ACORDA THERAPEUTICS INC
Form 10-Q
November 09, 2010
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2010
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 x No o

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

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

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller Reporting Company o
(Do not check if a

smaller reporting
company)

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

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, 2010
Common Stock, $0.001 par value per share	39,079,688 shares

ACORDA THERAPEUTICS, INC.

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This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would,' 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, 2009 and our Form 10-Q for the quarter ended June 30, 2010, 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.

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PART I

Item 1. Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	September 30, 2010 (unaudited)	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$82,404,827	$47,314,412
Restricted cash	301,848	301,160
Short-term investments	163,412,360	224,778,023
Trade accounts receivable, net	18,228,831	5,739,013
Prepaid expenses	5,722,357	4,274,625
Finished goods inventory held by the Company	24,079,937	4,497,533
Finished goods inventory held by others	2,101,926	2,394,980
Other current assets	3,260,669	3,980,601
Total current assets	299,512,755	293,280,347
Property and equipment, net of accumulated depreciation	3,320,957	1,891,321
Intangible assets, net of accumulated amortization	22,013,430	17,148,631
Non-current portion of deferred cost of license revenue	6,215,001	6,710,001
Other assets	359,045	440,318
Total assets	$331,421,188	$319,470,618
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$17,363,236	$11,613,434
Accrued expenses and other current liabilities	25,803,985	14,975,794
Deferred product revenue—Zanaflex tablets	8,709,065	9,214,742
Deferred product revenue—Zanaflex Capsules	20,617,977	21,489,081
Current portion of deferred license revenue	9,428,571	9,428,571
Current portion of revenue interest liability	6,381,187	6,178,697
Current portion of convertible notes payable	1,144,275	—
Total current liabilities	89,448,296	72,900,319
Non-current portion of deferred license revenue	88,785,714	95,857,142
Put/call liability	318,500	637,500
Non-current portion of revenue interest liability	4,374,627	5,630,862
Non-current portion of convertible notes payable	6,132,134	7,112,027
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value. Authorized 80,000,000 shares at September 30, 2010 and December 31, 2009; issued and outstanding 38,568,369 and 37,935,075 shares as of September 30, 2010 and December 31, 2009, respectively	38,569	37,935
Additional paid-in capital	586,058,355	565,503,101
Accumulated deficit	(443,757,145)	(428,316,881)
Accumulated other comprehensive income	22,138	108,613

Total stockholders' equity	142,361,917	137,332,768
Total liabilities and stockholders' equity	$331,421,188	$319,470,618

See accompanying Unaudited Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

	Three-month period ended September 30, 2010	Three-month period ended September 30, 2009	Nine-month period ended September 30, 2010	Nine-month period ended September 30, 2009
Revenues:				
Gross product sales	$66,188,194	$14,463,303	$126,884,766	$43,834,948
Less: discounts and allowances	(4,923,295)	(1,606,126)	(9,751,194)	(5,959,234)
Net sales	61,264,899	12,857,177	117,133,572	37,875,714
License revenue	2,357,143	2,357,144	7,071,428	2,357,144
Total net revenues	63,622,042	15,214,321	124,205,000	40,232,858
Costs and expenses:				
Cost of sales	11,666,020	2,602,064	22,573,938	8,112,490
Research and development	7,970,073	8,197,789	22,627,938	23,982,123
Selling, general and administrative	30,723,444	23,415,132	91,548,951	67,362,421
Total operating expenses	50,359,537	34,214,985	136,750,827	99,457,034
Operating income (loss)	13,262,505	(19,000,664)	(12,545,827)	(59,224,176)
Other expense (net):				
Interest and amortization of debt discount expense	(943,975)	(704,229)	(3,352,305)	(3,703,552)
Interest income	110,528	314,000	449,736	1,478,996
Other income	8,132	—	8,132	5,365
Loss on disposal of property and equipment	—	(38,914)	—	(23,514)
Total other expense (net)	(825,315)	(429,143)	(2,894,437)	(2,242,705)
Net income (loss)	$12,437,190	$(19,429,807)	$(15,440,264)	$(61,466,881)
Net income (loss) per share—basic	$0.32	$(0.51)	$(0.40)	$(1.63)
Net income (loss) per share—diluted	$0.31	$(0.51)	$(0.40)	$(1.63)
Weighted average common shares outstanding used in computing net income (loss) per share—basic	38,449,917	37,749,920	38,260,608	37,700,747
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	39,987,644	37,749,920	38,260,608	37,700,747

See accompanying Unaudited Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

	Nine-month period ended September 30, 2010	Nine-month period ended September 30, 2009
Cash flows from operating activities:		
Net loss	$(15,440,264)	$(61,466,881)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Share-based compensation expense	12,557,768	8,885,986
Amortization of net premiums and discounts on short-term investments	2,891,356	3,399,860
Amortization of revenue interest issuance cost	80,693	78,242
Depreciation and amortization expense	2,818,092	2,074,183
(Gain) loss on put/call liability	(319,000)	75,000
Loss on disposal of property and equipment	—	23,514
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(12,489,818)	376,637
Increase in prepaid expenses and other current assets	(727,800)	(3,648,754)
(Increase) decrease in inventory held by the Company	(19,582,404)	823,951
Decrease in inventory held by others	293,054	111,871
Decrease (increase) in non-current portion of deferred cost of license revenue	495,000	(6,875,001)
Decrease in other assets	580	6,279
Increase (decrease) in accounts payable, accrued expenses, other current liabilities	16,731,204	(2,826,805)
Increase in revenue interest liability interest payable	337,487	48,675
(Decrease) increase in non-current portion of deferred license revenue	(7,071,428)	107,642,856
(Decrease) increase in deferred product revenue—Zanaflex tablets	(505,677)	335,887
(Decrease) increase in deferred product revenue—Zanaflex Capsules	(871,104)	2,486,481
Restricted cash	(688)	(2,860)
Net cash (used in) provided by operating activities	(20,802,949)	51,549,121
Cash flows from investing activities:		
Purchases of property and equipment	(2,207,442)	(1,903,764)
Purchases of intangible assets	(6,893,914)	—
Purchases of short-term investments	(217,862,168)	(278,897,068)
Proceeds from maturities of short-term investments	276,250,000	224,650,000
Net cash provided by (used in) investing activities	49,286,476	(56,150,832)
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	7,998,120	2,277,073
Repayments of revenue interest liability	(1,391,232)	(1,580,300)
Net cash provided by financing activities	6,606,888	696,773
Net increase (decrease) in cash and cash equivalents	35,090,415	(3,904,938)
Cash and cash equivalents at beginning of period	47,314,412	29,612,916
Cash and cash equivalents at end of period	$82,404,827	$25,707,978
Supplemental disclosure:		
Cash paid for interest	2,850,437	3,158,931

See accompanying Unaudited Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(unaudited)

(1) Organization and Business Activities

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

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

These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company as of and for the year ended December 31, 2009 included in the Company’s Annual Report on Form 10-K for such year, as filed with the Securities and Exchange Commission (the “SEC”).

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

(2) Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include research and development and share-based compensation accounting, which are largely dependent on the fair value of the Company's equity securities. In addition, the Company recognizes Zanaflex revenue based on estimated prescriptions filled. The Company adjusts its Zanaflex inventory value based on an estimate of inventory that may be returned. Actual results could differ from those estimates.

Revenue Recognition

Zanaflex

The Company applies the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules. The Company has accumulated some sales history with Zanaflex Capsules; however, due to existing and potential generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we do not believe we can reasonably determine a return rate at this time. As a result, the Company accounts for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the cost basis of the product held by the wholesaler as a component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized is based on (1) the estimated prescription demand, based on pharmacy sales for its products; and (2) the Company's analysis of third-party information, including third-party market research data. The Company's estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition reflects the Company's estimates of actual product prescribed to the end-user. The Company expects to be able to apply a more traditional revenue recognition policy such that revenue is recognized following shipment to the customer when it believes it has sufficient data to develop reasonable estimates of expected returns based upon historical returns and greater certainty regarding generic competition.

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The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that 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 statement of operations. Adjustments are recorded for estimated chargebacks, rebates, and discounts. These allowances 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 allowances. Allowances 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 the low end of the range of the Company's estimated returns. Product shipping and handling costs are included in cost of sales.

Ampyra

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail and Kaiser Permanente ("Kaiser"). Ampyra will not be available in retail pharmacies. The Company applies the revenue recognition guidance in Staff Accounting Bulletin (SAB) 104 and does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured. The Company recognizes product sales of Ampyra following shipment of product to a network of specialty pharmacy providers and Kaiser. As of September 30, 2010, inventory levels at specialty pharmacy providers that distribute Ampyra (excluding Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers and Kaiser are contractually obligated to hold no more than 30 days of inventory.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated rebates, discounts and returns. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies and Kaiser, an adjustment is recorded for estimated rebates, discounts and returns. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Allowances for rebates, discounts and returns are established based on the contractual terms with customers, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

Based on the Company's specialty distribution model where it sells to only 12 specialty pharmacies and Kaiser, the inventory and prescription data it receives from these distributors, and returns experience of other specialty products with similar selling models, the Company has been able to make a reasonable estimate for product returns. At September 30, 2010, inventory levels at the specialty pharmacies (excluding Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers and Kaiser have contractually agreed to hold no more than 30 days inventory. The Company will accept returns of Ampyra for two months prior to and six months after the product expiration date. The Company will provide a credit for such returns to customers with whom we

have a direct relationship. Once product is prescribed, it cannot be returned. The Company does not exchange product from inventory for the returned product.

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Milestones and royalties

Revenue from milestones is recognized when earned, as evidenced by written acknowledgement from the other party to a contract, provided that (i) the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, and the Company has no further performance obligations relating to that event, and (ii) collectability is reasonably assured. If these criteria are not met, the milestone payment is recognized over the remaining period of our performance obligations under the arrangement. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

Collaborations

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

Ampyra Inventory

Prior to regulatory approval of Ampyra, the Company incurred expenses for the manufacture of bulk, unpackaged product of Ampyra that ultimately became available to support the commercial launch of this drug candidate. Until the necessary initial regulatory approval was received, we charged all such amounts to research and development expenses as there was no alternative future use prior to regulatory approval. As a result, our initial sales of Ampyra will result in higher gross margins than if the inventory costs had not previously been expensed. Upon regulatory approval of Ampyra, the Company began capitalizing the commercial inventory costs associated with manufacturing with Elan and its second manufacturer, Patheon.

Concentration of Risk

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

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.

(3) Share-based Compensation

During the three-month periods ended September 30, 2010 and 2009, the Company recognized share-based compensation expense of $4.8 million and $3.2 million, respectively. During the nine-month periods ended September

30, 2010 and 2009, the Company recognized share-based compensation expense of $12.6 million and $8.9 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2010 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, 2010 and 2009 were approximately $19.75 and $16.75, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2010 and 2009 were approximately $19.37 and $17.59, respectively.

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The following table summarizes share-based compensation expense included within our consolidated statements of operations:

(In millions)	For the three-month period ended September 30, 2010	2009	For the nine-month period ended September 30, 2010	2009
Research and development	$1.4	$0.9	$3.6	$2.5
Selling, general and administrative	3.4	2.3	9.0	6.4
Total	$4.8	$3.2	$12.6	$8.9

A summary of share-based compensation activity for the nine-month period ended September 30, 2010 is presented below:

Stock Option Activity

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value
Balance at January 1, 2010	3,711,778	$15.25		
Granted	1,098,169	32.61		
Cancelled	(88,289)	24.89		
Exercised	(623,294)	12.92		
Balance at September 30, 2010	4,098,364	$20.05	7.1	$53,896,144
Vested and expected to vest at September 30, 2010	4,008,207	$19.83	7.1	$53,588,108
Vested and exercisable at September 30, 2010	2,278,343	$14.12	5.9	$43,143,212

Restricted Stock Activity

Restricted Stock	Number of Shares
Nonvested at January 1, 2010	203,776
Granted	334,178
Vested	(10,000)
Forfeited	(12,185)
Nonvested at September 30, 2010	515,769

As of September 30, 2010, there was $37.0 million of total unrecognized compensation costs related to unvested options and restricted stock awards that the Company expects to recognize over a weighted average period of approximately 2.6 years.

(4) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the three and nine-month periods ended September 30, 2010 and 2009:

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	Three-month period ended September 30, 2010	Three-month period ended September 30, 2009	Nine-month period ended September 30, 2010	Nine-month period ended September 30, 2009
Basic and diluted				
Net income (loss)	$ 12,437,191	$(19,429,807)	$(15,440,264)	$(61,466,881)
Weighted average common shares outstanding used in computing net income (loss) per share—basic	38,449,917	37,749,920	38,260,608	37,700,747
Plus: net effect of dilutive stock options and restricted common shares	1,537,727	—	—	—
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	39,987,644	37,749,920	38,260,608	37,700,747
Net income (loss) per share—basic	$ 0.32	$(0.51)	$(0.40)	$(1.63)
Net income (loss) per share—diluted	$ 0.31	$(0.51)	$(0.40)	$(1.63)

The difference between basic and diluted shares is that diluted shares include the dilutive effect of the assumed exercise of outstanding securities. The Company's stock options and unvested shares of restricted common stock could have the most significant impact on diluted shares.

Securities that could potentially be dilutive are excluded from the computation of diluted earnings per share when a loss from continuing operations exists or when the exercise price exceeds the average closing price of the Company's common stock during the period, because their inclusion would result in an anti-dilutive effect on per share amounts.

For the three months ended September 30, 2010 and 2009, options to purchase 2,841,156 shares and 3,720,272 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive because their exercise price was in excess of the average closing price of the common stock during the period. For the nine months ended September 30, 2010 and 2009, options to purchase 4,080,052 shares and 3,562,639 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive.

For the three months ended September 30, 2010 and 2009, 371,945 and 332,074 shares, respectively, of unvested restricted stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive. For the nine months ended September 30, 2010 and 2009, 406,847 and 287,803 shares, respectively, of unvested restricted stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive.

(5) Income Taxes

The Company had available net operating loss carryforwards (NOL) of approximately $270.1 million and $249.5 million as of September 30, 2010 and December 31, 2009, respectively, for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2019 and 2030. The Company also has research and development tax credit carryforwards of approximately $1.6 million as of both September 30, 2010 and December 31, 2009, for federal income tax reporting purposes that are available to

reduce federal income taxes, if any, and expire in future years beginning in 2020.

At September 30, 2010 and December 31, 2009, the Company had a deferred tax asset of $160.7 million and $147.2 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. Accordingly, the Company’s ability to utilize the aforementioned carryforwards may be limited. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes. Because of the above mentioned factors, the Company has not recognized its gross deferred tax assets as of and for all periods presented. As of September 30, 2010, management believes that it is more likely than not that the gross deferred tax assets will not be realized based on future operations and reversal of deferred tax liabilities. Accordingly, the Company has provided a full valuation allowance against its gross deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

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(6) Fair Value Measurements

The following table presents information about our assets and liabilities measured at fair value on a recurring basis as of September 30, 2010 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability. The Company's Level 1 assets consist of time deposits and investments in a Treasury money market fund and high-quality government bonds. The Company's Level 3 liability represents our put/call liability related to the Paul Royalty Fund (PRF) transaction. No changes in valuation techniques or inputs occurred during the three months ended September 30, 2010. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine-month period ended September 30, 2010.

	Level 1	Level 2	Level 3
Assets Carried at Fair Value:			
Cash equivalents	$76,104,201	$—	$—
Short-term investments	163,412,360	—	—
Liabilities Carried at Fair Value:			
Put/call liability	—	—	318,500

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

	Balance as of December 31, 2009	Realized (gains) losses included in net loss	Unrealized (gains) losses included in other comprehensive loss	Balance as of September 30, 2010
Liabilities Carried at Fair Value:				
Put/call liability	$ 637,500	$(319,000)	$ —	$318,500

We estimate the fair value of our put/call liability using a discounted cash flow valuation technique. Using this approach, expected future cash flows are calculated over the expected life of the PRF agreement, are discounted to a single present value and then exercise scenario probabilities are applied. Some of the more significant assumptions made in the present value calculations include (i) the estimated Zanaflex revenue forecast and (ii) the likelihood of put/call exercise trigger events. Realized gain and losses are included in sales, general and administrative expenses.

Our put/call liability has been classified as a Level 3 asset as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market due to the lack of trading in the security. If different assumptions were used for the various inputs to the valuation approach including, but not limited to, assumptions involving the estimated Zanaflex revenue forecast and the likelihood of trigger events, the estimated fair value of these investments could be significantly higher or lower than the fair value we determined. We may be required to record losses in future periods.

(7) Short-Term Investments

The Company has determined that all of its short-term investments are classified as available-for-sale. Available-for-sale securities are carried at fair value with interest on these securities included in interest income. Available-for-sale securities consisted of the following:

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	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
September 30, 2010				
US Treasury bonds	$163,390,222	$24,182	$(2,044)	$163,412,360
December 31, 2009				
US Treasury bonds	224,669,409	126,169	(17,556)	224,778,023

The contractual maturities of available-for-sale debt securities at September 30, 2010 and December 31, 2009 are within one year. The Company has determined that there were no other-than-temporary declines in the fair values of its short term investments as of September 30, 2010. Short-term investments with maturity of three months or less from date of purchase have been classified as cash equivalents, and amounted to $76,104,201 and $43,471,757 as of September 30, 2010 and December 31, 2009, respectively.

(8) Biogen Collaboration Agreement

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

Under the Collaboration Agreement, the Company was entitled to an upfront payment of $110.0 million as of June 30, 2009, which was received on July 1, 2009, and will be entitled to receive additional payments of up to approximately $400 million based on the successful achievement of future regulatory and sales milestones. Due to the uncertainty surrounding the achievement of the future regulatory and sales milestones, these payments will not be recognized as revenue unless and until they are earned. The Company is not able to reasonably predict if and when the milestones will be achieved. Under the Collaboration Agreement, Biogen Idec will be required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. In addition, the consideration that Biogen Idec will pay for licensed products under the Supply Agreement will reflect the price owed to the Company’s suppliers under its supply arrangements with Elan or other suppliers for ex-U.S. sales, including manufacturing costs and royalties owed. The Company and Biogen Idec may also carry out future joint development activities regarding licensed product under a cost-sharing arrangement. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen Idec, will participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the United States pursuant to that agreement. Acorda will continue to develop and commercialize Ampyra independently in the United States.

As of June 30, 2009, the Company recorded a license receivable and deferred revenue of $110.0 million for the upfront payment due to the Company from Biogen Idec under the Collaboration Agreement. Also, as a result of such payment to Acorda, a payment of $7.7 million became payable by Acorda to Elan and was recorded as a cost of license payable and deferred expense. The payment of $110.0 million was received from Biogen Idec on July 1, 2009 and the payment of $7.7 million was made to Elan on July 7, 2009.

The Company considered the following deliverables with respect to the revenue recognition of the $110.0 million upfront payment: (1) the license to use the Company's technology, (2) the Collaboration Agreement to develop and commercialize licensed product in all countries outside the U.S., and (3) the supply agreement. The Company has determined that the identified deliverables would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and reliable evidence of fair value for the deliverables. Accordingly, the deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen Idec as revenue and the associated payment to Elan as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as we had determined this was the most probable expected benefit period. The Company recognized $7.1 million in license revenue, a portion of the $110.0 million received from Biogen Idec and $495,000 in cost of license revenue, a portion of the $7.7 million paid to Elan during the nine-month period ended September 30, 2010. The Company currently estimates the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

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(9) Commitments and Contingencies

A summary of the Company's commitments and contingencies was included in the Company's Annual Report on Form 10-K for the twelve-month period ended December 31, 2009. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. The Company believes that the ultimate resolution of these matters will not have a material adverse effect on the Company's financial condition or liquidity. However, adjustments, if any, to the Company's estimates could be material to operating results for the periods in which adjustments to the liability are recorded.

(10) Intangible Assets

The Company acquired all of Elan's U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004 for $2.0 million plus $675,000 for finished goods inventory. The Company was also responsible for up to $19.5 million in future contingent milestone payments based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of December 31, 2009, the Company made $19.5 million of these milestone payments which were recorded as intangible assets in the consolidated financial statements.

In connection with this transaction, the Company acquired the rights to the trade name "Zanaflex®", one issued U.S. patent and two patent applications related to Zanaflex Capsules, and the remaining tablet inventory on hand with Elan. Additionally, the Company assumed Elan's existing contract with Novartis to manufacture Zanaflex tablets and entered into a separate contract with Elan to manufacture Zanaflex Capsules. The Company separately launched Zanaflex Capsules in April 2005. The Company did not acquire any receivables, employees, facilities or fixed assets. The Company allocated, on a relative fair value basis, the initial and milestone payments made to Elan to the assets acquired, principally the Zanaflex trade name and the capsules patent. There is no expected residual value of these intangible assets. The Company amortizes the allocated fair value of the trade name and patent over their estimated future economic benefit to be achieved. The Zanaflex trade name was fully amortized as of December 31, 2008.

On January 22, 2010, the Company received marketing approval from the FDA for Ampyra triggering two milestone payments of $2.5 million to Elan and $750,000 to Rush-Presbyterian St. Luke's Medical Center (Rush). As of September 30, 2010, the Company made or accrued these milestone payments totaling $3.25 million and they were recorded as intangible assets in the consolidated financial statements. The payment to Elan was made during the three-months ended June 30, 2010.

In 1990, Elan licensed from Rush know-how relating to dalfampridine (4-aminopyridine, 4-AP, the formulation used in Ampyra), for the treatment of MS. The Company subsequently licensed this know-how from Elan. In September 2003, the Company entered into an agreement with Rush and Elan terminating the Rush license to Elan and providing for mutual releases. The Company also entered into a license agreement with Rush in 2003 in which Rush granted the Company an exclusive worldwide license to its know-how relating to dalfampridine for the treatment of MS. Rush has also assigned to the Company its Orphan Drug Designation for dalfampridine for the relief of symptoms of MS.

The Company agreed to pay Rush a license fee, milestone payments of up to $850,000 and royalties based on net sales of the product for neurological indications. As of December 31, 2009, the Company had made an aggregate of $100,000 in payments under this agreement. The FDA approval of Ampyra triggered the final milestone of $750,000 which was paid during the three-months ended March 31, 2010. As of September 30, 2010, the Company made or accrued royalty payments totaling $1.6 million.

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In August 2003, the Company entered into an Amended and Restated License Agreement with the Canadian Spinal Research Organization (CSRO). Under this agreement, the Company was granted an exclusive and worldwide license under certain patent assets and know-how of CSRO relating to the use of dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject. The agreement required the Company to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including royalties on the sale of Ampyra and on the sale of dalfampridine for any other indication. No royalty payments have been made to date. During the three-month period ended March 31, 2010, the Company purchased CSRO's rights to all royalty payments under the agreement with CSRO for $3.0 million. This payment was recorded as an intangible asset in the consolidated financial statements.

Intangible assets also include certain website development costs which have been capitalized. The Company has developed several websites, each with its own purpose, including the general corporate website, product information websites and websites focused on the MS community.

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its intangible assets may warrant revision or that the carrying value of these assets may be impaired. The Company evaluates the realizability of its intangible assets based on profitability and cash flow expectations for the related assets. As of September 30, 2010, the Company does not believe that there are any facts or circumstances that would indicate a need for changing the estimated useful life of the Zanaflex or Ampyra patents.

Intangible assets consisted of the following:

	September 30, 2010	December 31, 2009	Estimated remaining useful lives as of September 30, 2010
Zanaflex patents	$19,350,000	$ 19,350,000	11 years
Zanaflex trade name	2,150,000	2,150,000	0 years
Ampyra milestones	3,250,000	—	7 years
CSRO Royalty Buyout	3,000,000	—	7 years
Website development costs(1)	2,871,195	1,444,749	3 years
Website development costs – in process websites (2)	—	782,531	3 years
	30,621,195	23,727,280	
Less accumulated amortization	8,607,764	6,578,649	
	$22,013,431	$ 17,148,631	

(1) Represents capitalized website development costs for fully developed and launched websites.

(2) Represents websites in development which had not been completed and therefore had not been launched as of December 31, 2009.

The Company recorded $2,029,115 and $794,513 in amortization expense related to these intangible assets in the nine-month periods ended September 30, 2010 and 2009, respectively.

Estimated future amortization expense for these intangible assets subsequent to December 31, 2009 for the next five years is as follows:

2010	$2,700,347

2011	3,127,212
2012	2,801,439
2013	2,410,262
2014	2,182,817
	$13,222,077

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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 MS and other neurological disorders. Ampyra, the first product for which we completed clinical development, was approved by the FDA in January 2010 for the improvement of walking in people with MS. This was demonstrated by an increase in walking speed. To our knowledge, Ampyra is the first and only product approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the U.S. in March 2010. Gross sales of Ampyra were $52.6 million for the quarter ended September 30, 2010.

Our other marketed drug, Zanaflex Capsules, which we began marketing in 2005, is FDA-approved as a short-acting drug for the management of spasticity. Gross sales of Zanaflex Capsules, together with the generic version of tablets sold by us, were $58.3 million in 2009 and $41.1 million for the nine months ended September 30, 2010. We expect that our gross sales of Zanaflex Capsules for 2010 will decline, principally due to increasing managed care pressure, among other factors. Managed care organizations have increasingly established plans and programs to drive utilization of low-cost generic tizanidine tablets over higher-cost Zanaflex Capsules by making it more difficult for patients to obtain Zanaflex Capsules through restrictions and higher out-of-pocket (co-pay) costs. There was a 9% price increase on Zanaflex Capsules and tablets effective November 1, 2010.

Ampyra is being marketed in the U.S. through our own specialty sales force and commercial infrastructure, which is also responsible for sales and marketing of Zanaflex Capsules. We completed the expansion of our sales force in March and currently have approximately 100 sales representatives in the field calling on a priority target list of approximately 10,000 physicians, which we expanded from our original priority target list of 5,500. We also have established teams of Regional Scientific Managers and Managed Markets representatives who provide information on Ampyra to physicians and payors. As of September 30, 2010, approximately 6,300 healthcare professionals had written at least one prescription for Ampyra.

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail and Kaiser Permanente (Kaiser), and is supported by Ampyra Patient Support Services (APSS), a dedicated resource for healthcare providers and people with MS. This distribution process is well established within the MS community, and physicians and patients are familiar with this model. Prior to the launch of Ampyra, we contracted with a third party organization with extensive experience in coordinating patient benefits to run APSS. The customer care agents at Ampyra Patient Support Services are responsible for helping healthcare professionals process prescriptions, working with insurance carriers to facilitate coverage, and directing patients to available co-pay and patient assistance programs. The process begins when a prescription is submitted by a physician to APSS. Once this process is completed, the prescription is sent to a specialty pharmacy, which confirms the benefits and mails the prescription directly to the patient. In some cases, the specialty pharmacy rather than APSS performs the benefits investigation.

A prescription request backlog was experienced at APSS early in the launch due to pent-up demand, and we implemented process improvements and staffing adjustments to address the backlog. We continued to fill the backlog

during the quarter ended June 30, 2010, and it was eliminated by the end of the quarter. Third quarter sales were significantly impacted by the large backlog of prescription requests that were submitted earlier in the year and were not all filled until the third quarter. This backlog was eliminated in the third quarter, and fourth quarter sales may be lower than third quarter sales. Processing of most incoming requests for prescriptions now begins within 24 hours of receipt. Patients will still experience a range of times to receive their first shipment based on their insurance requirements. As with any new prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription.

As of September 30, 2010, approximately 31,000 people with MS had filled a prescription for Ampyra, representing almost 8% of all MS patients in the U.S. As of September 30, 2010, the rate of first refill was 67%, based on a weighted average from a cohort of approximately 17,500 patients who received an initial one-month prescription in March through August. Approximately 85% to 90% of total prescriptions written have been for a one month supply, with most of the balance being for three months. Currently, approximately 10% of shipped product is for no-cost use by patients enrolled in the Ampyra patient assistance program.

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Our managed markets representatives continue to meet with payors to provide information on Ampyra and discuss patient access. As of September 30, 2010, approximately 75% of commercially-insured individuals had no or limited prior authorizations (PAs) for Ampyra. Limited PAs are defined as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. Approximately 20% of commercially-insured individuals are subject to more restrictive PAs, which may include requirements for multiple timed walk tests and/or EDSS (Expanded Disability Status Scale) score requirements to initiate therapy, and/or objective measures of ambulation improvement to reauthorize Ampyra therapy. We estimate that approximately 5% of commercially-insured individuals are currently blocked from receiving reimbursement for Ampyra. Access figures have been calculated based on the number of pharmacy lives reported by commercial healthcare plans.

As of September 30, 2010, inventory levels at the specialty pharmacy providers that distribute Ampyra (does not include Kaiser) was approximately two-weeks. The specialty pharmacy providers and Kaiser are contractually obligated to hold no more than 30 days of inventory.

The FDA granted Ampyra orphan drug status, which will provide seven years of market exclusivity for the drug. In addition, we have issued patents that cover the formulation and use of Ampyra. We filed for patent term extension for Ampyra pursuant to the provisions of the Hatch-Waxman Act that allows for up to five additional years of patent protection based on the development timeline of a drug. Although we have applied to extend both Ampyra patents listed in the FDA Orange Book, we will ultimately need to select only one patent for extension, if granted. We received non-final rejection letters from the U.S. Patent and Trademark Office (USPTO) on two patent applications for Ampyra filed in late 2004 and early 2005. We have until March17, 2011 and November 25, 2010, respectively, to respond to the letters.

In October 2010, the European Patent Office (EPO) posted a “Communication of Intent to Grant a Patent” for a patent we submitted with “composition for use” and other use claims directed to sustained release aminopyridine compositions for, among other things, increased walking speed, improving lower extremity muscle strength, or improving lower extremity muscle tone, in patients with MS. A corresponding patent is currently under review by the USPTO. The USPTO operates independently of the EPO, and the EPO’s decision should not be taken to indicate the outcome for the U.S. patent.

In June 2009, we entered into the Collaboration Agreement with Biogen Idec. In January 2010, Biogen Idec announced that it submitted a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and a New Drug Submission (NDS) to Health Canada for Ampyra, which is known outside the U.S. as fampridine.

We have three preclinical programs focused on novel approaches to repair damaged components of the CNS. We believe all of our preclinical programs—neuregulins, remyelinating antibodies and chondroitinase—have broad applicability and have the potential to be first-in-class therapies. While these programs have initially been focused on MS and spinal cord injury (SCI), we believe they may be applicable across a number of CNS disorders, including stroke and traumatic brain injury, because many of the mechanisms of tissue damage and repair are similar. In addition, we believe that these programs may have applicability beyond the nervous system, including in such fields as cardiology, oncology, orthopedics and ophthalmology.

In March 2010, we filed an Investigational New Drug (IND) application for GGF2 as a therapy for heart failure, and in April 2010 the IND became effective. In 2008, we began to work with a contract manufacturer to develop larger scale manufacturing and purification processes for GGF2, one of the neuregulins, under cGMP (good manufacturing practices) in preparation for our IND application to support human clinical trials for the treatment of heart failure. If

we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product either by entering into a partnership, most likely with a cardiovascular-focused company, or developing it on our own. We had originally targeted the start of a Phase 1 trial for mid-2010, but there was a delay in completing production of GGF2 clinical study medication due to deficiencies in the vial filling process. We have resolved the vial filling issues and we are now completing preparations for the start of the Phase 1 trial. We and Vanderbilt University received a $1 million Cardiac Translational Research Implementation Program (C-TRIP) grant from the National Heart, Lung and Blood Institute (NHLBI) to support research on GGF2. If these studies are successful, Acorda and Vanderbilt will be eligible to apply for a second phase C-TRIP grant of at least $7.5 million. We began work with a contract manufacturer in 2009 to scale up manufacturing and purification processes for one of the remyelinating antibodies, rHIgM22, under cGMP for preparation for a future IND application. These manufacturing processes have been completed and we are now in formal preclinical safety and toxicity studies. If rHIgM22 proves to have a satisfactory preclinical safety profile, we expect to file an IND for the treatment of MS. We also are continuing research on the potential use of chondroitinases for the treatment of injuries to the brain and spinal cord. The chondroitinase program is in the research and translational development phases and has not yet entered formal preclinical development.

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We have had significant operating losses since inception as a result of our focus on clinical and preclinical development activities and our goal of building an internal sales, managed markets and marketing organization in the U.S. We may incur losses for the next several years as we continue to support an expanded sales and marketing organization and other activities in connection with the commercial launch of Ampyra and the advancement of our clinical and preclinical development programs. We expect that our sales and marketing, general and administrative expenses in 2010 will increase substantially over 2009 levels, primarily due to launch costs and sales and marketing expenses for Ampyra, including increases in sales, managed markets and medical affairs staff and the implementation of the work needed for FDA post-marketing study commitments for Ampyra. Due to the delay in production of GGF2 clinical study medication and the consequent delay in the start of the Phase 1 trial originally targeted for mid-2010, we expect that R&D expenses for 2010 will slightly decrease over total R&D expenses incurred in 2009.

We will also continue to explore opportunities to expand our pipeline through the potential in-licensing and/or acquisition of select products and technologies in neurology. We are interested in both clinical and commercial state products, with a particular focus on Phase 2 product candidates, although we are open to assessing compounds at other stages as well. We do not currently plan to acquire a marketed product for launch during the first year of Ampyra's commercial launch.

In August 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In October 2007, the Company filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) for patent infringement in relation to the filing of the ANDA by Apotex. The defendants answered the Company’s complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. The Company denied those counterclaims. In March 2008, Apotex filed a motion, which the Company opposed, for partial judgment on the pleadings dismissing the Company’s request for relief on the ground that the case is “exceptional” under U.S.C. §§ 271(e)(4) or 285. The court ruled in the Company’s favor and denied Apotex’s motion in December 2008. Fact discovery in the case has been completed. On July 2, 2010, the U.S. District Court held a Markman hearing to determine the interpretation of certain terms in the Company’s Zanaflex Capsules patent that is at issue in this litigation. The Court ruled favorably on a number of those terms, and the case is proceeding, with expert discovery scheduled to be completed by early January 2011.

Our timely filing of a lawsuit against Apotex in October 2007 triggered an automatic stay on FDA approval of the Apotex ANDA for 30 months. That stay expired in March 2010. Consequently, Apotex will be able to receive FDA approval of its ANDA, if Apotex is able otherwise to satisfy FDA's review requirements for ANDAs, at which time it could begin selling a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets, even if our patent litigation remains pending. If Apotex begins selling its product before it is successful in challenging the validity, infringement, or enforceability of our patent, Apotex would be selling at the risk of our ultimately prevailing on our patent infringement claims and its being held liable for damages for patent infringement.

The Company accrues for amounts related to loss contingencies if it is probable that a liability has been incurred and the amount is reasonably estimable. As of September 30, 2010, there have been no accruals for loss contingencies aside from payments related to the litigation itself.

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Results of Operations

Three-Month Period Ended September 30, 2010 Compared to September 30, 2009

Net Revenue

Total net revenues are summarized in the following table:

	Three-month period ended September 30, 2010	Three-month period ended September 30, 2009
Gross product sales		
Ampyra	$ 52,584,094	$ —
Zanaflex	13,604,100	14,463,303
Total gross product sales	66,188,194	14,463,303
Discounts and allowances		
Ampyra	(2,846,762)	—
Zanaflex	(2,076,533)	(1,606,126)
Total discounts and allowances	(4,923,295)	(1,606,126)
License revenue		
Ampyra	2,357,143	2,357,144
Zanaflex	—	—
Total license revenue	2,357,143	2,357,144
Total net revenue	$ 63,622,042	$ 15,214,321

Gross Product Sales

Ampyra

We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers and Kaiser. We recognized revenue from the sale of Ampyra of $52.6 million for the three-month period ended September 30, 2010. Third quarter sales were significantly impacted by the large backlog of prescription requests that were submitted earlier in the year and were not all filled until the third quarter. This backlog was eliminated in the third quarter, and fourth quarter sales may be lower than third quarter sales.

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Zanaflex

We recognize product sales of Zanaflex Capsules and Zanaflex tablets 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 $13.6 million for the three-month period ended September 30, 2010, as compared to $14.5 million for the three-month period ended September 30, 2009. The decrease was due to a decrease in both shipments and prescriptions due to increasing managed care pressure, among other factors, partially offset by a 15% price increase for Zanaflex Capsules effective February 1, 2010. As previously projected, we expect sales of Zanaflex Capsules to decline in 2010.

Discounts and Allowances

Ampyra

We recorded discounts and allowances of $2.8 million for the three-month period ended September 30, 2010 which consists of allowances for customer credits, including estimated rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers and Kaiser. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

Zanaflex

We recorded discounts and allowances of $2.1 million for the three-month period ended September 30, 2010 as compared to $1.6 million for the three-month period ended September 30, 2009. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances for the three-month period ended September 30, 2010 consisted of $1.1 million in allowances for chargebacks and rebates $698,000 in fees for services payable to wholesalers, and $325,000 in cash discounts and patient program rebates. Discounts and allowances for the three-month period ended September 30, 2009 consisted of $597,000 in allowances for chargebacks and rebates, $785,000 in fees for services payable to wholesalers and $225,000 in cash discounts and patient program rebates.

Healthcare Reform

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contains several provisions that will affect our business. Although many provisions of the new legislation do not take effect immediately, several provisions became effective in the first quarter of 2010. We do not expect these 2010 changes to have a material impact on our discounts and allowances.

Beginning in 2011, the new law requires drug manufacturers to provide a 50% discount to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the “donut hole”). Also, beginning in 2011, we will be assessed our share of a new fee (which will not be deductible for tax purposes) payable by all branded prescription drug manufacturers and importers. The manner in which this new legislation will be implemented is still being formulated; therefore, we cannot currently quantify the potential impact of this part of the legislation.

License Revenue

The Company recognized $2.4 million in license revenue related to the $110.0 million received from Biogen Idec in 2009 for the three-month periods ended September 30, 2010 and 2009.

Cost of Sales

Ampyra

We recorded cost of sales of $9.3 million for the three-month period ended September 30, 2010. Cost of sales for the three-month period ended September 30, 2010 consisted primarily of $8.0 million in inventory costs related to recognized revenues. Our launch stock inventory was received in bulk form prior to regulatory approval; therefore, the manufacturing cost associated with this inventory was classified as research and development expense as there was no alternative future use prior to regulatory approval. This expensed inventory represented approximately 8% of the total cost basis of our launch stock inventory. The remaining packaged portion of the inventory cost was received after regulatory approval and thus capitalized. This reduction to our cost basis effectively reduced our cost of sales related to recognized revenues by approximately $683,000 for the three-month period ended September 30, 2010. At September 30, 2010, we are carrying the launch inventory on our balance sheet with a reduction to the cost basis of approximately $191,000. We expect our reduced cost basis inventory to be sold during the remainder of 2010.

Cost of sales for the three-month period ended September 30, 2010 also consisted of $1.0 million in royalty fees based on net sales, $225,000 in amortization of intangible assets, and $67,000 in period costs related to packaging, freight and stability testing. We expect cost of sales for the remainder for the year to be approximately 21% of net Ampyra sales.

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Zanaflex

We recorded cost of sales of $2.3 million for the three-month period ended September 30, 2010 as compared to $2.6 million for the three-month period ended September 30, 2009. Cost of sales for the three-month period ended September 30, 2010 consisted of $1.2 million in inventory costs primarily related to recognized revenues, $799,000 in royalty fees based on net product shipments, $321,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $39,000 in period costs related to freight and stability testing. Cost of sales for the three-month period ended September 30, 2009 consisted of $1.4 million in inventory costs primarily related to recognized revenues, $878,000 in royalty fees based on net product shipments, $321,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $50,000 in period costs related to packaging, freight, and stability testing. Payments to and interest expense related to the PRF transaction discussed below in the section titled “Liquidity and Capital Resources” do not impact the Company’s cost of sales.

Research and Development

Research and development expenses for the three-month period ended September 30, 2010 were $8.0 million as compared to $8.2 million for the three-month period ended September 30, 2009, a decrease of approximately $200,000, or 3%. The decrease was primarily attributable to a decrease in regulatory expenses of $1.4 million which were incurred in 2009 related to NDA preparation and support for Ampyra. The decrease was also related to a reduction in expenses allocated to research and development of $536,000 for Ampyra manufacturing and stability work that was classified as research and development for the three-month period ended September 30, 2009 as it was incurred prior to FDA approval of the drug.

The decrease in research and development expenses was partially offset by an increase of $967,000 for clinical costs associated with the close-out of our MS extension study sites and an increase of $711,000 related to work on one of our preclinical pipeline products, GGF2, including an increase in research and development staff and compensation to support this initiative. The Company’s previous guidance was that R&D expenses would increase in 2010 over 2009. Due to the delay in production of GGF2 clinical study medication announced last quarter as a result of the deficiencies in the vial filling process and the consequent delay in the start of the Phase 1 trial originally targeted for mid-2010, we now expect that R&D expenses will slightly decrease in 2010 over 2009.

Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2010 were $19.0 million compared to $15.6 million for the three-month period ended September 30, 2009, an increase of approximately $3.4 million or 22%. This increase was primarily attributable to an increase in staff and compensation of $4.1 million resulting from the expansion of our field sales staff and the overall commercial department in order to support the launch of Ampyra offset by a decrease of $692,000 primarily in marketing and trade and distribution expenses related to Zanaflex Capsules.

General and administrative expenses for the three-month period ended September 30, 2010 were $11.6 million compared to $7.7 million for the three-month period ended September 30, 2009, an increase of approximately $3.9 million, or 51%. This increase was the result of an increase in general and administrative staff and compensation and other expenses of $1.9 million related to supporting the growth of the overall organization, an increase in costs related to Ampyra post-approval regulatory and manufacturing support expenses of $1.0 million, an increase in medical affairs expenses including educational programs of $655,000 and an increase in legal expenses of $275,000.

SG&A expenses decreased in the third quarter from the second quarter, but we still expect 2010 SG&A expenses to be substantially higher than in 2009.

Other Expense

Other expense was $825,000 for the three-month period ended September 30, 2010 compared to $429,000 for the three-month period ended September 30, 2009. Other expense for the three-month period ended September 30, 2010 consisted of interest expense principally related to the PRF revenue interest agreement of $944,000 and interest income of $111,000. Other expense for the three-month period ended September 30, 2009 consisted of interest expense principally related to the PRF revenue interest agreement of $704,000 and interest income of $314,000. The decrease in interest expense resulted from lower Zanaflex shipments for the three-month period ended September 30, 2010 as compared to the same period in 2009. The decrease in interest income for the three-month period ended June 30, 2010 is due to a lower average interest rate than for the same period in 2009.

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Nine-Month Period Ended September 30, 2010 Compared to September 30, 2009

Net Revenue

Total net revenues are summarized in the following table:

	Nine-month period ended September 30, 2010	Nine-month period ended September 30, 2009
Gross product sales		
Ampyra	$85,738,013	$—
Zanaflex	41,146,753	43,834,948
Total gross product sales	126,884,766	43,834,948
Discounts and allowances		
Ampyra	(4,979,432)	—
Zanaflex	(4,771,762)	(5,959,234)
Total discounts and allowances	(9,751,194)	(5,959,234)
License revenue		
Ampyra	7,071,428	2,357,144
Zanaflex	—	—
Total license revenue	7,071,428	2,357,144
Total net revenue	$124,205,000	$40,232,858

Gross Product Sales

Ampyra

We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers and Kaiser. We recognized revenue from the sale of Ampyra of $85.7 million for the nine-month period ended September 30, 2010. Third quarter sales were significantly impacted by the large backlog of prescription requests that were submitted earlier in the year and were not all filled until the third quarter. This backlog was eliminated in the third quarter, and fourth quarter sales may be lower than third quarter sales.

Zanaflex

We recognize product sales of Zanaflex Capsules and Zanaflex tablets 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 $41.1 million for the nine-month period ended September 30, 2010, as compared to $43.8 million for the nine-month period ended September 30, 2009. The decrease was due to a decrease in both shipments and prescriptions

due to increasing managed care pressure, among other factors, partially offset by a 15% price increase for Zanaflex Capsules effective February 1, 2010. As previously projected, we expect sales of Zanaflex Capsules to decline in 2010.

Discounts and Allowances

Ampyra

We recorded discounts and allowances of $5.0 million for the nine-month period ended September 30, 2010, which consists of allowances for customer credits, including estimated rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers and Kaiser. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

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Zanaflex

We recorded discounts and allowances of $4.8 million for the nine-month period ended September 30, 2010 as compared to $6.0 million for the nine-month period ended September 30, 2009. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances for the nine-month period ended September 30, 2010 consisted of $1.8 million in fees for services payable to wholesalers, $1.9 million in allowances for chargebacks and rebates, and $1.0 million in cash discounts and patient program rebates. Discounts and allowances for the nine-month period ended September 30, 2009 consisted of $2.8 million in allowances for chargebacks and rebates which includes an adjustment of $865,000, $226,000 related to the first and second quarters of 2009 and $639,000 related to 2008. This adjustment resulted from a Department of Defense (DOD) regulation finalized during the three-month period ended March 31, 2009 which purports to require manufacturers to pay rebates to DOD on utilization distributed to TriCare beneficiaries through retail pharmacies retroactive to January 28, 2008. The application of the regulation is currently being challenged in court by a coalition representing a number of manufacturers. Discounts and allowances for the nine-month period ended September 30, 2009 also included $2.0 million in fees for services payable to wholesalers and $1.1 million in cash discounts and patient program rebates.

Healthcare Reform

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contains several provisions that will affect our business. Although many provisions of the new legislation do not take effect immediately, several provisions became effective in the first quarter of 2010. We do not expect these 2010 changes to have a material impact on our discounts and allowances.

Beginning in 2011, the new law requires drug manufacturers to provide a 50% discount to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the “donut hole”). Also, beginning in 2011, we will be assessed our share of a new fee (which will not be deductible for tax purposes) payable by all branded prescription drug manufacturers and importers. The manner in which this new legislation will be implemented is still being formulated; therefore we cannot currently quantify the potential impact of this part of the legislation.

License Revenue

The Company recognized license revenue related to the $110.0 million received from Biogen Idec in 2009 of $7.1 million for the nine-month period ended September 30, 2010 as compared to $2.4 million for the nine-month period ended September 30, 2009. The increase is the result of a full nine months of revenue in 2010 versus a single quarter in 2009.

Cost of Sales

Ampyra

We recorded cost of sales of $15.5 million for the nine-month period ended September 30, 2010. Cost of sales for the nine-month period ended September 30, 2010 consisted of $13.0 million in inventory costs related to recognized revenues. Our launch stock inventory was received in bulk form prior to regulatory approval; therefore the manufacturing cost associated with this inventory was classified as research and development expense as there was no alternative future use prior to regulatory approval. This expensed inventory cost represented approximately 8% of the total cost basis of our launch stock inventory. The remaining packaged portion of the inventory cost was received after regulatory approval and thus capitalized. This reduction to our cost basis effectively reduced our cost of sales related to recognized revenues by approximately $1.1 million for the nine-month period ended September 30, 2010. At

September 30, 2010, we are carrying the launch inventory on our balance sheet with a reduction to the cost basis of approximately $191,000. We expect our reduced cost basis inventory to be depleted during the remainder of the year.

Cost of sales for the nine-month period ended September 30, 2010 also consisted of $1.7 million in royalty fees based on net sales, $564,000 in amortization of intangible assets, and $210,000 in period costs related to packaging, freight and stability testing. We expect cost of sales for the remainder for the year to be approximately 21% of net Ampyra sales.

Zanaflex

We recorded cost of sales of $7.1 million for the nine-month period ended September 30, 2010 as compared to $8.1 million for the nine-month period ended September 30, 2009. Cost of sales for the nine-month period ended September 30, 2010 consisted of $3.6 million in inventory costs primarily related to recognized revenues, $2.4 million in royalty fees based on net product shipments, $962,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $135,000 in period costs related to freight and stability testing. Cost of sales for the nine-month period ended September 30, 2009 consisted of $4.2 million in inventory costs primarily related to recognized revenues, $2.8 million in royalty fees based on net product shipments, $962,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $152,000 in period costs related to packaging, freight, and stability testing. Payments to and interest expense related to the PRF transaction discussed below in the section titled “Liquidity and Capital Resources” do not impact the Company’s cost of sales.

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Research and Development

Research and development expenses for the nine-month period ended September 30, 2010 were $22.6 million as compared to $23.9 million for the nine-month period ended September 30, 2009, a decrease of approximately $1.3 million, or 5%. The decrease was primarily attributable to a decrease in regulatory expenses of $3.5 million which were incurred in 2009 related to NDA preparation and support. The decrease was also related to a reduction in expenses allocated to research and development of $275,000 for Ampyra manufacturing and stability work that was classified as research and development for the three-month period ended September 30, 2009 prior to FDA approval of the drug.

The decrease in research and development expenses was partially offset by an increase of $2.2 million related to work on one of our preclinical pipeline products, GGF2, including an increase in overall research and development staff and compensation to support this initiative as well as two milestones expenses recorded during the three-month period ended March 31, 2010 which were related to the filing of the IND for GGF2. One was for $500,000 payable to Paion AG (formerly CeNeS) and one was for $150,000 payable to Brigham and Women's Hospital. The overall decrease in research and development expense was also offset by a net increase of $274,000 for clinical costs associated with the close-out of our MS extension study sites. The Company's previous guidance was that R&D expenses would increase in 2010 over 2009. Due to the delay in production of GGF2 clinical study medication announced last quarter as a result of the deficiencies in the vial filling process and the consequent delay in the start of the Phase 1 trial originally targeted for mid-2010, we now expect that R&D expenses will slightly decrease in 2010 over 2009.

Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2010 were $59.8 million compared to $44.1 million for the nine-month period ended September 30, 2009, an increase of approximately $15.7million or 36%. This increase was primarily attributable to an increase in staff and compensation of $12.0 million resulting from the expansion of our field sales staff and the overall commercial department in order to support the launch of Ampyra as well as an increase of $3.7 million in marketing, trade and distribution expenses, and various launch activities associated with Ampyra.

General and administrative expenses for the nine-month period ended September 30, 2010 were $31.3 million compared to $23.1 million for the nine-month period ended September 30, 2009, an increase of approximately $8.2 million, or 35%. This increase was the result of an increase in medical affairs expenses including educational programs of $3.2 million, an increase in general and administrative staff and compensation and other expenses of $2.8 million related to supporting the overall growth of the organization, and an increase in costs related to Ampyra post-approval regulatory and manufacturing support expenses of $2.4 million. The overall increase in general and administrative expenses is offset by a decrease in legal expenses of $268,000.SG&A expenses decreased in the third quarter from the second quarter, but we still expect 2010 SG&A expenses to be substantially higher than in 2009.

Other Expense

Other expense was $2.9 million for the nine-month period ended September 30, 2010 compared to $2.2 million for the nine-month period ended September 30, 2009, an increase of approximately $652,000 or 29%. The increase was primarily due to a decrease in interest income of $826,000 resulting from a lower average interest rate than for the same period in 2009. The decrease in interest income was partially offset by a $351,000 decrease in interest expense principally related to the PRF revenue interest agreement.

Liquidity and Capital Resources

We have incurred annual operating losses since inception and, as of September 30, 2010, we had an accumulated deficit of approximately $443.8 million. We have financed our operations primarily through private placements of our securities, public offerings of our common stock, our Collaboration and Licensing Agreement, sales of Zanaflex Capsules and Ampyra, and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

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Financing Arrangements

In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. As of September 30, 2010, $5.0 million of these promissory notes plus $2.3 million of accrued interest was outstanding. The first of seven annual payments on this note is due on the one year anniversary after Ampyra approval on January 22, 2011.

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid us $5.0 million in November 2006 and an additional $5.0 million in February 2007 as our net revenues during the fiscal year 2006 exceeded $25.0 million. Under the terms of the amendment, we were required to pay PRF $5.0 million on December 1, 2009. This payment was made. We are required to make an additional $5.0 million payment 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 $11.5 million. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 5.7%. 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, 2010, cash and cash equivalents and short-term investments were approximately $245.8 million, as compared to $272.1 million at December 31, 2009. As of September 30, 2010, our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in a Treasury money market fund and high-quality government bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of September 30, 2010, our cash and cash equivalents were $82.4 million, as compared to

$47.3 million as of December 31, 2009. Our short-term investments consist of US Treasury bonds with original maturities greater than three months and less than one year. The balance of these investments was $163.4 million as of September 30, 2010, as compared to $224.8 million as of December 31, 2009.

Net Cash Used in Operations

Net cash (used in) provided by operations was $(20.8) million and $51.5 million for the nine-month period ended September 30, 2010 and 2009, respectively. Cash used in operations for the nine-month period ended September 30, 2010 was primarily attributable to a net loss of $15.4 million. It was also attributable to an increase in inventory held by the Company of $19.6 million primarily due to the purchase of Ampyra launch stock and additional Ampyra inventory to meet demand, an increase in accounts receivable of $12.5 million resulting from an increase in gross product sales for Ampyra, and a decrease in the non-current portion of deferred license revenue of $7.1 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009. Cash used in operations for the nine-month period ended September 30, 2010 also included a net increase of $15.4 million due to changes in working capital items. Cash used in operations was partially offset by a non-cash share-based compensation expense of $12.6 million, amortization of net premiums and discounts on short-term investments of $2.9 million, and depreciation and amortization of $2.8 million.

Cash provided by operations for the nine-month period ended September 30, 2009 was primarily attributable to a net loss of $61.5 million, an increase in the non-current portion of deferred cost of license revenue of $6.9 million, and a decrease of $2.3 million due to changes in working capital items. Cash used in operations for the nine-month period ended September 30, 2009, was partially offset by an increase in the non-current portion of deferred license revenue of 107.6 million, a non-cash share-based compensation expense of $8.9 million, a decrease in inventory held by the Company of $800,000, amortization of net premiums and discounts on short-term investments of $3.4 million, and depreciation and amortization of $2.1 million.

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Net Cash Provided by Investing

Net cash provided by investing activities for the nine-month period ended September 30, 2010 was $49.3 million, primarily due to $276.3 million in proceeds of short-term investments which was partially offset by $217.9 million in purchases of short-term investments and $9.1 million in purchases of intangible assets and property and equipment.

Net Cash Provided by Financing

Net cash provided by financing activities for the nine-month period ended September 30, 2010 was $6.6 million due to $8.0 million in net proceeds from option exercises which was offset by $1.4 million in repayments to PRF.

Future Capital Needs

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Zanaflex Capsules and Ampyra, the continued progress of our research and development activities, the timing and outcome of regulatory approvals, the amount and timing of milestone or other payments made or received under collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights and the acquisition or in-licensing of new products or compounds and development costs relating to those new products or compounds. We may continue to incur losses from operations as we continue to support our sales and marketing infrastructure for the commercialization of Zanaflex Capsules and Ampyra, increase our efforts to support launch activities for Ampyra and its commercialization, and continue our clinical development and advance our preclinical programs.

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

A summary of our minimum contractual obligations related to our major outstanding contractual commitments is included in our Annual Report on Form 10-K for the year ended December 31, 2009. Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. Under certain supply agreements and other agreements with manufacturers and suppliers, we are required to make payments for the manufacture and supply of our clinical and approved products. During the nine-month period ended September 30, 2010, commitments related to the purchase of inventory consistent with our normal course of business increased. As of September 30, 2010, we have inventory-related purchase commitments totaling approximately $21.4 million within the next year.

Under certain license agreements, we are required to pay royalties for the use of technologies and products in our R&D activities and in the commercialization of products. The amount and timing of any of the foregoing payments are not known due to the uncertainty surrounding the successful research, development and commercialization of the products.

Under certain license agreements, we are also required to pay license fees and milestones for the use of technologies and products in our R&D activities and in the commercialization of products. We have committed to make potential future milestone payments to third parties of up to approximately $32.1 million as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of September 30, 2010, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

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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, inventory, research and development, income taxes, and share-based compensation.

Revenue Recognition

Zanaflex

We apply the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. We have accumulated some sales history with Zanaflex Capsules; however, due to existing and potential generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we cannot reasonably determine a return rate at this time and, thus, are not permitted to recognize revenue based on shipments to wholesalers. As a result, we account for sales of these products using a deferred revenue recognition model. We continue to accumulate data and when we are able to reasonably estimate product returns based on this data and based on greater certainty regarding generic competition we will then begin to recognize revenue based on shipments of product to our wholesale drug distributors.

Under our deferred revenue model, we do not recognize revenue following shipment of Zanaflex Capsules and Zanaflex tablets to our wholesale drug distributors. Instead, we record deferred revenue at gross invoice sales price, and classify the cost basis of the inventory held by the wholesaler as a component of inventory. 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. 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.

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

Our net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that 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 statement of income. Adjustments are recorded for estimated chargebacks, rebates, and discounts. These allowances 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. Allowances 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. Product shipping and handling costs are included in cost of

sales.

We accept returns of Zanaflex Capsules and Zanaflex tablets for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. We do not exchange product from inventory for the returned product. Returns of products sold by us are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize. In addition, we record a charge to cost of goods sold for the cost basis of the estimated product returns we believe may ultimately be realized at the time of product shipment to wholesalers. We recognize this charge at the date of shipment since it is probable that we will receive a level of returned products; upon the return of such product we will be unable to resell the product considering its expiration dating; and, we can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns.

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Ampyra

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail and Kaiser Permanente (Kaiser). We recognize revenue by applying the guidance in Staff Accounting Bulletin (SAB) 104 which requires that we do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, the Company has no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured. We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers and Kaiser. As of September 30, 2010, inventory levels at specialty pharmacy providers that distribute Ampyra (does not include Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers and Kaiser are contractually obligated to hold no more than 30 days of inventory.

Our net revenues represent total revenues less allowances for customer credits, including estimated rebates, discounts and returns. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies and Kaiser, an adjustment is recorded for estimated chargebacks, rebates, and returns. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such reserves. In determining the amounts of certain allowances and accruals, we must make significant judgments and estimates. Allowances for rebates, discounts and returns are established based on the contractual terms with customers, 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. Product shipping and handling costs are included in cost of sales.

Based on our specialty distribution model where we sell to only 12 specialty pharmacy providers and Kaiser, the data we receive from these distributors, and returns experience of other specialty products with similar selling models, we have been able to make a reasonable estimate for product returns. At September 30, 2010, inventory levels at the specialty pharmacy providers (this does not include Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers and Kaiser have contractually agreed to hold no more than 30 days of inventory. We will accept returns of Ampyra for two months prior to and six months after its expiration date. We will provide a credit to customers with whom we have a direct relationship. Once our product is prescribed, it cannot be returned. We do not exchange product from inventory for the returned product.

Collaborations

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

Ampyra Inventory

Prior to regulatory approval of Ampyra, the Company incurred expenses for the manufacture of several batches of Ampyra that ultimately became available to support the commercial launch of this drug candidate. Until the necessary initial regulatory approval was received, we charged all such amounts to research and development expenses. As a

result, our initial sales of Ampyra will result in higher gross margins than if the inventory costs had not previously been expensed. Upon regulatory approval of Ampyra, the Company began capitalizing the commercial inventory costs associated with manufacturing with Elan and at its second manufacturer, Patheon.

The cost of Ampyra inventory manufactured by Elan is based on specified prices calculated as a percentage of net product sales of the product shipped by Elan to Acorda. In the event Elan does not manufacture the products, Elan is entitled to a compensating payment for the quantities of product provided by the alternative manufacturer. This compensating payment is included in our inventory balances.

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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, fees paid to professional service providers for independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials, costs of contract manufacturing services for our preclinical program, costs of materials used in clinical trials and research and development and depreciation of capital resources used to develop our products. In addition, research and development expenses include expenses related to grant revenue, the cost of clinical trial drug supply shipped to our clinical study vendors and the cost of Ampyra inventory received up until regulatory approval. 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. With respect to previously established clinical study accruals in prior periods, for the three and nine-month periods ended September 30, 2010 we did not make any significant adjustments to our clinical study costs. All research and development costs are expensed as incurred except when we are accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. In these cases, these payments are capitalized at the time of payment and expensed when the research and development activity has been performed.

Income Taxes

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

We have not recorded any tax provision or benefit for the nine-month periods ended September 30, 2010 and 2009. We have provided a valuation allowance for the full amount of our gross deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carryforwards cannot be sufficiently assured at September 30, 2010.

As of September 30, 2010, we had available net operating loss carryforwards of approximately $270.1 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2019 and 2030 and research and development tax credit carryforwards of approximately $1.6 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2018. Since our inception, we have incurred substantial losses and expect to incur substantial and recurring losses in future periods. The Internal Revenue Code of 1986, as amended (the “Code”), provides for a limitation of the annual use of net operating loss and research and development tax credit carry forwards (following certain ownership changes, as defined by the Code) that could significantly limit our ability to utilize these carryforwards. 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 carryforwards 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 and non-employees by recognizing the costs resulting from all share-based payment transactions in the financial statements at their fair values. We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, prevailing interest rates, and an estimated forfeiture rate.

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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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash equivalents, short-term investments, grants receivable, convertible notes payable, accounts payable, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at September 30, 2010.

We have cash equivalents and short-term investments at September 30, 2010, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds and US Treasury bonds, the carrying value of our cash equivalents and short-term investments approximate their fair value at September 30, 2010. At September 30, 2010, we held $245.8 million in cash and cash equivalents and short-term investments which had an average interest rate of approximately 0.1%.

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 Securities Exchange Act of 1934 (the “Exchange Act”) we carried out an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of September 30, 2010, our disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted 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 or submitted 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.

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Change in internal control over financial reporting

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our chief executive officer and chief financial officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended September 30, 2010 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.

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PART II—OTHER INFORMATION

Item 1. Legal Proceedings

In August 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In October 2007, the Company filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) for patent infringement in relation to the filing of the ANDA by Apotex. The defendants answered the Company's complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. The Company denied those counterclaims. In March 2008, Apotex filed a motion, which the Company opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in the Company's favor and denied Apotex's motion in December 2008. Fact discovery in the case has been completed. On July 2, 2010, the U.S. District Court held a Markman hearing to determine the interpretation of certain terms in the Company's Zanaflex Capsules patent that is at issue in this litigation. The Court ruled favorably on a number of those terms, and the case is proceeding, with expert discovery scheduled to be completed by early January 2011.

Our timely filing of a lawsuit against Apotex in October 2007 triggered an automatic stay on FDA approval of the Apotex ANDA for 30 months. That stay expired in March 2010. Consequently, Apotex will be able to receive FDA approval of its ANDA, if Apotex is able otherwise to satisfy FDA's review requirements for ANDAs, at which time it could begin selling a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets, even if our patent litigation remains pending. If Apotex begins selling its product before it is successful in challenging the validity, infringement, or enforceability of our patent, Apotex would be selling at the risk of our ultimately prevailing on our patent infringement claims and its being held liable for damages for patent infringement.

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, 2009 and Part II, Item 1A of our Form 10-Q for the quarter ended June 30, 2010, all of which could materially affect our business, financial condition or future results. The risks described or referred to herein are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 6. Exhibits

31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* In accordance with Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall be deemed to be “furnished” and not “filed.”

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Acorda Therapeutics, Inc.

Date: November 9, 2010	By:	/s/ Ron Cohen Ron Cohen, M.D. President, Chief Executive Officer and Director (Principal Executive Officer)
Date: November 9, 2010	By:	/s/ David Lawrence David Lawrence, M.B.A. Chief Financial Officer (Principal Financial and Accounting Officer)

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Exhibit Index

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