

# ACORDA THERAPEUTICS INC

## FORM 10-Q (Quarterly Report)

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

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2011**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 000-50513**

**ACORDA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of Incorporation)

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

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

(Address, Including Zip Code, and Telephone Number,  
Including Area Code, of Registrant's Principal Executive Offices)

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

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

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

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

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

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

**Class**

Common Stock, \$0.001 par value  
per share

**Outstanding at October 31, 2011**

39,667,483 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, including: our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of anticipated potential generic competition on Zanaflex Capsules revenues; failure to protect our intellectual property, to defend against the intellectual property claims of others, or to obtain third party intellectual property licenses needed for the commercialization of our products; the ability to obtain additional financing to support our operations; and unfavorable results from our research and development programs. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this report, in our Quarterly Reports on Form 10-Q for the quarters ended March 31 and June 30, 2011, and in our Annual Report on Form 10-K for the year ended December 31, 2010, particularly in the "Risk Factors" section (as updated by the disclosures in our subsequent quarterly reports), 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. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.*

*We own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks "Acorda Therapeutics," our stylized Acorda Therapeutics logo, "Ampyra," "Zanaflex," and "Zanaflex Capsules." Also, our mark "Fampyra" is a registered mark in the European Community Trademark Office and we have registrations or pending applications for this mark in other jurisdictions. Our trademark portfolio also includes several registered trademarks and pending trademark applications in the U.S. and worldwide for potential product names or for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.*

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**PART I****Item 1. Financial Statements****ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

(In thousands, except share data)	September 30, 2011 (unaudited)	December 31, 2010
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 44,385	\$ 34,641
Restricted cash	303	302
Short-term investments	224,428	205,389
Trade accounts receivable, net	20,608	22,272
Prepaid expenses	7,099	6,413
Finished goods inventory held by the Company	28,617	36,232
Finished goods inventory held by others	1,152	2,186
Other current assets	7,781	3,734
<b>Total current assets</b>	<b>334,373</b>	<b>311,169</b>
Property and equipment, net of accumulated depreciation	3,595	3,203
Intangible assets, net of accumulated amortization	7,053	21,336
Non-current portion of deferred cost of license revenue	5,600	6,050
Other assets	477	343
<b>Total assets</b>	<b>\$ 351,098</b>	<b>\$ 342,101</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 13,943	\$ 16,961
Accrued expenses and other current liabilities	19,239	33,769
Deferred product revenue—Zanaflex tablets	9,918	9,526
Deferred product revenue—Zanaflex Capsules	19,401	21,770
Current portion of deferred license revenue	9,057	9,429
Current portion of revenue interest liability	1,735	1,297
Current portion of convertible notes payable	1,144	1,144
<b>Total current liabilities</b>	<b>74,437</b>	<b>93,896</b>
Non-current portion of deferred license revenue	80,007	86,429
Put/call liability	1,457	391
Non-current portion of revenue interest liability	2,618	3,586
Non-current portion of convertible notes payable	5,183	6,185
Other non-current liabilities	480	353
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at September 30, 2011 and December 31, 2010; issued and outstanding 39,121,293 and 38,779,370 shares as of September 30, 2011 and December 31, 2010, respectively	39	39
Treasury stock at cost (12,420 shares at September 30, 2011 and December 31, 2010)	(329)	(329)
Additional paid-in capital	609,312	591,650
Accumulated deficit	(422,175)	(440,086)
Accumulated other comprehensive income	69	(13)
<b>Total stockholders' equity</b>	<b>186,916</b>	<b>151,261</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 351,098</b>	<b>\$ 342,101</b>

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(unaudited)

	Three-month period ended September 30, 2011	Three-month period ended September 30, 2010	Nine-month period ended September 30, 2011	Nine-month period ended September 30, 2010
(In thousands, except per share data)				
Revenues:				
Net sales	65,420	61,265	187,222	117,134
Milestone revenue	25,000	—	25,000	—
License revenue	2,264	2,357	6,793	7,071
Royalty revenue	347	—	578	—
Total net revenues	93,031	63,622	219,593	124,205
Costs and expenses:				
Cost of sales	26,651	11,666	50,749	22,574
Cost of milestone and license revenue	1,908	165	2,225	495
Research and development	9,088	7,970	31,804	22,628
Selling, general and administrative	34,718	30,558	112,788	91,054
Total operating expenses	72,365	50,359	197,566	136,751
Operating income (loss)	20,666	13,263	22,027	(12,546)
Other expense (net):				
Interest and amortization of debt discount expense	(947)	(944)	(3,359)	(3,352)
Interest income	134	111	408	450
Other income	—	8	—	8
Total other expense (net)	(813)	(825)	(2,951)	(2,894)
Income (loss) before taxes	19,853	12,438	19,076	(15,440)
Provision for income taxes	(986)	—	(1,165)	—
Net income (loss)	\$ 18,867	\$ 12,438	\$ 17,911	\$ (15,440)
Net income (loss) per share—basic	\$ 0.48	\$ 0.32	\$ 0.46	\$ (0.40)
Net income (loss) per share—diluted	\$ 0.47	\$ 0.31	\$ 0.45	\$ (0.40)
Weighted average common shares outstanding used in computing net loss				
per share—basic	39,100	38,450	38,940	38,261
Weighted average common shares outstanding used in computing net loss				
per share—diluted	40,174	39,988	40,035	38,261

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(unaudited)

(In thousands)	Nine-month period ended September 30, 2011	Nine-month period ended September 30, 2010
Cash flows from operating activities:		
Net income (loss)	\$ 17,911	\$ (15,440)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Share-based compensation expense	13,847	12,557
Amortization of net premiums and discounts on short-term investments	5,033	2,891
Amortization of revenue interest issuance cost	88	80
Depreciation and amortization expense	3,208	2,818
Intangible asset impairment	13,038	—
Loss (gain) on put/call liability	1,066	(319)
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	1,664	(12,490)
Increase in prepaid expenses and other current assets	(4,734)	(728)
Decrease (increase) in inventory held by the Company	7,615	(19,582)
Decrease in inventory held by others	1,034	293
Decrease in non-current portion of deferred cost of license revenue	450	495
Increase in other assets	(222)	1
(Decrease) increase in accounts payable, accrued expenses, other current liabilities	(18,811)	16,303
Increase in revenue interest liability interest payable	823	337
Decrease in current portion of deferred license revenue	(371)	—
Decrease in non-current portion of deferred license revenue	(6,422)	(7,071)
Increase in other non-current liabilities	127	429
Increase (decrease) in deferred product revenue—Zanaflex tablets	392	(506)
Decrease in deferred product revenue—Zanaflex Capsules	(2,370)	(871)
Net cash provided by (used in) operating activities	33,366	(20,803)
Cash flows from investing activities:		
Purchases of property and equipment	(1,232)	(2,207)
Purchases of intangible assets	(863)	(6,894)
Purchases of short-term investments	(203,989)	(217,862)
Proceeds from maturities of short-term investments	180,000	276,250
Net cash (used in) provided by investing activities	(26,084)	49,287
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	3,816	7,998
Repayments of revenue interest liability	(1,354)	(1,391)
Net cash provided by financing activities	2,462	6,607
Net increase in cash and cash equivalents	9,744	35,091
Cash and cash equivalents at beginning of period	34,641	47,314
Cash and cash equivalents at end of period	\$ 44,385	\$ 82,405
Supplemental disclosure:		
Cash paid for interest	2,394	2,850

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements

(unaudited)

#### (1) Organization and Business Activities

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis (MS), spinal cord injury (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, 2010 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 Ampyra and Zanaflex Capsules and Zanaflex tablets (collectively “Zanaflex”), 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*

###### *Ampyra*

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail, Kaiser Permanente (Kaiser), and the U.S. Department of Veterans Affairs (VA). Ampyra is not 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, Kaiser and the specialty distributor to the VA. As of September 30, 2011, inventory levels at specialty pharmacy providers that distribute Ampyra (excluding Kaiser and the specialty distributor to the VA) were approximately two weeks of their anticipated usage. The specialty pharmacy providers, Kaiser and the specialty distributor to the VA 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, Kaiser and the specialty distributor to the VA, 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, Kaiser and the VA (through a specialty distributor), 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, 2011, inventory levels at the specialty pharmacies (excluding Kaiser and the specialty distributor to the VA) represented approximately two weeks of their anticipated usage. 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.

### *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 is 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.

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.

### *Milestones and royalties*

In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards (FASB) guidance on the milestone method of revenue recognition. At the inception of a collaboration agreement the Company evaluates if payments are substantive. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. 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 in the three-month period ended March 31, 2010, 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 resulted 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 Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan), and its second manufacturer, Patheon. During the third quarter of 2011, Alkermes acquired the Elan business that supplies our Ampyra inventory.

### *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 products or product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate products or product candidates or by location and does not have separately reportable segments.

Certain prior period amounts have been reclassified to conform to current year presentation.

**Recent Accounting Pronouncements**

In June 2011, the FASB issued an accounting standards update regarding the presentation of comprehensive income in financial statements. The provisions of this standard provide an option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The provisions of this new disclosure standard are effective January 1, 2012. The Company does not believe this accounting standard update will have a material effect on its financial statements.

**(3) Share-based Compensation**

During the three-month periods ended September 30, 2011 and 2010, the Company recognized share-based compensation expense of \$5.1 million and \$4.8 million, respectively. During the nine-month periods ended September 30, 2011 and 2010, the Company recognized share-based compensation expense of \$13.8 million and \$12.5 million, respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2011 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, 2011 and 2010 were approximately \$13.61 and \$19.75, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2011 and 2010 were approximately \$13.11 and \$19.37, respectively.

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

(In millions)	For the three-month period ended September 30,		For the nine-month period ended September 30,	
	2011	2010	2011	2010
Research and development	\$ 1.5	\$ 1.4	\$ 4.1	\$ 3.6
Selling, general and administrative	3.5	3.4	9.7	8.9
Total	\$ 5.0	\$ 4.8	\$ 13.8	\$ 12.5

A summary of share-based compensation activity for the nine-month period ended September 30, 2011 is presented below:

*Stock Option Activity*

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value (In thousands)
Balance at January 1, 2011	4,084	\$ 20.13		
Granted	1,132	23.72		
Cancelled	(127)	25.95		
Exercised	(320)	11.94		
Balance at September 30, 2011	4,769	\$ 21.38	6.9	\$ 13,589
Vested and expected to vest at September 30, 2011	4,677	\$ 21.29	6.9	\$ 13,589
Vested and exercisable at September 30, 2011	2,795	\$ 17.94	5.7	\$ 13,570

*Restricted Stock Activity*

(In thousands)

<b>Restricted Stock</b>	<b>Number of Shares</b>
Nonvested at January 1, 2011	324
Granted	276
Vested	(22)
Forfeited	(19)
Nonvested at September 30, 2011	<u>559</u>

As of September 30, 2011, there was \$36.7 million of total unrecognized compensation costs related to unvested options and restricted stock awards that the Company expects to recognize over a weighted average period of approximately 2.5 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, 2011 and 2010:

(In thousands, except per share data)	<b>Three-month period ended September 30, 2011</b>	<b>Three-month period ended September 30, 2010</b>	<b>Nine-month period ended September 30, 2011</b>	<b>Nine-month period ended September 30, 2010</b>
<b><i>Basic and diluted</i></b>				
Net income (loss)	\$ 18,867	\$ 12,438	\$ 17,911	\$ (15,440)
Weighted average common shares outstanding used in computing net loss per share—basic	39,100	38,450	38,940	38,261
Plus: net effect of dilutive stock options and restricted common shares	<u>1,074</u>	<u>1,538</u>	<u>1,095</u>	<u>—</u>
Weighted average common shares outstanding used in computing net loss per share—diluted	40,174	39,988	40,035	38,261
Net loss per share—basic	<u>\$ 0.48</u>	<u>\$ 0.32</u>	<u>\$ 0.46</u>	<u>\$ (0.40)</u>
Net loss per share—diluted	<u>\$ 0.47</u>	<u>\$ 0.31</u>	<u>\$ 0.45</u>	<u>\$ (0.40)</u>

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 nine months ended September 30, 2010, options to purchase 4,098,364 shares 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 nine months ended September 30, 2010, 515,769 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 federal net operating loss (NOL) carry-forwards of approximately \$234.0 million and \$266.9 million and state NOL carry-forwards of approximately \$223.1 million and \$261.0 million as of September 30, 2011 and December 31, 2010 respectively which may be available to offset future taxable income, if any. The federal losses are expected to expire between 2021 and 2030 while the state losses are expected to expire between 2012 and 2030. The Company also has research and development tax credit carry-forwards of approximately \$3.9 million as of September 30, 2011, for federal income tax reporting purposes that may be available to reduce federal income taxes, if any, and expire in future years beginning in 2019. The Company is no longer subject to federal or state income tax audits for tax years prior to 2006; however, such taxing authorities can review any net operating losses utilized by the Company in years subsequent to 1999. The Company also has Alternative Minimum Tax credit carry-forwards of \$1.0 million as of September 30, 2011, respectively. Such credits can be carried forward indefinitely and have no expiration date.

At September 30, 2011 and December 31, 2010, the Company had a deferred tax asset of \$148.7 million and \$153.8 million, respectively, offset by a full valuation allowance. Since inception, the Company has incurred substantial losses and expects to incur substantial losses in future periods. The Tax Reform Act of 1986 (the "Act") provides for a limitation of the annual use of NOL and research and development tax credit carryforwards (following certain ownership changes, as defined by the Act) that could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes as a result of past financings. 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, 2011, 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.

**(6) Fair Value Measurements**

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2011 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, 2011. 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, 2011.

(In thousands)	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>Assets Carried at Fair Value:</b>			
Cash equivalents	\$ 44,385	\$ —	\$ —
Short-term investments	224,428	—	—
<b>Liabilities Carried at Fair Value:</b>			
Put/call liability	—	—	1,457

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.

(In thousands)	<u>Balance as of December 31, 2010</u>	<u>Realized (gains) losses included in net loss</u>	<u>Unrealized (gains) losses included in other comprehensive loss</u>	<u>Balance as of September 30, 2011</u>
<b>Liabilities Carried at Fair Value:</b>				
Put/call liability	\$ 391	\$ 1,066	\$ —	\$ 1,457

The Company estimates 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 gains and losses are included in sales, general and administrative expenses.

The 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. The Company may be required to record losses in future periods, which may be significant.

**(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 and are recorded based primarily on quoted market prices. Available-for-sale securities consisted of the following:

(In thousands)	<u>Amortized Cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Estimated fair value</u>
September 30, 2011				
US Treasury bonds	\$ 224,358	\$ 88	\$ (18)	\$ 224,428
December 31, 2010				
US Treasury bonds	205,402	5	(18)	205,389

The contractual maturities of available-for-sale debt securities at September 30, 2011 and December 31, 2010 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, 2011. Short-term investments with maturity of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$34.8 million and \$23.5 million as of September 30, 2011 and December 31, 2010, 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 Fampyra 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 Alkermes (formerly Elan). Biogen Idec has responsibility for regulatory activities and future clinical development of Fampyra 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 Alkermes. During the third quarter of 2011, Alkermes acquired the Elan business that granted the license described above and supplies the Company’s Ampyra inventory.

Under the Collaboration Agreement, the Company was entitled to an upfront payment of \$110.0 million as of June 30, 2009, which was received in July 2009, and a \$25 million milestone payment upon approval of the product in the European Union, which was received in August 2011. The Company is also entitled to receive additional payments of up to \$10 million based on the successful achievement of future regulatory milestones and up to \$365 million based on the successful achievement of future 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 Alkermes 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. Due to the inherent uncertainty in obtaining regulatory approval, the applicability of the Supply Agreement is outside the control of the Company and Biogen Idec. Accordingly, we have determined the Supply Agreement is a contingent deliverable at the onset of the agreement. As a result, the Company has determined the Supply Agreement does not meet the definition of a deliverable that needs to be accounted for at the inception of the arrangement. The Company has also determined that there is no significant and incremental discount related to the supply agreement since Biogen Idec will pay the same amount for inventory that the Company would pay and the Company effectively acts as a middle man in the arrangement for which it adds no significant value due to various factors such as the Company does not have any manufacturing capabilities or other knowhow with respect to the manufacturing process.

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) 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 non-contingent 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 \$2.3 million and \$6.8 million in license revenue, a portion of the \$110.0 million received from Biogen Idec, and \$159,000 and \$476,000 in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during the three and nine-month periods ended September 30, 2011, respectively.

On January 21, 2011 Biogen Idec announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of Fampyra to improve walking ability in adult patients with multiple sclerosis. Biogen Idec, working closely with the Company, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization, and in July 2011 Biogen Idec received conditional approval from the European Commission for, Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). The Company changed the amortization period on a prospective basis during the three-month period ended March 31, 2011 by five months and currently estimates the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

As part of its ex-U.S. license agreement, Biogen Idec owes Acorda royalties based on ex-U.S. net sales, and milestones based on ex-U.S. regulatory approval, new indications, and ex-U.S. net sales. These milestones included a \$25 million payment for approval of the product in the European Union which was recorded and paid in the three month period ended September 30, 2011. Based on Acorda's worldwide license and supply agreement with Elan, Elan received 7% of this milestone payment from Acorda during the same period. For revenue recognition purposes, the Company has determined this milestone to be substantive in accordance with applicable accounting guidance related to milestone revenue. Therefore, the payment was recognized in its entirety as revenue and the cost of the milestone revenue was recognized in its entirety as an expense during the three-month period ended September 30, 2011.

Cost of milestone and license revenue includes \$159,000 and \$476,000 in cost of license revenue, which represents the amortized portion of the \$7.7 million paid to Alkermes in 2009, for the three and nine-month periods ended September 30, 2011, respectively. It also includes \$1.8 million in cost of milestone revenue, which represents the 7% Elan portion of the \$25 million milestone paid during the three-month period ended September 30, 2011.

## **(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, 2010. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

In June 2011, the Company entered into a 15 year lease for an aggregate of approximately 138,000 square feet of laboratory and office space in Ardsley, New York. The Company plans to relocate its corporate headquarters, and all employees based at its Hawthorne, New York location, to the Ardsley facility. The company anticipates taking possession of the new space in June 2012, subject to completion of certain improvements to the facility prior to the Company's occupancy. The commencement of the term would be deferred in the case of certain delays in the completion of those improvements. The Company has options to extend the term of the lease for three additional five-year periods, and the Company has an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, the Company has rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. The Company's extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that the Company not be in default under the lease. The lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to the Company's occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. The base rent will initially be \$3.4 million per year, and will be subject to a 2.5% annual increase.

In June 2011, the Company licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc., which the Company refers to as AC105. The Company made a \$3 million upfront payment to Medtronic during the three-month period ended June 30, 2011 and recorded the expense as research and development expense. The Company will make up to \$32 million in regulatory and development milestone payments, if achieved. A single-digit sales royalty will also be paid by the Company to Medtronic if AC105 is commercialized by the Company.

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 capsulation 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.

The Company had sued Apotex Corp. and Apotex Inc. (collectively, "Apotex") for patent infringement related to Apotex Inc.'s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. On September 7, 2011, the Company announced that the U.S. District Court for the District of New Jersey had ruled against it in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex. The Company is appealing the decision. However, Apotex will be



able to receive FDA approval of its ANDA and launch generic hydrochloride capsules, if Apotex is able otherwise to satisfy the FDA's review requirements for ANDAs. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. If approved by the FDA, this would lead to additional generic tizanidine hydrochloride capsules entering the marketplace, which would likely cause the Company's sales of Zanaflex Capsules to decline significantly. The Company believes that the intangible asset associated with Zanaflex Capsules were fully impaired based on estimated undiscounted cash flows and the associated fair value of this asset and therefore the Company recorded an asset impairment charge of approximately \$13.0 million to write-off the remaining carrying value of this asset during the three-month period ended September 30, 2011.

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). The Company made these milestone payments totaling \$3.25 million and they were recorded as intangible assets in the consolidated financial statements during the three-month period ended March 31, 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. 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 December 31, 2010, the Company had made an aggregate of \$850,000 in milestone payments under this agreement. As of September 30, 2011, the Company made or accrued royalty payments totaling \$5.7 million.

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. 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.

On April 19, 2011 the Company announced the United States Patent and Trademark Office (USPTO) allowed U.S. Patent Application No. 11/010,828 entitled "Sustained Release Aminopyridine Composition." The claims of the patent application relate to methods to improve walking in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent that issued from this application, described below, was accorded an initial patent term adjustment by the USPTO of 298 days, initially extending its term to early October 2025. The Company re-evaluated the useful life of the Ampyra milestones and Ampyra CSRO royalty buyout intangible assets during the three-month period ending June 30, 2011 and the revised estimated remaining useful lives of the assets are presented in the table below.

On August 30, 2011 the United States Patent and Trademark Office (USPTO) issued the Company's Patent Application No. 11/010,828 as U.S. Patent No. US 8,007,826 entitled "Sustained Release Aminopyridine Composition." The patent, which is eligible for listing in the FDA Orange Book, is now expected to expire in May 2027, including patent term adjustment. The final patent life issuance did not have a material impact on the amortization expense for the current or future periods.

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. As noted above, the Company evaluated the value and remaining useful lives of the Zanaflex Capsule patents as of September 30, 2011 and recorded a charge of approximately \$13.0 million to fully impair these assets. However, as of this

date, the Company does not believe that there are any facts or circumstances that would indicate a need for changing the estimated remaining useful life of the Company's intangible assets related to Ampyra.

Intangible assets consisted of the following:

(In thousands)	September 30, 2011	December 31, 2010	Estimated remaining useful lives as of September 30, 2011
Zanaflex Capsule patents	\$ 19,350	\$ 19,350	0 years
Zanaflex trade name	2,150	2,150	0 years
Ampyra milestones	3,250	3,250	15 years
CSRO royalty buyout	3,000	3,000	9 years
Website development costs	3,058	2,975	0-3 years
Website development costs-in process	781	—	3 years
	<u>31,589</u>	<u>30,725</u>	
Less accumulated amortization	<u>24,536</u>	<u>9,389</u>	
	<u>\$ 7,053</u>	<u>\$ 21,336</u>	

The Company recorded \$15.1 million and \$2.0 million in amortization expense related to these intangible assets in the nine-month periods ended September 30, 2011 and 2010, respectively, including the asset impairment charge of \$13.0 million in 2011.

Estimated future amortization expense for intangible assets subsequent to December 31, 2010 for the next five years is as follows (in thousands):

2011 (Note 1)	\$ 15,661
2012	1,394
2013	1,155
2014	491
2015	473
	<u>\$ 19,174</u>

Note 1: Includes \$13.0 million for Zanaflex Capsule intangible asset impairment recorded during the three-month period ended September 30, 2011.

## 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 U.S. Food and Drug Administration (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. Net revenue for Ampyra was \$153.3 million for the nine months ended September 30, 2011 and \$80.8 million for the nine months ended September 30, 2010. There was a 7.5% increase for the wholesale acquisition price of Ampyra effective March 4, 2011 and a 14% increase for Zanaflex tablets and Zanaflex Capsules effective October 1, 2011.

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. Combined net revenue of Zanaflex Capsules and Zanaflex tablets, which we also sell, was \$33.9 million for the nine months ended September 30, 2011 and \$36.4 million for the nine months ended September 30, 2010. Managed care organizations have increasingly established plans and programs to drive utilization of low-cost generic tizanidine hydrochloride tablets over higher-cost Zanaflex Capsules by making it more difficult for patients to obtain Zanaflex Capsules through restrictions and higher out-of-pocket (copay) costs.

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 currently have approximately 100 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Regional Scientific Managers, Business Relations Directors, and Managed Markets account managers who provide information relating to Ampyra to physicians and payers.

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail, Kaiser Permanente (Kaiser), and the U.S. Department of Veterans Affairs (VA), and is supported by Ampyra Patient Support Services (APSS), a dedicated resource for healthcare providers and people with MS. The distribution process through specialty pharmacies is well established within the MS community, and physicians and patients are familiar with this model. We have contracted with a third party organization with extensive experience in coordinating patient benefits to run APSS. The customer care agents at APSS are responsible for helping healthcare professionals process prescriptions, working with insurance carriers to facilitate coverage, and directing patients to available copay 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 insurance benefits and mails the prescription directly to the patient. In some cases, the specialty pharmacy rather than APSS performs the insurance benefits investigation or receives a submitted prescription directly.

Processing of most incoming requests for prescriptions by APSS begins within 24 hours of receipt. Patients will 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.

Our Managed Markets account managers continue to meet with payers to provide information on Ampyra and discuss patient access. As of September 30, 2011, approximately 75% of commercially-insured individuals had no or limited prior authorizations (PAs) for Ampyra. We define limited PAs 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. As of September 30, 2011, approximately 20% of commercially-insured individuals were 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, as of September 30, 2011, approximately 5% of commercially-insured individuals were blocked from receiving reimbursement for Ampyra. Access figures were calculated based on the number of pharmacy lives reported by commercial healthcare plans. Aetna, one of the largest national health plans in the country that provides pharmacy benefits, listed AMPYRA as a preferred drug on their commercial formulary beginning August 1, 2011. With this addition to United Healthcare and Cigna, three of the largest national health plans in the U.S. have AMPYRA in the preferred tiers of the commercial formulary.

As of September 30, 2011, inventory levels at the specialty pharmacy providers that distribute Ampyra (excluding Kaiser and the specialty distributor to the VA) were approximately two-weeks. The specialty pharmacy providers, Kaiser and the specialty distributor to the VA are contractually obligated to hold no more than 30 days of inventory.

The FDA granted Ampyra orphan drug status, which provides 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 both are granted.

On August 30, 2011, the USPTO issued the Company's Patent Application No. 11/010,828 as U.S. Patent No. US 8,007,826 entitled "Sustained Release Aminopyridine Composition." The claims of the patent relate to methods to improve walking in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent, which is eligible for listing in the FDA Orange Book, is expected to expire in May 2027, including patent term adjustment.

On August 10, 2011, the Company announced that the USPTO had allowed U.S. Patent Application No. 11/102,559 entitled “Method of Using Sustained Release Aminopyridine Compositions.” The claims of the patent application relate to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent that issues from this application, which will be eligible for listing in the FDA Orange Book, is currently set to expire in April 2025 but is also eligible for patent term adjustment, to be determined by the USPTO based on the prosecution history.

In November 2010, the European Patent Office (EPO) posted a Communication of Intention to Grant a Patent for a patent application 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. This patent application corresponds to the U.S. Patent Application No. 11/102,559, referred to above, that was allowed by the USPTO in August 2011. We timely paid the grant fee for this application in March 2011 and the patent issued in June 2011.

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 Fampyra. In January 2011, the EMA’s Committee for Medicinal Products for Human Use (CHMP) decided against approval. Biogen Idec, working closely with us, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization of, and in July 2011 Biogen Idec received conditional approval from the European Commission for, Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). In September 2011, Biogen Idec launched Fampyra in Germany. It is available in the UK and Australia and availability in other European countries is expected to follow. As part of its ex-U.S. license agreement, Biogen Idec will pay Acorda royalties based on ex-U.S. net sales, and milestones based on new indications and ex-U.S. net sales. These milestones include a \$25 million payment in August 2011 for approval of the product in the European Union. Based on our worldwide license and supply agreement with Elan, Elan received 7% of this milestone payment from Acorda. The next expected milestone would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters. Biogen Idec received a Notice of Deficiency from Health Canada regarding its application for approval of Fampyra in Canada and it responded to the Notice of Deficiency in April 2011. Health Canada will have approximately a year to reply to that response.

In June 2011, we entered into a License Agreement with Medtronic, Inc. and one of its affiliates pursuant to which we licensed from them worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol, which we refer to as AC105. We plan to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as spinal cord injury (SCI) and traumatic brain injury (TBI), and we expect to begin enrolling participants in a Phase 2 clinical trial in patients with acute SCI in the second half of 2012. Under the License Agreement, we made a \$3 million upfront payment and we will make up to \$32 million in regulatory and development milestone payments. We will also pay a single-digit sales royalty if we commercialize AC105. Our development and commercialization rights are exclusive in all fields (including SCI, TBI and stroke) for certain formulations of the licensed compound. For other formulations, our rights are exclusive for indications of interest to us, including SCI, TBI, stroke and all other traumatic and ischemic central nervous system indications, while Medtronic and its affiliate have non-exclusive (with Acorda) development rights in specific areas, including certain areas of pain and musculoskeletal indications.

During a traumatic neurological injury, depletion of magnesium at the site of injury has been shown to contribute to tissue injury and lesion development. AC105 addresses this issue by formulating magnesium in such a way that the magnesium is delivered to the central nervous system. AC105 has been shown to reduce lesion size and enhance recovery in animal models of SCI. AC105 has been shown to be safe and tolerable in a small number of healthy normal subjects in Phase 1 human trials.

We have three other research and development programs focused on novel approaches to limit and repair damage to components of the CNS: neuregulins, remyelinating antibodies and chondroitinase. We believe our existing research and development programs and the new AC105 program have broad applicability and have the potential to be first-in-class therapies. While our existing programs have been focused on MS and spinal cord injury, 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 some of our research and development programs may have applicability beyond the nervous system, including in the field of cardiology.

In March 2010, we filed an Investigational New Drug (IND) application for Glial Growth Factor 2 (GGF2), the lead product candidate for our neuregulins program, as a therapy for heart failure, and in April 2010 the IND became effective. In December 2010, the first patient was enrolled in the first clinical trial of GGF2. Acorda is collaborating with the Vanderbilt University Heart and Vascular Institute and a private non-profit clinical research institute to conduct this Phase 1 single-dose trial in patients with 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 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 separate from the Phase 1 clinical trial. Acorda and Vanderbilt have applied for a second phase C-TRIP grant of at least \$5 million.

We expect to file an IND for one of the remyelinating antibodies, rHlgM22, for the treatment of MS in the first half of 2012. In preparation for a filing, we worked with a contract manufacturer to complete the scale up manufacturing and purification processes, and we recently completed formal preclinical safety and toxicity studies. The manufacturing data, clinical plans and preclinical safety profile will be subject to FDA review in connection with the filing of an IND. 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.

In June 2011, we entered into a 15 year lease for an aggregate of approximately 138,000 square feet of laboratory and office space in Ardsley, New York. The Company plans to relocate its corporate headquarters, and all employees based at its Hawthorne, New York location, to the Ardsley facility. The company anticipates taking possession of the new space in June 2012, subject to completion of certain improvements to the facility prior to the Company's occupancy. The commencement of the term would be deferred in the case of certain delays in the completion of those improvements. The Company has options to extend the term of the lease for three additional five-year periods, and the Company has an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, the Company has rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. The Company's extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that the Company not be in default under the lease. The lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to the Company's occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. The base rent will initially be \$3.4 million per year, and will be subject to a 2.5% annual increase.

We have had significant operating losses since inception as a result of our focus on clinical and research and 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 commercialization of Ampyra and the advancement of our research and development programs. Our current guidance is for Ampyra 2011 full year net revenue to increase over the prior year to \$205-\$230 million. Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be \$130-\$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra. Research and development (R&D) expenses for the full year 2011 are currently expected to be \$35-\$40 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2 as well as our \$3 million upfront payment for the Medtronic license. The projected amounts of SG&A and R&D for the full year 2011 in this paragraph and elsewhere in this report are non-GAAP financial measures because they exclude share-based compensation charges. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures, when viewed in conjunction with our GAAP results, provides investors with a more meaningful understanding of our projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe that non-GAAP financial measures that exclude share-based compensation charges help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding projected operating performance. Also, management uses non-GAAP financial measures that exclude share-based compensation charges to establish budgets and operational goals, and to manage the Company's business and to evaluate its performance.

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 stage products, with a particular focus on Phase 2 product candidates and products that would reach the commercial stage in 2012 or beyond, although we are open to assessing compounds at other stages as well.

In October 2011, Enrique J. Carrazana, M.D., joined the Company as Chief Medical Officer, replacing Thomas C. Wessel, M.D., Ph.D., who resigned from that role September 30, 2011. In this role, Dr. Carrazana will be responsible for managing development programs and regulatory filings for the Company's pipeline products, Ampyra post-marketing studies, and the Company's medical affairs, clinical operations, regulatory affairs, drug safety and biostatistics departments. Dr. Carrazana is a Board-certified neurologist with over 20 years of experience in the pharmaceutical industry and clinical practice. Most recently, he was Director of the Epilepsy Center of Excellence at the Miami Veterans' Administration (VA) Hospital and Associate Professor of Neurology at the University of Miami Miller School of Medicine. Prior to this, Dr. Carrazana held various medical leadership roles at Novartis Pharmaceuticals. His last role was Vice President, Global Head Established Medicines Development Franchise based in Basel, Switzerland. Dr. Carrazana was a practicing neurologist before working in the pharmaceutical industry, during which time he served as a principal investigator for numerous clinical trials in the areas of epilepsy, neurodegenerative disorders and neuropathic pain. Dr. Carrazana completed his residency in Neurology and fellowship in Neurophysiology at the Harvard Longwood Neurology Program. He graduated from the Harvard Medical School.

The Company had sued Apotex Corp. and Apotex Inc. (collectively, "Apotex") for patent infringement related to Apotex Inc.'s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. On September 7, 2011, the Company announced that the U.S. District Court for the District of New Jersey had ruled against it in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex. The Company is appealing the decision. However, Apotex will be able to receive FDA approval of its ANDA and launch generic tizanidine hydrochloride capsules, if Apotex is able otherwise to satisfy the FDA's review requirements for ANDAs. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. If approved by the FDA, this would lead to additional generic tizanidine hydrochloride capsules entering the marketplace, which would likely cause the Company's sales of Zanaflex Capsules to decline significantly. The Company believes that the intangible assets associated Zanaflex Capsules are now fully impaired based on estimated undiscounted cash flows and associated fair value of this asset. For the three-month period ending September 30, 2011, the Company recorded an asset impairment charge of approximately \$13.0 million to write-off the remaining carrying value of this asset. In connection with the outcome of the litigation, the Company also recorded a loss on our put/call liability resulting from a change in its fair market value of \$1.1 million related to the PRF revenue interest agreement as well as an inventory reserve of approximately \$1.3 million consisting of a \$1.0 million charge for commercial inventory and a \$336,000 charge for sample inventory. 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, 2011, there have been no accruals for loss contingencies aside from payments related to the litigation itself.

## Results of Operations

### *Three-Month Period Ended September 30, 2011 Compared to September 30, 2010*

#### Net Revenue

##### *Ampyra*

We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra of \$54.7 million and \$49.7 million for the three-month periods ended September 30, 2011 and 2010, respectively. There was a 7.5% increase for the wholesale acquisition price of Ampyra effective March 4, 2011.

Discounts and allowances which are included as an offset in net revenue consists of allowances for customer credits, including estimated chargebacks, rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. For the three-month period ended September 30, 2011 discounts and allowances also consisted of rebate allowances for the new Medicare Part D coverage gap (see also discussion under the "Healthcare Reform" header below). Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future and we incur costs incurred related to new Healthcare Reform Medicare rebates described under the "Healthcare Reform" header below.

Our current guidance is for Ampyra 2011 full year net revenue to increase over the prior year to \$205-\$230 million.

## *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 net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$10.7 million for the three-month period ended September 30, 2011, as compared to \$11.5 million for the three-month period ended September 30, 2010. The decrease was due to a decrease in prescriptions due to managed care pressure, among other factors offset by a 9% price increase for Zanaflex Capsules effective November 1, 2010. Sales of Zanaflex Capsules may decline in 2011. In September 2011, a U.S. federal court ruled against us in our patent litigation against Apotex Corp. and Apotex, Inc. (collectively, "Apotex"). The Company is appealing the decision. However, Apotex will be able to receive FDA approval of its ANDA and launch generic tizanidine hydrochloride capsules, if Apotex is able otherwise to satisfy the FDA's review requirements for ANDAs. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. If approved by the FDA, this would lead to additional generic tizanidine hydrochloride capsules entering the marketplace, which would likely cause the Company's sales of Zanaflex Capsules to decline significantly.

Discounts and allowances, which are included as an offset in net revenue, consist of allowances for customer credits, including estimated chargebacks, rebates, and discounts. Adjustments are recorded for estimated chargebacks, rebates, and discounts.

## *Healthcare Reform*

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contains several provisions that will affect our business. 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, the new healthcare reform legislation requires certain drug manufactures to pay a new excise drug fee. It is based on certain government sales of certain branded prescription drug sales in 2009. This fee will not be material to our 2011 financial statements.

## *Milestone Revenue*

The Company recognized \$25.0 million in milestone revenue for the three-month period ended September 30, 2011 as part of its ex-U.S. license agreement with Biogen Idec. In July 2011, Biogen Idec reached an agreement milestone when they received conditional approval from the European Commission for Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). For revenue recognition purposes, the milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period.

## *License Revenue*

The Company recognized \$2.3 million and \$2.4 million in license revenue for the three-month periods ended September 30, 2011 and 2010, respectively related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

## *Royalty Revenue*

The Company recognized \$347,000 in royalty revenue for the three-month period ended September 30, 2011 related to ex-U.S. sales of Fampyra by Biogen Idec.

## *Cost of Sales*

### *Ampyra*

We recorded cost of sales of \$10.5 million for the three-month period ended September 30, 2011 as compared to \$9.3 million for the three-month period ended September 30, 2010. Cost of sales for the three-month period ended September 30, 2011 consisted primarily of \$9.3 million in inventory costs related to recognized revenues. Cost of sales for the three-

month period ended September 30, 2011 also consisted of \$1.1 million in royalty fees based on net sales, \$118,000 in amortization of intangible assets, and \$28,000 in period costs related to packaging, freight and stability testing.

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. In 2010, 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. Our reduced cost basis inventory was sold during the year ended December 31, 2010 and as of this date we are not carrying any launch inventory on our balance sheet with a reduced cost basis.

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.

#### *Zanaflex*

We recorded cost of sales of \$16.1 million for the three-month period ended September 30, 2011 as compared to \$2.3 million for the three-month period ended September 30, 2010. Cost of sales for the three-month period ended September 30, 2011 consisted of \$13.4 million in amortization of intangibles assets including an asset impairment charge of \$13.0 million due to the Apotex patent litigation trial court decision. Cost of sales for the three-month period ended September 30, 2011 also included \$2.0 million in inventory costs consisting of an inventory reserve charge of \$1.0 million and a charge of \$1.0 million related to recognized revenues, \$715,000 in royalty fees based on net product shipments, and \$70,000 in period costs related to freight and stability testing. 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 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.

#### *Cost of Milestone & License Revenue*

We recorded cost of milestone and license revenue of \$1.9 million and \$165,000 for the three-month periods ended September 30, 2011 and 2010, respectively. Cost of milestone revenue represents a 7% payment to Elan on the \$25.0 million milestone revenue received from Biogen Idec in accordance with our worldwide license and supply agreement with Elan. For revenue recognition purposes, the related milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period. The corresponding cost of milestone revenue was also recognized in its entirety in this period. Cost of License revenue represents the recognition of a portion of the deferred \$7.7 million paid to Elan in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

#### *Research and Development*

Research and development expenses for the three-month period ended September 30, 2011 were \$9.1 million as compared to \$8.0 million for the three-month period ended September 30, 2010, an increase of approximately \$1.1 million, or 14%. The increase was attributable to an increase in clinical trial expenses of \$1.3 million related to post-marketing clinical studies of Ampyra, an increase in Phase I GGF2 preclinical and clinical trial expenses of \$870,000, and an increase of \$350,000 for work on our life cycle management program for Ampyra. The overall increase in research and development expenses was offset by a decrease of \$1.5 million in clinical costs associated with the close-out of our MS extension study.

Research and development (R&D) expenses for the full year 2011 are currently expected to be \$35-\$40 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2.



Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2011 were \$19.5 million compared to \$19.0 million for the three-month period ended September 30, 2010, an increase of approximately \$590,000 or 3%. This increase was primarily attributable to a net increase in Zanaflex sales and marketing expenses of \$700,000 resulting from a sample inventory reserve charge and a bad debt expense charge.

General and administrative expenses for the three-month period ended September 30, 2011 were \$15.2 million compared to \$11.6 million for the three-month period ended September 30, 2010, an increase of approximately \$3.6 million, or 31%. This increase was the result of a \$1.2 million increase in Ampyra post-approval regulatory expenses and other expenses related to supporting the growth of the overall organization including an increase of \$647,000 for staff and compensation expenses. General and administrative expenses for the three-month period ended September 30, 2011 also included an increase in the loss of our put/call liability related to the PRF revenue interest agreement of \$1.1 million, a \$560,000 increase in other expenses related to the Zanaflex Capsule patent infringement litigation and an increase in medical affairs expenses including educational programs and research of \$461,000.

Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be \$130-\$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra.

Other Expense

Other expense was \$813,000 and \$825,000 for the three-month periods ended September 30, 2011 and 2010, respectively. Other expense for the three-month period ended September 30, 2011 consisted of interest expense principally related to the PRF revenue interest agreement of \$947,000 and interest income of \$134,000. 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.

*Net Revenue*

*Ampyra*

We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra of \$153.3 million and \$80.8 million for the nine-month periods ended September 30, 2011 and 2010, respectively. There was a 7.5% increase for the wholesale acquisition price of Ampyra effective March 4, 2011.

Discounts and allowances, which are included as an offset in net revenue consists of allowances for customer credits, including estimated chargebacks, rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. For the nine-month period ended September 30, 2011 discounts and allowances also consisted of rebate allowances for the new Medicare Part D coverage gap (see also discussion under the “Healthcare Reform” header below). Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future and we incur costs incurred related to new Healthcare Reform Medicare rebates described under the “Healthcare Reform” header below.

Our current guidance is for Ampyra 2011 full year net revenue to increase over the prior year to \$205-\$230 million.

*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 net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$33.9 million for the nine-month period ended September 30, 2011, as compared to \$36.4 million for the nine-month period ended September 30, 2010. The decrease was due to a decrease in prescriptions due to managed care pressure, among other factors offset by a 9% price increase for Zanaflex Capsules effective November 1, 2010. Sales of Zanaflex Capsules

may decline in 2011. We had sued Apotex Corp. and Apotex Inc. (collectively, “Apotex”) for patent infringement related to Apotex Inc.’s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. On September 7, 2011, we announced that the U.S. District Court for the District of New Jersey had ruled against us in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex. We are appealing the decision. However, Apotex will be able to receive FDA approval of its ANDA and launch generic tizanidine hydrochloride capsules, if Apotex is able otherwise to satisfy the FDA’s review requirements for ANDAs. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. If approved by the FDA, this would lead to additional generic tizanidine hydrochloride capsules entering the marketplace, which would likely cause our sales of Zanaflex Capsules to decline significantly.

Discounts and allowances which are included as an offset in net revenue, consist of allowances for customer credits, including estimated chargebacks, rebates, and discounts. Adjustments are recorded for estimated chargebacks, rebates, and discounts.

#### *Healthcare Reform*

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contains several provisions that will affect our business. 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, the new healthcare reform legislation requires certain drug manufactures to pay a new excise drug fee. It is based on certain government sales of certain branded prescription drug sales in 2009. This fee was not material to our 2011 financial statements.

#### *Milestone Revenue*

The Company recognized \$25.0 million in milestone revenue for the nine-month period ended September 30, 2011 as part of its ex-U.S. license agreement with Biogen Idec. In July 2011, Biogen Idec reached an agreement milestone when they received conditional approval from the European Commission for Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). For revenue recognition purposes, the milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period.

#### *License Revenue*

The Company recognized \$6.8 million and \$7.1 million in license revenue related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement for the nine-month periods ended September 30, 2011 and 2010, respectively.

On January 21, 2011 Biogen Idec announced that the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of Fampyra to improve walking ability in adult patients with multiple sclerosis. Biogen Idec, working closely with us, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization of, and in July 2011 Biogen Idec received conditional approval from the European Commission for, Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). We changed the amortization period on a prospective basis during the three-month period ended March 31, 2011 by 5 months and currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

#### *Royalty Revenue*

The Company recognized \$578,000 in royalty revenue for the nine-month period ended September 30, 2011 related to ex-U.S. sales of Fampyra by Biogen Idec.

Cost of Sales

*Ampyra*

We recorded cost of sales of \$30.4 million for the nine-month period ended September 30, 2011 as compared to \$15.5 million for the nine-month period ended September 30, 2010. Cost of sales for the nine-month period ended September 30, 2011 consisted primarily of \$26.7 million in inventory costs related to recognized revenues. Cost of sales for the nine-month period ended September 30, 2011 also consisted of \$3.1 million in royalty fees based on net sales, \$425,000 in amortization of intangible assets, and \$138,000 in period costs related to packaging, freight and stability testing.

In April 2011 we announced the United States Patent and Trademark Office (USPTO) allowed U.S. Patent Application No. 11/010,828 entitled "Sustained Release Aminopyridine Composition." The claims of the patent application relate to methods to improve walking in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent that issued from this application, described below, was accorded an initial patent term adjustment by the USPTO of 298 days, initially extending its term to early October 2025. We re-evaluated the useful life of the Ampyra milestones and Ampyra CSRO royalty buyout intangible assets resulting in a decrease of approximately \$36,000 to the monthly amortization beginning in the three-month period ended June 30, 2011. The total impact for the year-ending December 31, 2011 is expected to be approximately \$356,000 in reduced amortization expense and \$427,000 annually thereafter; however, the total amortization period has now been extended.

On August 30, 2011, the USPTO issued the Company's Patent Application No. 11/010,828 as U.S. Patent No. US 8,007,826 entitled "Sustained Release Aminopyridine Composition." The patent, which is eligible for listing in the FDA Orange Book, is now expected to expire in May 2027, including patent term adjustment. The final patent life issuance did not have a material impact on the amortization expense for the current or future periods.

Cost of sales for the nine-month period ended September 30, 2010 consisted primarily of \$13.0 million in inventory costs related to recognized revenues. In 2010, 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 \$1.1 million for the nine-month period ended September 30, 2010. Our reduced cost basis inventory was sold during the year ended December 31, 2010 and as of this date we are not carrying any launch inventory on our balance sheet with a reduced cost basis.

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, \$594,000 in amortization of intangible assets, and \$210,000 in period costs related to packaging, freight and stability testing.

*Zanaflex*

We recorded cost of sales of \$20.4 million for the nine-month period ended September 30, 2011 as compared to \$7.1 million for the nine-month period ended September 30, 2010. Cost of sales for the nine-month period ended September 30, 2011 consisted of \$14.0 million in amortization of intangibles assets including an asset impairment charge of \$13.0 million. Cost of sales for the nine-month period ended September 30, 2011 also included \$4.1 million in inventory costs consisting of an inventory reserve charge of \$1.0 million and a charge of \$3.1 million related to recognized revenues, \$2.1 million in royalty fees based on net product shipments, and \$163,000 in period costs related to freight and stability testing. 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 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.

Cost of Milestone & License Revenue

We recorded cost of milestone and license revenue of \$2.2 million and \$495,000 for the nine-month periods ended September 30, 2011 and 2010, respectively. Cost of milestone revenue represents a 7% payment to Elan on the \$25.0 million milestone revenue received from Biogen Idec in accordance with our worldwide license and supply agreement with Elan. For revenue recognition purposes, the related milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period. The corresponding cost of milestone revenue was also recognized in its entirety in this period. Cost of License revenue represents the recognition of a portion of the deferred \$7.7 million paid to Elan in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

Research and Development

Research and development expenses for the nine-month period ended September 30, 2011 were \$31.8 million as compared to \$22.6 million for the nine-month period ended September 30, 2010, an increase of approximately \$9.2 million, or 41%. The increase was primarily attributable to clinical trial expenses of \$5.2 million related to post-marketing clinical studies of Ampyra, the Medtronic AC105 license expense of \$3.0 million, an increase in Phase I GGF2 preclinical and clinical trial expenses of \$3.0 million, and \$2.1 million for work on our life cycle management program for Ampyra.

The overall increase in research and development expenses was offset by a decrease of \$2.7 million in clinical costs associated with the close-out of our MS extension study sites. The overall increase was also offset by a decrease related to a reduction in expenses allocated to research and development of \$1.5 million for Ampyra manufacturing and stability work that was classified as research and development for the three-month period ended March 31, 2010 as it was incurred prior to FDA approval of the drug.

Research and development (R&D) expenses for the full year 2011 are currently expected to be \$35-\$40 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2.

Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2011 were \$65.4 million compared to \$59.8 million for the nine-month period ended September 30, 2010, an increase of approximately \$5.6 million or 9%. This increase was primarily attributable to an increase of \$3.2 million in marketing, trade and distribution expenses, managed markets, and various activities associated with Ampyra as well as an increase in staff and compensation of \$2.0 million resulting from the expansion of our field sales staff and the overall commercial department in order to support the Ampyra brand. The increase in sales and marketing expense for the nine-month period ended September 30, 2011 was partially offset by a net increase in Zanaflex sales and marketing expense of \$400,000 resulting from a sample inventory reserve charge and a bad debt expense charge offset by a decrease in overall Zanaflex marketing spend.

General and administrative expenses for the nine-month period ended September 30, 2011 were \$47.4 million compared to \$31.3 million for the nine-month period ended September 30, 2010, an increase of approximately \$16.1 million, or 51%. This increase was the result of a \$7.4 million increase in Ampyra post-approval regulatory expenses and other expenses related to supporting the growth of the overall organization including an increase of \$3.2 million for staff and compensation expenses. General and administrative expenses for the nine-month period ended September 30, 2011 also included an increase in the loss of our put/call liability related to the PRF revenue interest agreement of \$1.4 million, a \$5.3 million increase in other expenses related to the Zanaflex Capsule patent infringement litigation and an increase in medical affairs expenses including educational programs and research of \$2.1 million.

Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be \$130-\$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra.

Other expense was \$3.0 million and \$2.9 million for the nine-month periods ended September 30, 2011 and 2010, respectively. Other expense for the nine-month period ended September 30, 2011 consisted of interest expense principally related to the PRF revenue interest agreement of \$3.4 million and interest income of \$408,000. Other expense for the nine-month period ended September 30, 2010 consisted of interest expense principally related to the PRF revenue interest agreement of \$3.4 million and interest income of \$450,000.

## **Liquidity and Capital Resources**

We have incurred annual operating losses since inception and, as of September 30, 2011, we had an accumulated deficit of approximately \$422.2 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.

### *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, 2011, \$3.9 million of these promissory notes plus \$2.4 million of accrued interest was outstanding. The first of seven annual payments on this note was paid on the one year anniversary after Ampyra approval in January 2011.

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which PRF paid us an initial \$15.0 million and 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 paid PRF two \$5.0 million payments on December 1, 2009 and 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 \$4.4 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 5.5%. 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, 2011, cash and cash equivalents and short-term investments were approximately \$268.8 million, as compared to \$240.0 million at December 31, 2010. As of September 30, 2011, 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, 2011, our cash and cash equivalents were \$44.4 million, as compared to \$34.6 million as of December 31, 2010. 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 \$224.4 million as of September 30, 2011, as compared to \$205.4 million as of December 31, 2010.

### *Net Cash Provided by (Used in) Operations*

Net cash provided by operations was \$33.4 million for the nine-month period ended September 30, 2011 compared to cash used in operations of \$20.8 million for the nine-month period ended September 30, 2010. Cash provided by operations for the nine-month period ended September 30, 2011 was primarily attributable to net income of \$17.9 million principally resulting from a milestone revenue payment from Biogen Idec, a non-cash share-based compensation expense of \$13.8 million, an asset impairment charge of \$13.0 million, an increase in inventory held by the Company of \$7.6 million, amortization of net premiums and discounts on short-term investments of \$5.0 million, depreciation and amortization of \$3.2 million, a \$1.1 million loss on our put/call liability, and a decrease in accounts receivable of \$1.7 million. Cash provided by operations was partially offset by a net decrease of \$23.5 million due to changes in working capital items primarily due to the payment of 2010 accruals and prepaid items during the nine-month period ended September 30, 2011. It was also attributable to a decrease in the deferred license revenue of \$6.8 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 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.

### *Net Cash Used in Investing*

Net cash used in investing activities for the nine-month period ended September 30, 2011 was \$26.1 million, primarily due to \$204.0 million in purchases of short-term investments and \$2.1 million in purchases of intangible assets and property and equipment which was partially offset by \$180.0 million in proceeds of short-term investments.

### *Net Cash Provided by Financing*

Net cash provided by financing activities for the nine-month period ended September 30, 2011 was \$2.4 million due to \$3.8 million in net proceeds from option exercises which was partially offset by \$1.4 million in repayments to PRF.

### *Future Capital Needs*

Our current guidance is for Ampyra 2011 full year net revenue to increase over the prior year to \$205-\$230 million. Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be \$130-\$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra. Research and development (R&D) expenses for the full year 2011 are currently expected to be \$35-\$40 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2.

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Ampyra and Zanaflex Capsules, the continued progress of our research and development activities, the timing

and outcome of regulatory approvals, the amount and timing of milestone or other payments made or received under collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights and 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 Ampyra and Zanaflex Capsules, increase our efforts to support the sales of Ampyra, 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, 2010. 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, 2011, commitments related to the purchase of inventory consistent with our normal course of business decreased as compared to December 31, 2010. As of September 30, 2011, we have inventory-related purchase commitments totaling approximately \$11.1 million within the next year.

In June 2011, we entered into a 15 year lease for an aggregate of approximately 138,000 square feet of laboratory and office space in Ardsley, New York. We plan to relocate its corporate headquarters, and all employees based at our Hawthorne, New York location, to the Ardsley facility. We anticipate taking possession of the new space in June 2012, subject to completion of certain improvements to the facility prior to our occupancy. The commencement of the term would be deferred in the case of certain delays in the completion of those improvements. We have options to extend the term of the lease for three additional five-year periods, and we have an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, we have rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. Our extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that the Company not be in default under the lease. The lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to our occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. The base rent will initially be \$3.4 million per year, and will be subject to a 2.5% annual increase.

In June 2011, we licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc., which will be referred to as AC105. We made a \$3 million upfront payment to Medtronic during the three-month period ended June 30, 2011 and recorded the expense as research and development expense. We will make up to \$32 million in regulatory and development milestone payments, if achieved. A single-digit sales royalty will also be paid by the Company to Medtronic if AC105 is commercialized by the Company.

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 \$64 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, 2011, 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.

## **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**

#### *Ampyra*

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail, Kaiser Permanente (Kaiser), and the U.S. Department of Veterans Affairs (VA). 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, Kaiser and the specialty distributor to the VA. As of September 30, 2011, inventory levels at specialty pharmacy providers that distribute Ampyra (does not include Kaiser or the specialty distributor to the VA) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers, Kaiser, and the specialty distributor to the VA 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, Kaiser and the specialty distributor to the VA, 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, Kaiser and the specialty distributor to the VA, 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, 2011, inventory levels at the specialty pharmacy providers (this does not include Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers, Kaiser, and the specialty distributor to the VA 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.

#### *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. We have not made any shipments as a result of incentives to our wholesalers and our policy is not to ship in excess of our wholesalers' inventory levels maintained in the ordinary course of business.

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.

We initiated a product recall for three lots of Zanaflex Capsules in February 2011 due to two reports of empty Zanaflex Capsules that had been distributed to pharmacies and sold to patients. Returns of this recalled product are being charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize. Some shipments of Zanaflex Capsules during the nine-month period ended September 30, 2011 were likely to replace this recalled product. As of September 30, 2011 we received approximately \$3.4 million in recall returns which was charged directly against deferred revenue. Under the terms of our agreement with Alkermes, they are responsible for the cost of replacing the inventory and any reasonable and actual costs and expenses that we incur in connection with the recall.

### *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 in 2010, 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 resulted 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.

## **Research and Development**

Research and development expenses include the costs associated with our internal research and development activities including, employee compensation and benefits, occupancy costs, and research and development conducted for us by third parties, such as sponsored university-based research, clinical trial vendors, contract manufacturing for our preclinical program, costs of materials used in clinical trials and depreciation of capital resources used to develop our products and regulatory consulting to support 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, the cost of Ampyra inventory received up until regulatory approval and expenses related to the acquisition of in-process research and development licensed rights. 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 nine-month period ended September 30, 2011 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 ratably over the period the research and development activity is 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 recorded a \$986,000 provision for income taxes for the three-month period ended September 30, 2011. We did not record any tax provision or benefit for the nine-month period ended September 30, 2010. 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, 2011.

As of September 30, 2011, we had available federal net operating loss carry-forwards of approximately \$234.0 million and state net operating carry-forwards of approximately \$223.1 million, which may be available to offset future taxable income, if any. The federal losses are expected to expire between 2021 and 2030 while the state losses are expected to expire between 2012 and 2030. We also have research and development tax credit carry-forwards of approximately \$3.9 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2019. Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Internal Revenue Code of 1986, as amended, the Code, provides for a limitation of the annual use of net operating loss and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Code) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-

forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry-forwards may be applied against future taxes we may not be able to take full advantage of these attributes for federal income tax purposes.

### Share-based Compensation

We account for stock options and restricted stock granted to employees 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.

We have based our current assumptions on the following:

Assumption	Method of estimating
<ul style="list-style-type: none"> <li>• Estimated expected term of options</li> <li>• Expected volatility</li> </ul>	<ul style="list-style-type: none"> <li>• Historical term data</li> <li>• Combination of historic volatility of our common stock since October 1, 2006 and the historic volatility of the stock of our peer companies</li> </ul>
<ul style="list-style-type: none"> <li>• Risk-free interest rate</li> </ul>	<ul style="list-style-type: none"> <li>• Yields of U.S. Treasury securities corresponding with the expected life of option grants</li> </ul>
<ul style="list-style-type: none"> <li>• Forfeiture rates</li> </ul>	<ul style="list-style-type: none"> <li>• Historical forfeiture data</li> </ul>

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, 2011.

We have cash equivalents and short-term investments at September 30, 2011, 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, 2011. At September 30, 2011, we held \$268.8 million in cash and cash equivalents and short-term investments which had an average interest rate of approximately 0.10%.

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 third quarter of 2011, 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, 2011, our disclosure controls and procedures were effective to achieve their stated purpose.

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, regulations, and forms. Disclosure controls and procedures include, without limitation, 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.

***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, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

The Company had sued Apotex Corp. and Apotex Inc. (collectively, “Apotex”) for patent infringement related to Apotex Inc.’s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. On September 7, 2011, the Company announced that the U.S. District Court for the District of New Jersey had ruled against it in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex. The Company is appealing the decision. However, Apotex will be able to receive FDA approval of its ANDA and launch generic tizanidine hydrochloride capsules, if Apotex is able otherwise to satisfy the FDA’s review requirements for ANDAs. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. If approved by the FDA, this would lead to additional tizanidine hydrochloride capsules entering the marketplace, which would likely cause the Company’s sales of Zanaflex Capsules to decline significantly.

Item 1 of Part II of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2011, and June 30, 2011, include prior updates to the litigation described above.

### 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, 2010, as updated by the information in Item 1A of Part II of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2011, and June 30, 2011, and as further updated by this Item 1A, 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. Following is the restated text of individual risk factors with changes that have occurred since our publication of risk factors in our 2010 Annual Report and our updates to the risk factors in our Quarterly Reports for the quarters ended March 31, 2011, and June 30, 2011.

***The pharmaceutical industry is subject to stringent regulation and failure to obtain regulatory approval will prevent commercialization of our product candidates and, if we do not comply with FDA regulations if we obtain regulatory approval, approved products could be withdrawn from the market.***

Our research, development, preclinical and clinical trial activities, as well as the manufacture and marketing of any products that we may successfully develop, are subject to an extensive regulatory approval process by the FDA and other regulatory agencies abroad. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Any regulatory approvals may contain limitations on the indicated usage of a drug or, distribution restrictions, or may be conditioned on burdensome post-approval study or other requirements, including the requirement that we institute and follow a special risk management plan to monitor and manage potential safety issues, all of which may eliminate or reduce the drug’s market potential. Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Post-market evaluation of a product could result in marketing restrictions or withdrawal from the market.

Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

In order to conduct clinical trials to obtain FDA approval to commercialize any product candidate, an IND application must first be submitted to the FDA and must become effective before clinical trials may begin. Subsequently, an NDA must be submitted to the FDA, including the results of adequate and well-controlled clinical trials demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. In addition, the manufacturing facilities used to produce the products must comply with current good manufacturing practices, or cGMPs, and must pass a pre-approval FDA inspection. Extensive submissions of preclinical and clinical trial data are required to demonstrate the safety, efficacy, potency and purity for each intended use. The FDA may refuse to accept our regulatory submissions for filing if they are incomplete.

Clinical trials are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA’s good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We

depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices required by regulators. If any such standards are not complied with in our clinical trials, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate such trial, which would severely delay our development and possibly end the development of such product candidate.

In addition, we are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and we may be subject to other local, state, federal and foreign regulations. We cannot predict the impact of such regulations on us, although it could impose significant restrictions on our business and additional expenses to comply with these regulations.

We also are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to other regulatory requirements that apply to marketed drugs manufactured or distributed by us. If we receive a notice of inspectional observations or deficiencies from the FDA, we may be required to undertake corrective and preventive actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses on how we conduct the affected activities. For example, the FDA conducted an inspection of our adverse event reporting in February 2009 that resulted in a Form FDA 483 with five inspectional observations. The observations cited the failure to submit NDA field alert reports for Zanaflex Capsules in a timely manner, the failure to review adequately complaints concerning distributed product, the late submission of NDA annual reports, and inadequate written procedures for our quality control unit, NDA field alert reporting, and the training of our personnel. We have undertaken corrective and preventive actions in order to address the FDA's concerns cited in the Form FDA 483. However, the FDA might identify different or additional deficiencies in subsequent inspections. The FDA also conducted two inspections beginning in July 2011. The first inspection focused on our Risk Evaluation and Mitigation Strategy (REMS) and the second inspection focused on our adverse event reporting system. The REMS inspection resulted in verbal comments pertaining to formalization of procedures and enhanced quality assurance responsibilities. The adverse event reporting inspection resulted in an FDA Form 483 focused primarily on timeliness of reporting, formalization and enhancement of certain procedures and processes, communication of Ampyra post-marketing commitments, and Acorda access to source documentation. Acorda has provided the FDA with formal responses to the inspectional observations as well as to the verbal comments and is in the process of implementing specific actions to address the FDA's concerns and enhance our overall pharmacovigilance process. Nevertheless, the FDA may decide that Acorda's responses are not adequate and may decide to issue a written warning letter or take other enforcement action. In addition, although Ampyra was approved by the FDA on January 22, 2010, the FDA has not inspected our third party suppliers' drug product manufacturing sites in connection with that approval. The process validation efforts and manufacturing process at these sites could be inspected at a later date and the FDA might find what it considers to be deficiencies in the manufacturing process or process validation efforts, which could negatively impact the availability of product supply.

We and our third party suppliers are generally required to maintain compliance with cGMPs and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. In addition, the FDA must approve any significant changes to our suppliers or manufacturing methods. If we or our third party suppliers cannot demonstrate ongoing cGMP compliance, we may be required to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions. Non-compliance could increase our costs, cause us to lose revenue, and damage our reputation.

Even if our suppliers or manufacturing methods are in compliance with applicable requirements, we may encounter problems with the manufacture of our products. To investigate and/or resolve these problems, we may be required to withdraw or recall product and interrupt commercial supply of our products. These events could increase our costs, cause us to lose revenue, and damage our reputation. We are required to submit field alert reports to the FDA if we learn of certain reported problems with our products, and we are required to investigate the causes of the reported problems. For example, in February 2011, we filed a field alert report with the FDA pertaining to two reports of empty Zanaflex Capsules that had been distributed to pharmacies and sold to patients. In March 2011, after investigation of the issue and discussion with the FDA, we implemented a Class II, Level II Recall of three lots of Zanaflex Capsules. The FDA agreed with our proposal to conduct a phased approach of recalling product from our wholesalers and then from our retailers in order to appropriately address the issue and to mitigate an out-of-stock situation. In addition, in April 2011, we filed a field alert with the FDA pertaining to two reports that empty Ampyra bottles had been distributed to a specialty pharmacy and sold to patients. In May 2011, we filed a field alert with the FDA pertaining to an Ampyra bottle with no label, and in June 2011 we filed a field alert pertaining

to a bottle of Ampyra that was missing a lot number and expiration date. We are currently investigating the causes of these reported problems and, depending on the results of the investigation, further action may be required

***If we cannot protect, maintain and, if necessary, enforce our intellectual property, our ability to develop and commercialize our products will be severely limited.***

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent and trademark protection for the technologies, compounds and products, if any, resulting from our licenses and development programs. Without protection for the intellectual property we use or intend to use, other companies could offer substantially identical products for sale without incurring the sizable discovery, research, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

We have invented, in-licensed or are the assignee of over 45 U.S. patents, over 115 foreign patents and over 255 patent applications pending worldwide for technologies we invented or in-licensed. The process of obtaining patents and trademarks can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent or trademark may not issue, it may not issue in a timely manner, or it may not have sufficient scope or strength to protect the technology it was intended to protect or to provide us with any commercial advantage. We may never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because patent applications are confidential until they are published, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not allowed or issued for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or trademarks or the patents or trademarks of our licensors.

We may initiate actions to protect our intellectual property and in any litigation in which our intellectual property or our licensors' intellectual property is asserted, a court may determine that the intellectual property is invalid or unenforceable. Even if the validity or enforceability of that intellectual property is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by, for example, the patent claims. In addition, effective intellectual property enforcement may be unavailable or limited in some foreign countries for a variety of legal and public policy reasons. From time to time we may receive notices from third parties alleging infringement of their intellectual property rights. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, would be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in areas that are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which could have an adverse effect on us, even if we are successful in defending such claims.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, collaborators, advisors and others. Nonetheless, those agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, collaborators, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, joint ownership may result, which could undermine the value of the intellectual property to us or disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.



We had sued Apotex Corp. and Apotex Inc. (collectively, “Apotex”) for patent infringement related to Apotex Inc.’s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. On September 7, 2011, we announced that the U.S. District Court for the District of New Jersey had ruled against us in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid and not infringed by Apotex. We are appealing the decision. However, if the FDA approves Apotex’s ANDA, Apotex would be permitted to sell generic tizanidine hydrochloride capsules. Other third parties may bring similar claims to Apotex and may also seek approval from the FDA for generic tizanidine hydrochloride capsules. We would face significant competition from any generic brand of tizanidine hydrochloride capsule, which would cause significant declines in our revenue and profit margin. If a generic tizanidine hydrochloride capsule were approved and commercialized, Zanaflex Capsules would face significant competition, which would likely cause significant declines in our revenue from this product.

## **Item 5. Other Information**

The Company is a party to employment agreements (the “Employment Agreements”) with each of Andy Blight, Ph.D., the Company’s Chief Scientific Officer, David Lawrence, the Company’s Chief Financial Officer, and Jane Wasman, the Company’s Executive Vice President, General Counsel and Corporate Secretary (the “Executives”). Pursuant to the Employment Agreements, among other things, each of the Executives are entitled to specified payments and other benefits if his or her employment is terminated by the Company without “Cause” or by the Executive for “Good Reason” (as such terms are defined in the Employment Agreements). On November 7, 2011, the Company entered into an amendment to each Employment Agreement with each of the Executives (the “Amendments”) to modify certain of the payments and other benefits to which the Executives are entitled under these circumstances, as further described below.

Pursuant to the Employment Agreements prior to the Amendments, if the Company terminated an Executive’s employment without Cause, or if one of the Executives voluntarily terminated his or her employment for Good Reason, among other things the Company was obligated to make severance payments equal to nine months of base salary, in the case of Dr. Blight, and seven months of base salary, in the case of Mr. Lawrence and Ms. Wasman, as well as COBRA premium payments for the severance period. Pursuant to the Amendments, if an Executive’s employment terminates under these circumstances, (a) the amount of the severance payments was increased to 12 months of base salary, (b) the period for payment of COBRA premium payments was similarly increased to 12 months, and (c) the Executive will be paid his or her target cash bonus for the year of termination, prorated based on the number of days in the calendar year elapsed as of the termination date.

Also, pursuant to the Employment Agreements prior to the Amendments, if the Company terminated an Executive’s employment without Cause, or if one of the Executives voluntarily terminated his or her employment for Good Reason, within 18 months after a “Change in Control” (as defined in the Employment Agreements), among other things, the Company was obligated to make a lump sum severance payment equal to 12 months of base salary, in the case of Dr. Blight, and nine months of base salary, in the case of Mr. Lawrence and Ms. Wasman, as well as COBRA premium payments for the severance period. The Company was also obligated to pay the Executive a bonus equal to the last annual bonus received by the Executive, prorated based on the number of days in the calendar year elapsed as of the termination date. Pursuant to the Amendments, if an Executive’s employment terminates under these circumstances, (a) the amount of the severance payment was increased to 24 months of base salary, (b) the period for payment of COBRA premium payments was similarly increased to 24 months, and (c) the bonus payable to the Executive was modified to be an amount equal to two (2) times his or her target cash bonus for the year of termination.

The Amendments also modified certain provisions of the Employment Agreements to ensure that the terms of the Employment Agreements are compliant with applicable laws, including Section 409A of the Internal Revenue Code. The Amendments did not otherwise modify the payments or other benefits to which the Executives are entitled under the Employment Agreements, or any of the terms or conditions applicable to any of the payments or other benefits to which the Executives are entitled under the Employment Agreements.

**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.DEF*	XBRL Taxonomy Extension Definition 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.”



## Exhibit Index

Exhibit No.	Description
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\* 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.”



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

I, Ron Cohen, certify that:

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

Date: November 7, 2011

/s/ RON COHEN

Ron Cohen

*Chief Executive*

*Officer*

*(Principal*

*Executive Officer)*

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

I, David Lawrence, certify that:

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

Date: November 7, 2011

/s/ DAVID  
LAWRENCE

David Lawrence  
Chief Financial  
Officer  
(Principal  
Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Acorda Therapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ron Cohen, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RON COHEN  
RON COHEN  
Chief Executive Officer  
(Principal Executive Officer)  
November 7, 2011

[A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc. and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.]

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

In connection with the Quarterly Report on Form 10-Q of Acorda Therapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Lawrence, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DAVID LAWRENCE  
DAVID LAWRENCE  
Chief Financial Officer  
(Principal Financial Officer)  
November 7, 2011

[A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc. and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.]

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