

ACORDA THERAPEUTICS INC
Form 10-Q
August 08, 2012

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

FORM 10-Q

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 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)

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 No

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

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

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

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smaller reporting
company)

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

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

Class	Outstanding at July 31, 2012
Common Stock, \$0.001 par value per share	40,093,273 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; 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," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this report and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 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

(In thousands, except share data)	June 30, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$64,717	\$ 57,954
Restricted cash	303	303
Short-term investments	191,133	237,953
Trade accounts receivable, net of allowances of \$994 and \$879, as of June 30, 2012 and December 31, 2011, respectively	23,607	22,828
Prepaid expenses	8,655	6,534
Finished goods inventory held by the Company	28,494	27,256
Finished goods inventory held by others	919	1,126
Other current assets	9,409	6,988
Total current assets	327,237	360,942
Long-term investments	47,118	—
Property and equipment, net of accumulated depreciation	14,290	3,858
Intangible assets, net of accumulated amortization	8,755	8,769
Non-current portion of deferred cost of license revenue	5,125	5,442
Other assets	528	477
Total assets	\$403,053	\$ 379,488
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$19,721	\$ 21,393
Accrued expenses and other current liabilities	28,205	24,149
Deferred product revenue—Zanaflex tablets	9,910	9,967
Deferred product revenue—Zanaflex Capsules	19,081	20,632
Current portion of deferred license revenue	9,057	9,057
Current portion of revenue interest liability	1,315	1,001
Current portion of convertible notes payable	1,144	1,144
Total current liabilities	88,433	87,343
Non-current portion of deferred license revenue	73,214	77,742
Put/call liability	511	1,030
Non-current portion of revenue interest liability	1,537	1,898
Non-current portion of convertible notes payable	4,165	5,230
Other non-current liabilities	5,543	1,036
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at June 30, 2012 and December 31, 2011; issued and outstanding 39,467,153 and 39,328,495 shares, including those held in treasury, as of June 30, 2012 and December 31, 2011,	39	39

respectively

Treasury stock at cost (12,420 shares at June 30, 2012 and December 31, 2011)	(329)	(329)
Additional paid-in capital	627,069	614,914
Accumulated deficit	(397,090)	(409,481)
Accumulated other comprehensive income (loss)	(39)	66
Total stockholders' equity	229,650	205,209
Total liabilities and stockholders' equity	\$403,053	\$ 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 June 30, 2012	Three-month period ended June 30, 2011	Six-month period ended June 30, 2012	Six-month period ended June 30, 2011
Revenues:				
Net product revenues	\$ 69,112	\$ 62,878	\$ 134,785	\$ 121,803
License revenue	2,264	2,264	4,529	4,529
Royalty revenues	4,280	134	7,590	230
Total net revenues	75,656	65,276	146,904	126,562
Costs and expenses:				
Cost of sales	13,576	12,048	26,040	24,098
Cost of license revenue	158	159	317	317
Research and development	12,634	12,008	23,659	22,716
Selling, general and administrative	44,230	40,141	82,975	78,070
Total operating expenses	70,598	64,356	132,991	125,201
Operating income	5,058	920	13,913	1,361
Other expense (net):				
Interest and amortization of debt discount expense	(356)	(1,276)	(1,122)	(2,412)
Interest income	123	133	252	273
Total other expense (net)	(233)	(1,143)	(870)	(2,139)
Income (loss) before taxes	4,825	(223)	13,043	(778)
Provision for income taxes	(280)	(62)	(652)	(179)
Net income (loss)	\$ 4,545	\$ (285)	\$ 12,391	\$ (957)
Net income (loss) per share:				
Net income (loss) per share—basic	\$ 0.12	\$ (0.01)	\$ 0.31	\$ (0.02)
Net income (loss) per share—diluted	\$ 0.11	\$ (0.01)	\$ 0.31	\$ (0.02)
Weighted average common shares outstanding used in computing net income (loss) per share:				
Weighted average common shares outstanding used in computing net income (loss) per share—basic	39,433	38,937	39,387	38,859
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	40,099	38,937	40,253	38,859

See accompanying Unaudited Notes to Consolidated Financial Statements

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)

(unaudited)

(In thousands)	Three-month period ended June 30, 2012	Three-month period ended June 30, 2011	Six-month period ended June 30, 2012	Six-month period ended June 30, 2011
Net income (loss)	\$ 4,545	\$ (285)	\$ 12,391	\$ (957)
Other comprehensive income (loss):				
Unrealized gains (losses) on available for sale securities	(5)	72	(105)	124
Other comprehensive income (loss)	(5)	72	(105)	124
Comprehensive income (loss)	\$ 4,540	\$ (213)	\$ 12,286	\$ (833)

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)	Six-month period ended June 30, 2012	Six-month period ended June 30, 2011
Cash flows from operating activities:		
Net income (loss)	\$ 12,391	\$(957)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Share-based compensation expense	9,784	8,791
Amortization of net premiums and discounts on investments	2,736	3,460
Amortization of revenue interest issuance cost	45	63
Depreciation and amortization expense	1,952	2,175
Gain on put/call liability	(519)	(17)
Changes in assets and liabilities:		
Increase in accounts receivable	(779)	(1,145)
Increase in prepaid expenses and other current assets	(4,543)	(1,643)
Increase in inventory held by the Company	(1,238)	(3,848)
Decrease in inventory held by others	207	121
Decrease in non-current portion of deferred cost of license revenue	317	291
Increase in other assets	(96)	(157)
Increase (decrease) in accounts payable, accrued expenses, other current liabilities	1,331	(10,418)
Increase in revenue interest liability interest payable	428	840
Decrease in current portion of deferred license revenue	—	(371)
Decrease in non-current portion of deferred license revenue	(4,528)	(4,157)
Decrease in other non-current liabilities	(517)	—
Increase (decrease) in deferred product revenue—Zanaflex tablets	(56)	293
Decrease in deferred product revenue—Zanaflex Capsules	(1,552)	(2,715)
Net cash provided by (used in) operating activities	15,363	(9,394)
Cash flows from investing activities:		
Purchases of property and equipment	(6,418)	(1,081)
Purchases of intangible assets	(938)	(612)
Purchases of investments	(137,889)	(135,511)
Proceeds from maturities of investments	134,750	158,000
Net cash (used in) provided by investing activities	(10,495)	20,796
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	2,371	3,533
Repayments of revenue interest liability	(476)	(941)
Net cash provided by financing activities	1,895	2,592
Net increase in cash and cash equivalents	6,763	13,994
Cash and cash equivalents at beginning of period	57,954	34,641
Cash and cash equivalents at end of period	\$ 64,717	\$ 48,635
Supplemental disclosure:		
Cash paid for interest	614	1,477

Cash paid for taxes	793	117
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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 distributor to the VA are contractually 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, we do not believe we can reasonably determine a return rate at this time. As a result, the Company accounts for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the cost basis of the product held by the wholesaler as a component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized is based on (1) the estimated prescription demand, based on pharmacy sales for

its products; and (2) the Company's analysis of third-party information, including third-party market research data. The Company's estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information is itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition reflects the Company's estimates of actual product prescribed to the end-user. The Company expects to be able to apply a more traditional revenue recognition policy such that revenue is recognized following shipment to the customer when it believes it has sufficient data to develop reasonable estimates of expected returns based upon historical returns and greater certainty regarding generic competition.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be

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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 June 30, 2012 and 2011, the Company recognized share-based compensation expense of \$5.6 million and \$5.0 million, respectively. During the six-month periods ended June 30, 2012 and 2011, the Company recognized share-based compensation expense of \$9.8 million and \$8.8 million, respectively. Activity in options and restricted stock during the three-month period ended June 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 June 30, 2012 and 2011 were approximately \$12.13 and \$16.46, respectively. The weighted average fair value per share of options granted to employees for the six-month periods ended June 30, 2012 and 2011 were approximately \$13.79 and \$13.09, respectively.

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

(In millions)	For the three-month period ended June 30,		For the six-month period ended June 30,	
	2012	2011	2012	2011
Research and development	\$1.3	\$1.5	\$2.3	\$2.6
Selling, general and administrative	4.3	3.5	7.5	6.2
Total	\$5.6	\$5.0	\$9.8	\$8.8

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

Stock Option Activity

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value (In thousands)
Balance at January 1, 2012	4,793	\$21.31		
Granted	1,112	25.78		
Cancelled	(86)	27.52		
Exercised	(117)	20.39		
Balance at June 30, 2012	5,702	\$22.11	7.0	\$21,950
Vested and expected to vest at June 30, 2012	5,622	\$22.06	6.9	\$21,912
Vested and exercisable at June 30, 2012	3,317	\$19.41	5.6	\$20,486

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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	(6)
Nonvested at June 30, 2012	639

As of June 30, 2012, there was \$44.9 million of total unrecognized compensation costs related to unvested options and restricted stock awards that the Company expects to recognize over a weighted average period of approximately 2.6 years.

(4) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the three and six-month periods ended June 30, 2012 and 2011:

(In thousands, except per share data)	Three-month period ended June 30, 2012	Three-month period ended June 30, 2011	Six-month period ended June 30, 2012	Six-month period ended June 30, 2011
Basic and diluted				
Net income (loss)	\$ 4,545	\$ (285)	\$12,391	\$(957)
Weighted average common shares outstanding used in computing net income (loss) per share—basic	39,433	38,937	39,387	38,859
Plus: net effect of dilutive stock options and restricted common shares	666	—	866	—
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	40,099	38,937	40,253	38,859
Net income (loss) per share—basic	\$ 0.12	\$ (0.01)	\$0.31	\$(0.02)
Net income (loss) per share—diluted	\$ 0.11	\$ (0.01)	\$0.31	\$(0.02)

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:

(In thousands) Three-month Three-month Six-month Six-month

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	period ended June 30, 2012	period ended June 30, 2011	period ended June 30, 2012	period ended June 30, 2011
Denominator				
Dilutive stock options and restricted common shares	5,675	5,344	5,475	5,344
Convertible note	67	67	67	67

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(5) Income Taxes

The Company had available federal net operating loss (NOL) carryforwards of approximately \$204.9 million and \$230.4 million and state NOL carryforwards of approximately \$165.0 million and \$205.9 million as of June 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 \$4.0 million as of June 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 \$1.6 million and \$1.1 million as of June 30, 2012 and December 31, 2011, respectively. Such credits can be carried forward indefinitely and have no expiration date.

At June 30, 2012 and December 31, 2011, the Company had a deferred tax asset of \$142.0 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 June 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 June 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 six months ended June 30, 2012. During the six-month period ended June 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
June 30, 2012			
Assets Carried at Fair Value:			

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Cash equivalents	\$64,717	\$—	\$—
Short-term investments	—	191,133	—
Long-term investments	—	47,118	—
Liabilities Carried at Fair Value:			
Put/call liability	—	—	511
December 31, 2011			
Assets Carried at Fair Value:			
Cash equivalents	\$38,340	\$—	\$—
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.

(In thousands)	Three-month period ended June 30, 2012	Three-month period ended June 30, 2011	Six-month period ended June 30, 2012	Six-month period ended June 30, 2011
Put/call liability:				
Balance, beginning of period	\$ 495	\$ 391	\$1,030	\$391
Total realized and unrealized (gains) losses included in selling, general and administrative expenses:	16	(17)	(519)	(17)
Balance, end of period	\$ 511	\$ 374	\$511	\$374

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:

(In thousands)	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
June 30, 2012				
US Treasury bonds	\$238,290	\$2	\$(41)	\$238,251
December 31, 2011				
US Treasury bonds	237,887	72	(6)	237,953

The contractual maturities of short-term available-for-sale debt securities at June 30, 2012 and December 31, 2011 are within one year. The contractual and intended maturities of long-term available-for-sale debt securities at June 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 June 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 \$64.7 million and \$38.3 million as of June 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 \$4.5 million in license revenue, a portion of the \$110.0 million received from Biogen Idec, and \$159,000 and \$317,000 in cost of license revenue, a portion of the

\$7.7 million paid to Alkermes, during the three and six-month periods ended June 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 six-month periods ended June 30, 2012, the Company recognized royalty revenue of \$1.8 million and \$3.3 million, respectively, related to the gross margin of the Zanaflex Capsule authorized generic. During the three and six-month periods ended June 30, 2012, the Company also recognized revenue and a corresponding cost of sales of \$288,000 and \$1.4 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 six-month period ended June 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.

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. The Company believes that the ultimate resolution of these matters will not have a material adverse effect on the Company's financial condition or liquidity. However, adjustments, if any, to the Company's estimates could be material to operating results for the periods in which adjustments to the liability are recorded. As of June 30, 2012, there have been no accruals for loss contingencies aside from payments related to litigation itself.

(10) Subsequent Event

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 June 30, 2012 would be no more than approximately \$2.5 million. The Company's review is ongoing.

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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 \$66.3 million for the three-months ended June 30, 2012 and \$51.8 million for the three-months ended June 30, 2011. As of May 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 received a sixth refill, 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.

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 across the entire European Union, Norway, Iceland, Canada, Australia and New Zealand. To date Biogen Idec has launched Fampyra in Germany, the United Kingdom, Denmark, Norway, Iceland, Canada, Australia and New Zealand. Launch in most of the remaining EU countries is expected by the end of 2012. Biogen Idec plans to submit regulatory filings for Fampyra in more than 30 countries in 2012. 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

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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 is 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. The first phase of this proof-of-concept study is primarily to evaluate safety and tolerability prior to proceeding to a multi-dose cohort. We expect to announce results from this single-dose phase by the end of 2012. 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 early 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 few 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.

Patent Update Related to Ampyra

On August 30, 2011, the United States Patent and Trademark Office, or USPTO, issued 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 USPTO's final patent term adjustment calculation this patent will extend into 2027. This patent is listed in the Orange Book.

On August 10, 2011, we announced that the USPTO had allowed U.S. Patent Application No. 11/102,559 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, the Company requested further review by the USPTO of the U.S. 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 and the patent application is therefore subject to further review by the USPTO.

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 \$2.6 million for the three-months ended June 30, 2012 and \$11.1 million for the three-months ended June 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 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 significantly 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. We have since asked the FDA to delist 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

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of our research and development programs may have applicability beyond the nervous system, including in the field of cardiology.

Glial Growth Factor 2

We expect to announce preliminary results from a Phase 1 clinical trial of GGF2 in heart failure patients in the second half of 2012. 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 previously announced problems with a bioactivity assay that had delayed our filing of an IND for one of the remyelinating antibodies, rHIgM22, for the treatment of MS. During the second quarter of 2012, we successfully completed the qualification of the bioactivity assay and we are now preparing an IND for submission. 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 will be subject to FDA review as part of an 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 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 AC105). 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 AC105, we will also be obligated to pay a single-digit royalty on sales. We plan to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as SCI and TBI. We expect to begin enrollment in a Phase 2 clinical trial in patients with acute SCI in the second half of 2012.

Relocation of Corporate Headquarters; Ardsley Lease

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.

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.

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- Research and development expenses are expected to range from \$50 million to \$60 million, excluding share-based compensation charges. 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.
- 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.

The range of SG&A and R&D expenditures for 2012 are non-GAAP financial measures because they exclude share-based compensation charges. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures, when viewed in conjunction with 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. We believe that non-GAAP financial measures that exclude share-based compensation charges help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected operating performance. Also, our management uses non-GAAP financial measures that exclude share-based compensation charges 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:

- Our Phase 2 proof-of-concept clinical trial of dalfampridine in adults with cerebral palsy, which was commenced in December 2011, is ongoing. We expect to announce study results for the initial single-dose phase by the end of 2012.
 - 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 early 2013.
- We expect to announce initial study results from our GGF2 Phase 1 clinical trial in heart failure patients in the second half of 2012.
 - A Phase 2 clinical trial of AC105 in patients with acute SCI is expected to begin in the second half of 2012.
- 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.
- A post-approval commitment study examining the use of a 5mg dose of Ampyra has completed enrollment. We expect to announce results of the study in August 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.

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The closing is subject to a number of conditions including our satisfaction with the results of a meeting to be held 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 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. We expect that these expenses would not exceed \$8 million in 2012.

Results of Operations

Three-Month Period Ended June 30, 2012 Compared to June 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 \$66.3 million and \$51.8 million for the three-month periods ended June 30, 2012 and 2011, respectively. This net revenue of Ampyra reflects a 15% increase in our sale price effective January 3, 2012.

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 launched during the three-month period ended June 30, 2012. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$2.5 million for the three-month period ended June 30, 2012, as compared to \$11.1 million for the three-month period ended June 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 \$288,000, which represents the sale of Zanaflex Capsules authorized generic product to Watson for the three-month period ended June 30, 2012. Generic competition has caused a decline in sales of Zanaflex Capsules and is expected to cause the Company's net revenue from Zanaflex Capsules to decline significantly in 2012 and beyond.

Discounts and allowances, which are included as an offset in net revenue, consist of allowances for customer credits,

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including estimated chargebacks, rebates, and discounts. Adjustments are recorded for estimated chargebacks, rebates, and discounts.

License Revenue

The Company recognized \$2.3 million in license revenue for the three-month periods ended June 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

The Company recognized \$2.5 million and \$134,000 in royalty revenue for the three-month period ended June 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.

The Company recognized \$1.8 million in royalty revenue for the three-month period ended June 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 \$12.9 million for the three-month period ended June 30, 2012 as compared to \$10.1 million for the three-month period ended June 30, 2011. Cost of sales for the three-month period ended June 30, 2012 consisted primarily of \$10.8 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 June 30, 2012 also consisted of \$1.9 million in royalty fees based on net sales, \$147,000 in amortization of intangible assets, and \$29,000 in period costs related to freight and stability testing.

Cost of sales for the three-month period ended June 30, 2011 consisted primarily of \$8.9 million in inventory costs related to recognized revenues. Cost of sales for the three-month period ended June 30, 2011 also consisted of \$1.1 million in royalty fees based on net sales, \$82,000 in amortization of intangible assets, and \$77,000 in period costs related to freight and stability testing.

Zanaflex

We recorded cost of sales of \$359,000 for the three-month period ended June 30, 2012 as compared to \$2.0 million for the three-month period ended June 30, 2011. Cost of sales for the three-month period ended June 30, 2012 consisted of \$270,000 in inventory costs primarily related to recognized revenues, \$66,000 in royalty fees based on net product shipments, and \$22,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$288,000, which represents the cost of Zanaflex Capsules authorized generic product sold for the three-month period ended June 30, 2012.

Cost of sales for the three-month period ended June 30, 2011 consisted of \$1.0 million in inventory costs primarily related to recognized revenues, \$612,000 in royalty fees based on net product shipments, \$321,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$26,000 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 License Revenue

We recorded cost of license revenue of \$158,000 and \$159,000 for the three-month periods ended June 30, 2012 and 2011, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Elan in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

Research and Development

Research and development expenses for the three-month period ended June 30, 2012 were \$12.6 million as compared to \$12.0 million for the three-month period ended June 30, 2011, an increase of approximately \$626,000, or 5%. The increase was primarily due to an increase of \$1.4 million in our life cycle management program for Ampyra and a \$459,000 increase in Phase 1 GGF2 preclinical and clinical trial expenses. The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$797,000 to support the various research and development initiatives and a \$700,000 charge for Neuronex expenses representing the remaining payment for research funding per the terms of the agreement we entered into with Neuronex during the first quarter of 2012. These increases were offset by a decrease attributable to the Medtronic AC105 license expense of \$3.0 million during the same period in 2011.

Selling, General and Administrative

Sales and marketing expenses for the three-month period ended June 30, 2012 were \$27.6 million compared to \$23.4 million for the three-month period ended June 30, 2011, an increase of approximately \$4.2 million, or 18%. The increase was attributable to an increase in overall marketing, selling, distribution, and market research expenses for Ampyra of \$2.5 million. The increase was also related to an increase in overall compensation, benefits, and other selling expenses attributable to Ampyra of \$1.9 million. These increases were partially offset by a decrease in selling, marketing, and distribution expenses for Zanaflex Capsules of \$155,000 due to the introduction of generic competition in the marketplace.

General and administrative expenses for the three-month period ended June 30, 2012 were \$16.6 million compared to \$16.9 million for the three-month period ended June 30, 2011, a decrease of approximately \$300,000, or 2%. This decrease was primarily related to a decrease in expenses related to the Zanaflex Capsule patent infringement litigation of \$1.6 million offset by an increase in staff and compensation expenses to support the overall growth of the organization of \$1.5 million.

Other Expense

Other expense was \$233,000 for the three-month period ended June 30, 2012 compared to \$1.1 million for the three-month period ended June 30, 2011, a decrease of approximately \$910,000, or 80%. The decrease was primarily due to a decrease in interest expense of \$920,000 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 \$280,000 and \$62,000 for the three-month periods ended June 30, 2012 and 2011, respectively which represents Federal AMT and gross receipts taxes for certain states.

Six-Month Period Ended June 30, 2012 Compared to June 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 \$123.6 million and \$98.6 million for the six-month periods ended June 30, 2012 and 2011, respectively. This net revenue of Ampyra reflected a 7.5% increase in our sale price effective March 4, 2011 and a 15% increase in our sale price effective January 3, 2012.

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.

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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 six-month period ended June 30, 2012. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$9.8 million for the six-month period ended June 30, 2012, as compared to \$23.2 million for the six-month period ended June 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 \$1.4 million, which represents the sale of Zanaflex Capsules authorized generic product to Watson for the six-month period ended June 30, 2012. Generic competition has caused a decline in sales of Zanaflex Capsules and is expected to cause the Company’s net revenue from Zanaflex Capsules to decline significantly 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

The Company recognized \$4.5 million in license revenue for the six-month periods ended June 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

The Company recognized \$4.3 million and \$230,000 in royalty revenue for the six-month period ended June 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.

The Company recognized \$3.3 million in royalty revenue for the six-month period ended June 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 \$23.2 million for the six-month period ended June 30, 2012 as compared to \$19.8 million for the six-month period ended June 30, 2011. Cost of sales for the six-month period ended June 30, 2012 consisted primarily of \$19.7 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 six-month period ended June 30, 2012 also consisted of \$3.1 million in royalty fees based on net sales, \$294,000 in amortization of intangible assets, and \$85,000 in period costs related to freight and stability testing.

Cost of sales for the six-month period ended June 30, 2011 consisted primarily of \$17.4 million in inventory costs related to recognized revenues. Cost of sales for the six-month period ended June 30, 2011 also consisted of \$2.0 million in royalty fees based on net sales, \$307,000 in amortization of intangible assets, and \$110,000 in period costs related to freight and stability testing.

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Zanaflex

We recorded cost of sales of \$1.4 million for the six-month period ended June 30, 2012 as compared to \$4.3 million for the six-month period ended June 30, 2011. Cost of sales for the six-month period ended June 30, 2012 consisted of \$898,000 in inventory costs primarily related to recognized revenues, \$515,000 in royalty fees based on net product shipments, and \$34,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$1.4 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the six-month period ended June 30, 2012.

Cost of sales for the six-month period ended June 30, 2011 consisted of \$2.1 million in inventory costs primarily related to recognized revenues, \$1.4 million in royalty fees based on net product shipments, \$641,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$93,000 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 License Revenue

We recorded cost of license revenue of \$317,000 for the six-month periods ended June 30, 2012 and 2011, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Elan in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

Research and Development

Research and development expenses for the six-month period ended June 30, 2012 were \$23.7 million as compared to \$22.7 million for the six-month period ended June 30, 2011, an increase of approximately \$943,000, or 4%. 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 \$1.3 million to support the various research and development initiatives. The increase was also due to a \$219,000 increase in Phase 1 GGF2 preclinical and clinical trial expenses. These were 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 \$1.6 million in preclinical expenses for the remyelinating antibodies program (rHIgM22).

Selling, General and Administrative

Sales and marketing expenses for the six-month period ended June 30, 2012 were \$52.7 million compared to \$45.8 million for the six-month period ended June 30, 2011, an increase of approximately \$6.9 million, or 15%. The increase was attributable to an increase in overall marketing, selling, distribution, and market research expenses for Ampyra of \$4.9 million. The increase was also related to an increase in overall compensation, benefits, and other selling expenses attributable to Ampyra of \$2.2 million. These increases were partially offset by a decrease in selling, marketing, and distribution expenses for Zanaflex Capsules of \$308,000 due to the introduction of generic competition in the marketplace.

General and administrative expenses for the six-month period ended June 30, 2012 were \$30.3 million compared to \$32.6 million for the six-month period ended June 30, 2011, a decrease of approximately \$2.3 million, or 7%. This decrease was primarily related to a decrease in expenses related to the Zanaflex Capsule patent infringement litigation of \$3.1 million, a gain on our put/call liability related to the PRF revenue interest agreement of \$502,000 and a decrease in post-approval Ampyra technical work of \$558,000. 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 \$2.7 million.

Other Expense

Other expense was \$870,000 for the six-month period ended June 30, 2012 compared to \$2.1 million for the six-month period ended June 30, 2011, a decrease of approximately \$1.3 million, or 59%. The decrease was primarily due to a decrease in interest expense of \$1.3 million principally related to the PRF revenue interest agreement due to a decrease in Zanaflex sales.

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Provision for Income Taxes

We recorded a provision for income taxes of \$651,000 and \$179,000 for the six-month periods ended June 30, 2012 and 2011, respectively which represents Federal AMT and gross receipts taxes for certain states.

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 June 30, 2012, we had \$303.0 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 in for 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 June 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

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•with respect to Zanaflex net revenues in excess of \$60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF has received and retained payments under the agreement that are at least 2.1 times the aggregate amount PRF has paid us under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we recorded a liability as of June 30, 2012, referred to as the revenue interest liability, of approximately \$2.9 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 \$511,000 as of June 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.

Investment Activities

At June 30, 2012, cash, cash equivalents, short-term and long-term investments were approximately \$303.0 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 June 30, 2012, our cash and cash equivalents were \$64.7 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 \$191.1 million as of June 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 \$47.1 million as of June 30, 2012, as compared to zero as of December 31, 2011.

Net Cash Provided by/(Used in) Operations

Net cash provided by (used in) operations was \$15.4 million and \$(9.4) million for the six-month periods ended June 30, 2012 and 2011, respectively. Cash provided by operations for the six-month period ended June 30, 2012 was primarily attributable to net income of \$12.4 million principally resulting from license and royalty revenues, a non-cash share-based compensation expense of \$9.8 million, amortization of net premiums and discounts on investments of \$2.7 million and depreciation and amortization of \$2.0 million. Cash provided by operations was partially offset by a net decrease of \$4.7 million due to changes in working capital items primarily due to the payment of prepaid items during the six-month period

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ended June 30, 2012 and a decrease in deferred product revenue of \$1.6 million. These working capital decreases were partially offset by an increase in accounts payable and accrued expenses of \$1.3 million. The offset to cash provided by operations was also attributable to a decrease in non-current portion of deferred license revenue of \$4.5 million due to the amortization of the upfront collaboration payment received during the six-month period ended September 30, 2009, a decrease in the loss on our put/call liability of \$519,000, and an increase in inventory held by the Company of \$1.2 million.

Cash used in operations for the six-month period ended June 30, 2011 was primarily attributable to a net decrease of \$13.5 million due to changes in working capital items primarily due to the payment of 2010 accruals during the six-month period ended June 30, 2011. It was also attributable to a decrease in the deferred license revenue of \$4.5 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009, an increase in inventory held by the Company of \$3.8 million, an increase in accounts receivable of \$1.1 million resulting from an increase in Ampyra gross sales and the 7.5% price increase for Ampyra effective in March 2011 and a net loss of \$957,000. Cash used in operations for the six-month period ended June 30, 2011 was offset by a non-cash share-based compensation expense of \$8.8 million, amortization of net premiums and discounts on short-term investments of \$3.5 million and depreciation and amortization of \$2.2 million.

Net Cash Used in Investing

Net cash used in investing activities for the six-month period ended June 30, 2012 was \$10.5 million, primarily due to \$137.9 million in purchases of investments, purchases of intangible assets of \$938,000 and purchases of property and equipment of \$6.4 million, partially offset by \$134.8 million in proceeds from maturities and sales of investments.

Net Cash Provided by Financing

Net cash provided by financing activities for the six-month period ended June 30, 2012 was \$1.9 million, primarily due to \$2.4 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by \$476,000 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 six-month period ended June 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 June 30, 2012, we have inventory-related purchase commitments totaling approximately \$6.6 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 \$64 million as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of

these milestones had not occurred as of June 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 June 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 June 30, 2012.

We have cash equivalents, short-term and long-term investments at June 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 June 30, 2012. At June 30, 2012, we held \$303.0 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 second 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 June 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 June 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 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules. The patent expires in 2021.

In November 2007, Apotex answered our complaint, asserting patent invalidity and non-infringement. Apotex also counterclaimed, seeking a declaratory judgment of patent invalidity and non-infringement. We denied those counterclaims. A bench trial was held in May 2011. On September 7, 2011, we announced that the Court had ruled against us in the litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid as not enabled and not infringed by Apotex. We appealed the decision to the U.S. Court of Appeals for the Federal Circuit. On June 11, 2012, the Federal Circuit affirmed the decision of the District Court. We do not intend to seek any further appeals of the decision. We also asked the FDA to delist from the Orange Book the patent that was held invalid.

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 Report on Form 10-Q for the fiscal quarter ended March 31, 2012 includes 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 quarter ended March 31, 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 Report for the quarter ended March 31, 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 include a

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commitment to the FDA to conduct a trial to evaluate a 5mg twice daily dosing regimen, the results from which we expect to announce in August 2012. Although we do not expect a 5mg dose to be as efficacious as a 10mg dose, we cannot predict the results of this study or whether it will lead to the marketing of any new dosages of Ampyra and, if so, the impact on Ampyra revenues.

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 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. The FDA instructed us to immediately discontinue using the promotional video and any other promotional materials containing similar violations, and to submit a written response to their letter. In compliance with the FDA request, we submitted a written response and in July 2012 we discontinued use of the video and we have also suspended use of some other promotional material that we are evaluating in light of the untitled FDA letter.

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.

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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 are making to the Ampyra product labeling 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.

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

If the specialty pharmacies that we rely upon to sell Ampyra in the U.S. fail to perform, our business may be adversely affected.

Our success in increasing sales of Ampyra will depend on the continued customer support efforts of our network of specialty pharmacies. A specialty pharmacy is a pharmacy that specializes in the dispensing of injectable, infused or certain other medications typically for complex or chronic conditions, which often require a high level of patient education and ongoing management. Specialty pharmacies are commonly used to dispense MS drugs, many of which are injectable. The use of specialty pharmacies involves certain risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using Ampyra, Ampyra adverse events, or Ampyra complaints;
 - not effectively dispense or support Ampyra;
- reduce their efforts or discontinue dispensing or supporting Ampyra;
- not devote the resources necessary to dispense Ampyra in the volumes and within the time frames that we expect;
 - be unable to satisfy financial obligations to us or others;
 - not have the required licenses to distribute drugs; or
 - cease operations.

In late 2010 and early 2011, we learned that two of the specialty pharmacies that dispense Ampyra failed to timely report to us some of the reports of adverse events that they received, which we believe was in violation of our contracts with them. Because the specialty pharmacies did not report these adverse events to us in a timely manner, while we reported them to the FDA, we did not report them in a timely manner. To our knowledge, no regulatory action has been taken against us or the specialty pharmacies involved by the FDA. However, if these specialty pharmacies continue to experience problems with adverse event reporting, and even if they do not, the FDA could take regulatory action against us and/or the specialty pharmacies. In 2011 the FDA conducted an inspection focused primarily on our adverse event reporting system, including reporting of adverse events by our specialty

pharmacies. Issues were identified on a September 2011 Form 483, and 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.

We may incur significant liability if it is determined that we are promoting the “off-label” use of Ampyra or any other marketed drug.

Physicians may prescribe drug products for uses that are not described in the product’s labeling and that differ from

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those approved by the FDA or, outside the U.S., other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict promotion of a drug other than in accordance with labeling approved by the FDA or other applicable regulatory agency. Companies may not promote drugs for off-label uses. Accordingly, without FDA approval of Ampyra for use in any indications other than improving walking ability in people with MS, we may not promote Ampyra in the U.S. for these indications. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have engaged in off-label promotion may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other applicable regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. Although we believe that all of our communications regarding our marketed products are in compliance with off-label promotion restrictions, the FDA or another regulatory or enforcement authority may disagree. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. 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 Ampyra and minimizes important risk information. This untitled FDA letter is discussed in further detail above in these risk factors.