ACORDA THERAPEUTICS INC Form 10-Q November 08, 2012

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

### FORM 10-Q

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

For the quarterly period ended September 30, 2012

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)

o

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

420 Saw Mill River Road Ardsley, New York 10502 (914) 347-4300

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

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

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

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

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

smaller reporting company)

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

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

Class
Common Stock, \$0.001 par value
per share

Outstanding at October 31, 2012 40,157,651 shares

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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 or from our other research and development programs, including any acquired or in-licensed programs; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of 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; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. 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," "participates," "expects," "expects," "intends," "may," "participates," "expects," "intends," "may," "participates," "expects," "intends," "may," "participates," "expects," "expects," "intends," "may," "participates," "expects," "expects," "intends," "may," "participates," "expects," "expect "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 and in our Quarterly Reports on Form 10-O for the quarters ended March 31 and June 30, 2012, and in our Annual Report on Form 10-K for the year ended December 31, 2011, 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

	September	
	30,	December 31,
(In thousands, except share data)	2012	2011
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$40,026	\$ 57,954
Restricted cash	469	303
Short-term investments	192,204	237,953
Trade accounts receivable, net of allowances of \$1,039 and \$879, as of September 30,		
2012 and December 31, 2011, respectively	23,227	22,828
Prepaid expenses	8,180	6,534
Finished goods inventory held by the Company	18,406	27,256
Finished goods inventory held by others	834	1,126
Other current assets	9,483	6,988
Total current assets	292,829	360,942
Long-term investments	86,434	
Property and equipment, net of accumulated depreciation	16,437	3,858
Intangible assets, net of accumulated amortization	9,279	8,769
Non-current portion of deferred cost of license revenue	4,967	5,442
Other assets	507	477
Total assets	\$410,453	\$ 379,488
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$18,460	\$ 21,393
Accrued expenses and other current liabilities	23,243	24,149
Deferred product revenue—Zanaflex tablets	9,941	9,967
Deferred product revenue—Zanaflex Capsules	18,859	20,632
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interest liability	1,335	1,001
Current portion of convertible notes payable	1,144	1,144
Total current liabilities	82,039	87,343
Non-current portion of deferred license revenue	70,949	77,742
Put/call liability	554	1,030
Non-current portion of revenue interest liability	1,247	1,898
Non-current portion of convertible notes payable	4,205	5,230
Other non-current liabilities	5,992	1,036
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at September 30, 2012 and December 31, 2011; issued and outstanding 39,494,095 and 39,328,495 shares,	39	39

including those held in treasury, as of September 30, 2012 and December 31, 2011, respectively

Treasury stock at cost (12,420 shares at September 30, 2012 and December 31, 2011)	(329	) (329	)
Additional paid-in capital	633,184	614,914	
Accumulated deficit	(387,496	) (409,481	)
Accumulated other comprehensive income	69	66	
Total stockholders' equity	245,467	205,209	
Total liabilities and stockholders' equity	\$410,453	\$ 379,488	

See accompanying Unaudited Notes to Consolidated Financial Statements

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(unaudited)

(In thousands, except per share data)	Three-month period ended September 30, 2012	Three-month period ended September 30, 2011	Nine-month period ended September 30, 2012	Nine-month period ended September 30, 2011
(In thousands, except per share data)	30, 2012	30, 2011	2012	2011
Revenues:	¢ 72 206	¢ 65 400	¢206.002	¢ 107 222
Net product revenues	\$ 72,206	\$ 65,420 347	\$206,992	\$187,222 578
Royalty revenues	2,967		10,557	
Milestone revenue	2.264	25,000		25,000
License revenue	2,264	2,264	6,793	6,793
Total net revenues	77,437	93,031	224,342	219,593
Costs and amount				
Costs and expenses:	14761	26.651	40.000	50.740
Cost of sales	14,761	26,651	40,802	50,749
Cost of milestone and license revenue	159	1,908	476	2,225
Research and development	12,031	9,088	35,690	31,804
Selling, general and administrative	40,121	34,718	123,096	112,788
Total operating expenses	67,072	72,365	200,064	197,566
Operating income	10,365	20,666	24,278	22,027
Other expense (net):				
Interest and amortization of debt discount expense	(373	( )	(-,	) (3,359 )
Interest income	135	134	393	408
Total other expense (net)	(238	(813)	(1,108	) (2,951 )
Income before taxes	10,127	19,853	23,170	19,076
Provision for income taxes	(533	(986)	(1,185	) (1,165 )
Net income	\$ 9,594	\$ 18,867	\$21,985	\$17,911
Net income per share—basic	\$ 0.24	\$ 0.48	\$0.56	\$0.46
Net income per share—diluted	\$ 0.24	\$ 0.47	\$0.55	\$0.45
Weighted average common shares outstanding used in computing net income per share—basic	39,463	39,100	39,412	38,940
Weighted average common shares outstanding used in computing net income per share—diluted	40,159	40,174	40,222	40,035

See accompanying Unaudited Notes to Consolidated Financial Statements

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Comprehensive Income

(unaudited)

			Nine-month	Nine-month
	Three-month		period	period
	period	Three-month	ended	ended
	ended	period ended	September	September
	September	September	30,	30,
(In thousands)	30, 2012	30, 2011	2012	2011
Net income	\$ 9,594	\$ 18,867	\$21,985	\$17,911
Other comprehensive income (loss):				
Unrealized gains (losses) on available for sale securities	108	(42)	3	82
Other comprehensive income (loss)	108	(42)	3	82
Comprehensive income	\$ 9,702	\$ 18,825	\$21,988	\$17,993

See accompanying Unaudited Notes to Consolidated Financial Statements

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

## (unaudited)

(In thousands)	Nine-month period ended September 30, 2012		Nine-month period ended September 30, 2011	
Cash flows from operating activities:				
Net income	\$21,985		\$17,911	
Adjustments to reconcile net income to net cash provided by operating activities:				
Share-based compensation expense	15,349		13,847	
Amortization of net premiums and discounts on investments	3,700		5,033	
Amortization of revenue interest issuance cost	58		88	
Depreciation and amortization expense	3,050		3,208	
Intangible asset impairment	<u> </u>		13,038	
Gain on put/call liability	(476	)	1,066	
Changes in assets and liabilities:	· ·		·	
(Decrease) increase in accounts receivable	(399	)	1,664	
Increase in prepaid expenses and other current assets	(4,307	)	(4,734	)
Decrease in inventory held by the Company	8,850	ĺ	7,615	
Decrease in inventory held by others	292		1,034	
Decrease in non-current portion of deferred cost of license revenue	476		450	
Increase in other assets	(88)	)	(222	)
Decrease in accounts payable, accrued expenses, other current liabilities	(4,854	)	(18,811	)
Increase in revenue interest liability interest payable	495		823	
Decrease in current portion of deferred license revenue	_		(371	)
Decrease in non-current portion of deferred license revenue	(6,793	)	(6,422	)
(Decrease) increase in other non-current liabilities	(160	)	127	
(Decrease) increase in deferred product revenue—Zanaflex tablets	(26	)	392	
Decrease in deferred product revenue—Zanaflex Capsules	(1,774	)	(2,370	)
Net cash provided by operating activities	35,378		33,366	
Cash flows from investing activities:				
Purchases of property and equipment	(9,167	)	(1,232	)
Purchases of intangible assets	(1,865	)	(863	)
Purchases of investments	(232,633	)	(203,989	)
Proceeds from maturities of investments	188,250		180,000	
Net cash used in investing activities	(55,415	)	(26,084	)
Cash flows from financing activities:				
Proceeds from issuance of common stock and option exercises	2,921		3,816	
Repayments of revenue interest liability	(812	)	(1,354	)
Net cash provided by financing activities	2,109		2,462	
Net (decrease) increase in cash and cash equivalents	(17,928	)	9,744	
Cash and cash equivalents at beginning of period	57,954		34,641	
Cash and cash equivalents at end of period	\$40,026		\$44,385	
Supplemental disclosure:				

Cash paid for interest	881	2,394
Cash paid for taxes	1,097	151

See accompanying Unaudited Notes to Consolidated Financial Statements

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### ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements

(unaudited)

### (1) Organization and Business Activities

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

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, 2011 included in the Company's Annual Report on Form 10-K for such year, as filed with the Securities and Exchange Commission (the "SEC").

### (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 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.

### Investments

Both short-term and long-term investments consist of US Treasury bonds. The Company classifies marketable securities available to fund current operations as short-term investments in current assets on its consolidated balance sheets. Marketable securities are classified as long-term investments in long-term assets on the consolidated balance sheets if (i) they have been in an unrealized loss position for longer than one year and (ii) the Company has the ability and intent to hold them (a) until the carrying value is recovered and (b) such holding period may be longer than one

year. The Company classifies its investments as available-for-sale. Available-for-sale securities are recorded at fair value of the investments based on quoted market prices.

Unrealized holding gains and losses on available-for-sale securities, which are determined to be temporary, are excluded from earnings and are reported as a separate component of accumulated other comprehensive income (loss).

Premiums and discounts on investments are amortized over the life of the related available-for-sale security as an adjustment to yield using the effective-interest method. Dividend and interest income are recognized when earned. Amortized premiums and discounts, dividend and interest income and realized gains and losses are included in interest income.

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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), which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which is the exclusive specialty pharmacy distributor for Ampyra to the U.S. Department of Veterans Affairs (VA). Ampyra is not available in retail pharmacies. The Company 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. The specialty pharmacy providers, Kaiser, and the specialty obligated to hold no more than an agreed number of days of inventory, ranging from between 10 to 30 days.

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 specialty pharmacies, Kaiser and the specialty distributor to the VA, 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. 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, the Company does not believe it 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

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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.

### Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of investments in cash, cash equivalents, restricted cash and accounts receivable. The Company maintains cash, cash equivalents, restricted cash, short-term and long-term investments with approved financial institutions. The Company is exposed to credit risks and liquidity 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.

### Reclassification

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

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### (3) Share-based Compensation

During the three-month periods ended September 30, 2012 and 2011, the Company recognized share-based compensation expense of \$5.6 million and \$5.0 million, respectively. During the nine-month periods ended September 30, 2012 and 2011, the Company recognized share-based compensation expense of \$15.3 million and \$13.8 million, respectively. Activity in options and restricted stock during the three-month period ended September 30, 2012 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, 2012 and 2011 were approximately \$13.0 and \$13.61, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2012 and 2011 were approximately \$13.74 and \$13.11, respectively.

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

	For the three-month period ended September 30,			nine-month od ended
			Septe	mber 30,
(In millions)	2012	2011	2012	2011
Research and development	\$1.4	\$1.5	\$3.7	\$4.1
Selling, general and administrative	4.2	3.5	11.6	9.7
Total	\$5.6	\$5.0	\$15.3	\$13.8

A summary of share-based compensation activity for the nine-month period ended September 30, 2012 is presented below:

### **Stock Option Activity**

			Weighted	
	Number of	Weighted	Average	Intrinsic
	Shares	Average	Remaining	Value
	(In	Exercise	Contractual	(In
	thousands)	Price	Term	thousands)
Balance at January 1, 2012	4,793	\$21.31		
Granted	1,187	25.73		
Cancelled	(125)	27.93		
Exercised	(143)	20.37		
Balance at September 30, 2012	5,712	\$22.11	6.7	\$28,741
Vested and expected to vest at September 30, 2012	5,645	\$22.07	6.7	\$28,662
Vested and exercisable at September 30, 2012	3,521	\$19.83	5.5	\$25,670

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### Restricted Stock Activity

(In thousands)	
Restricted Stock	Number of Shares
Nonvested at January 1, 2012	377
Granted	290
Vested	(22)
Forfeited	(11)
Nonvested at September 30, 2012	634

As of September 30, 2012, there was \$40.1 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, 2012 and 2011:

			Nine-month	Nine-month
			period	period
	Three-month	Three-month	ended	ended
	period ended	period ended	September	September
	September	September	30,	30,
(In thousands, except per share data)	30, 2012	30, 2011	2012	2011
Basic and diluted				
Net income	\$ 9,594	\$ 18,867	\$21,985	\$17,911
Weighted average common shares outstanding used in				
computing net income per share—basic	39,463	39,100	39,412	38,940
Plus: net effect of dilutive stock options and restricted				
common shares	696	1,074	810	1,095
Weighted average common shares outstanding used in				
computing net income per share—diluted	40,159	40,174	40,222	40,035
Net income per share—basic	\$ 0.24	\$ 0.48	\$0.56	\$0.46
Net income per share—diluted	\$ 0.24	\$ 0.47	\$0.55	\$0.45

The difference between basic and diluted shares is that diluted shares include the dilutive effect 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.

The following amounts were not included in the calculation of net income per diluted share because their effects were anti-dilutive:

Three-month Three-month Nine-month period ended period ended period endedperiod endedperio					
September September September					
30, 2012	30, 2011	30, 2012	30, 2011		
5,650	4,254	5,536	4,233		
67	67	67	67		
	period ended September 30, 2012	period ended period ended September September 30, 2012 30, 2011 5,650 4,254	period ended period ended period ended September September September 30, 2012 30, 2011 30, 2012 5,650 4,254 5,536		

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### (5) Income Taxes

The Company had available federal net operating loss (NOL) carryforwards of approximately \$194.6 million and \$230.4 million and state NOL carryforwards of approximately \$155.1 million and \$205.9 million as of September 30, 2012 and December 31, 2011, respectively, which may be available to offset future taxable income, if any. The federal losses are expected to expire between 2022 and 2030 while the state losses are expected to expire between 2018 and 2030. The Company also has research and development tax credit carryforwards of approximately \$4.4 million as of September 30, 2012, 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 carryforwards of \$1.7 million and \$1.1 million as of September 30, 2012 and December 31, 2011, respectively. Such credits can be carried forward indefinitely and have no expiration date.

At September 30, 2012 and December 31, 2011, the Company had a net deferred tax asset of \$138.8 million and \$147.6 million, respectively, offset by a full valuation allowance. Since inception, the Company has incurred substantial losses and may incur 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, 2012, 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, 2012 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 the Company's Level 2 assets consist of high-quality government bonds and are valued using market prices on the active markets. Level 1 instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets and Level 2 assets are valued using quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves. 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 nine months ended September 30, 2012. During the nine-month period ended September 30, 2012 the Company reclassified its US Treasury bonds in short-term and long-term investments from Level 1 assets to Level 2 assets.

(In thousands)	Level 1	Level 2	Level 3
September 30, 2012			
Assets Carried at Fair Value:			
Cash equivalents	\$31,255	<b>\$</b> —	<b>\$</b> —

Short-term investments	_	192,204	_
Long-term investments	_	86,434	_
Liabilities Carried at Fair Value:			
Put/call liability	_	_	554
December 31, 2011			
Assets Carried at Fair Value:			
Cash equivalents	\$38,340	<b>\$</b> —	\$
Short-term investments	_	237,953	_
Long-term investments	_	_	_
Liabilities Carried at Fair Value:			
Put/call liability			1,030

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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.

	Three-month		Nine-month	Nine-month
	period	Three-month	period	period
	ended	period ended	ended	ended
	September	September	September	September
(In thousands)	30, 2012	30, 2011	30, 2012	30, 2011
Put/call liability:				
Balance, beginning of period	\$ 511	\$ 374	\$1,030	\$391
Total realized and unrealized (gains) losses included in				
selling, general and administrative expenses:	43	1,083	(476)	1,066
Balance, end of period	\$ 554	\$ 1,457	\$554	\$1,457

The Company currently estimates the fair value of our put/call liability using a discounted cash flow valuation technique. Using this approach, historical and expected future cash flows are calculated over the expected life of the PRF agreement, are discounted, and then exercise scenario probabilities are applied. Some of the more significant assumptions made in the valuation include (i) the estimated Zanaflex revenue forecast and (ii) the likelihood of put/call exercise trigger events such as bankruptcy and change of control. The valuation is performed periodically when the significant assumptions change. 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 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) Investments

The Company has determined that all of its 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:

	Amortized	Gross unrealized	Gross unrealized	Estimated fair
(In thousands)	Cost	gains	losses	value
September 30, 2012				
US Treasury bonds	\$278,569	\$70	\$(1	) \$278,638
December 31, 2011				
US Treasury bonds	237,887	72	(6	) 237,953

The contractual maturities of short-term available-for-sale debt securities at September 30, 2012 and December 31, 2011 are within one year. The contractual and intended maturities of long-term available-for-sale debt securities at September 30, 2012 and December 31, 2011 are greater than one year. The Company has determined that there were no other-than-temporary declines in the fair values of its investments as of September 30, 2012. Short-term

investments with maturity of three months or less from date of purchase have been classified as cash equivalents, and amounted to \$31.3 million and \$38.3 million as of September 30, 2012 and December 31, 2011, respectively.

(8) Collaborations, Alliances, and Other Agreements

### Biogen

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 plc (Alkermes), formerly Elan Corporation, plc (Elan). Biogen Idec has

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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.

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. 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 Alkermes 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 Alkermes 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, the Company has 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 Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company 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, 2012, 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.

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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 Alkermes, Alkermes 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. Substantive uncertainty existed at the inception of the arrangement as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in the research and development of new products and the uncertainty involved with obtaining regulatory approval. Biogen leveraged Acorda's U.S. Ampyra study results that contributed to the regulatory approval process. Therefore, the milestone was achieved based in part on Acorda's past performance. The milestone was also reasonable relative to all deliverable and payment terms of the collaboration arrangement. 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.

### Watson

The Company has an agreement with Watson Pharma, Inc., a subsidiary of Watson Pharmaceuticals, Inc., to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, which was launched in February 2012. In accordance with the Watson agreement, the Company receives a royalty based on Watson's gross margin, as defined by the agreement, of the authorized generic product. During the three and nine-month periods ended September 30, 2012, the Company recognized royalty revenue of \$1.5 million and \$4.7 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the three and nine-month periods ended September 30, 2012, the Company also recognized revenue and a corresponding cost of sales of \$550,000 and \$2.0 million, respectively, related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Watson, which is recorded in net product revenues and cost of sales.

### Neuronex

In February 2012, the Company and its wholly-owned subsidiary ATI Development Corp. (ATI) entered into an agreement to acquire (the Agreement) Neuronex, Inc., a privately-held development stage pharmaceutical company (Neuronex). Neuronex is developing Diazepam nasal spray, or DZNS, under Section 505(b)(2) of the Food, Drug and Cosmetic Act as a rescue treatment for certain seizures.

Under the terms of the Agreement, upon closing of the acquisition, Acorda would pay \$6.8 million in cash, subject to adjustment in accordance with the provisions of the Agreement. After closing, the former equity holders of Neuronex will be entitled to receive from Acorda up to an additional \$18 million in contingent earnout payments upon the achievement of specified regulatory and manufacturing-related milestones with respect to the DZNS product, and up to \$105 million upon the achievement of specified sales milestones with respect to the DZNS product. The former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments, ranging from the upper single digits to lower double digits, on worldwide net sales of DZNS products. These payments are payable on a country-by-country basis until the earlier to occur of ten years after the first commercial sale of a product in such country and the entry of generic competition in such country as defined in the Agreement.

Neuronex licenses the patent and other intellectual property and other rights relating to the DZNS product from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which grants worldwide rights to Neuronex, except certain specified Asian countries, Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the DZNS product and up to \$3 million upon the achievement of specified sales milestones with respect to the DZNS product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit

royalty on net sales of DZNS products. Upon the potential closing of the acquisition, Acorda will be responsible for these milestone payments and royalties, in addition to the earnout payments described above.

Consummation of the acquisition is subject to certain conditions, including (i) Acorda's receipt of the official minutes (the "FDA Minutes") from a meeting contemplated by the Agreement to be held among Acorda, Neuronex, and the U.S. Food and Drug Administration with respect to the DZNS product and a contemplated filing of the New Drug Application for the product, (ii) consent of SK to the transactions contemplated by the Agreement, and (iii) other conditions customary for a transaction of this type.

Consummation of the acquisition is also subject to the parties not exercising their rights to terminate the

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Agreement. Under the Agreement, (i) Acorda has the right to terminate the Agreement at any time prior to closing, even if the closing conditions have been satisfied, and Neuronex can terminate the Agreement after a specified time period has elapsed after receipt of the FDA Minutes, and (ii) both Acorda and Neuronex have termination rights in the event of certain breaches of representations or covenants by the other party.

Under the terms of the Agreement, the Company made an upfront payment of \$2.0 million. Also, we paid \$500,000 during the three-month period ended March 31, 2012 and an additional \$700,000 during the three-month period ended June 30, 2012 pursuant to a commitment under the Agreement to fund up to \$1.2 million for research to prepare for the diazepam nasal spray pre-NDA meeting with the FDA. Following the pre-NDA meeting, if the conditions described above have been met and termination rights are not exercised, the Company will complete the acquisition of Neuronex by paying the \$6.8 million closing payment referred to above.

The Company evaluated the transaction based upon the guidance of ASC 805, Business Combinations, and concluded that it will only acquire inputs and will not acquire any processes. The Company will need to develop its own processes in order to produce an output. Therefore the Company expects to account for the transaction as an asset acquisition and accordingly the \$2.0 million upfront payment and \$1.2 million in research funding were expensed as research and development expense during the nine-month period ended September 30, 2012.

### (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, 2011. The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business.

On August 3, 2012, the Company received a letter from PRF alleging that it breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also includes an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it does not specify or quantify those injuries. The Company believes that the allegations are without merit and that the put option has not been validly exercised. Although the letter from PRF does not include a purported calculation of the put option price, if it were validly exercised, we estimate that the incremental cost to the Company in excess of amounts already accrued to PRF at September 30, 2012 would be no more than approximately \$2.5 million.

The Company is, from time to time, involved in or 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 the disputes and claims that we have from time to time been involved in or a party to 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. As of September 30, 2012, there have been no accruals for loss contingencies aside from payments related to litigation itself.

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

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

### Background

We are a commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis, or MS, spinal cord injury, or SCI, and other disorders of the nervous system.

### Ampyra

### General

Ampyra was approved by the FDA in January 2010 for the improvement of walking in people with MS. 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 United States in March 2010. Net revenue for Ampyra was \$69.8 million for the three-months ended September 30, 2012 and \$54.7 million for the three-months ended September 30, 2011. As of the end of September 2012, approximately 70% of all people with MS who were prescribed Ampyra received a first refill, and approximately 40% of all people with MS who were prescribed Ampyra have been dispensed at least six months of the medicine through refills, consistent with previously reported trends.

Ampyra is marketed in the United States through our own specialty sales force and commercial infrastructure. We currently have approximately 90 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, Regional Reimbursement Directors, and Managed Markets account managers who provide information and assistance to payers and physicians on Ampyra, and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Pursuant to our REMS approved by the FDA, Ampyra is distributed in the United States exclusively through: a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which is the exclusive specialty pharmacy distributor for Ampyra to the U.S. Department of Veterans Affairs, or VA. All of these customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from between 10 to 30 days.

We have contracted with a third party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, or APSS, a dedicated resource that coordinates the prescription process among healthcare providers, people with MS, and insurance carriers. 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 the processing time for insurance requirements. As with any prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription.

Three of the largest national health plans in the U.S. – Aetna, United Healthcare and Cigna – have listed Ampyra in the lowest branded co-pay tier of their commercial preferred drug list or formulary. These co-pay tiers were recently

renewed. Approximately 75% of commercially insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, 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 a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by commercial health plans.

License and Collaboration Agreement with Biogen Idec

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec International GmbH, or Biogen Idec, under a license and collaboration agreement that we entered into in June 2009. Biogen Idec now has approval for Fampyra in more

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than 30 markets outside the U.S., including the entire European Union, Canada, Australia New Zealand, Israel and South Korea. To date, commercial launches have taken place in Germany and many other EU countries, as well as in Canada, New Zealand, Australia, and Israel. We received a \$25 million milestone payment from Biogen Idec in 2011, which was triggered by Biogen Idec's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters.

### Ampyra Development Programs

We believe there may be potential for Ampyra to be applied to other indications within MS and also in other neurological conditions. For example, in December 2011, we initiated a Phase 2 proof-of-concept clinical study of dalfampridine in adults with cerebral palsy, or CP. The first part of this proof-of-concept study, which has been completed, was a single-dose phase primarily to evaluate safety and tolerability prior to proceeding to a multi-dose cohort. This 10-person, single dose part of the study detected no safety signals that would prevent additional study of the drug in the treatment of CP. We are currently enrolling the second part, a multi-dose study including 20 people with CP, to evaluate both safety and efficacy. We expect to announce results of this part of the study by mid-2013. Also, in June 2012 we enrolled the first patient in a Phase 2 proof-of-concept trial of dalfampridine in post-stroke deficits, and we expect to announce initial study results in the second quarter of 2013. This study is exploring the use of dalfampridine in patients who have experienced a stroke and who have stabilized with chronic neurologic deficits, which may include walking impairment and arm weakness. Over the first six months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. This trial is targeting motor impairments that remain after such recovery. We also are providing grants for investigator-initiated studies looking for potential benefits on a range of functional deficits in MS and other neurological disorders.

We are also working with external partners on a once-daily formulation of Ampyra, and expect to begin human pharmacokinetic testing shortly.

### Ampyra Patent Update

We have two issued patents listed in the Orange Book for Ampyra, as follows:

- The first is U.S. Patent No. US 8,007,826 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027.
- •The Second is U.S. Patent No. 5,540,938 ("the '938 patent"), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In October 2012, the USPTO determined that the '938 patent is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the '938 patent would expire in 2018.

In 2011, the USPTO allowed U.S. Patent Application No. 11/102,559 (the '559 patent application') with claims relating 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. Also in 2011, the European Patent Office, or EPO, granted the counterpart European patent with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking

speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmBH filed oppositions with the EPO challenging this granted European patent. We intend to vigorously defend the European patent, although the outcome of opposition proceedings is unpredictable. In light of the European oppositions, in April 2012, we requested further review by the USPTO of the '559 patent application which was allowed but had not yet issued. After further review, the USPTO again allowed this patent application, but in July 2012 we filed a request for continued examination. In August 2012, the USPTO again allowed the '559 patent application.

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Dalfampridine-ER 5 mg. Post-Approval Commitment Study

In August 2012, we announced results from a post-approval commitment study examining the use of a 5mg dose of dalfampridine-ER to improve walking in people with MS. The study failed to confirm efficacy of the 5mg dose. We believe that this study, together with Ampyra registration studies, continue to show that 10mg twice daily is the appropriate, safe, and effective dose. The study results will be provided to the FDA by the March 1, 2013 FDA deadline and presented in peer-reviewed scientific forums. We are continuing to analyze data from the study.

### Zanaflex

Zanaflex Capsules and Zanaflex tablets are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many central nervous system, or CNS, disorders, including MS and SCI. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. We launched Zanaflex Capsules in April 2005 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. Combined net revenue of Zanaflex Capsules and Zanaflex tablets was \$1.9 million for the three-months ended September 30, 2012 and \$10.7 million for the three-months ended September 30, 2011. In February 2012, Apotex commercially launched a generic version of tizanidine hydrochloride capsules, and we also launched our own authorized generic version, which is being marketed by Watson Pharma. The commercial launch of these generic tizanidine hydrochloride capsules has caused a significant decline in sales of Zanaflex Capsules, and the launch of these generic versions and the potential launch of other generic versions is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2012 and beyond. In May 2012, we received a Paragraph IV Certification Notice from Mylan Laboratories Limited advising us that Mylan Laboratories has filed an Abbreviated New Drug Application for generic versions of the three dosage strengths of Zanaflex Capsules. Based upon our request, the FDA has delisted from the Orange Book the patent against which Mylan Laboratories filed the Paragraph IV Certification Notice.

### Research & Development Programs

Our lead research and development programs include three distinct therapeutic approaches to restoring neurologic and cardiac function and a fourth program, initiated in 2011, to develop an acute treatment for neurological trauma. We believe that these programs have broad applicability and have the potential to be first-in-class therapies. While our existing programs have been focused on MS and SCI, we believe they may be applicable across a number of CNS disorders, including stroke and TBI, 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.

### Glial Growth Factor 2

We have completed enrollment in our GGF2 Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-ups at one, three, and six months. We expect to complete analysis of the three-month data by the end of 2012, which we plan to present in a peer-review setting. We will also discuss the data with the FDA before proceeding to a multiple dose study. 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 independently or to enter into a partnership, most likely with a cardiovascular-focused company.

### Remyelinating Antibodies

We have submitted an IND application to the FDA for one of the remyelinating antibodies, rHIgM22, for the treatment of MS. The FDA has requested additional information, and we expect to submit a response by the end of

2012. We had previously announced problems with a bioactivity assay that had delayed the filing but we successfully completed the qualification of the bioactivity assay in the second quarter of 2012. In preparation for an IND filing, we worked with a contract manufacturer to complete the scale-up manufacturing and purification processes and completed formal preclinical safety and toxicity studies. The manufacturing data, clinical plans and preclinical safety profile are subject to FDA review as part of the IND filing.

### Chondroitinase Program

We are continuing research, which has been funded in part by federal and state grants, on the potential use of chondroitinases for the treatment of injuries to the brain and spinal cord, as well as other neurotraumatic indications. The

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chondroitinase program is in the research and translational development phase and has not yet entered formal preclinical development. We are exploring the possibility of obtaining additional research grants from the National Institutes of Health, or NIH, as well as potential partnerships with other companies to support our efforts.

### AC 105

In June 2011, we entered into a License Agreement with Medtronic, Inc. and one of its affiliates, pursuant to which we acquired worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol (which we refer to as AC 105). Pursuant to the License Agreement, we paid Medtronic an upfront fee of \$3 million and are obligated to pay up to an additional \$32 million upon the achievement of specified regulatory and development milestones. If we commercialize AC 105, we will also be obligated to pay a single-digit royalty on sales. We plan to study AC 105 as an acute treatment for patients who have suffered neurological trauma, such as SCI and traumatic brain injury, or TBI. We have submitted a Phase 2 clinical trial protocol for AC 105 for acute treatment of SCI to the FDA for review, and we are continuing preparations to initiate the trial.

### Corporate Updates

In July 2012, we relocated our corporate headquarters from Hawthorne, New York, to a facility in Ardsley, New York consisting of an aggregate of approximately 138,000 square feet of office and laboratory space. Base rent is initially \$3.4 million per year, subject to a 2.5% annual increase. Our lease of the facility has a 15 year term, but we have options to extend the lease term for three additional five-year periods, and we may terminate the lease after 10 years, subject to payment of an early termination fee. We also have the right to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location.

In October 2012, we named Jane Wasman as President, International. Ms. Wasman most recently has served as the Company's Chief, Strategic Development and General Counsel. In her new role, Ms. Wasman will lead our efforts to identify and launch in-licensing and commercial opportunities outside the United States. She will also be responsible for managing our collaboration with Biogen Idec in their international development and commercialization of Fampyra (prolonged-release fampridine tablets). Ms. Wasman will also continue to lead our global strategic development and will retain the title of General Counsel and Corporate Secretary.

### Outlook for 2012

### Financial Guidance for 2012

We are providing the following guidance with respect to our 2012 financial performance. The following does not reflect any potential expenditures related to the Neuronex transaction described below.

- We expect 2012 net revenue from the sale of Ampyra to range from \$255 million to \$275 million.
- We expect combined net revenues from sales of Zanaflex Capsules (including from sales of authorized generic tizanidine hydrochloride under our agreement with Watson Pharma) and Zanaflex tablets, and royalty revenue from sales by Biogen Idec of Fampyra outside the U.S., of at least \$25 million.
- Research and development expense guidance has been revised downward, and research and development expenses are now expected to be approximately \$45 million, excluding share-based compensation charges and future expenses related to the potential acquisition of Neuronex and its Diazepam nasal spray product, discussed below. These expenses will include post-marketing studies for Ampyra, Phase 2 proof-of-concept studies in

cerebral palsy and post-stroke deficits, and sponsorship of investigator-initiated studies of Ampyra. This revision to our prior guidance results from changes in the timing of several of our research and development programs.

- Selling, general and administrative expenses are expected to range from \$145 million to \$160 million, excluding share-based compensation charges. The principal factors affecting SG&A will be commercial and administrative costs related to Ampyra.
  - We expect to be cash flow positive in 2012.

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The projected amounts of SG&A and R&D expenditures for 2012 are non-GAAP financial measures because they exclude share-based compensation charges and future expenditures related to the potential acquisition of Neuronex and diazepam nasal spray. 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 actual 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 and expenses and income that do not arise from the ordinary course of our business. We believe that non-GAAP financial measures help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses non-GAAP financial measures to establish budgets and operational goals, and to manage our business and to evaluate its performance.

Key 2012 Initiatives and Expected Developments

Our key initiatives and expected developments during 2012 are as follows:

**Targeted Development Milestones** 

Our goals with respect to our development pipeline in 2012 are as follows:

- We are currently enrolling the second phase of our Phase 2 proof-of-concept clinical trial of dalfampridine in adults with CP. This is a multi-dose study including 20 people with CP, to evaluate both safety and efficacy. We expect to announce results of this phase of the study by mid-2013.
- A Phase 2 proof-of-concept clinical trial of dalfampridine in patients with post stroke deficits began in the second quarter of 2012 and is ongoing. We expect to announce initial study results in the second quarter of 2013.
- We submitted an IND application to the FDA for rHIgM22, a remyelinating antibody for the treatment of MS. The FDA has requested additional information, and we expect to submit a response by the end of 2012. We plan to begin a Phase 1 study following FDA review of the study protocol.
- We have completed enrollment in our GGF2 Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose. We expect to complete data analysis by the end of 2012, and we plan to present findings in a peer-review setting. We will discuss the data with the FDA before proceeding to a multiple dose study.
- We submitted a Phase 2 clinical trial protocol for AC 105 for acute treatment of SCI to the FDA for review, and we are continuing preparations to initiate the trial.
- Funding of investigator-initiated studies of Ampyra in MS, focused on a range of neurological functions and other neurological disorders, will be ongoing in 2012.

Neuronex Acquisition Agreement and Development of DZNS

On February 15, 2012, we entered into an agreement with Neuronex, Inc., which is preparing a 505(b)(2) type NDA for a proprietary nasal spray formulation of Diazepam, or DZNS, as a rescue treatment for certain epilepsy patients. Pursuant to the acquisition agreement, we made an upfront payment of \$2 million upon signing the agreement and agreed to fund up to \$1.2 million in research and development costs prior to closing. We paid \$500,000 of the research and development funding commitment during the three-month period ended March 31, 2012,

and we paid the remaining \$700,000 of this commitment during the three-month period ended June 30, 2012. Also, in July 2012 we further agreed with Neuronex that we would fund up to an additional approximately \$165,000 for specified development work relating to DZNS.

The closing is subject to a number of conditions including our satisfaction with the results of a meeting with the FDA regarding Neuronex's expected NDA filing. Following the pre-NDA meeting, we can, at our option, complete the acquisition by paying an additional \$6.8 million in consideration. If we do not complete the transaction, other than as a result of a breach by Neuronex, Neuronex is entitled to retain all amounts previously paid by us as a break-up fee and we have no further obligations to Neuronex.

If we consummate the acquisition and the Neuronex product is approved by the FDA, additional potential payments would include up to \$18 million to the former Neuronex equity holders in earnout payments upon the achievement of

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specified regulatory and manufacturing-related milestones and up to \$105 million upon the achievement of specified sales milestones. The former Neuronex equity holders would also be entitled to receive milestone and royalty-like earnout payments from us based on worldwide net sales, ranging from the upper single digits to lower double digits.

In addition to the potential payments to former Neuronex equity holders, if we consummate the acquisition, we would be obligated to pay certain amounts to SK Biopharmaceuticals Co., Ltd. ("SK"), the licensor of the patent and other intellectual property and other rights relating to the DZNS product, under its license agreement with Neuronex. Pursuant to this license, Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the DZNS product (including \$1 million upon the FDA's acceptance of the NDA for the DZNS product), and up to \$3 million upon the achievement of specified sales milestones with respect to the DZNS product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of DZNS products.

If the acquisition is completed, we will assume oversight and financial responsibility for Neuronex's development and regulatory programs for diazepam nasal spray.

**Results of Operations** 

Three-Month Period Ended September 30, 2012 Compared to September 30, 2011

Net Product Revenues

### Ampyra

We recognize product sales of Ampyra following shipment of product to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra to these customers of \$69.8 million as compared to \$54.7 million for the three-month periods ended September 30, 2012 and 2011, respectively, an increase of \$15.1 million, or 28%. The net revenue increase was comprised of net volume increases of \$6.7 million and price increases and discount and allowance adjustments of \$8.4 million. Net revenue from sales of Ampyra increased in the three months ended September 30, 2012 compared to the three months ended September 30, 2011 due to greater demand we believe due to, in part, the success of certain marketing programs such as our First Step program.

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. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances also consist of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts or amend specialty pharmacy contracts in the future.

### 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 also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules during the three-month period ended September 30, 2012. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$1.9 million for the three-month period ended

September 30, 2012, as compared to \$10.7 million for the three-month period ended September 30, 2011. The decrease was due to the commercial launch of generic versions of tizanidine hydrochloride capsules in February 2012. Net product revenues also include \$550,000, which represents the sale of Zanaflex Capsules authorized generic product to Watson for the three-month period ended September 30, 2012. Generic competition has caused a significant decline in sales of Zanaflex Capsules and is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2012 and beyond.

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.

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#### Milestone Revenue

We recognized \$25.0 million in milestone revenue for the three-month period ended September 30, 2011 as part of our 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 the three-month period ended September 30, 2011. We did not reach any milestones for the three-month period ended September 30, 2012.

#### License Revenue

We recognized \$2.3 million in license revenue for the three-month periods ended September 30, 2012 and 2011, 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 Revenues

We recognized \$1.5 million and \$347,000 in royalty revenue for the three-month periods ended September 30, 2012 and 2011, respectively related to ex-U.S. sales of Fampyra by Biogen Idec. Beginning on August 1, 2012 and for the remainder of 2012, Biogen will record Fampyra revenue from sales in Germany at a reduced price due to ongoing pricing discussions with the German Federal Joint Committee or G-BA. Until a final price is determined, Biogen will record revenue at a reduced price and we will record royalty revenue based on this reduced price. When pricing negotiations are finalized between Biogen and the G-BA, revenue for Fampyra as well as our royalty revenue will be reconciled retroactive to August 1, 2012.

We recognized \$1.4 million in royalty revenue for the three-month period ended September 30, 2012 related to the authorized generic sale of Zanaflex Capsules which started in February 2012.

### Cost of Sales

#### **Ampyra**

We recorded cost of sales of \$13.8 million for the three-month period ended September 30, 2012 as compared to \$10.5 million for the three-month period ended September 30, 2011. Cost of sales for the three-month period ended September 30, 2012 consisted primarily of \$12.0 million in inventory costs related to recognized revenues. The cost of Ampyra inventory is based on a percentage of net product sales of the product in the quarter shipped to Acorda by Alkermes or our alternative manufacturer. Cost of sales for the three-month period ended September 30, 2012 also consisted of \$1.6 million in royalty fees based on net sales, \$147,000 in amortization of intangible assets, and \$42,000 in period costs related to freight and stability testing.

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 freight and stability testing.

#### Zanaflex

We recorded cost of sales of \$398,000 for the three-month period ended September 30, 2012 as compared to \$16.1 million for the three-month period ended September 30, 2011. Cost of sales for the three-month period ended September 30, 2012 consisted of \$249,000 in inventory costs primarily related to recognized revenues, \$114,000 in royalty fees based on net product shipments, and \$35,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$550,000, which represents the cost of Zanaflex Capsules authorized generic product sold for the three-month period ended September 30, 2012.

Cost of sales for the three-month period ended September 30, 2011 consisted \$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,

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\$715,000 in royalty fees based on net product shipments, and \$70,000 in period costs related to 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 license revenue of \$159,000 and \$159,000 for the three-month periods ended September 30, 2012 and 2011, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan) in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement. We recorded cost of milestone revenue of \$1.8 million for the three-month period ended September 30, 2011. Cost of milestone revenue represents a 7% payment to Alkermes on the \$25.0 million milestone revenue received from Biogen Idec in accordance with our worldwide license and supply agreement with Alkermes. For revenue recognition purposes, the related milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in the three-month period ended September 30, 2011. The corresponding cost of milestone revenue was also recognized in its entirety in this period. We did not record milestone revenue or a corresponding cost of milestone revenue for the three-month period ended September 30, 2012.

### Research and Development

Research and development expenses for the three-month period ended September 30, 2012 were \$12.0 million as compared to \$9.1 million for the three-month period ended September 30, 2011, an increase of approximately \$2.9 million, or 32%. The increase was primarily due to an increase of \$1.5 million in our life cycle management program for Ampyra an increase of \$439,000 in research costs related to our chondroitinase program, and an increase of \$152,000 in technical operations costs associated with our various pipeline initiatives. The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$1.6 million to support the various research and development initiatives. These increases were offset by a decrease in preclinical expenses for the remyelinating antibodies program (rHIgM22) of \$774,000 and a decrease of \$205,000 in Phase 1 GGF2 preclinical and clinical trial expenses.

## Selling, General and Administrative

Sales and marketing expenses for the three-month period ended September 30, 2012 were \$23.6 million compared to \$19.5 million for the three-month period ended September 30, 2011, an increase of approximately \$4.1 million, or 21%. The increase was attributable to an increase in overall marketing, selling, distribution, and market research expenses for Ampyra of \$3.2 million. The increase was also related to an increase in overall compensation, benefits, and other selling expenses attributable to Ampyra of \$1.8 million. These increases were partially offset by a decrease in sales and marketing expenses for Zanaflex Capsules of \$960,000 primarily due to a sample inventory reserve charge and a bad debt expense charge in 2011.

General and administrative expenses for the three-month period ended September 30, 2012 were \$16.5 million compared to \$15.2 million for the three-month period ended September 30, 2011, an increase of approximately \$1.3 million, or 10%. This increase was the result of an increase of \$1.9 million for staff and compensation expenses and other expenses related to supporting the growth of the organization and an increase of \$719,000 in safety and surveillance expenses. The increase in general and administrative expenses for the three-month period ended September 30, 2012 was offset by \$1.0 million due to a loss in our put/call liability related to the PRF revenue interest agreement recorded in 2011 due to the Zanaflex patent infringement trial court decision.

## Other Expense

Other expense was \$239,000 for the three-month period ended September 30, 2012 compared to \$812,000 for the three-month period ended September 30, 2011, a decrease of approximately \$573,000, or 71%. The decrease was due to a decrease in interest expense of \$573,000 principally related to the PRF revenue interest agreement due to a decrease in Zanaflex sales.

### Provision for Income Taxes

We recorded a provision for income taxes of \$533,000 and \$986,000 for the three-month periods ended September 30, 2012 and 2011, respectively which represents Federal AMT and gross receipts taxes for certain states.

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Nine-Month Period Ended September 30, 2012 Compared to September 30, 2011

Net Product Revenues

### Ampyra

We recognize product sales of Ampyra following shipment of product to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra to these customers of \$193.4 million as compared to \$153.3 million for the nine-month periods ended September 30, 2012 and 2011, respectively, an increase of \$40.1 million, or 26%. The net revenue increase was comprised of net volume increases of \$13.9 million and price increases and discount and allowance adjustments of \$26.2 million. Net revenue from sales of Ampyra increased in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 due to greater demand we believe due to, in part, the success of certain marketing programs such as our First Step program.

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. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances also consist of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

### 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 also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules launched during the nine-month period ended September 30, 2012. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$11.6 million for the nine-month period ended September 30, 2012, as compared to \$33.9 million for the nine-month period ended September 30, 2011. The decrease was due to the commercial launch of generic versions of tizanidine hydrochloride capsules in February 2012. Net product revenues also include \$2.0 million, which represents the sale of Zanaflex Capsules authorized generic product to Watson for the nine-month period ended September 30, 2012. Generic competition has caused a significant decline in sales of Zanaflex Capsules and is expected to cause the Company's net revenue from Zanaflex Capsules to decline further in 2012 and beyond.

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.

### License Revenue

We recognized \$6.8 million in license revenue for the nine-month periods ended September 30, 2012 and 2011 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 Revenues

We recognized \$5.8 million and \$578,000 in royalty revenue for the nine-month period ended September 30, 2012 and 2011, respectively related to ex-U.S. sales of Fampyra by Biogen Idec. Beginning on August 1, 2012 and for the remainder of 2012, Biogen will record Fampyra revenue from sales in Germany at a reduced price due to ongoing pricing discussions with the German Federal Joint Committee or G-BA. Until a final price is determined, Biogen will record revenue at a reduced price and we will record royalty revenue based on this reduced price. When pricing negotiations are finalized between Biogen and the G-BA, revenue for Fampyra as well as our royalty revenue will be reconciled retroactive to August 1, 2012.

We recognized \$4.7 million in royalty revenue for the nine-month period ended September 30, 2012 related to the authorized generic sale of Zanaflex Capsules which started in February 2012.

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#### Milestone Revenue

We recognized \$25.0 million in milestone revenue for the nine-month period ended September 30, 2011 as part of our 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 the three-month period ended September 30, 2011. We did not reach any milestones for the nine-month period ended September 30, 2012.

### Cost of Sales

### Ampyra

We recorded cost of sales of \$37.0 million for the nine-month period ended September 30, 2012 as compared to \$30.4 million for the nine-month period ended September 30, 2011. Cost of sales for the nine-month period ended September 30, 2012 consisted primarily of \$31.7 million in inventory costs related to recognized revenues. The cost of Ampyra inventory is based on a percentage of net product sales of the product in the quarter shipped to Acorda by Alkermes or our alternative manufacturer. Cost of sales for the nine-month period ended September 30, 2012 also consisted of \$4.7 million in royalty fees based on net sales, \$441,000 in amortization of intangible assets, and \$127,000 in period costs related to freight and stability testing.

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 freight and stability testing.

#### Zanaflex

We recorded cost of sales of \$1.8 million for the nine-month period ended September 30, 2012 as compared to \$20.4 million for the nine-month period ended September 30, 2011. Cost of sales for the nine-month period ended September 30, 2012 consisted of \$1.1 million in inventory costs primarily related to recognized revenues, \$629,000 in royalty fees based on net product shipments, and \$69,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$2.0 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the nine-month period ended September 30, 2012.

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. Payments to and interest expense related to the PRF transaction discussed below in the section titled "Liquidity and Capital Resources" do not impact the Company's cost of sales.

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#### Cost of Milestone & License Revenue

We recorded cost of license revenue of \$476,000 for the nine-month periods ended September 30, 2012 and 2011, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement. We recorded cost of milestone revenue of \$1.8 million for the nine-month period ended September 30, 2011. Cost of milestone revenue represents a 7% payment to Alkermes on the \$25.0 million milestone revenue received from Biogen Idec in accordance with our worldwide license and supply agreement with Alkermes. 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 the three-month period ended September 30, 2011. We did not record milestone revenue or a corresponding cost of milestone revenue for the three-month period ended September 30, 2012.

### Research and Development

Research and development expenses for the nine-month period ended September 30, 2012 were \$35.7 million as compared to \$31.8 million for the nine-month period ended September 30, 2011, an increase of approximately \$3.9 million, or 12%. The increase was primarily due to a \$3.2 million charge for Neuronex expenses representing a \$2.0 million upfront payment plus a payment of \$1.2 million for research funding per the terms of the agreement we entered into with Neuronex during the first quarter of 2012. The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$3.0 million to support the various research and development initiatives. The increase was also due to an increase of \$1.4 million in our life cycle management program for Ampyra, an increase of \$439,000 in research costs related to our chondroitinase program, a \$372,000 increase in Phase 1 GGF2 preclinical and clinical trial expenses, a \$260,000 increase in technical operations costs associated with our various pipeline initiatives, and an increase of \$260,000 related to our AC105 research. The increase in research and development expenses for the nine-month period ended September 30, 2012 were partially offset by a decrease attributable to the Medtronic AC105 license expense of \$3.0 million during the same period in 2011 and a decrease of \$2.3 million in preclinical expenses for the remyelinating antibodies program (rHIgM22).

## Selling, General and Administrative

Sales and marketing expenses for the nine-month period ended September 30, 2012 were \$76.3 million compared to \$65.4 million for the nine-month period ended September 30, 2011, an increase of approximately \$10.9 million, or 17%. The increase was attributable to an increase in overall marketing, selling, distribution, and market research expenses for Ampyra of \$6.9 million. The increase was also related to an increase in overall compensation, benefits, and other selling expenses attributable to Ampyra of \$5.2 million. These increases were partially offset by a decrease in selling, marketing, and distribution expenses for Zanaflex Capsules of \$1.3 million due to the introduction of generic competition in the marketplace.

General and administrative expenses for the nine-month period ended September 30, 2012 were \$46.8 million compared to \$47.4 million for the nine-month period ended September 30, 2011, a decrease of approximately \$569,000, or 1%. This decrease was primarily related to a decrease in expenses related to the Zanaflex Capsule patent infringement litigation of \$3.7 million a decrease due to a loss in our put/call liability related to the PRF revenue interest agreement recorded in 2011 due to the Zanaflex patent infringement trial court decision of \$1.5 million and a decrease in post-approval Ampyra technical work of \$976,000. The overall decrease in general and administrative expenses was partially offset by an increase in staff, compensation and related expenses to support the overall growth of the organization of \$5.0 million and an increase in safety and surveillance expenses of \$1.1 million.

## Other Expense

Other expense was \$1.1 million for the nine-month period ended September 30, 2012 compared to \$3.0 million for the nine-month period ended September 30, 2011, a decrease of approximately \$1.8 million, or 60%. The decrease was primarily due to a decrease in interest expense of \$1.9 million principally related to the PRF revenue interest agreement due to a decrease in Zanaflex sales.

### Provision for Income Taxes

We recorded a provision for income taxes of \$1.2 million for the nine-month periods ended September 30, 2012 and 2011, which represents Federal AMT and gross receipts taxes for certain states.

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### Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of our common stock and preferred stock, payments received under our collaboration and licensing agreements, sales of Ampyra and Zanaflex Capsules, and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

We were cash flow positive in 2011 and, at September 30, 2012, we had \$318.7 million of cash, cash equivalents and short-term and long-term investments, compared to \$295.9 million at December 31, 2011. We expect to be cash flow positive in 2012. We believe that we have sufficient cash, cash equivalents, short-term and long-term investments on hand, in addition to cash expected to be generated from operations, to fund our business plan for the next twelve months, including our currently anticipated development pipeline activities for at least the next twelve months and our anticipated payment commitments to Neuronex.

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 amount and timing of milestone or other payments payable under collaboration, license and acquisition agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, and the extent to which we acquire or in-license new products and compounds including the development costs relating to those products or compounds. 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. If we require additional financing in the future, we cannot assure you that it will be available to us on favorable terms, or at all.

### Financing Arrangements

In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, Elan transferred these promissory notes to funds affiliated with Saints Capital. As of September 30, 2012, \$5.3 million of these promissory notes was outstanding, which amount includes accrued interest. The second of seven annual payments on this note was due and paid on the two year anniversary of Ampyra approval on January 22, 2012 and will continue to be paid annually until paid in full.

On December 23, 2005, we entered into a revenue interest assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products including the authorized generic version of Zanaflex Capsules being sold by Watson effective in February 2012. 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, including the authorized generic version of Zanaflex Capsules revenue, 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. An additional \$5.0 million was due to us if net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in our December 31, 2006 financial statements. Under the terms of the amendment, we repaid PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met.

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

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revenues. In connection with the transaction, we recorded a liability as of September 30, 2012, referred to as the revenue interest liability, of approximately \$2.6 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 5.6%. Payments made to PRF as a result of Zanaflex sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability.

Upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain of the covenants, representations or warranties we make under the agreement, PRF may (i) require us to repurchase the rights we sold them at the "put/call price" in effect on the date such right is exercised or (ii) foreclose on the Zanaflex assets that secure our obligations to PRF. Except in the case of certain bankruptcy events, if PRF exercises its right, which we refer to as PRF's put option, to cause us to repurchase the rights we assigned to it, PRF may not foreclose unless we fail to pay the put/call price as required. If we experience a change of control we have the right, which we refer to as our call option, to repurchase the rights we sold to PRF at the "put/call price" in effect on the date such right is exercised. The put/call price on a given date is the greater of (i) all payments made by PRF to us as of such date, less all payments received by PRF from us as of such date, and (ii) an amount that would generate an internal rate of return to PRF of 25% on all payments made by PRF to us as of such date, taking into account the amount and timing of all payments received by PRF from us as of such date. We have determined that PRF's put option and our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. Therefore, we recorded a net liability of \$554,000 as of September 30, 2012 related to the put/call option to reflect its current estimated fair value. This liability is revalued on an as needed basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings.

During any period during which PRF has the right to receive 15% of Zanaflex net revenues (as defined in the agreement), then 8% of the first \$30.0 million in payments from Zanaflex sales we receive from wholesalers will be distributed to PRF on a daily basis. Following the end of each fiscal quarter, if the aggregate amount actually received by PRF during such quarter exceeds the amount of net revenues PRF was entitled to receive, PRF will remit such excess to us. If the amount of net revenues PRF was entitled to receive during such quarter exceeds the aggregate amount actually received by PRF during such quarter, we will remit such excess to PRF.

On August 3, 2012, we received a letter from PRF alleging that it breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also includes an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it does not specify or quantify those injuries. We believe that the allegations are without merit and that the put option has not been validly exercised. Although the letter from PRF does not include a purported calculation of the put option price, if it were validly exercised, we estimate that the incremental cost to the Company in excess of amounts already accrued to PRF at September 30, 2012 would be no more than approximately \$2.5 million. Our review is ongoing.

### **Investment Activities**

At September 30, 2012, cash, cash equivalents, short-term and long-term investments were approximately \$318.7 million, as compared to \$295.9 million at December 31, 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, 2012, our cash and cash equivalents were \$40.0 million, as compared to \$58.0 million as of December 31, 2011. 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 \$192.2 million as of September 30, 2012, as compared to \$238.0 million as of December 31, 2011. Our long-term investments consist of US Treasury bonds with original maturities greater than one year. The balance of these investments was \$86.4 million as of September 30, 2012, as compared to zero as of December 31, 2011.

### Net Cash Provided by Operations

Net cash provided by operations was \$35.4 million and \$33.4 million for the nine-month periods ended September 30, 2012 and 2011, respectively. Cash provided by operations for the nine-month period ended September 30, 2012 was primarily attributable to net income of \$21.8 million principally resulting from net product and license and royalty revenues,

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a non-cash share-based compensation expense of \$15.3 million, amortization of net premiums and discounts on investments of \$3.7 million and depreciation and amortization of \$3.1 million. Cash provided by operations was partially offset by a net decrease of \$1.9 million due to changes in working capital items primarily due to the payment of prepaid and accrued items totaling \$8.9 million during the nine-month period ended September 30, 2012, a decrease in deferred product revenue of \$1.8 million, and an increase in accounts receivable of \$399,000. These working capital decreases were partially offset by a decrease in inventory held by the company and others of \$9.1 million and an increase in the revenue interest liability of \$495,000. The offset to cash provided by operations was also attributable to a decrease in non-current portion of deferred license revenue of \$6.8 million due to the amortization of the upfront collaboration payment received during the nine-month period ended September 30, 2009 and a decrease in the loss on our put/call liability of \$476,000.

Net 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.

### Net Cash Used in Investing

Net cash used in investing activities for the nine-month period ended September 30, 2012 was \$55.4 million, primarily due to \$232.6 million in purchases of investments, purchases of intangible assets of \$1.9 million and purchases of property and equipment of \$9.2 million, partially offset by \$188.3 million in proceeds from maturities and sales of investments.

### Net Cash Provided by Financing

Net cash provided by financing activities for the nine-month period ended September 30, 2012 was \$2.1 million, primarily due to \$2.9 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by \$812,000 in repayments to PRF.

#### **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, 2011. 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, 2012, commitments related to the purchase of inventory consistent with our normal course of business increased as compared to December 31, 2011. As of September 30, 2012, we have inventory-related purchase commitments totaling approximately \$21.7 million.

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 \$65 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, 2012, 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. This also excludes any potential payments as part of the Neuronex transaction as these are not yet commitments to us until the transaction is consummated.

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## Critical Accounting Policies and Estimates

Our critical accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2011. As of September 30, 2012, our critical accounting policies have not changed materially from December 31, 2011.

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

Our financial instruments consist of cash equivalents, short-term and long-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, 2012.

We have cash equivalents, short-term and long-term investments at September 30, 2012, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds and US Treasury bonds, the carrying value of our cash equivalents and investments approximate their fair value at September 30, 2012. At September 30, 2012, we held \$318.7 million in cash, cash equivalents, short-term and long-term investments which had an average interest rate of approximately 0.06%.

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 and to meet operating needs. 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 2012, 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, 2012, 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, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Limitations on the effectiveness of controls

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

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#### PART II—OTHER INFORMATION

## Item 1. Legal Proceedings

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc., advising that it had submitted an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex in the U.S. District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557. In September 2011, the Court ruled against us and, following our appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We do not intend to seek any further appeals of the decision. On September 6, 2011, we filed a citizen petition with the FDA requesting that the FDA not approve Apotex's ANDA because of public-safety concerns about Apotex's proposed drug. On December 2, 2011, Apotex filed suit against us in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleges, among other claims, that we engaged in anticompetitive behavior and false advertising in connection with the development and marketing of Zanaflex Capsules, including that the citizen petition we filed with the FDA delayed FDA approval of Apotex's generic tizanidine capsules. On January 26, 2012, we moved to dismiss or stay Apotex's suit. On February 3, 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. On February 21, 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise makes allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. We intend to defend ourselves vigorously in the litigation. We filed a motion to dismiss the amended complaint, and await further action by the Court.

Item 1 of Part II of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31 and June 30, 2012 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, 2011, as updated by the information in Item 1A of Part II of our Quarterly Report on Form 10-Q for the fiscal quarters ended March 31 and June 30, 2012, 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 2011 Annual Report and our update to the risk factors in our Quarterly Reports for the quarters ended March 31 and June 30, 2012.

Even though we have obtained marketing approval for Ampyra, the approval is subject to a REMS and post-marketing commitments, which may affect the success of Ampyra.

The marketing approval we received for Ampyra is subject to risk mitigation activities we must undertake in accordance with a risk evaluation and mitigation strategy, or REMS, a commitment to report all seizures we learn about in post-approval use to the FDA on an expedited basis, and requirements for potentially costly follow-up animal and clinical studies and analyses. The post-approval requirements impose burdens and costs on us. If the post-approval animal and clinical studies and analyses identify new safety concerns, or if our REMS and other measures are not effective in preventing or minimizing the prevalence of seizures or other serious safety risks, the approval of Ampyra could be further limited or withdrawn, or we might be required to undertake additional burdensome post-approval activities. In addition, failure to complete the required studies and meet our other

post-approval commitments could lead to negative regulatory action at the FDA, which could include withdrawal of regulatory approval. Also, our Ampyra marketing approval requirements included a commitment to the FDA to conduct a trial to evaluate a 5mg twice daily dosing regimen, the results from which we announced in August 2012. Although we believe that the study failed to confirm efficacy of the 5mg dose, and that the study, together with the Ampyra registration studies, continue to show that 10 mg. twice daily is the appropriate, safe and effective dose, the study results will be provided to the FDA and we cannot predict whether the FDA will request that we conduct any additional studies or make a lower dose of Ampyra available.

The FDA-approved product labeling for Ampyra is limited and may adversely affect market acceptance of Ampyra.

Ampyra was approved with an indicated use limited to improving walking in patients with MS and specifies that this

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was demonstrated by an increase in walking speed. The approved labeling also contains other limitations on use and warnings and contraindications for risks. If potential purchasers or those influencing purchasing decisions, such as physicians and pharmacists or third party payers, react negatively to Ampyra because of their perception of the limitations or safety risks in the approved product labeling, it may result in lower product acceptance and lower product revenues.

In addition, our promotion of Ampyra must reflect only the specific approved indication as well as other limitations on use, and disclose the safety risks associated with the use of Ampyra as set out in the approved product labeling. We must submit all promotional materials to the FDA at the time of their first use. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and provide corrective information to healthcare practitioners, and we may face other adverse enforcement action. For example, in June 2012 we received an untitled letter from the FDA stating that one of our Ampyra promotional videos does not comply with applicable law and is misleading because it overstates the efficacy of and minimizes important safety information associated with Ampyra. In compliance with the untitled FDA letter, we discontinued use of the video, and in light of the FDA letter we also evaluated and discontinued the use of some other promotional material. Based on a September 2012 letter from the FDA, we believe that we have resolved the specific issues identified by the FDA in the June untitled letter but we have a continuing obligation to ensure that our promotional materials are compliant.

If we or others identify previously unknown side effects of Ampyra, or known side effects are more frequent or severe than in the past, our business would be adversely affected and these events could lead to a significant decrease in sales of Ampyra or to the FDA's withdrawal of marketing approval.

Based on our clinical trials, the side effects of Ampyra include seizures, urinary tract infection, trouble sleeping (insomnia), dizziness, headache, nausea, weakness, back pain, and problems with balance. However, if we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for Ampyra or any products perceived to be similar to Ampyra, then in any of these circumstances:

- sales of Ampyra may be significantly decreased from projected sales;
  - regulatory approvals for Ampyra may be restricted or withdrawn;
- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;
- reformulation of the product, additional preclinical or clinical studies, changes in labeling or changes to or reapprovals of manufacturing facilities may be required;
  - our reputation in the marketplace may suffer; and
  - government investigations and lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of Ampyra and increase our expenses, which would impair our business.

Furthermore, since Ampyra is commercially available, it is being used in a wider population and in a less rigorously controlled environment than in clinical studies. Some patients exposed to Ampyra have reportedly experienced serious adverse side effects, including seizures. As a result, regulatory authorities, healthcare practitioners, third party payers

or patients may perceive or conclude that the use of Ampyra is associated with serious adverse effects, which could result in harm to Ampyra sales and our profitability. For example, as part of an annual REMS review of Ampyra, in July 2012 the FDA issued a safety communication relating to seizures based on post-marketing data from March 2010 through March 2011. These data showed no new safety signals related to seizure risk with Ampyra and are consistent with the data from clinical trials of Ampyra. However, the FDA safety updates and related changes that we have made to the Ampyra product labeling, or additional changes that we might have to make in the future, could change perceptions about Ampyra safety and therefore harm sales. We also constantly monitor adverse event reports for signals regarding potential additional adverse events, which could result in the need for further label changes, which might harm Ampyra sales. For example, in August 2012 we made another label change relating to rare reports of anaphylactic reactions.

Under FDA regulations and our REMS for Ampyra, we are required to monitor the safety of Ampyra and inform

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health care professionals about the risks of drug-associated seizures with Ampyra. We are required to document and investigate reports of adverse events, and to report them to the FDA in accordance with regulatory timelines based on their severity and expectedness. Failure to make timely safety reports and to establish and maintain related records could result in withdrawing of marketing authorization or other regulatory action, civil actions against us, or criminal penalties, any of which could harm our business. For example, in 2011 the FDA conducted an inspection focused primarily on our adverse event reporting system, including the timeliness of reporting of adverse events by our specialty pharmacies. Issues were identified on a September 2011 Form 483, and then in May 2012 we received a warning letter from the FDA regarding some of the issues identified in the inspection. The Form 483 and warning letter are discussed in further detail below in these risk factors.

Our products and product candidates may not gain market acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenue.

Market acceptance of our products and product candidates depends on the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness and our ability to demonstrate these benefits to physicians and patients. We believe market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payers, as well as on the effectiveness of our sales and marketing activities. Physicians may not prescribe our products, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Zanaflex Capsules outweigh their higher cost in relation to Zanaflex tablets or generic tizanidine hydrochloride tablets, or that the benefits of Ampyra are meaningful for patients. As described above in these risk factors, FDA-approved product labeling for Ampyra is limited and may harm its market acceptance. Also, if Ampyra is not listed on the preferred drug lists of third-party payers, or Ampyra is on the preferred drug list but subject to unfavorable limitations or preconditions or in disadvantageous positions on tiered formularies, our sales may suffer.

In the U.S., the federal government has provided significantly increased funding for comparative effectiveness research, which may compare our products with other treatments and may result in published findings that would, in turn, discourage use of our products by physicians and payments for our products by payers. Similar research is funded in other countries, including in Europe. The failure of any of our products or product candidates, once approved, to achieve market acceptance would limit our ability to generate revenue and would harm our results of operations.

If our products are approved in the EU, their success there will also depend largely on obtaining and maintaining government reimbursement because, in many European countries, patients will not use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by one year or more. Even if reimbursement is available, reimbursement policies may harm sales of our products and therefore our ability or that of our partners, such as Biogen Idec, to sell our products on a profitable basis. In response to the recent downturn in global economic conditions, governments in a number of international markets have announced or implemented austerity measures aimed at reducing healthcare costs to constrain the overall level of government expenditures. This includes Germany and other countries in the EU, where Biogen Idec has obtained approval for Fampyra. The measures vary by country and include, among other things, mandatory rebates and discounts, price reductions and suspensions on pricing increases on pharmaceuticals. These measures may harm net revenue from Biogen Idec sales of Fampyra and therefore the amount of the royalty we receive from Biogen Idec. Furthermore, if these measures prevent Biogen Idec from selling Fampyra on a profitable basis in a particular country, they could prevent the commercial launch of Fampyra in that country or cause discontinuance of commercialization in that country after launch.

For example, in August 2012 the German Joint Federal Committee (G-BA) publicly announced its final assessment of the additional benefit of Fampyra, giving Fampyra a rating of no added benefit compared to physiotherapy. Although

the G-BA decision does not impact access to Fampyra for patients in Germany, it provides a comparator price range that will form the basis for Biogen Idec's negotiation of a price for Fampyra in Germany with the Federal Association of Statutory Health Insurance Funds. The comparator price range is substantially lower than the current price of Fampyra in Germany. In addition, German prices are typically used by a number of other countries as a reference price, which therefore can negatively impact the price to be paid for reimbursement of Ampyra by other countries, particularly in the EU. A reduction in the amount of sales of Fampyra by Biogen Idec will reduce the amount of royalties Biogen Idec must pay us.

Several additional factors may limit the market acceptance of products, including:

• rate of adoption by healthcare practitioners;

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- rate of a product's acceptance by the target population,
- timing of market entry relative to competitive products,
  - availability of alternative therapies,
  - perceived advantages of alternative therapies,
  - price of product relative to alternative therapies,
    - extent of marketing efforts,
- unavailability of adequate reimbursement by third parties, and
- side effects or unfavorable publicity concerning the products or similar products.

If market acceptance of our products in the U.S., EU, or other countries does not meet expectations, our revenues or royalties from product sales would suffer and this could cause our stock price to decline.

### Item 6. Exhibits

Exhibit No.	Description
10.1	Letter agreement dated September 4, 2012, between the Registrant and Enrique Carrazana.
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

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

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### **SIGNATURES**

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

Acorda Therapeutics, Inc.

By: /s/ Ron Cohen Ron Cohen, M.D.

President, Chief Executive Officer and Director

Date: November 8, 2012 (Principal Executive Officer)

By: /s/ David Lawrence

David Lawrence, M.B.A. Chief Financial Officer

Date: November 8, 2012 (Principal Financial and Accounting Officer)

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## Exhibit Index

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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

<sup>\*</sup> 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."