 30, 2009 compared to \$1.5 million of expense for the nine-month period ended September 30, 2008, an increase of approximately \$785,000 or 54%. This change was due to a decrease in interest expense of \$1.3 million resulting primarily from the impact of a \$1.4 million out-of-period adjustment made during the second quarter of 2008. The out-of-period adjustment was made to correct an error identified in the previously recorded effective interest expense recognized related to the November 2006 amended revenue interests assignment with PRF. This out-of-period adjustment did not increase the total interest expense associated with this agreement, but corrected its timing of recognition. The increase in other income (expense) was also attributable to a decrease in investment interest income of \$2.0 million resulting from a lower average interest rate than for the same period in 2008.

## Liquidity and Capital Resources

We have incurred annual operating losses since inception and, as of September 30, 2009, we had an accumulated deficit of approximately \$405.8 million. We have financed our operations primarily through private placements of our securities, public offerings of our common stock, our collaboration and licensing agreement, and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

### *Financing Arrangements*

In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. As of September 30, 2009, \$5.0 million of these promissory notes were outstanding.

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006 and an additional \$5.0 million in February 2007 as our net revenues during the fiscal year 2006 exceeded \$25.0 million. Under the terms of the amendment, we are required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010.

Under the agreement and the amendment, PRF is entitled to the following portion of Zanaflex net revenues:

- with respect to Zanaflex net revenues up to and including \$30.0 million for each fiscal year during the term of the agreement, 15% of such net revenues;
- with respect to Zanaflex net revenues in excess of \$30.0 million but less than and including \$60.0 million for each fiscal year during the term of the agreement, 6% of such net revenues; and
- with respect to Zanaflex net revenues in excess of \$60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF has received and retained payments under the agreement that are at least 2.1 times the aggregate amount PRF has paid us under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we have a liability recorded, referred to as the revenue interest liability, of approximately \$17.1 million. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 6.0%. Payments made to PRF as a result of Zanaflex sales levels reduce the accrued interest liability and the principal amount of the revenue interest liability.

*Investment Activities*

At September 30, 2009, cash and cash equivalents and short-term investments were approximately \$292.4 million, as compared to \$246.0 million at December 31, 2008. As of September 30, 2009, our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in a Treasury money market fund and high-quality government bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of September 30, 2009, our cash and cash equivalents were \$25.7 million, as compared to \$29.6 million as of December 31, 2008. Our short-term investments consist of US Treasury bonds with original maturities greater than three months and less than one year. The balance of these investments was \$266.7 million as of September 30, 2009, as compared to \$216.4 million as of December 31, 2008.

*Net Cash Provided by (Used in) Operations*

Net cash provided by (used in) operations was \$51.5 million and (\$32.2) million for the nine-month period ended September 30, 2009 and 2008, respectively. Cash used in operations for the nine-month period ended September 30, 2009 was primarily attributable to a net loss of \$61.5 million, an increase in the non-current portion of deferred cost of license revenue of \$6.9 million and an increase in prepaid expenses and other current assets of \$3.6 million. Cash used in operations for the nine-month period ended September 30, 2009, was partially offset by an increase in deferred license revenue of \$107.6 million, a non-cash share-based compensation expense of \$8.9 million, amortization of net premiums and discounts on short-term investments of \$3.4 million, an increase in Zanaflex Capsules deferred product revenues of \$2.5 million and depreciation and amortization of \$2.1 million. Cash used in operations for the nine-month period ended September 30, 2008 was primarily attributable to a net loss of \$54.1 million, amortization of the discount on short-term investments of \$2.4 million, an increase in inventory held by others of \$416,000, a decrease in Zanaflex tablets deferred product revenues of \$142,000, and a gain on our put/call liability of \$50,000. Cash used in operations for the nine-month period ended September 30, 2008, was partially offset by an increase in accounts payable, accrued expenses, and other current liabilities of \$7.6 million, a non-cash share-based compensation expense of \$7.1 million, a decrease in inventory held by the Company of \$2.8 million, a non-cash expense for the acquisition of NRI assets of \$2.7 million, depreciation and amortization of \$2.5 million, an increase in Zanaflex Capsules deferred product revenues of \$1.7 million, a decrease in accounts receivable of \$249,000, and a decrease in prepaid expenses and other current assets of \$236,000.

*Net Cash Used in Investing*

Net cash used in investing activities for the nine-month period ended September 30, 2009 was \$56.2 million, primarily due to \$278.9 million in purchases from maturities of short-term investments which was partially offset by \$224.7 million in proceeds of short-term investments and \$1.9 million in purchases of property and equipment.

*Net Cash Provided by Financing*

Net cash provided by financing activities for the nine-month period ended September 30, 2009 was \$697,000 due to \$2.3 million in proceeds from option exercises which was offset by \$1.6 million in repayments to PRF.

*Future Capital Needs*

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Zanaflex Capsules, revenue from Fampridine-SR, if approved, the continued progress of our research and development activities, the timing and outcome of regulatory

approvals, the amount and timing of milestone or other payments made or received under collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights and the acquisition of licenses to new products or compounds. We expect to continue to incur losses from operations as we continue to support our sales and marketing infrastructure for the commercialization of Zanaflex Capsules, increase our efforts to support pre-launch activities for Fampridine-SR and its commercialization, if approved, and continue our clinical development and advance our preclinical programs.

We believe our year-end 2009 cash, cash equivalents and investment balances will be in excess of \$250.0 million. To the extent our capital resources are insufficient to meet future operating requirements we will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund our operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, we may be required to curtail our sales and marketing efforts, delay, reduce the scope of or eliminate some of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

### **Critical Accounting Policies and Estimates**

The following discussion of critical accounting policies identifies the accounting policies that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. It is not intended to be a comprehensive list of all of our significant accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which the selection of an available alternative policy would not produce a materially different result. We have identified the following as our areas of critical accounting policies: sales revenue recognition, research and development, income taxes, and stock-based compensation.

### **Revenue Recognition**

We apply the revenue recognition guidance in SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, [Accounting Standards Codification (ASC) 605-15-25], which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. We cannot recognize revenue until we can reasonably estimate the likely return rate for our products. Since we have only limited sales history with Zanaflex Capsules and due to generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we do not believe we can reasonably determine a return rate. As a result, we account for sales of these products using a deferred revenue recognition model. At a future point in time when we are able to reasonably estimate product returns we will begin to recognize revenue based on shipments of product to our wholesale drug distributors.

Under our deferred revenue model, we do not recognize revenue upon shipment of product to our wholesale drug distributors. Instead, we record deferred revenue at gross invoice sales price, and classify the cost basis of the inventory shipped as inventory held by others. We recognize revenue when prescriptions are filled to an end-user because once a prescription is filled the product cannot be returned. We use monthly prescription data that we purchase to determine the amount of revenue to be recognized. We use the number of units of product prescribed to record gross sales. We then reduce deferred revenue and record cost of goods sold. We began receiving end-user prescription data in March 2005 which enabled us to begin recognizing revenue from Zanaflex tablet sales. We began marketing Zanaflex Capsules in April 2005 and began receiving prescription data and recognizing revenue in the same month.

In addition to the prescription data we purchase, we also receive data that we use to monitor trends in sales from wholesalers to their customers. We receive this data from an outside vendor on a monthly basis. This data includes the number of bottles shipped from certain wholesalers to their customers. We also compare our shipments to wholesalers to prescription reports to further assess inventory in the distribution channel on a monthly basis. We use the wholesaler sales trend data and the wholesaler vs. prescription comparison to better understand market conditions, but not as a basis for recognizing revenue.

We accept returns of products for six months prior to and 12 months after their expiration date. Returns of products sold by us are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize.

We recognize collaboration revenues by analyzing each element of the agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

## **Research and Development**

Research and development expenses include the costs associated with our internal research and development activities including, salaries and benefits, occupancy costs, and research and development conducted for us by third parties, such as sponsored university-based research, clinical trial vendors, contract manufacturing for our preclinical program, and regulatory consulting to support our NDA filing. In addition, research and development expenses include expenses related to grant revenue and the cost of clinical trial drug supply shipped to our clinical study vendors. We account for our clinical study costs by estimating the patient cost per visit in each clinical trial and recognizing this cost as visits occur, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations. All research and development costs are expensed as incurred except where EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*, [ASC 730-20-25], applies. In these cases, non-refundable advance payments for goods and services that will be used in future research and development activities are capitalized at the time of payment and expensed when the research and development activity has been performed.

## **Income Taxes**

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the asset and liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We have not recorded any tax provision or benefit for the three and nine-month periods ended September 30, 2009 and 2008. We have provided a valuation allowance for the full amount of our gross deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured at September 30, 2009.

As of September 30, 2009, we had available net operating loss carry-forwards of approximately \$216.5 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2010 and 2028 and research and development tax credit carry-forwards of approximately \$1.6 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2018. Since our inception, we have incurred substantial losses and expect to incur substantial and recurring losses in future periods. The Internal Revenue Code of 1986, as amended, the Code, provides for a limitation of the annual use of net operating loss and research and development tax credit carry forwards (following certain ownership changes, as defined by the Code) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry-forwards may be applied against future taxes we may not be able to take full advantage of these attributes for federal income tax purposes.

### Share-based Compensation

We account for stock options and restricted stock granted to employees according to the provisions of SFAS No. 123R, *Share Based Payment*, [ASC 718-50-30], which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, prevailing interest rates, and an estimated forfeiture rate.

We have based our current assumptions on the following:

Assumption	Method of estimating
• Estimated expected term of options	• Based on the 50 <sup>th</sup> percentile of our peer companies
• Expected volatility	• Combination of historic volatility of our common stock since October 1, 2006 and the historic volatility of the stock of our peer companies
• Risk-free interest rate	• Yields of U.S. Treasury securities corresponding with the expected life of option grants
• Forfeiture rates	• Historical forfeiture data

Of these assumptions, the expected term of the option and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of the employees and expected performance of our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash equivalents, short-term investments, grants receivable, convertible notes payable, accounts payable, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at September 30, 2009.

We have cash equivalents and short-term investments at September 30, 2009, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds and US Treasury bonds, the carrying value of our cash equivalents and short-term investments approximate their fair value at September 30, 2009. At September 30, 2009, we held \$292.4 million in cash and cash equivalents and short-term investments which had an average interest rate of approximately 0.4%.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

#### **Item 4. Controls and Procedures**

##### ***Evaluation of disclosure controls and procedures***

As required by Rule 13a-15 under the Exchange Act we carried out an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of September 30, 2009, our disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding disclosure.

##### ***Change in internal control over financial reporting***

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our chief executive officer and chief financial officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended September 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

##### ***Limitations on the effectiveness of controls***

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure 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 a company have been detected.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it filed an ANDA with the FDA to market generic versions of each of the three Zanaflex Capsules dosage strengths marketed by us. In response to that Notice, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) in the United States District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557 relating to methods of reducing drowsiness in patients with immediate release multiparticulate tizanidine formulations, including those sold by us as Zanaflex Capsules. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We have denied those counterclaims.

In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing our request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex's motion in December 2008. Fact discovery in the case has been completed. The court has also determined that a Markman hearing on the construction of certain terms contained in the patent will be held, and the parties have completed related depositions and submission of briefs to the Court. The hearing was set for November 18, 2009 but the Court has postponed it without yet setting a new date. Apotex has filed a motion to exclude certain evidence from consideration at the hearing, which Acorda has opposed.

### Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2008 and our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2009 and June 30, 2009, all of which could materially affect our business, financial condition or future results. The risks described or referred to herein are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

### Item 6. Exhibits

- 31.1 Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
- 31.2 Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
- 32.1 Certification Pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.



**Exhibit Index**

<b>Exhibit No.</b>	<b>Description</b>
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.



**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO  
RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, Ron Cohen, certify that:

1. I have reviewed this report on Form 10-Q of Acorda Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2009

/s/ RON COHEN

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Ron Cohen  
*Chief Executive Officer*

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QuickLinks

Exhibit 31.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934

**CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO  
RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, David Lawrence, certify that:

1. I have reviewed this report on Form 10-Q of Acorda Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2009

/s/ DAVID LAWRENCE

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David Lawrence  
*Chief Financial Officer*

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QuickLinks

Exhibit 31.2

CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350  
ACORDA THERAPEUTICS, INC.  
CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Acorda Therapeutics, Inc. (the "Company") hereby certifies to his knowledge that the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2009 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RON COHEN

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Ron Cohen  
*Chief Executive Officer*  
*(Principal Executive Officer)*  
November 6, 2009

/s/ DAVID LAWRENCE

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David Lawrence  
*Chief Financial Officer*  
*(Principal Accounting and Financial Officer)*  
November 6, 2009

\* A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This written statement accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and will not be incorporated by reference into any filing of Acorda Therapeutics, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, irrespective of any general incorporation language contained in such filing.

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QuickLinks

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 ACORDA THERAPEUTICS, INC. CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002