ACORDA THERAPEUTICS INC
Form 10-Q
November 10, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2008

OR

o **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

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3831168**
(State of incorporation)	(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 ý No o

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

Large accelerated filer o Accelerated filer ý

Non-accelerated filer o (Do not check if a smaller reporting company) Smaller Reporting Company o

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

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

Class	Outstanding at October 31, 2008
Common Stock, $0.001 par value per share	37,714,846 shares

ACORDA THERAPEUTICS, INC.

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PART I FINANCIAL INFORMATION

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, 2007, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008 and June 30, 2008, 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 SUBSIDIARY

Consolidated Balance Sheets

	September 30, 2008 (unaudited)	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 79,785,248	$ 16,810,415
Restricted cash	295,628	288,194
Short-term investments	183,459,536	78,310,241
Trade accounts receivable, net	4,016,551	4,265,581
Prepaid expenses	2,423,114	2,341,585
Finished goods inventory held by the Company	5,163,222	5,849,929
Finished goods inventory held by others	2,290,629	1,874,405
Other current assets	975,810	1,293,496
Total current assets	278,409,738	111,033,846
Property and equipment, net of accumulated depreciation	1,868,815	1,651,739
Intangible assets, net of accumulated amortization	17,155,048	13,943,888
Other assets	544,959	676,993
Total assets	$ 297,978,560	$ 127,306,466
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,249,900	$ 6,675,894
Accrued expenses and other current liabilities	11,501,324	8,777,645
Deferred product revenue Zanaflex tablets	7,771,672	7,913,776
Deferred product revenue Zanaflex Capsules	15,603,391	13,923,781
Current portion of notes payable		187,645
Current portion of revenue interest liability	1,337,993	1,785,018
Total current liabilities	48,464,280	39,263,759
Put/call liability	412,500	462,500
Non current portion of revenue interest liability	17,902,938	17,444,324
Long-term convertible notes payable	6,854,471	6,703,235
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value. Authorized 80,000,000 shares at September 30, 2008 and December 31, 2007; issued and outstanding 37,512,934 and 28,574,678 shares as of September 30, 2008 and December 31, 2007, respectively	37,512	28,575
Additional paid-in capital	547,600,149	333,144,051
Accumulated deficit	(324,144,865)	(270,035,770)
Other comprehensive income	851,575	295,792
Total stockholders' equity	224,344,371	63,432,648
Total liabilities and stockholders' equity	$ 297,978,560	$ 127,306,466

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Operations

(unaudited)

	Three-month period ended September 30, 2008	Three-month period ended September 30, 2007	Nine-month period ended September 30, 2008	Nine-month period ended September 30, 2007
Gross sales Zanaflex	$ 13,666,496	$ 11,506,696	$ 39,441,848	$ 30,810,390
Less: discounts and allowances	(1,224,065)	(1,067,668)	(4,153,070)	(2,576,340)
Net sales	12,442,431	10,439,028	35,288,778	28,234,050
Grant revenue	23,097	20,277	76,022	36,464
Total net revenue	12,465,528	10,459,305	35,364,800	28,270,514
Less: cost of sales	(2,700,772)	(2,181,565)	(8,516,743)	(5,746,485)
Gross profit	9,764,756	8,227,740	26,848,057	22,524,029
Operating expenses:				
Research and development	8,650,305	5,602,828	25,758,150	12,854,260
Sales and marketing	14,419,938	7,917,861	36,349,099	22,005,596
General and administrative	5,948,193	3,720,222	17,391,817	12,550,151
Total operating expenses	29,018,436	17,240,911	79,499,066	47,410,007
Operating loss	(19,253,680)	(8,963,171)	(52,651,009)	(24,885,978)
Other income (expense):				
Interest and amortization of debt discount expense	(873,838)	(1,008,244)	(5,002,014)	(2,208,650)
Interest income	1,239,144	1,440,559	3,505,296	2,804,679
Other income	32,612	(1,584)	38,630	45,057
Total other income (expense)	397,918	430,731	(1,458,088)	641,086
Net loss	(18,855,762)	(8,832,440)	(54,109,097)	(24,244,892)
Net loss per share basic and diluted	$ (0.53)	$ (0.30)	$ (1.65)	$ (0.95)
Weighted average common shares outstanding used in computing net loss per share basic and diluted	35,265,445	28,209,406	32,723,694	25,467,580

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(unaudited)

	Nine-month period ended September 30, 2008	Nine-month period ended September 30, 2007
Cash flows from operating activities:		
Net loss	$ (54,109,097)	$ (24,244,893)
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	7,096,851	5,927,181
Amortization of net premiums and discounts on short-term investments	(2,431,768)	(1,916,724)
Amortization of revenue interest issuance cost	82,464	56,835
Depreciation and amortization expense	2,509,431	1,464,063
(Gain) Loss on put/call liability	(50,000)	12,500
(Gain) Loss on disposal of property and equipment		(23,750)
Changes in assets and liabilities:		
Decrease in accounts receivable	249,030	582,618
Decrease (increase) in prepaid expenses and other current assets	236,157	(1,107,715)
Decrease (increase) in inventory held by the Company	2,786,920	(774,385)
Increase in inventory held by others	(416,224)	(182,474)
Decrease (increase) in other assets	49,570	(3,459)
Increase in accounts payable, accrued expenses, other current liabilities	7,620,667	5,313,849
Decrease in deferred product revenue tablets	(142,104)	(1,260,360)
Increase in deferred product revenue Capsules	1,679,610	391,723
Restricted cash	(7,434)	(10,290)
Net cash used in operating activities	(32,159,927)	(15,775,281)
Cash flows from investing activities:		
Purchases of property and equipment	(737,092)	(1,114,433)
Purchases of intangible assets	(5,000,000)	(10,000,000)
Purchases of short-term investments	(229,461,739)	(106,521,591)
Proceeds from maturities of short-term investments	127,300,000	59,800,000
Net cash used in investing activities	(107,898,831)	(57,836,024)
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	204,682,184	74,254,130
Proceeds from sale of revenue interest		5,000,000
Repayments of revenue interest liability	(1,460,948)	(2,549,244)
Repayments of notes payable	(187,645)	(768,217)
Net cash provided by financing activities	203,033,591	76,136,669
Net increase in cash and cash equivalents	62,974,830	2,525,365
Cash and cash equivalents at beginning of period	16,810,415	18,100,908
Cash and cash equivalents at end of period	$ 79,785,248	$ 20,626,272
Supplemental disclosure:		
Cash paid for interest	3,379,794	1,898,504
Non-cash activities:		
Accrued Inventory	2,100,213	

See accompanying Unaudited Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

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 condensed 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, 2007 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 completed a follow-on public offering in July 2007. As part of that offering, 4,189,460 shares of the Company's common stock were sold, resulting in proceeds of approximately $72.2 million, net of issuance costs.

The Company completed a follow-on public offering in February 2008. As part of that offering, 3,712,000 shares of the Company's common stock were sold, resulting in proceeds of approximately $74.6 million, net of issuance costs.

The Company completed a follow-on public offering in August 2008. As part of that offering, 4,600,000 shares of the Company's common stock were sold, resulting in proceeds of approximately $126.6 million, net of issuance costs.

In February 2008, the Company acquired certain assets from Neurorecovery, Inc. (NRI). These assets will enable Acorda to explore additional therapeutic indications for its investigational compound Fampridine-SR, as well as provide access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, Acorda was assigned two key licensing and research agreements relating to the use of aminopyridines in peripheral neuropathies and two early stage development candidates. Acorda also acquired NRI's pre-clinical and clinical data, regulatory filings (including Orphan Drug designations), copyrights, trademarks and domain names relating to the three products. Acorda issued 100,000 shares of its Common Stock as the purchase price for these assets. The transaction was accounted for as an acquisition of in-process research and development assets and, as such, resulted in a non-cash expense in the first quarter of 2008 of approximately $2.7 million.

The Company finances its operations through a combination of issuance of equity securities, revenues from Zanaflex Capsules and tablets, 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. The Company believes that its current financial resources and sources of liquidity will be sufficient to fund operations and meet financial obligations into the fourth quarter of 2010 based on the Company's current projected revenue and spending levels.

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements (Continued)

(unaudited)

(1) Organization and Business Activities (Continued)

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 subsidiary. 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 (clinical trial accrual) and share-based compensation accounting, which are largely dependent on the fair value of the Company's equity security. 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*, 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

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements (Continued)

(unaudited)

(2) Summary of Significant Accounting Policies (Continued)

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 believes 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*, 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 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 an estimated rate of the Company's expected returns.

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, accounts receivable and debt securities. The Company maintains cash and cash equivalents, restricted cash and debt securities with approved financial institutions. The Company is exposed to credit 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*, by dividing the net loss by the weighted average number of shares of common stock outstanding. The Company has stock options and restricted stock (see Note 3), 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.

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements (Continued)

(unaudited)

(2) Summary of Significant Accounting Policies (Continued)

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*.

Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits an entity to measure certain financial assets and financial liabilities at fair value on an instrument by instrument basis. Under SFAS 159, entities that elect the fair value option will report unrealized gains and losses in earnings at each subsequent reporting date. For the Company, SFAS 159 is effective as of January 1, 2008, but we did not elect to measure any additional financial instruments at fair value as a result of this statement. Therefore, the adoption of SFAS 159 did not have a material impact on our consolidated financial statements.

In June 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. EITF Issue No. 07-3 provides guidance concerning the accounting for non-refundable advance payments for goods and services that will be used in future R&D activities and requires that they be expensed when the research and development activity has been performed and not at the time of payment. The Company adopted EITF No. 07-3 as of January 1, 2008. The adoption has not had an impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. This statement is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, the new standard requires that all acquisition-related costs be expensed as incurred, that acquired in-process research and development be recorded at fair value as an indefinite-lived asset at the acquisition date and that all restructuring costs related to acquired operations be expensed as incurred. This new standard also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed and, for acquisitions both prior and subsequent to December 31, 2008, requires the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances. The Company does not expect the adoption of SFAS No. 141R to have a material impact on the its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 will change the accounting for minority interests, which will be recharacterized as noncontrolling interests and classified by the parent company as a component of equity. This statement is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited. Upon adoption, SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests and prospective adoption for all other

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements (Continued)

(unaudited)

(2) Summary of Significant Accounting Policies (Continued)

requirements. The Company does not expect the adoption of SFAS No. 160 to have a material impact on the its financial statements.

In April 2008, the FASB issued Final FASB Staff Position (FSP), FAS 142-3, *Determination of the Useful Life of Intangible Assets,* which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. This FSP shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company will ascertain its impact, if any, during the three-month period ending March 31, 2009.

In October 2008, the FASB issued FASB Staff Position (FSP), FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of FASB SFAS No. 157, *Fair Value Measurements*, in a market that is not active and illustrates key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP does not currently have an impact on our financial statements.

(3) Share-based Compensation

The Company accounts for share-based compensation, including options and restricted stock, according to the provisions of SFAS No. 123R, *Share Based Payment*. During the three-month periods ended September 30, 2008 and 2007, the Company recognized share-based compensation expense of $2.7 million and $1.9 million, respectively. During the nine-month periods ended September 30, 2008 and 2007, the Company recognized share-based compensation expense of $7.1 million and $5.9 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2008 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, 2008 and 2007 amounted to approximately $18.30 and $12.47, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2008 and 2007 amounted to approximately $20.91 and $13.00, respectively.

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

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, 2008 is presented below:

Stock Option Activity

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value
Balance at January 1, 2008	2,999,513	$ 10.18		
Granted	799,838	21.59		
Forfeited	(115,882)	16.21		
Exercised	(486,011)	7.17		
Balance at September 30, 2008	3,197,458	$ 13.27	7.6	$34,600,488
Vested and expected to vest at September 30, 2008	3,102,976	$ 13.08	7.6	$34,100,802
Vested and exercisable at September 30, 2008	1,597,086	$ 8.88	6.6	$23,923,706

Restricted Stock Activity

Restricted Stock	Number of Shares
Nonvested at January 1, 2008	39,722
Granted	200,000
Vested	(40,245)
Forfeited	(11,673)
Nonvested at September 30, 2008	187,804

As of September 30, 2008, there was $19.7 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

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. In addition, in May 2007, the FASB issued FASB Staff Position FIN 48-1 which provided guidance on how an enterprise should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits. The Interpretation and Staff Position established criteria for recognizing and measuring the financial statement tax effects of positions taken on a company's tax returns. A two-step process is prescribed whereby the threshold for recognition is a more likely-than-not test that the tax position will be sustained upon examination and the tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company adopted FIN 48 as of January 1, 2007. The adoption of this

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements (Continued)

(unaudited)

(4) Income Taxes (Continued)

Interpretation had no impact on the Company's results of operations or financial position. The Company has no reserves for uncertain tax positions.

The Company had available net operating loss carry-forwards ("NOL") of approximately $244.6 million and $179.9 million as of September 30, 2008 and December 31, 2007, 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 2026. The Company also has research and development tax credit carryforwards of approximately $1.5 million and $1.4 million as of September 30, 2008 and December 31, 2007, respectively, 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, 2008 and December 31, 2007, the Company had a deferred tax asset of $112.8 million and $97.8 million, respectively, offset by a full valuation allowance. Since inception, the 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 and its initial public offering in February 2006, private placement in October 2006, and follow-on public offerings in June 2007, February 2008 and August 2008. 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 net deferred tax assets as of and for all periods presented. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

(5) Elan Milestones

In July 2004, we acquired all of Elan's research, development, distribution, sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. We made an upfront payment to Elan of $2.0 million and are obligated to pay royalties on sales and to make milestone payments upon achievement of specified sales levels. During the three-month period ended March 31, 2008, the Company reached the fifth and final cumulative product sale milestone threshold and accordingly, accrued a payment of $5.0 million, which was made to Elan during the three-month period ended June 30, 2008. As of September 30, 2008, the Company made a total of $19.5 million of these milestone payments and has no further Zanaflex milestone payment obligations with Elan.

(6) Fair Value Measurements

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value and expands required disclosures about fair value measurements. Under the standard, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. The impact

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements (Continued)

(unaudited)

(6) Fair Value Measurements (Continued)

of adopting SFAS No. 157 as of January 1, 2008 was not material to our consolidated financial statements.

FSP FAS No. 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13*, removed leasing transactions accounted for under SFAS No. 13, *Accounting for Leases*, and related guidance from the scope of SFAS No. 157. FSP FAS No. 157-2, *Effective Date of FASB Statement No. 157* deferred the effective date of SFAS No. 157 for the Company in relation to all nonfinancial assets and nonfinancial liabilities to January 1, 2009.

SFAS No. 157 establishes a fair value hierarchy which requires us to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. We primarily apply the market approach for recurring fair value measurements. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table presents information about our assets and liabilities measured at fair value on a recurring basis as of September 30, 2008 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(in thousands)	Level 1	Level 2	Level 3
Assets Carried at Fair Value:			
Cash equivalents	$ 79,093	$	$
Short-term investments	183,460		
Liabilities Carried at Fair Value:			
Put/call liability			413

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

(in thousands)	Balance as of December 31, 2007	Realized (gains) losses included in net loss	Unrealized losses included in other comprehensive loss	Balance as of September 30, 2008
Liabilities Carried at Fair Value:				
Put/call liability	$ 463	$ (50)	$	$ 413

We evaluate the 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.

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.

In May 2007, we reached agreement with the FDA on a Special Protocol Assessment (SPA) for a second Phase 3 trial of Fampridine-SR in MS, MS-F204, and we initiated this trial in June 2007. In June 2008, the Company announced positive results from its second Phase 3 clinical trial of Fampridine-SR (MS-F204) on walking ability in people with multiple sclerosis (MS). 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. The FDA has agreed that this trial, together with our first Phase 3 trial, MS-F203, would be adequate to support a New Drug Application (NDA) for Fampridine-SR. We expect to submit an NDA for Fampridine-SR in the first quarter of 2009. 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 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. 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. Our preclinical programs also target MS and SCI, as well as other CNS disorders, including stroke and traumatic brain injury.

On February 1, 2008 the Company acquired certain assets of Neurorecovery, Inc., (NRI). These assets will enable Acorda to explore additional therapeutic indications for its investigational compound Fampridine-SR, as well as gain access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, Acorda was assigned two key licensing and research agreements relating to the use of aminopyridines in peripheral neuropathies and two early stage development candidates. Acorda also acquired NRI's pre-clinical and clinical data, regulatory filings (including Orphan Drug designations), copyrights, trademarks and domain names relating to the three products. Acorda issued 100,000 shares of its Common Stock as the purchase price for these assets which were valued at $26.86 per share. The transaction was accounted for as an acquisition of in-process research and development assets and, as such, resulted in a non-cash expense in the first quarter of 2008 of $2,686,000.

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 for the foreseeable future.

Our U.S. patent on Zanaflex Capsules expires in 2021. In September 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. 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 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 Corp. and Apotex Inc. were successful in challenging the validity of the patent, Apotex Corp. and Apotex Inc. could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules.

We have established our own specialty sales force in the United States, which consisted of 63 sales professionals as of September 30, 2008. This sales force has targeted neurologists and other prescribers who specialize in treating people with conditions that involve spasticity. Members of this sales force also 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.

Results of Operations

Three-Month Period Ended September 30, 2008 Compared to September 30, 2007

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 $13.7 million for the three-month period ended September 30, 2008, as compared to $11.5 million for the three-month period ended September 30, 2007. The increase is the result of an increase in prescriptions written for our products that we believe is the result of our expanding our sales force in 2006 and 2007 as well as an increase in our marketing efforts.

Discounts and Allowances

We recorded discounts and allowances of $1.2 million for the three-month period ended September 30, 2008 as compared to $1.1 million for the three-month period ended September 30, 2007. 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, 2008 consisted of $651,000 in fees for services payble to wholesalers, $449,000 in allowances for chargebacks and rebates, and $124,000 in cash discounts and patient program rebates. Discounts and allowances for the three-month period ended September 30, 2007 consisted of $480,000 in fees for services paid to wholesalers, $313,000 in allowances for chargebacks and rebates, and $275,000 in cash discounts.

Grant Revenue

Grant revenue for the three-month period ended September 30, 2008 was $23,000 compared to $20,000 for the three-month period ended September 30, 2007. 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 $2.7 million for the three-month period ended September 30, 2008 as compared to $2.2 million for the three-month period ended September 30, 2007. The increase was

primarily due to the increase in gross sales. Cost of sales for the three-month period ended September 30, 2008 consisted of $1.3 million in inventory costs 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. We expect Zanaflex cost of sales to be approximately 21% of gross sales for the remainder of 2008. Cost of sales for the three-month period ended September 30, 2007 consisted of $990,000 in inventory costs related to recognized revenue, $766,000 in royalty fees based on net product shipments, $389,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $36,000 in period costs related to packaging, freight, and stability testing. Payments to and interest expense related to our Paul Royalty Fund, or 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, 2008 were $8.7 million as compared to $5.6 million for the three-month period ended September 30, 2007, an increase of approximately $3.1 million, or 54%. Pre-clinical research contracts increased $1.1 million to $1.2 million for the three-month period ended September 30, 2008 due to the development of two of our preclinical pipeline products for potential IND filings in late 2009. This increase was partially offset by a decrease in MS clinical development program expense of $236,000 or 11% to $1.9 million for the three-month period ended September 30, 2008. This decrease was primarily due to an initial ramp up of expenses related to our second Phase 3 clinical trial of Fampridine-SR during the same period in 2007.

Operating expenses for clinical development, preclinical research and development and regulatory were $4.8 million for the three-month period ended September 30, 2008, compared to $2.8 million for the three-month period ended September 30, 2007, an increase of $2.0 million, or 70%. This increase was primarily attributable to an increase in regulatory expenses of $1.4 million for the preparation of an NDA for Fampridine-SR and related consulting fees and an increase in research and development staff and compensation of $700,000 to support pre-clinical research and development, Fampridine-SR long-term extension studies and NDA preparation.

Sales and Marketing

Sales and marketing expenses for the three-month period ended September 30, 2008 were $14.4 million compared to $7.9 million for the three-month period ended September 30, 2007, an increase of approximately $6.5 million or 82%. This increase was primarily attributable to an increase of $5.1 million attributable to pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved, and an increase in sales and marketing staff and compensation of $1.4 million to support promotion of Zanaflex Capsules and Fampridine-SR pre-launch activities. Sales and marketing expenses are expected to continue to increase in 2008 and in 2009 primarily due to an increase in our expected pre-launch costs.

General and Administrative

General and administrative expenses for the three-month period ended September 30, 2008 were $5.9 million compared to $3.7 million for the three-month period ended September 30, 2007, an increase of approximately $2.2 million, or 60%. This increase was the result of an increase in staff and compensation and other expenses related to supporting the growth of the overall organization of $1.4 million, an increase in costs associated with medical affairs research and educational programs of $389,000, and an increase in legal fees of $318,000.

Other Income (Expense)

Other income was $398,000 for the three-month period ended September 30, 2008 compared to other income of $431,000 for the three-month period ended September 30, 2007, a decrease of approximately $33,000 or 8%. The decrease was primarily due to a decrease in interest income of $201,000 resulting from a lower average interest rate than for the same period in 2007. The decrease in interest income was partially offset by a $134,000 decrease in interest expense principally related to the PRF revenue interest agreement.

Nine-Month Period Ended September 30, 2008 Compared to September 30, 2007

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 $39.4 million for the nine-month period ended September 30, 2008, as compared to $30.8 million for the nine-month period ended September 30, 2007. The increase is the result of an increase in prescriptions written for our products that we believe is the result of our expanding our sales force in 2006 and 2007 as well as an increase in our marketing efforts.

Discounts and Allowances

We recorded discounts and allowances of $4.2 million for the nine-month period ended September 30, 2008 as compared to $2.6 million for the nine-month period ended September 30, 2007. 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, 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. Discounts and allowances for the nine-month period ended September 30, 2007 consisted of $1.0 million in fees for services payable to wholesalers, $860,000 in allowances for chargebacks and rebates, and $692,000 in cash discounts.

Grant Revenue

Grant revenue for the nine-month period ended September 30, 2008 was $76,000 compared to $36,000 for the nine-month period ended September 30, 2007. 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 $8.5 million for the nine-month period ended September 30, 2008 as compared to $5.7 million for the nine-month period ended September 30, 2007. The increase was due to the increase in gross sales as well as an increase in amortization of intangible assets resulting from our achieving the final Elan sales milestone during the three-month period ended March 31, 2008. Cost of sales for the nine-month period ended September 30, 2008 consisted of $4.0 million in inventory costs 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. We expect Zanaflex cost of sales to be approximately 21% of gross sales for the remainder of 2008. Cost of sales for the nine-month period ended September 30, 2007 consisted of $2.7 million in inventory costs related to recognized revenue, $2.0 million in royalty fees based on net product shipments, $844,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $196,000 in period costs related to packaging,

freight, and stability testing. Payments to and interest expense related to our Paul Royalty Fund, or 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, 2008 were $25.8 million as compared to $12.9 million for the nine-month period ended September 30, 2007, an increase of approximately $12.9 million, or 100%. The Company's acquisition of certain in-process research and development assets of NRI resulted in a non-cash expense of approximately $2.7 million during the three month period ended March 31, 2008 in accordance with SFAS No. 2 *Accounting for Research and Development Expenses*. Pre-clinical research contracts increased $2.6 million to $2.6 million for the nine-month period ended September 30, 2008 due to the development of two of our preclinical pipeline products for potential IND filings in late 2009. MS clinical development program expense increased $1.8 million or 36% to $6.9 million for the nine-month period ended September 30, 2008 primarily due to the continuation and completion of our second Phase 3 clinical trial of Fampridine-SR which began in June 2007.

Operating expenses for clinical development, preclinical research and development and regulatory were $12.1 million for the nine-month period ended September 30, 2008, compared to $6.4 million for the nine-month period ended September 30, 2007, an increase of $5.7 million, or 90%. This increase was primarily attributable to an increase in regulatory expenses of $4.1 million for the preparation of an NDA for Fampridine-SR and related consulting fees and an increase in research and development staff and compensation of approximately $1.9 million.

Sales and Marketing

Sales and marketing expenses for the nine-month period ended September 30, 2008 were $36.3 million compared to $22.0 million for the nine-month period ended September 30, 2007, an increase of approximately $14.3 million or 65%. This increase was primarily attributable to an increase of $9.6 million attributable to pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved, an increase in sales and marketing staff and compensation of $2.4 million, an increase in other selling related expenses of $1.1 million and an increase of $1.0 million in Zanaflex Capsules sales and marketing initiatives. Sales and marketing expenses are expected to continue to increase in 2008 and in 2009 primarily due to an increase in our expected pre-launch costs.

General and Administrative

General and administrative expenses for the nine-month period ended September 30, 2008 were $17.4 million compared to $12.6 million for the nine-month period ended September 30, 2007, an increase of approximately $4.8 million, or 39%. This increase was primarily the result of an increase in staff and compensation and other expenses related to supporting the growth of the overall organization of $2.4 million, an increase in costs associated with medical affairs research and educational programs of $1.3 million and an increase in legal fees of $1.2 million primarily related to the Apotex patent infringement litigation.

Other Income (Expense)

Other expense was $1.5 million for the nine-month period ended September 30, 2008 compared to other income of $641,000 for the nine-month period ended September 30, 2007, an increase of approximately $2.1 million or 327%. The increase was primarily due to an increase in interest expense of $2.8 million. This increase was the result of a $1.4 million increase in interest expense under the PRF revenue interest agreement as a result of increased shipments and the impact of a $1.4 million out-of-period adjustment made during the second quarter of 2008 to correct an error identified in the previously recorded effective interest expense related to the November 2006 amended revenue interests

assignment agreement with PRF. This out-of-period adjustment did not increase the total interest expense associated with this agreement. The increase in interest expense was partially offset by a $701,000 increase in interest income as a result of the investment of net proceeds from our follow-on public offerings in February and August 2008.

Liquidity and Capital Resources

We have incurred annual operating losses since inception and, as of September 30, 2008, we had an accumulated deficit of approximately $324.1 million. We have financed our operations primarily through public offerings of our common stock, private placements of our securities and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

We completed a follow-on public offering in July 2007 in which approximately 4.2 million shares of our common stock were sold, resulting in proceeds to us of approximately $72.2 million, net of issuance costs.

We completed a follow-on public offering in February 2008 in which approximately 3.7 million shares of our common stock were sold, resulting in proceeds to us of approximately $74.6 million, net of issuance costs.

We completed a follow-on public offering in August 2008 in which approximately 4.6 million shares of our common stock were sold, resulting in proceeds of approximately $126.6 million, net of issuance costs.

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, Elan transferred these promissory notes to funds affiliated with Saints Capital. As of September 30, 2008, $5.0 million of these promissory notes were outstanding. In January 2005, we entered into a $6.0 million senior secured term loan, which is collateralized by all of our personal property and fixtures, other than the property that secures our revenue interests assignment arrangement with PRF, which has been repaid during the three-month period ended March 31, 2008.

On December 23, 2005, we entered into a revenue interests 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 $19.2 million in accordance with EITF 88-18, *Sales of Future Revenues*. 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 5.9%. 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, 2008, cash and cash equivalents and short-term investments were approximately $263.2 million, as compared to $95.1 million at December 31, 2007. As of September 30 2008, our cash and cash equivalents consist of highly liquid investments in a Treasury money market fund. Our cash and cash equivalents were $79.8 million as of September 30, 2008, as compared to $16.8 million as of December 31, 2007. Our short-term investments consist of US Treasuries, commercial paper and corporate debt securities with remaining maturities from one month to less than one year. The balance of these investments was $183.4 million as of September 30, 2008, as compared to $78.3 million as of December 31, 2007.

Net Cash Used in Operations

Net cash used in operations was $32.2 million and $15.8 million for the nine-month periods ended September 30, 2008 and 2007, respectively. 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 by operations for the nine-month period ended September 30, 2007 was primarily attributable to a net loss of $24.2 million, amortization of the discount on short-term investments of $1.9 million, a decrease in Zanaflex tablets deferred product revenues of $1.3 million, an increase in prepaid expenses and other current assets of $1.1 million, an increase in inventory held by the Company of $774,000, and an increase in inventory held by others of $182,000. Cash used in operations for the nine-month period ended September 30, 2007, was partially offset by a non-cash stock compensation expense of $5.9 million, an increase in accounts payable, accrued expenses, and other current liabilities of $5.3 million, depreciation and amortization of $1.5 million, a decrease in accounts receivable of $583,000, and a decrease in Zanaflex Capsules deferred product revenue of $392,000.

Net Cash Used in Investing

Net cash used in investing activities for the nine-month period ended September 30, 2008 was $107.9 million, primarily due to $229.5 million in purchases of short-term investments, a $5.0 million payment to Elan for the final Zanaflex milestone, and purchases of property and equipment of $737,000, partially offset by $127.3 million in proceeds from maturities of short-term investments.

Net Cash Provided by Financing

Net cash provided by financing activities for the nine-month period ended September 30, 2008 was $203.0 million, primarily due to $204.7 million in net proceeds from the issuance of common stock and option exercises, which was partially offset by $1.5 million in repayments to PRF and $188,000 for notes payable.

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, 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 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 incur losses from operations for at least the next several years as we continue to support our sales and marketing infrastructure and increase our marketing efforts to support the commercialization of Zanaflex Capsules, continue our clinical development and pre-launch planning for Fampridine-SR, and advance our preclinical programs.

We believe that our current financial resources and sources of liquidity will be sufficient to fund operations and meet financial obligations into the fourth quarter of 2010 based on our current projected revenue and spending levels. 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.

Contractual Obligations and Commitments

In January 2005, we entered into a $6.0 million senior secured term loan with GE Capital. In December 2005, we used a portion of the initial payment we received under our revenue interest assignment arrangement with PRF to repay approximately $3.0 million of this loan. We were required to pay monthly installments until February 2008, with interest-only payments for the first six months followed by principal and interest payments for the remaining 29 months. Interest was fixed at the rate of 9.93% per annum. The loan was secured by all of our personal property and fixtures, other than the property that secures our arrangement with PRF and was fully satisfied during the three-month period ended March 31, 2008.

In January 1997, EIS loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes. One promissory note in the principal amount of $5.0 million bears interest at a rate of 3% which began on the first anniversary of the note. The other promissory note in the amount of $2.5 million was non-interest bearing. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. In December 2006, Saints Capital exercised the conversion option of the $2.5 million convertible promissory note at an exercise price of $11.856 per share and

received 210,863 shares of common stock. The remaining $5.0 million convertible promissory note is convertible into 67,476 shares of common stock. Principal and interest are repayable, if not converted, ratably over a seven-year period, beginning one year after we receive regulatory approval for certain products to be developed, subject to limitations related to gross margin on product sales. If we and Saints Capital determine that regulatory approval will not likely occur, the $5.0 million promissory note will automatically convert into the underlying common stock unless Saints Capital elects to have the amount due on the note cancelled. If our license and supply agreements with Elan are terminated for any other reason, the principal and interest is repayable ratably over 15 years. The $5.0 million promissory note restricts our ability to incur indebtedness that is senior to the note, subject to certain exceptions, including for our revenue interests assignment arrangement with PRF.

In July 2004, we acquired all of Elan's research, development, distribution, sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. Under our Zanaflex purchase agreement with Elan, we are obligated to make milestone payments to Elan of up to $19.5 million based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of September 30, 2008, we made $19.5 million of these milestone payments including a $5.0 million milestone which was reached upon the achievement of $105.0 million in cumulative sales during the first quarter of 2008 and was paid during the second quarter of 2008. We have no further Zanaflex milestone payment obligations with Elan.

Under our Zanaflex supply agreement with Elan, we are required to provide to Elan an 18-month rolling forecast at the beginning of each month and a two-year forecast not later than July 1 of each year. We are required to order 100% of the forecast required quantities for each five-month period immediately following each monthly forecast report. At September 30, 2008, the forecast requirement for the five-month period following September 30, 2008 amounted to approximately $1.3 million.

Under our Fampridine-SR license agreement with Elan, we are obligated to make milestone payments to Elan of up to $15.0 million over the life of the contract and royalty payments as a percentage of product sales. We have not made any payments under this agreement to date. In addition, under our various other research, license and collaboration agreements with other parties we are obligated to make milestone payments of up to an aggregate of approximately $16.8 million over the life of the contracts.

In December 2005, we entered into a revenue interests assignment agreement with PRF pursuant to which we assigned PRF the right to receive a portion of our net revenues (as defined in the agreement, which definition is different from our net revenues as determined in accordance with generally accepted accounting principles) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all such Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement is terminated earlier. In consideration for the assignment, PRF paid us $15.0 million at signing. Under our agreement with PRF, we are required to use the net proceeds to support commercialization, sales, marketing, clinical and regulatory activities and other financial obligations related specifically and solely to our Zanaflex operations.

In November 2006, we entered into an amendment to the revenue interest assignment agreement with PRF. Under the amendment, PRF is entitled to a royalty consisting of certain specified percentages of Zanaflex net revenues, based upon the level of net revenues. Previously, once PRF had received and retained payments under the agreement that are at least twice the aggregate amount PRF paid us under the Agreement, the royalty rate would drop to 1% of Zanaflex net revenues. The amendment provides that the royalty rate will drop to 1% upon PRF's receipt of 2.1 times the aggregate amount PRF has paid us under the agreement, as amended. Under the terms of the amendment, PRF paid us $5.0 million in November 2006 and agreed that we would be entitled to an additional $5.0 million is due if our net revenues during the fiscal year 2006 equaled or exceeded $25.0 million. This milestone was met and the payment was received in February 2007. 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 terms of the employment agreement with our chief executive officer, Ron Cohen, we are obligated to pay severance under certain circumstances. If the employment agreement is terminated by us or by our chief executive officer for reasons other than for cause, we must pay an amount equal to (i) the base salary the chief executive officer would have received during the 15-month period immediately following the date of termination, plus (ii) the last annual bonus received by the chief executive officer multiplied by a fraction, the numerator of which is the number of days in the calendar year elapsed as of the termination date and the denominator of which is 365.

Under the terms of the employment agreements with our chief scientific officer, Andrew Blight, our chief financial officer, David Lawrence and our general counsel, Jane Wasman, we are obligated to pay severance under certain circumstances. In the event we terminate our employment agreement with Dr. Blight, Mr. Lawrence or Ms. Wasman without cause, or if one of them voluntarily terminates his or her agreements with good reason, we are obligated to make severance payments equal to nine months base annual salary, in the case of Dr. Blight, and seven months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, as well as COBRA premium payments for the severance period. In such event, all options, stock appreciation rights awards and restricted stock awards that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination. If Dr. Blight, Mr. Lawrence or Ms. Wasman voluntarily terminates his or her employment without good reason or if we terminate his or her employment without cause within 18 months after a change in control, we are obligated to make severance payments equal to one year's base annual salary, in the case of Dr. Blight, and nine months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, in each case paid in a lump sum within 30 days after termination, as well as COBRA premium payments for the severance period plus a bonus equal to the prior year's bonus pro rated for the number of days worked prior to termination. We are also obligated to pay salary earned but not paid, vacation and sick leave days that have accrued, and reimbursable business expenses incurred through the date of termination. In such event, not less than 50% of the unvested options, stock appreciation rights and restricted or other stock awards shall become immediately and full vested and shall remain exercisable for 18 months following such date. All options that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

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*, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. Under SFAS No. 48 we are not permitted to 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, we expect to be able to reasonably estimate product returns, at which point we believe 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. Gross sales data reported in the financial statements in this filing are based on three months of actual prescription data. When we receive the prescription data, 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 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.

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, and clinical trial 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. 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.

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, 2008 and 2007. We have provided a valuation allowance for the full amount of our net 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, 2008.

As of September 30, 2008, we had available net operating loss carry-forwards of approximately $244.6 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 2026 and research and development tax credit carry- forwards of approximately $1.5 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*, which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date of January 1, 2006.

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 50th 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.

We account for stock options granted to non-employees on a fair-value basis in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25*.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash equivalents, short-term investments, convertible notes payable and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at September 30, 2008.

We have cash equivalents and short-term investments at September 30, 2008, 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 corporate debt securities, the carrying value of our cash equivalents and short-term investments approximate their fair value at September 30, 2008. At September 30, 2008, we held $263.2 million in cash and cash equivalents and short-term investments which had an average interest rate of approximately 1.4%.

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, within 90 days prior to filing this report, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. 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, 2008, our disclosure controls and procedures were effective and designed to ensure that material information relating to us required to be included in our reports filed under the Exchange Act would be made known to them. There have been no changes in our internal controls over financial reporting (as defined in Rules 13a-15(b) and 15(d)-15(f) under the Exchange Act) or in other factors that has materially affected or is reasonably likely to materially affect internal controls over financial reporting.

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

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2008 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

See our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.

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, 2007, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008 and June 30, 2008, all of which could materially affect our business, financial condition or future results. Other than the revisions to the following risk factors set forth below, there have been no material changes from the risk factors referred to in the previous sentence. The risks described in the Annual Report and the Quarterly Report 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.

If we are unable to obtain regulatory approval for Fampridine-SR, or any approval is unduly limited in scope or delayed, our business prospects will be materially adversely affected.

We have reported positive results from two Phase 3 clinical trials of Fampridine-SR for the improvement of walking in patients with MS, most recently in June 2008. Both trials were conducted pursuant to SPAs from the FDA. The FDA has informed us that positive results from at least two successful Phase 3 clinical trials will be needed to support the filing of an NDA with the FDA. If the FDA determines that there is a new substantial scientific issue regarding walking in the MS population or Fampridine-SR, the FDA may alter its opinion expressed in the prior SPAs regarding the adequacy of the Phase 3 studies. The FDA also required us to execute a Thorough QT study of cardiac safety which was completed in January 2008. Although our QT consultants concluded that this study showed no safety signal for a risk of cardiac QT prolongation with Fampridine-SR at a therapeutic or supra-therapeutic dose, the FDA will make its own evaluation of the data when it is submitted as part of the NDA application and its interpretation of the results may differ.

The FDA may also identify a need for further studies in order to confirm efficacy or to examine safety or other properties or characteristics of Fampridine-SR. For example, in October 2007, we met with the FDA to discuss the completed preclinical studies proposed for the NDA for Fampridine-SR and the FDA asked us to complete a series of bridging studies to bring our older preclinical toxicology studies to current scientific standards. This included a requirement to complete new studies to fully characterize the toxicokinetics of fampridine in the blood of experimental animals given doses that were used in the full range of our previously performed preclinical toxicology studies, so the FDA can evaluate the suitability of those doses and routes of administration of drug in its evaluation of safety. We may also determine, on our own, to conduct additional studies from time to time to support our filing of an NDA or to otherwise provide additional data regarding the safety or efficacy of Fampridine-SR. If the studies that we are required to conduct, or any studies that we determine, on our own, to conduct, cause us to incur unanticipated expenses or delays, or yield unfavorable results, our ability to obtain regulatory approval of Fampridine-SR could be seriously delayed or impaired, in which case our business prospects will be materially adversely affected.

Earlier this year, we submitted a request to the FDA for Fast Track designation for Fampridine-SR. The FDA did not grant our request, stating that we had not at this time demonstrated that Fampridine-SR addresses an unmet medical need under the criteria for Fast Track designation. If we decide to request Priority Review of the NDA under the FDA's standards for designating NDAs for either Priority or Standard review, we may present additional information on the ways in which Fampridine-SR improves walking ability in patients with MS and differs in its effects from existing MS

therapies. If we apply for Priority Review, we may not be able to convince the FDA that Fampridine-SR addresses an unmet medical need for MS patients, in which case we would not receive Priority Review and our NDA would be subject to FDA's normal 10 month review time under the Prescription Drug User Free Act rather than an expedited review time of six months.

Notwithstanding the results of our clinical trials and pre-clinical studies, the FDA could determine that the overall balance of risks and benefits for Fampridine-SR is not adequate to support approval, or only justifies approval for a narrow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. Subjects taking Fampridine-SR have experienced adverse events, including falls, urinary tract infection, insomnia, dizziness, asthenia, headache, fatigue, nausea and balance disorder. A small number of subjects have also experienced seizures while taking Fampridine-SR, and there is a possibility that additional seizures will occur even at low doses of the drug. If the FDA denies approval of Fampridine-SR in MS, if FDA approval is substantially delayed, if approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or if the Fampridine-SR program is terminated, our business prospects will be materially adversely affected.

In March 2004, we completed two Phase 3 clinical trials of Fampridine-SR in SCI in which our results failed to reach their primary endpoints. We may resume development of Fampridine-SR for SCI after we have completed further development of the drug for MS. However, we cannot predict whether future clinical trials of Fampridine-SR in SCI will achieve their primary endpoints, how long these clinical trials will take or how much they will cost.

If our competitors develop and market products that are more effective, safer or more convenient than our approved products, or obtain marketing approval before we obtain approval of future products, our commercial opportunity will be reduced or eliminated.

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS and SCI. We are aware of a company developing a sodium/potassium channel blocker and a second company developing an immediate release form of 3,4 di-aminopyridine, both of which may compete with Fampridine-SR, if approved. In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis. We are aware that at present compounded fampridine is used by some people with MS or SCI and it is possible that some people will want to continue to use compounded formulations even if Fampridine-SR were approved. Several companies are engaged in developing products that include novel immune system approaches and cell transplant approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Fampridine-SR or our preclinical candidates.

Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. As of January 1, 2008, there were 12 companies with generic versions of tizanidine tablets on the market. To the extent that we are not able to differentiate Zanaflex Capsules from Zanaflex tablets and generic tizanidine tablets and/or pharmacists improperly substitute generic tizanidine tablets when filling prescriptions for Zanaflex Capsules, we may be unable to convert additional sales of Zanaflex tablets and generic tizanidine tablets to Zanaflex Capsules and our ability to generate revenue from this product will be adversely affected. Although no other FDA-approved capsule formulation of tizanidine exists, another company could develop a capsule or other formulation of tizanidine that competes with Zanaflex Capsules.

Our competitors may succeed in developing products that are more effective, safer or more convenient than our products or the ones we have under development or that render our approved or

proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective, safer or more convenient for patients, or is able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would adversely affect our ability to generate revenues and recover the substantial development costs we have incurred and will continue to incur.

Our products may be subject to competition from lower-priced versions of such products and competing products imported into the United States from Canada, Mexico and other countries where there are government price controls or other market dynamics that make the products lower priced.

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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the State of New York, on this 10th day of November 2008.

ACORDA THERAPEUTICS, INC.

By: /s/ RON COHEN

Ron Cohen
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ RON COHEN Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	November 10, 2008
/s/ DAVID LAWRENCE David Lawrence, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	November 10, 2008

Exhibit Index

Exhibit No.	Description
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